2015

A study of current maintenance strategies and the reliability of critical medical equipment in hospitals in relation to patient outcomes

Khelood A. Mkalaf
University of Wollongong

UNIVERSITY OF WOLLONGONG

Faculty of Engineering and Information Sciences

A Study of Current Maintenance Strategies and the Reliability of Critical Medical Equipment in Hospitals in Relation to Patient Outcomes

Khelood A. Mkalaf

This thesis is presented as part of the requirements for the award of the Degree of Doctor of Philosophy from University of Wollongong

31 August 2015

DECLARATION

I, Khelood A. Mkalaf, declare that this thesis, submitted in fulfilment of the requirement for award of Doctor of Philosophy, in the Faculty of Engineering and Information Sciences, University of Wollongong, is wholly my own work unless otherwise referenced or acknowledged.

This document has not been submitted for qualification at any academic institution.

Khelood A. Mkalaf

31August 2015

ABSTRACT

This study investigates the relationship between the reliability of Critical Medical Equipment (CME) and the maintenance management strategies influencing patient outcomes in Australian Public Hospitals in the state of NSW. The work examined the effectiveness of CME maintenance strategies used in this large public hospital system. The conceptual framework was designed to examine the significance of the relationships between five variables: (1) types of maintenance management strategies (2) maintenance practices (3) medical equipment reliability (4) maintenance costs and (5) patient outcomes.

The study initially focused on 14 types of CME where failure or non-availability posed a high level of risk to patients. The evaluation of the performance of CME was carried out by using qualitative and quantitative investigations in order to examine failure rates and their effects. The parameters used for measuring performance were CME availability, failure rate, MTBF (Mean Time Between failures) and MTTR. (Mean Time to Repair). The quantitative conclusions of this work have resulted from 84 valid responses to a survey consisting of 54 detailed questions. Respondents indicated that they use and/or are responsible for 5769 individual items of CME. This provides a substantial and likely statistically reliable sample from which data has been gathered. Due to difficulties in handling very large amounts of data, the 6 most representative of the 14 CME types on which data was obtained were examined. These were kidney dialysis, anesthesia, defibrillator, ECG, infusion pumps and ventilator machines. The study targeted a variety of departments in hospitals: biomedical engineering, surgical and theatre operations, kidney dialysis and renal and cardiac catheterisation. The breakdown of respondents comprised hospital staff from the following units: 3% biomedical engineering, 29% surgical, 25% theatre operations, 22% kidney dialysis, 9% cardiac catheterisation, 3% intensive care units and 9% hospital administration.

Results showed that there is significant correlation between current maintenance management strategies and the reliability of critical medical equipment affecting patient outcomes. The results also provide interesting insight into the effectiveness of the maintenance strategies being used. For example, there appears to be a significant probability of failure of anesthesia equipment when treating patients with resulting potential risks. The survey results also provide some findings to indicate that most

CME types surveyed fail while in service and there are some cases where patients have been exposed to harm due to breakdowns. Two hospitals reported cases of injury and one hospital reported a case of patient death due to the failure of anesthesia machines. One hospital reported a case of patient death due to the failure of a defibrillator machine, another hospital reported cases of patient death when using cardiac catheterisation machines and two hospitals reported cases of patient death due to the failure of diathermy machines. There are also some findings in relation to outsourcing maintenance strategies that point to further questions in relation to the cost of those services. For each of the variables listed results were reported in relation to the various types of maintenance management strategies in use.

Decision-makers may be able to use these results to adopt more effective maintenance strategies for CME which can lead to improved patient outcomes. The study goes on to propose a maintenance model for critical hospital equipment with greater emphasis on Reliability-Centred Maintenance (RCM), Condition Based Maintenance (CBM) and Total Productive Maintenance (TPM), which are advanced asset management and equipment maintenance strategies that have been developed and are now common in aviation and manufacturing industries.

This work highlights the economic life cycle operations and patient outcome priorities that are connected with critical medical equipment. While it must be acknowledged that the case for adopting a Reliability Centred Maintenance regime is not proven, it is interesting to note that, in line with RCM type philosophies, there is the possibility that some hospital equipment may be “over maintained” resulting in decreased reliability and increased costs. Certainly in the interests of patient safety and economic operation of CME, this work provides evidence that there is a need to reconsider and update current maintenance practices. The study paves the way for an in-depth enquiry and presents a proposal for a program of further work.

ACKNOWLEDGEMENTS

The author would like to thank and recognise the contribution, dedication and support of the following people who have offered their experiences to support this study and encouragement throughout the period my Doctoral study.

I would like to thank John Flanagan, Fellow of the University of Wollongong, recognised by the University for his outstanding achievement, exceptional service and significant contribution for offering professional advice and suggestions to me on using appropriate statistical analysis, in addition to his encouragement, guidance and patience. I can certainly vouch for the honours bestowed upon John by the University. He is truly one of the world's outstanding people and without his support and motivation I am doubtful this thesis could have ever have been completed. I have been greatly privileged to have worked with him.

I sincerely acknowledge my supervisor A/Professor Peter Gibson for his encouragement, guidance, patience. His support, suggestions and advice have made a crucial contribution to the integrity of this study.

I would like to thank co-supervisors A/Professor Naj Aziz and Dr. Senevi Siridena for their time, effort, patience and support and for reviewing the survey structure forms. My sincere thanks also to Ms Joan Phillips for her time and effort in reviewing this thesis. My sincere thanks also to Dr. Marika Batterham for her advice in using statistical analysis.

I would like to thank all University of Wollongong units and those individuals who supported this study.

I would like to thank the NSW public hospitals and those individuals who supported and participated in this survey.

Finally, I dedicate this research to my darling parents, brothers Khuldoun, Hayder, Osama and Ahmed, and my sisters Tagreed and Hala.

Khelood A. Mkalaf

TABLE OF CONTENTS

DECLARATION 0
ABSTRACT i
ACKNOWLEDGEMENTS iii
TABLE OF CONTENTS iv
LIST OF ACRONYMS 10
LIST OF FIGURES 12
LIST OF TABLES 16
CHAPTER 1: INTRODUCTION 19
1.0 Background 19
1.1 Purpose 20
1.2 Research Objectives 20
1.3 Significance 20
1.4 Problem Defined 21
1.5 Study Design 28
1.6 Scope 30
1.7 Research Questions 33
1.8 Research Methods 34
1.9 Contribution of the Study 35
1.10 Motivation to the Study 35
1.11 Organisation of the Thesis 36
1.12 Resources Statement 37
1.13 Summary 37
CHAPTER 2: LITERATURE REVIEW 39
2.0 Introduction 39
2.1 Maintenance Definition 39
2.1.1 Maintenance Management 41
2.1.2 Factors Affecting Maintenance Performance 42
2.1.3 Maintenance Management Strategies 44
2.1.4 Mixed Maintenance Management Strategies 49
2.1.5 Maintenance Management Strategies Classification 49

2.2 Reliability-Centred Maintenance (RCM) ... 59
2.3 Assessment of Current Maintenance Strategies ... 74
2.3.1 Asset Management (Medical Equipment) Issues ... 77
2.3.2 Maintenance Strategies for Medical Equipment ... 84
2.3.3 Type of Maintenance Service ... 92
2.3.4 Life Cycle Costs of Maintenance Strategies ... 98
2.3.5 Risk Based Maintenance ... 102
2.3.6 Computerised Maintenance Management Software (CMMS) ... 110
2.4 Summary ... 115
2.5 Maintenance Issues in Hospitals ... 115
2.5.1 Medical Equipment Error ... 115
2.5.2 Biomedical Engineering Department Requirements ... 118
2.5.3 Knowledge and Skills required ... 120
2.5.4 Increasing Health Care Expenditure ... 121
2.5.5 Capital Investment ... 122
2.5.6 Ownership Costs ... 123
2.5.7 Implications for research questions from this section: ... 132
2.6 Gaps in the literature and possible future directions ... 132
CHAPTER 3: RESEARCH METHODOLOGY 134
3.0 Introduction ... 134
3.1 Research Aims ... 134
3.2 Research Question ... 134
3.3 Theoretical and Conceptual Framework ... 135
3.4 Scope of Study, Sampling and Pilot Study ... 137
3.4.1 Scope of Study ... 137
3.4.2 Sampling ... 138
3.4.3 A Pilot Study ... 139
3.5 Recruitment and Participants ... 139
3.5.1 Recruitment Method ... 140
3.5.2 Assessing Participants ... 140
3.5.3 Participant Profile ... 141
3.6 Choice of Methodology ... 142
3.7 Improving the Structure of the Questionnaire ... 142

3.7.1 Variable Measurements 146
3.7.2 Qualitative Research: Interview Design and Questions 146
3.7.3 Rationale for a Mixed Method 147
3.7.4 Quantitative Research: Survey Design and Questions 147
3.8 Research Design 148
3.9 Data Collection Methods 150
3.9.1 Field Notes 150
3.9.2 Observation Phase 150
3.9.3 Data Management 151
3.10 Data Analysis 151
3.10.1 Qualitative Analysis 151
3.10.2 Quantitative Analysis 152
3.10.3 Bracketing 152
3.11 Ethical Conduct 152
3.11.1 Ethics Approval 153
3.11.2 Informed Consent 153
3.11.3 Confidentiality 153
3.11.4 Validity and Reliability 153
3.12 Summary 154
CHAPTER 4: FIELD SURVEY AND RESULTS 155
4.0 Introduction 155
4.1 Field Survey 155
4.2 Participants of Hospital Staff 157
4.3 The Vital Roles of District Managers and other Staff 158
4.4 Field Observations 160
4.5 Participant De-Identification 160
4.6 Field Study Results 161
4.6.1 Summaries of Staff Interviews and Observations 161
4.7 Major Issues Identified from Field Survey 173
4.8 Adequacy of Sampling 174
4.9 Conclusion 175
CHAPTER 5: SUMMARY OF QUESTIONNAIRE RESULTS 176
5.0 Introduction 176

5.1 General Descriptive Statistics for Each Machine Type 177
5.1.1 Number of Machines of Each Type 177
5.1.2 Availability of Alternative Equipment (e.g. backup, duplicates, equipment borrowed from other hospitals).. 180
5.2 Maintenance Management Strategies 184
5.2.1 Best Maintenance Strategy.. 186
5.2.2 Issues of Current Maintenance Strategies that affect the performance of CME.. 191
5.3 Maintenance Reliability (Medical Equipment Reliability)...................... 193
5.3.1 The Failure Rate (FR) 194
5.3.2 Reliability.. 200
5.3.4 Availability.. 201
5.3.5 Maintainability 202
5.4 Relationship between Current Maintenance Strategies and Reliability Factors 205
5.4.1 Summary 209
5.5 Effect upon Patient Outcomes... 209
5.5.1 Patient Lives and Critical Impact 210
5.5.2 Increased Injury... 211
5.5.3 Time Delays and Adverse Outcomes 212
5.6 Maintenance Practices... 212
5.6.1 Participation of Staff in Maintenance Decisions................................. 213
5.6.2 Strategies for Storing Critical Spare Parts 214
5.7 Classification of Critical Spare Parts 214
5.8 The Frequency of Availability of Spare Parts... 215
5.8.1 Lack of Available Critical Spare Parts in Australia 216
5.8.2 Contract Conditions with the Outsourced Maintenance Companies ... 216
5.8.3 Storage Problems 216
5.8.4 Accessing Difficulties Related to the Age of CME 217
5.8.5 Record Keeping of Maintenance Costs... 219
5.9 Types of Data Stored... 220
5.10 Database Systems.. 221
5.10.1 Outsourcing to Maintenance Companies 221

5.10.2 Impact of Maintenance Records on Maintenance Management Strategies 222
5.10.3 Recording of Maintenance and Subsequent Equipment Reliability 223
5.10.4 Different Methods of Record Keeping 224
5.10.5 Use of Maintenance Management Software Programs 225
5.11 Summary 228
5.12 Descriptive Analysis 229
5.12.1 Medical Equipment Performance 230
5.12.2 Availability of Back-Up Equipment 233
5.12.3 Critical Spare Parts Inventory, Suppliers and the Effects on Reliability 234
5.12.4 Medical Equipment Reliability 235
5.12.5 Efficiency and Reliability using Current Maintenance Strategies 238
5.12.6 Maintenance Records 240
5.12.7 The Effect of CME Maintenance Practices on Patient Outcomes 241
5.12.8 Maintenance Costs 243
5.12.9 Summary 245
CHAPTER 6: QUANTITATIVE RESULTS 248
6.0 Introduction 248
6.1 Correlation Analysis and Causality 248
6.2 Variable Measurements 250
6.3 Pearson Correlations of Maintenance Management System Variables with CME Reliability and Patient Outcomes 251
6.4 Data Analysis for Anaesthesia Machine 253
6.4.1 Reliability Measurement of Anaesthesia Machine 253
6.5 Data Analysis for the Defibrillator Machine 260
6.5.1 Reliability Measurement of Defibrillator Machine 260
6.6 Data Analysis for ECG Machines 263
Reliability Measurement of ECG Machine 263
6.6.1 Data Analysis of Infusion Pump Machines 263
6.7 Data Analysis of the Ventilator Machines 269
6.8 Data Analysis of the Kidney Dialysis Machines 271
6.9 Summary 272

CHAPTER 7: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS 274
7.0 Introduction 274
7.1 Adequacy of the Sample Studied 278
7.2 Limitations of the Pilot Study 279
7.3 Adequacy of Survey Questionnaire 279
7.4 Appropriateness of Critical Medical Equipment 280
7.5 Current Maintenance Strategies used for CME 281
7.6 Conclusions on Traditional Maintenance Strategies for In-House or Outsourced Maintenance Service: 283
7.7 Hypothesis Testing and Inferences 283
7.8 Qualitative Analysis and Inferences 285
7.9 Descriptive Analysis and Inferences 289
7.10 Correlation Analysis and Inferences 291
7.11 Summary 295
7.12 Conclusion and Contributions 296
7.13 Limitations of this Study 298
7.14 Future Research 299
REFERENCES ……………………………………………………………………...303
APPENDIX A: Survey Questionnaire Form ………………………………... A1-A30
APPENDIX B: A Pilot Study: Interviews and Survey Questionnaire Forms.. B1- B18
APPENDIX C: Published Conference Paper……………………………... C1- C12

LIST OF ACRONYMS

A	Availability
AHP	Analytic Hierarchy Process
AHS	Area Health Services
BMETs	Biomedical Engineering Technicians
BIPAP	Biphasic Positive Airway Pressure machine
CPAP	Continuous Positive Airway Pressure machine
CBM	Condition Based Maintenance
Cf	Criticality factor
CM	Corrective Maintenance
CME	Critical Medical Equipment
CMMS	Computerised Maintenance Management System
CMMSt	Current Maintenance Management Strategy
CMS	The Center for Medicare and Medicaid Services
DT	Down Time
DB	Department of Biomedical Engineering
DC	Cardiac Catheterisation Department
DD	Dialysis or Renal Department
DIC	Intensive Care Department
DO	Operating Theatre Department
DS	Surgical Department
ECG	Electrocardiography machine
E.N.T	Ear, Nose and Throat unit
FMAEA	Failure Mode and Effect Analysis
FR	Failure Rate
H	Hospital
HFE	Human Factors Engineering
JCAHO	The Joint Commission on Accreditation of Healthcare Organisations
ICU	Intensive Care Unite
LHD	Local Health District
MC	Maintenance costs
MMS	Maintenance Management Strategies
MMMS	Mixed Maintenance Management Strategies
MTBF	Mean Time Between Failure
MTTR	Mean Time To Repair
No of R	Number of Responses
NSW	New South Wales
OSA-CBM	Open System Architecture for Condition-Based Maintenance
PM	Preventive Maintenance
PDMH	District Managers of Hospitals,
PNUM	District Nurse Unit Managers,
PSMO	Staff Medical Officer

LIST OF ACRONYMS	
PN	Nurses and other users of CME
PB	Managers of Biomedical Engineering Departments
Pr.M	Predictive Maintenance
RCM	Reliability-Centred Maintenance
RUL	The remaining useful life
SMOs	Staff Medical Officers
TJC	The Joint Commission
TPM	Total Productive Maintenance
TQM	Total Quality Management
US	The United States
UoW	University of Wollongong

LIST OF FIGURES

Figure 1-1: Patients awaiting treatment in NSW Australian Public Hospitals 2008/09, 2009/10 and 2010/11 22
Figure 1-2: Results of the 2010 survey waiting-times for non-emergency or elective surgery in NSW public and private hospitals 24
Figure 1-3: Median waiting-times for all elective surgery in Australian public hospitals from 2000/2001 to 2009/2010 25
Figure 1-4: Median waiting-times for selected surgical procedures in NSW and all Australian public hospitals in 2009/2010 25
Figure 1-5: Hospitalisations by Local Health Districts in NSW over 10 years (2004-2013) 26
Figure 1-6: Maintenance costs from 2005/06 - 2010/11 in NSW hospitals 27
Figure 1-7: Maintenance and trade staff in NSW hospitals 27
Figure 1-8: Research model identifying the optimal maintenance strategies for critical medical equipment 29
Figure 1-9: NSW hospitals providing particular types of health care services 31
Figure 2-1: Terotechnology Economic Life-Cycle Maintenance Model 40
Figure 2-2: Total maintenance effectiveness based on an organisational effectiveness model (Kumar, 2006) 43
Figure 2-3: The key to successful maintenance management leading to maximised organisational profit (Cholasuke *et al.* 2004) 43
Figure 2-4: The reasons for TPM implementation in a company 46
Figure 2-5: Maintenance Classification Strategies proposed by Endrenyi *et al*. (2001) 50
Figure 2-6: Maintenance Classification Strategies proposed by 51
Figure 2-7: Machine maintenance supervision methods 57
Figure 2-8: Schematic Diagram Curve of a machine component's lifetime, related to condition and prognosis (Blechertas *et al.*, 2009) 59
Figure 2-9: A Failure Model and Effects Analysis flowchart by Teng and Ho 63
Figure 2-10: The functional modules of the RCM Analysis Decision System 66
Figure 2-11: Availability of medical equipment in the King Abdullah University Hospital in Jordan during 2005 by (Khalid *et al.*, 2006) 70

Figure 2-12: Reasons for machine downtime 73
Figure 2-13: Relationship between change in maintenance strategies and failure rates (Sethiya 2010) 76
Figure 2-14: Biomedical Technology structure in the healthcare system 80
Figure 2-15: Asset Maintenance Life Cycle (Levery 1998) 82
Figure 2-16: Asset Life Cycle (Kumar and Srinivas 2014) 83
Figure 2-17: Global model for dealing with PM and CM for infusion pumps and ventilator machines 86
Figure 2-18: Infusion Pump Development Timeline 86
Figure 2-19: Haemodialysis Devices 89
Figure 2-20: Ventilator machine 91
Figure 2-21: BIPAP-Vision and Respironics-CPAP machines 92
Figure 2-22: Cost model for selecting the best maintenance service 95
Figure 2-23: Cost and performance model for the best maintenance service (Da Rocha *et al.*, 2005) 96
Figure 2-24: Outsourced vs in-house repairs 1999-2004 by (De Vivo *et al.* 2004)... 97
Figure 2-25: Percentage reduction of annual maintenance fees 2002-2003 (De Vivo *et al.* 2004) 97
Figure 2-26: Input and output model for organisational maintenance systems (March, 2003) 101
Figure 2-27: Maintenance cost saving (Wu and Liu, 2010).................................... 102
Figure 2-28: Current frequency of electrical risk from machines 105
Figure 2-29: Cyclic behaviour of error-generating propogation 105
Figure 2-30: Pre- and post-implementation quality control for high risk medical equipment (Wu and Liu, 2010) 108
Figure 2-31: CMMS Equipment Obsolescence screen, Chilean Naval Hospital (Acevedo *et al.*, 2005) 112
Figure 2-32: Framework of an information system (Chien *et al.* 2006) 113
Figure 2-33: The usage rate change of using the system (Chien *et al.* 2006) 114
Figure 2-34: The relationship between the modules of the medical equipment management system (Chien *et al.* 2010) 114
Figure 2-35: Falls resulting in patient injury in a NSW healthcare setting 2007-08 118
Figure 2-36: Percentage of sentinel events reported to the TJC in 2011 124

Figure 2-37: Root causes of sentinel events, related to medical equipment 2004-2011 125
Figure 2-38: Replacement value of medical equipment by state (Australian Demographic Statistics 3101) by (Brown, *et al.*, 2001).................................. 128
Figure 2-39: Replacement value of medical equipment in Victorian hospitals (Brown *et al.*, 2001) 128
Figure 3-1: Conceptual framework of the variables affecting patient outcomes..... 135
Figure 3-2: Theoretical framework showing the relationship of the concepts described in Figure 3-1.. 136
Figure 3-3: Participating hospitals 137
Figure 3-4: The total number of critical medical equipment examined in this study 138
Figure 3-5: Response percentage 142
Figure 3-6: Theoretical and conceptual framework of the methodology................ 144
Figure 3-7: Research Model for project.. 149
Figure 4-1: Field Survey Participants by Hospital Department.............................. 156
Figure 4-2: Field Survey Participants by Staff Function 157
Figure 5-1: Provenance of 102 usable survey responses 177
Figure 5-2: The availability of alternative devices in case of failure of critical medical equipment 181
Figure 5-3: Percent of respondent hospitals that use each nominated type of maintenance strategy... 184
Figure 5-4: Respondents that reported problems in keeping critical medical equipment properly maintained and available for use 192
Figure 5-5: Number of responses counted for question shown 195
Figure 5-6: Percentage of responses confirming CME failure while providing health care services to patients.. 199
Figure 5-7: Average number of machine failures while in use (2007-2011)........... 199
Figure 5-8: Percentage of responses confirming use of reliability measurements to evaluate maintenance strategies 200
Figure 5-9: Reason for unavailability 201
Figure 5-10: Overall average of availability of critical medical equipment 2011-2012 202

Figure 5-11: Percentage of respondents operating particular CME types and average age of equipment 203
Figure 5-12: Percentage of hospital staff involved in decision-making related to CME maintenance policies 213
Figure 5-13: Frequency of record keeping of maintenance costs in hospitals 219
Figure 5-14: How often are data used for maintenance decisions 222
Figure 5-15: Types of maintenance records kept 224
Figure 5-16: Reasons for the failure of the critical medical equipment 237
Figure 6-1: Suggested causal flow model for Anaesthetic Machine failure rate 259
Figure 6-2: Suggested causal flow model for Defibrillator failure rate 262
Figure 6-3: Suggested causal flow model for ECG Failure Rate 266
Figure 7-1: Evaluation standard used to assess the quality of performance of maintenance management strategies 277
Figure 7-2: Number of hospitals distributed by the Local Health District 286
Figure 7-3: Maintenance and trades staff in NSW hospitals 287
Figure 7-4: Model for improving maintenance management strategies used for critical medical equipment 297

LIST OF TABLES

Table 1-1: Estimate of projected population growth distributed over Local Health Districts in NSW between 2011 and 2031 28
Table 2-1: Modern Strategies for Machine Maintenance 45
Table 2-2: Functioning Hierarchical Components of CBM...................................... 58
Table 2-3: Causes of Errors at the Good Samaritan Hospital in 2002 65
Table 2-4: Measurement of efficiency of a baby incubator in the Neonatal ICU Department at the Ahmed Maher Teaching Hospital in Cairo, Egypt 2008...... 71
Table 2-5: The percentage efficiency of the baby incubator Ahmed Maher Teaching Hospital in Cairo, Egypt 2008.. 72
Table 2-6: Predictive model results for cardiac equipment 73
Table 2-7: Generational Maintenance Concept Descriptions 75
Table 2-8: Maintenance Issues' from 38 medical stakeholders surveyed................. 85
Table 2-9: Preventative Maintenance Findings for Infusion Pumps.......................... 88
Table 2-10: Advantages and disadvantages of strategic maintenance services (De Vivo *et al.*, 2004) 94
Table 2-11: Maintenance Costs for In-House and Third Party maintenance services (Da Rocha *et al.*, 2005) 96
Table 2-12: Comparison between different maintenance strategies 100
Table 2-13: Examples of equipment classification by Wang B 107
Table 2-14: Risk management-based criteria (Khalaf *et al.*, 2010) 108
Table 2-15: Historical Overview of Medical Equipment Errors revealed in Clinical Diagnostic Laboratories, Emergency Departments and Intensive Care Units. 117
Table 2-16: Condition of donated equipment upon arrival (% of response)............ 120
Table 2-17: Total respondents who had difficulty finding qualified staff locally (by % of regional responses), (Mullally and Frize, 2008).................................... 120
Table 2-18: Cost drivers from Ginsburg (2008) 123
Table 2-19: TJC sentinel event data and estimates of patient incidents caused by maintenance omission 127
Table 2-20: Replacement value of medical equipment in sampled Victorian hospitals, ... 129
Table 2-21: Reported occurrence of medical mistakes survey 2010 130
Table 2-22 Financial position for plant and equipment 30 June 2013..................... 131

Table 2-23: Maintenance costs for plant and equipment 131
Table 3-1: Other critical medical equipment which could be considered in future research 139
Table 3-2: Hospital staff participating in the survey questionnaire 141
Table 3-3: Variables and their correlation with questions in the survey questionnaire 146
Table 4-1: General information about the critical medical equipment that served.. 162
Table 5-1: Summary of machine types held by respondents 178
Table 5-2: Equipment used in hospitals in this study and in NSW hospitals 179
Table 5-3: Other critical medical equipment to be considered in future research ... 180
Table 5-4: Alternative methods and devices used in case of critical medical equipment failure 182
Table 5-5: Frequency of alternative devices used to replace critical medical equipment.. 183
Table 5-6: Percept of respondent hospitals that used each nominated type of In-House Maintenance Strategy.. 185
Table 5-7: Percentage of respondent hospitals using each type of outsourced maintenance strategy.. 186
Table 5-8: Median failure rate and MTBF of selected CME 197
Table 5-9: ATTPP services by this critical medical equipment.............................. 197
Table 5-10: Management policy for failure of critical medical equipment 204
Table 5-11: Frequency that hospitals need substitute equipment 205
Table 5-12: Perception of causal relationship between maintenance strategy and failure of critical medical equipment 206
Table 5-13: Responses to whether the current maintenance strategy helps reduce the sudden breakdown of this critical device. 206
Table 5-14: Response to whether the current maintenance strategy helps increase the availability of this medical device.. 207
Table 5-15: Is the current maintenance strategy one of the reasons for the unavailability of critical medical equipment? 208
Table 5-16: Optimising maintenance to avoid over-servicing................................ 208
Table 5-17: Classification of critical parts of the critical medical equipment 214
Table 5-18: shows the percentage of readily available for critical spare parts 215

Table 5-19: Procedures used to access critical spare parts 218
In this study, 100 of the103 respondents fully completed Question 43. The results are presented in Table 5-20 below. Table 5-20: Frequency of keeping maintenance records and subsequent equipment reliability 223
Table 5-21 : Results of Questions 4, 5, 6 and 7 232
Table 5-22: Average Treatment Time per Patient... 233
Table 5-23: Annual Operation Time per machine per year 233
Table 5-24: Results for Question 10 234
Table 5-25: Results for Question 19 234
Table 5-26: Results for Question 33 235
Table 5-27: Results for Question 23: Failure rate and MTBF 236
Table 5-28: Results for Questions 37 and 38 238
Table 5-29 239
Table 5-30: Results for Questions 27 & 29.. 240
Table 5-31: Patient outcomes affected by maintenance issues 241
Table 5-32**:** Patient outcomes affected by maintenance practices 242
Table 5-33 Level of risk to patients posed by failure of equipment while in use 243
Table 5-34: In-house and outsourced maintenance costs per month 244
Table 5-35: Annual maintenance cost... 244
Table 6-1: Variables and their related questions in the survey questionnaire.......... 250
Table 6-2: Factors Related to FR and MTBF for anaesthesia machines 257
Table 6-3: Results of comparisons between failure rates and MTBF for the defibrillator machine 260
Table 6-4: Results of comparisons between failure rates for infusion pump machine (cont) 268
Table 6-5: Pearson Correlation of MTBF of the infusion pump machine 268
Table 6-6: Results of comparisons between MTBF and maintenance variables for ventilator machines 269
Table 6-7: Results of comparisons between failure rates and maintenance variables for ventilator machines.. 270
Table 6-8: Results of comparison between failure rate and MTBF of the kidney dialysis machine 271

CHAPTER 1: INTRODUCTION

1.0 Background

In hospitals, the management and the reliability of medical equipment is vital to patient outcomes and health care service availability. Maintenance engineering is, therefore, an important branch of hospital management, which an aim is to develop an optimal maintenance strategy that maximises equipment utilisation and minimises downtime. This has become complicated by the increasingly complex array of technical medical equipment in the health care sector (Khalaf *et al.* 2010; Mutia *et al.* 2012).

The purpose of medical equipment is to be of assistance in the diagnosis, monitoring and even the treatment of patients' medical conditions (Kumar and Srinivas 2014; Polisena *et al.* 2014). Medical equipment can be classified according to its use: critical, important or necessary, and also the risk its unavailability poses to patient outcomes: high, medium or low (Khalaf *et al.* 2010; Wang 2007; Wang and Levenson 2000). The type of medical equipment used in any hospital can be generally classified into biomedical, laboratory, ward; service support, utilities and hospital furniture. This study will focus on the maintenance strategy of selected critical-high risk bio-medical equipment: specifically the kidney dialysis machine, anaesthesia machine, defibrillator, diathermy and cardiac catheterisation machine.

Elements of Reliability-Centred Maintenance will be used to analyse the current maintenance strategies used on the selected critical medical equipment. These elements include quantitative and qualitative reliability analysis, both of which affect the operation of the equipment (Murthy *et al.* 2002). The quantitative analysis of reliability will be established through the calculation of the equipment's availability, Mean Time Between Failure (MTBF), Mean Time To Repair (MTTR), and Failure Rate (FR) (Medhat *et al.* 2008). Qualitative analysis is used to examine the various 'modes and causes' of failure and unreliability (Murthy *et al.* 2002; Tsantis and Apostolakis 2014).

De Groote (1995) has established that in an organisation, improving maintenance performance leads to increasing productivity, quality, safety and improving the environment. It has been shown that effectiveness and efficiency are the elements used to evaluate and improve processes or productivity (Medhat *et al.* 2008; Mutia *et*

al. 2012), and reduce unnecessary expenses that affect the total ownership costs for capital equipment (Hockel and Kintner 2014).

1.1 Purpose

The purpose of this study is to assist hospitals in general to improve their performance and patient outcomes by examining the relationship between the reliability of selected medical equipment and the type of maintenance strategies used.

1.2 Research Objectives

The objectives of this study are:

1. To identify and document the type of maintenance management strategies used for critical medical equipment, such as kidney dialysis and cardiac catheterisation, in selected NSW Public Hospitals;
2. To determine representative failures rates and mean time to repair statistics in relation to the critical medical equipment;
3. To determine the representative probability of harm to patients in the event of sudden (unpredicted) failure of critical medical equipment;
4. To determine if there is a statistically significant relationship between the availability of critical medical equipment and the effective and efficient treatment of patients and
5. To explore whether alternative 'state of the art' maintenance management strategies from other relevant industries have the potential to improve the availability of critical medical equipment.

1.3 Significance

The significance of this research can be summarised as follows:

1. This study provides measurements which can assist hospitals select optimal maintenance strategies for the use of critical medical equipment currently in use by identifying the gaps in the performance of maintenance activities. Importantly, it will determine the factors that lead to an increased incidence of failure and the time spent on repairs.
2. Reliability-Centred Maintenance will be investigated to assist hospital administration to make a decision on whether to either adopt the proposed

maintenance strategy or maintain the current one. It provides a scientific standard to enable the hospital to make an informed choice between repairing or replacing the critical medical equipment

3. The maintenance strategy proposed in this study will show how a hospital can rely on its own staff to repair critical medical equipment rather than rely on external maintenance companies. This work will consider whether an area of maintenance strategy known as RCM which involves equipment operators and owners optimising availability and the reliability may be the best approach.

1.4 Problem Defined

One problem identified in this study is that for maintenance and repair of critical medical equipment, hospitals use two types of maintenance services, in-house and outsourced. In-house and outsourced maintenance services include the following types of maintenance strategy; preventive, corrective and emergency maintenance. However, these maintenance strategies do not prevent the occurrence of sudden failure of critical medical equipment during the provision of health care services to patients. There needs, therefore, to be an increase in active maintenance for critical medical equipment after a sudden failure occurs. Hospitals presently rely broadly on external maintenance companies. Most of these services are contracted to the manufacturers of the pieces of critical medical equipment (or their spare parts).

The results of the survey reported later in this thesis indicate this may lead to the following:

1. Increase in the failure rate of critical medical equipment during the provision of medical services[1]
2. Confusion affecting the performance of medical staff due to repeated failure of critical medical equipment during the provision of medical services. Currently, the alternatives available to solve this problem are to use a backup or to borrow equipment from other hospitals located within the area.
3. Increase in waiting time for return of critical medical equipment to service, which leads to the adoption of a waiting list policy to provide treatment to patients.

[1]Chapter 5, Section 5.3.1; Failure Rate, pp. 194-196.

In relation to Waiting Time overdue patients are defined in NSW Health Annual Report (Dec. 2011, p.53) as "those who have not received treatment within the recommended timeframe".

The number of overdue patients and length of waiting time represent measures of hospital performance in the provision of health care services. Better management of hospital services could help patients avoid the experience of an excessive wait for booked treatment. Improved quality of life may be achieved more quickly, as well as gaining patient satisfaction and community confidence in the health system[2]. This thesis sets out to show that maintenance of critical equipment may be a major factor in reducing patient waiting time. Figure 1-1 shows the number of waiting patients as indicated in NSW Government Health Annual Report 2010/2011.

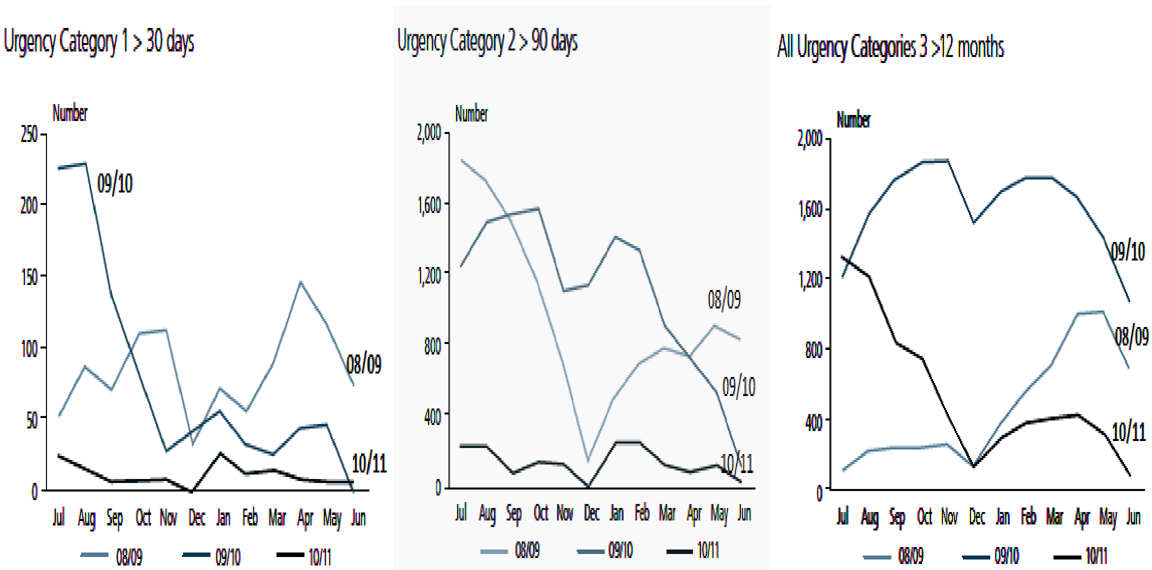


Figure 1-1: Patients awaiting treatment in NSW Australian Public Hospitals 2008/09, 2009/10 and 2010/11[2]

As can be seen in Figure 1-1, at the end of June 2011 there were only 6 Category 1 patients overdue, a significant reduction compared to the 74 at the end of July 2009. For Category 2 the number of overdue patients on the waiting list had decreased to 839 in June 2009 to 43 in June 2011. In June 2011 the total number of Category 3 patients was 96, a significant improvement from June 2010 when the number was 1,063[3].

---

[2]144 - NSW Ministry of Health Decmber 2011, *NSW Health Annual Report 2010 /2011'*, Sydney, Australia.
[3]NSW Ministry of Health (2011), p.54.

The *NSW Health Annual Performance Report (December 2010, pp 29-34)* reported that, compared with hospitals in other developed countries, in 2010 there were in NSW Public Hospitals[4]

- a total of 36% of patients waiting 2-7 days for a primary care appointment,
- more than 80% of visitors to emergency departments waiting less than four hours for treatment,
- more than half (63%) finding it difficult to access medical-care after-hours, except when admitted to hospital emergency departments,
- approximately one in six patients who received elective surgery in NSW public hospitals, reported waiting more than six months for their operation. NSW in Australia ranked particularly low in timeliness compared with other developed countries,

  "Elective or 'planned' surgery is defined as surgery that a doctor, or other health professional, believes to be clinically necessary, but which can be delayed for at least 24 hours. These operations are booked in advance, following medical assessment of the patient"[5].

- more than 8 out of 10 NSW patients (85%) receiving elective surgery in 2008-2009 commented, that they waited less than six months for their operation, and
- more NSW patients wait longer than six months for elective surgery (14%) than in many other countries surveyed in 2010 as shown in Figure 1-2. This thesis makes some observations on reasons why NSW hospitals are clearly inferior to those in other developed countries in terms of patient waiting times. This may be due to the unavailability of equipment. Figure 1-2 illustrates a comparison of patient waiting times in selected NSW public and private hospitals compared to hospitals in other countries.

---

[4] 35 - Bureau of Health Information December 2010, *Healthcare in Focus: How NSW Compares Internationally'*, Annual performance report, NSW Health Government, Sydney,NSW, Australia.
[5] *86 - Information, B. o. H. December 2010, Healthcare in Focus: How NSW compares internationally', Annual performance report: December 2010, Bureau of Health Information Sydney, NSW, Australia.*

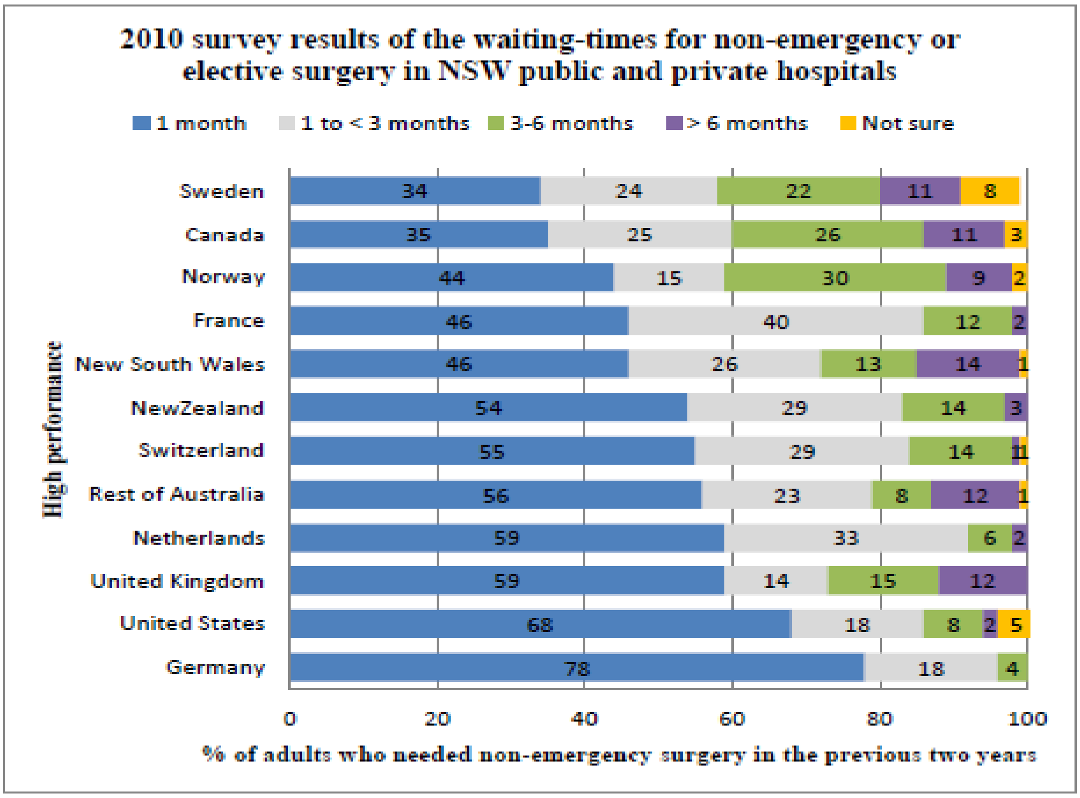
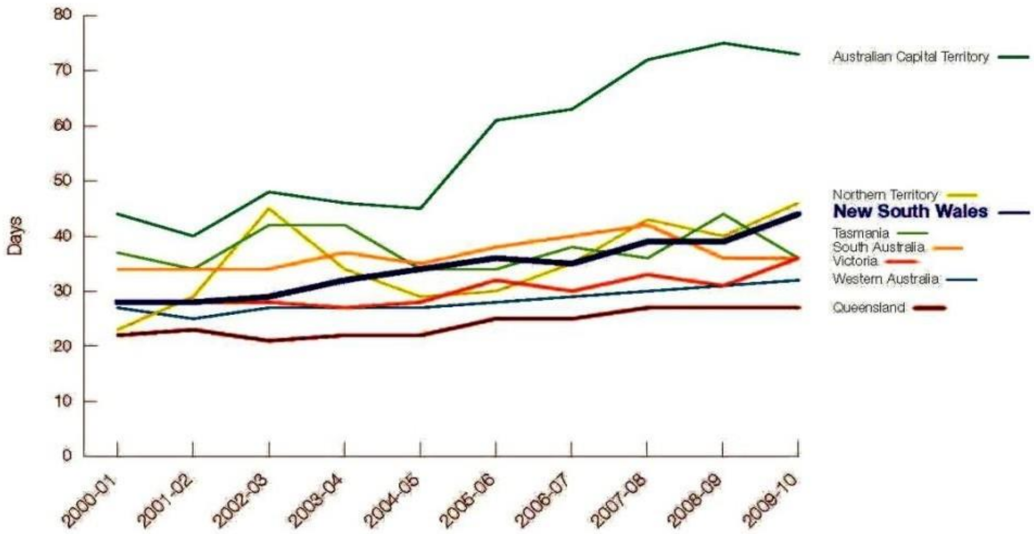


Figure 1-2: Results of the 2010 survey waiting-times for non-emergency or elective surgery in NSW public and private hospitals[6]

A comparison of medical procedures between states of Australia shows that:-

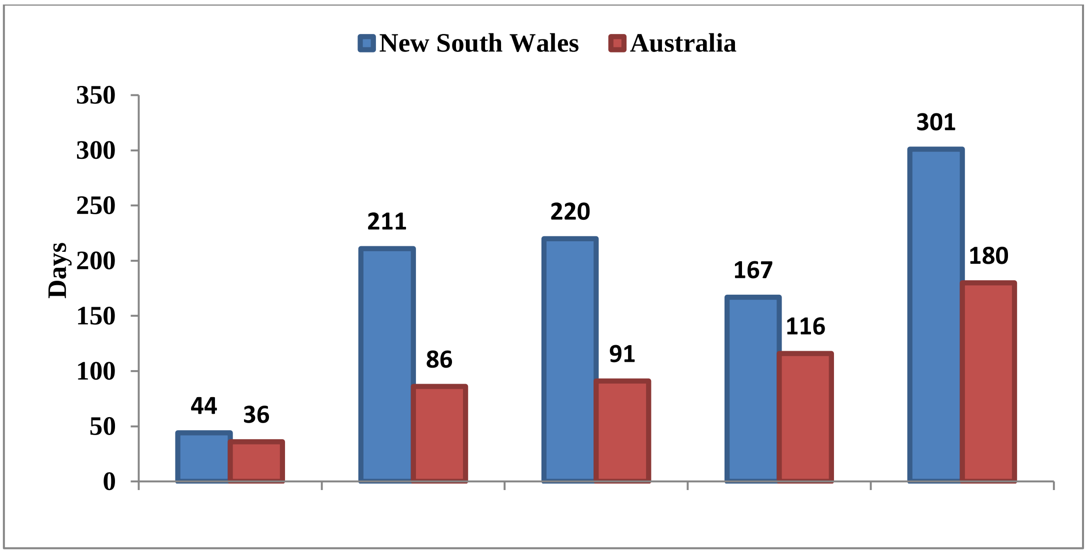
- in 2009-10 NSW had longer median waiting times for surgery (44 days) than all other states, except for the ACT (73 days) and NT (46 days) as shown in Figure 1-3. (the median waiting times refer to the number of days that the middle patient waited; i.e. half of all patients had a longer waiting time.)
- median waiting-times for specific procedures revealed some differences between NSW and Australia as a whole, as shown in Figure 1-4.
- minimal health services available in some NSW hospitals resulted in low levels of patient satisfaction during their waiting-times.
- increased number of hospitalisations for patients in Local Health Districts and Health Services in NSW over the 10 years (2003/2004-2012/2013) as shown in Figure 1- 5.

[6] BOHI December 2010, *Healthcare in Focus: How NSW compares internationally', Annual performance report: December 2010, Bureau of Health Information* Sydney, NSW, Australia.



2000/01 to 2009/10	Tasmania	South Australia	Queens -land	Victoria	NSW	Western Australia	Northern Territory	Australia Capital Territory
Change in median waits (days)	-1	2	5	8	16	12	21	28
% change in elective surgery admissions	29%	24%	9%	41%	3%	66%	72%	43%

Figure 1-3: Median waiting-times for all elective surgery in Australian public hospitals from 2000/2001 to 2009/2010[6]



Number of procedures 2009-10	Total	Cataract extraction	Tonsillectomy	Total hip replacement	Total knee replacement
New South Wales	198,503	19,070	4,946	3,023	5,217
Australia	609,505	52,091	16,833	8,572	12,513

Figure 1-4: Median waiting-times for selected surgical procedures in NSW and all Australian public hospitals in 2009/2010[5]

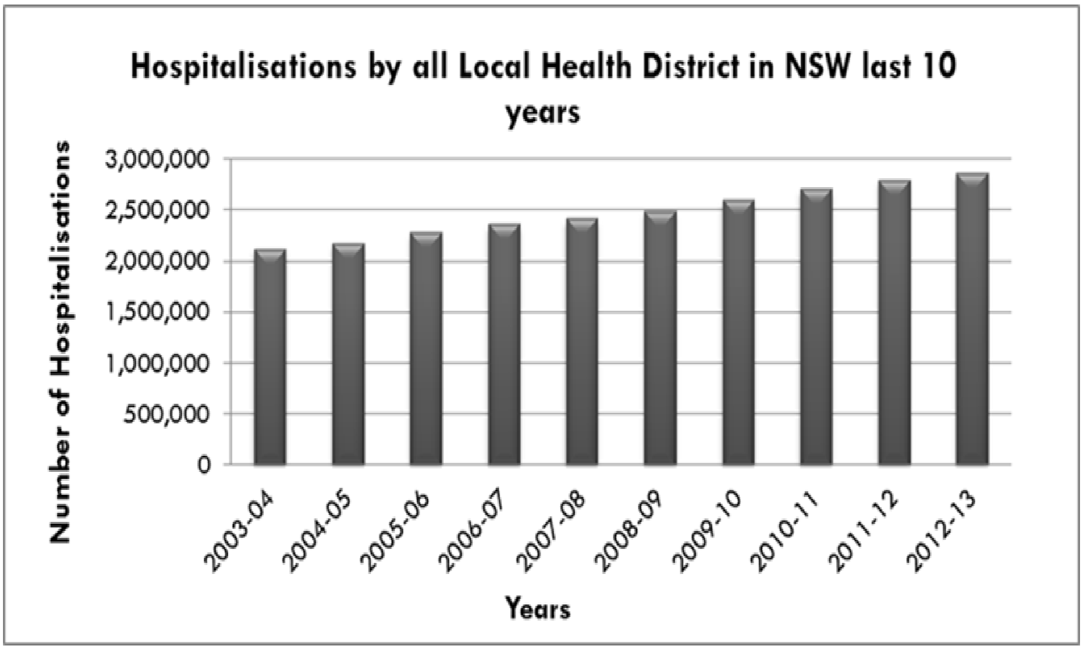


Figure 1-5: Hospitalisations by Local Health Districts in NSW over 10 years (2004-2013)[7]

- Maintenance and overall operating costs were high in the short term, specifically the cost of outsourcing. Figure 1-6 shows a comparison of maintenance costs between 2005/2006 to 2010/2011 in NSW hospitals, as indicated in the *NSW Government Health Annual Report 2010/2011*. The total maintenance costs were $356 million in 2010/2011. This report also showed the actual capital expenditure of the asset management was $742 million in 2009/2010 and $898 million in 2010/2011.

[7] 143 - NSW Health Statistics 2014, *Population Growth by Local Health District'*, NSW Ministry of Health Corporate Governance and Accountability Compendium, Sydeny, NSW, Australia.

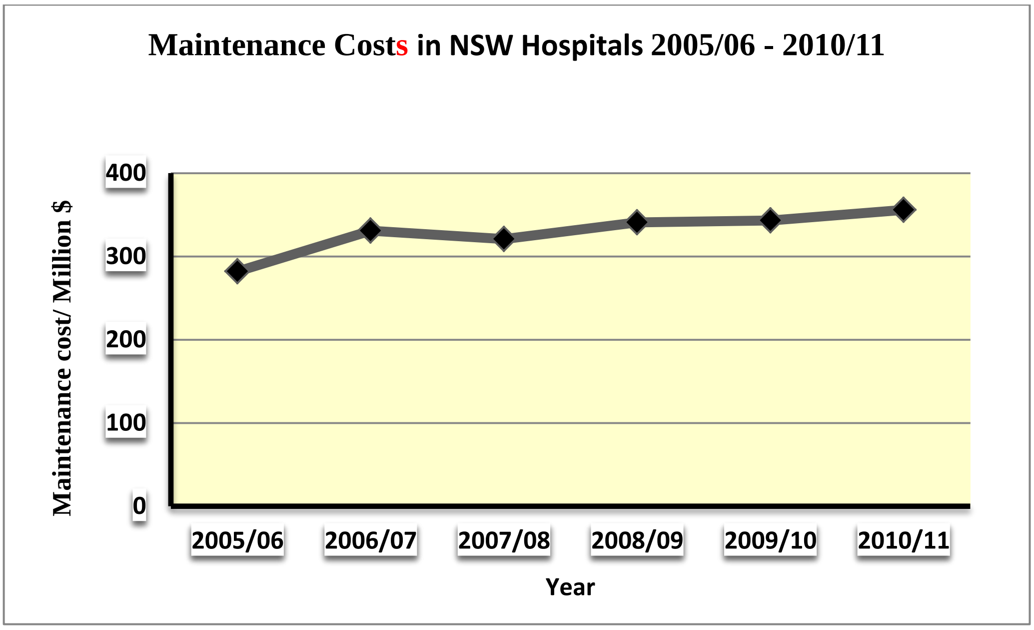


Figure 1-6: Maintenance costs from 2005/06 - 2010/11 in NSW hospitals[8]

- In 2010-2014, the number of maintenance and trade staff in NSW hospitals continued to decline (respectively 4%, 6%, 9%, and 10%) as indicated in the annual report to the NSW Ministry of Health in 2014, as shown in Figure 1-7.

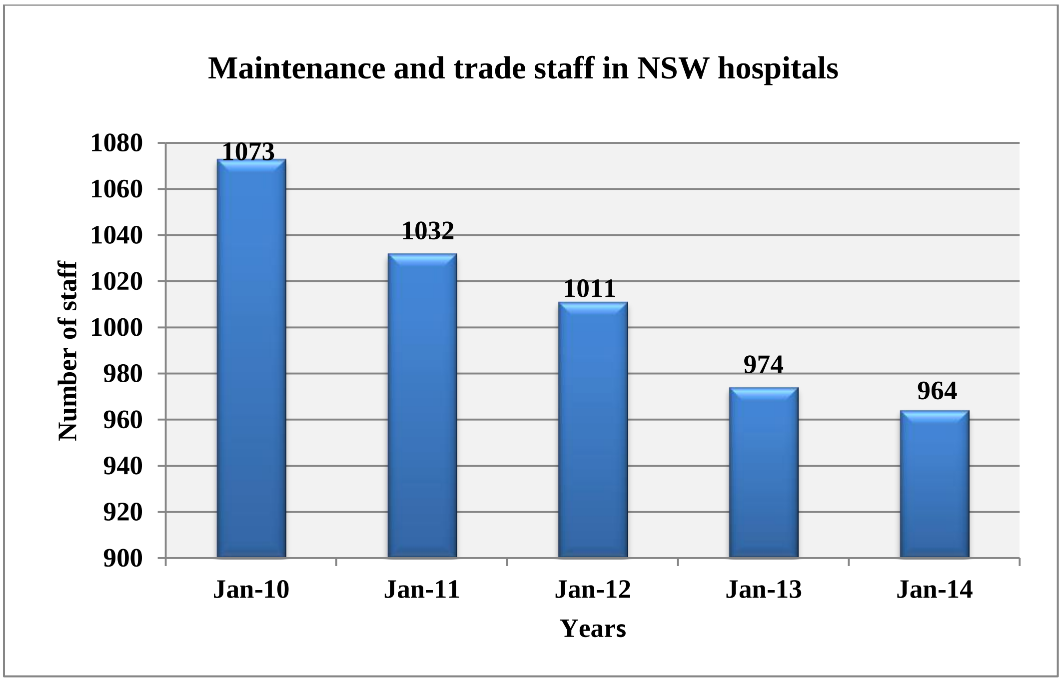


Figure 1-7: Maintenance and trade staff in NSW hospitals

[8] NSW Government Health: Annual Report in 2010-2011, Sydney, NSW, Australia.

- The estimated increase in population in NSW 2011 to 2031, as shown in Table 1-1, will lead to increased demand on health care services in local areas.

Table 1-1: Estimate of projected population growth distributed over Local Health Districts in NSW between 2011 and 2031[9]

Local Health Districts	Population		Per cent change
	2011	2031*	2011
Sydney	582,205	696,357	19.6
South Western Sydney	875,384	1,293,299	47.7
South Eastern Sydney	847,010	928,782	9.7
Illawarra Shoalhaven	384,144	459,427	19.6
Western Sydney	846,174	1,141,596	34.9
Nepean Blue Mountains	348,165	423,736	21.7
Northern Sydney	852,545	960,054	12.6
Central Coast	321,704	404,852	25.8
Hunter New England	873,741	1,013,535	16.0
Northern NSW	288,307	363,565	26.1
Mid North Coast	207,242	268,224	29.4
Southern NSW	196,128	258,512	31.8
Murrumbidgee	236,774	250,658	5.9
Western NSW	271,273	272,467	0.4
Far West	31,124	25,233	-18.9
Albury LGA Residents	49,548	56,725	14.5
All LHDs	7,211,468	8,817,023	22.3

1.5 Study Design

A wide review of previous studies on maintenance performance found that most agreed with the theoretical models for planning and scheduling maintenance activities as proposed by Wang *et al.*, (2006), but only a few included examples of their practical application, especially in the healthcare sector. Major reasons for this were: lack of data and information required for comparison between different maintenance strategies and different computerised maintenance management systems as indicated by Wang *et al.*, (2010).The research model proposed in this study, as shown in Figure 1-8, is a practical attempt to combine Reliability-Centred

[9] 143 - NSW Health Statistics 2014, *Population Growth by Local Health District'*, NSW Ministry of Health Corporate Governance and Accountability Compendium, Sydeny, NSW, Australia.

Maintenance (RCM) and Failure Mode and Effect Analysis to identify an optimal maintenance strategy for selected critical medical equipment. Formulation of the research model for this study depends on:

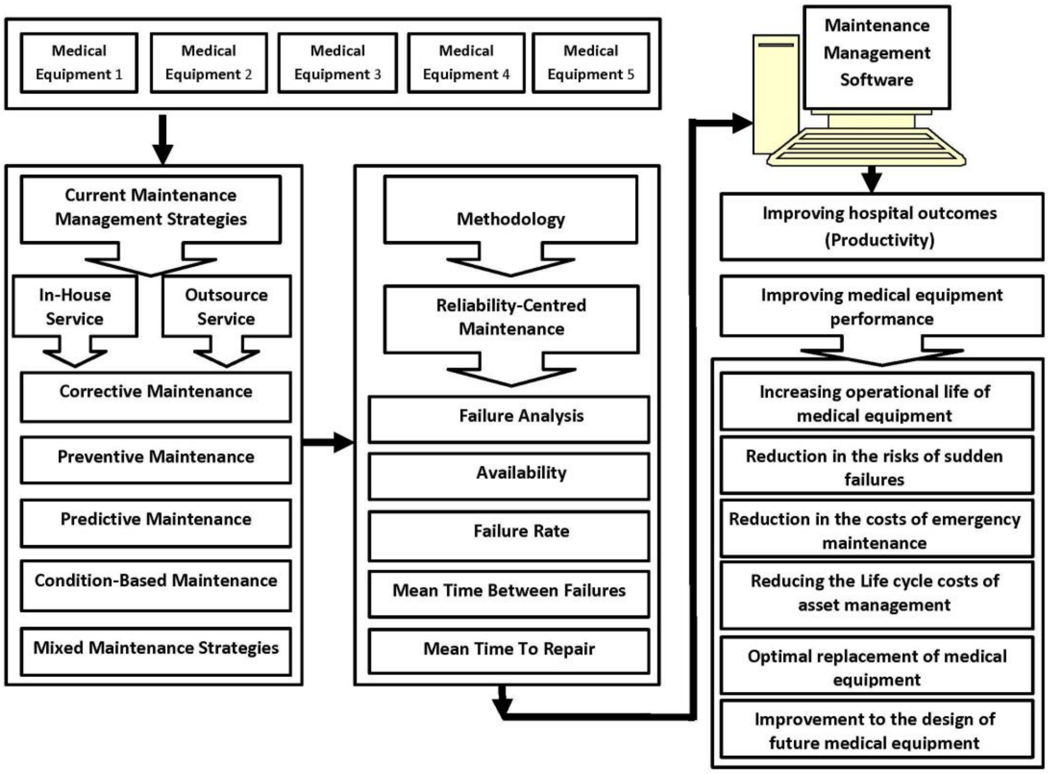


Figure 1-8: Research model identifying the optimal maintenance strategies for critical medical equipment

Figure 1-8 above shows the formulation of a research model in this study, where the author recommends suitable maintenance strategies for individual medical machines[10].

- Firstly, assessing the extent, effectiveness and efficiency of maintenance strategies currently used for critical medical equipment and their impact on the availability of this medical equipment,
- Secondly, by applying standards of measurement using Reliability-Centred Maintenance (RCM) based on failure mode and effect analysis to assess the performance of critical medical equipment as well as determining each of the

[10] Chapter 7, Figure 7-4, p. 297.

following: Availability (A), Failure Rate (FR), Mean Time Between Failure (MTBF) and Mean Time To Repair (MTTR).

- Thirdly, developing an action plan aimed at the use and application of appropriate maintenance management software in order to increase the efficiency of the maintenance strategies currently used in hospitals.
- Finally, using the results found in this study to focus on improving the performance of hospitals and patient outcomes. Improving both the performance of hospitals and the reliability of medical equipment can be achieved by assessing the impact of risk-based maintenance, life cycle cost of asset management, type of maintenance services and use of maintenance management software on the effectiveness of performance.

1.6 Scope

This study is principally focused on assessing current maintenance strategies and their influence on the reliability and availability of critical medical equipment, as well as their influence on patient outcomes in selected New South Wales public hospitals. The findings may be valuable for other researchers in carrying out similar research in hospitals in other Australian States. This research is also significant for the development of maintenance management strategies in developing countries. Its scope can be outlined as follows:

1. There are more than 230 public hospitals in New South Wales. These are distributed among 17 Local Health Districts and Health Services in order to provide free health care services to public patients. These hospitals can be classified according to:

   a) Type of health care services provided (E.N.T., cardiothoracic, gynaecology, neurosurgery, ophthalmology, opthopaedic surgery, plastic surgery, urology and vascular surgery), as shown in Figure 1-9.

   b) Size of hospitals and bed capacity, including approximately 65 aged care and rehabilitation hospitals and three children’s hospitals.

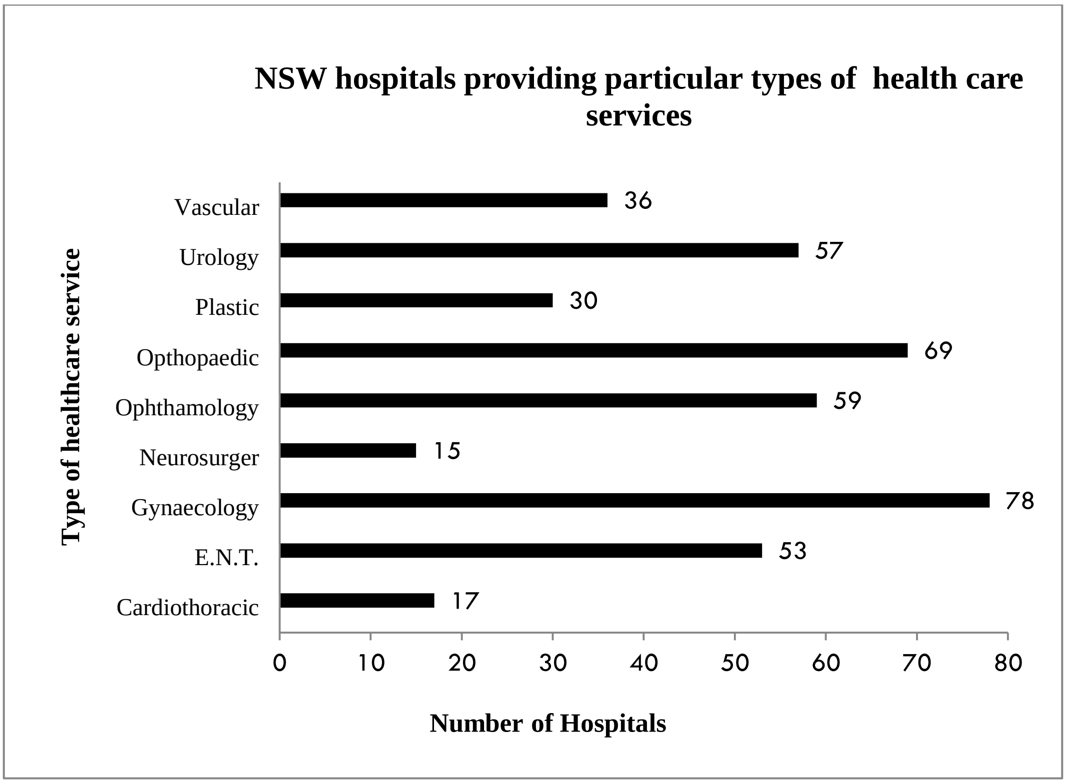


Figure 1-9: NSW hospitals providing particular types of health care services

2. 84 New South Wales Public Hospitals responded to this study, which contained some or all of the departments Kidney Dialysis, Cardiac Catheterisation, General Surgery or Theatre Operations and Biomedical and Clinical Engineering.
3. This study has selected 13 types of critical medical equipment, which have a high risk level such as the kidney dialysis machine, anaesthesia machine, defibrillator, defibrillator-manual, diathermy machine, cardiac catheterisation machine, respironics, BIPAP, CPAP, PUMP, ventilator, infusion pump, ECG machine, the electrosurgical machine, nebuliser and oxygen concentrator. The total number of targeted critical medical equipment in this study was (5769) units.
4. A survey questionnaire was distributed to Public hospitals in NSW in 17 Local Health Districts and Health Services (LHDs).
5. The target sample group used to provide data for this study included an average of 2.4 people per hospital, the total number being 103. The staff positions targeted in the survey questionnaire were District Managers of Hospitals, District Nurse Unit

Managers, Managers of Biomedical Engineering Departments, Staff Medical Officers (SMOs) and nurses plus other users of critical medical equipment[11].

6. The survey used in this study is consists of six significance sections. ***Section 1*** to assess current maintenance strategies used in these hospitals, including repair and replacement policy, spare parts availability and type of maintenance services. ***Section 2*** to determine the availability and reliability of critical medical equipment. ***Section 3*** to determine the types of equipment failure and causes. ***Section 4*** to determine the risk to patients resulting from the failure of critical medical equipment during the provision of healthcare services. ***Section 5*** to determine the cost of maintenance activities. ***Section 6*** to evaluate systems for keeping data on maintenance activities and the possibility of using maintenance management software as will be proposed by this study[12].
7. Hospitals were studied to ascertain if their maintenance of CME had been monitored by using the Reliability-Centred Maintenance (RCM) (Nowlan *et al.*, 1978) in terms of Availability (A), Failure Rate (FR), Mean Time Between Failure (MTBF) and Mean Time To Repair (MTTR). Due to the results of the pilot study, this study has chosen those hospitals that do not rely on predictive maintenance for CME[13]. It is also recognised that the lack of in-house biomedical engineering departments means that hospitals have to rely largely on contracts with maintenance companies[14].
8. The data analysis was carried out by using the Survey Monkey website as well as SPSS for Windows and Microsoft Excel.
9. A pilot study of 6 different units: kidney dialysis, surgical, cardiac catheterisation units in three hospitals included five types of critical medical equipment that had problems of non-availability and a high level risk of death or injury to patients if equipment failed during treatment e.g. kidney dialysis, anaesthesia, defibrillator, diathermy and cardiac catheterisation machines.

---

[11]Chapter 3, Section 3.5.3: Participant Profile, p. 141.
[12]Appendix A: Survey Questionnaire Form, p. A1-A30.
[13] Chapter 3, Section 3.4.3: A pilot study, p.139.
[14] Chapter 2, Section 2.2: Reliability-Centred Maintenance, p. 59.

Preliminary interviews and survey questionnaire forms were designed and used for collecting data at this stage[15].

10. The data collected in the pilot study was used to assess current maintenance strategies for critical medical equipment and to improve the final survey questionnaire design.

Three public hospitals in New South Wales were chosen for the pilot study for the following reasons:

I. Similarity of medical equipment, the reliability of which can be analysed using multi-quantitative and qualitative methods.

II. Unity of purpose in providing the best health services to patients.

III. Scientific status, the status of all hospitals involves a similarity of size and processes, which makes any of them an alternative in facilitating the process of research and study.

IV. Similarity of medical equipment; all hospitals have the same medical equipment in health service delivery. This leads to statistically similar data and information collection. The choice of these hospitals should give accurate results.

V. The inputs and outputs of the chosen hospital units strongly influence patient health outcomes.

VI. Sudden failure during health service delivery of selected critical medical equipment in this study may result in a high level of risk to patients' lives, and

VII. CME selected have a common three stage path of operational life which is Initial Failure, Chance Failure and Wear-out Failure (Slack *et al.*, 2014).

1.7 Research Questions

Q1. What are the opinions of users and maintainers in relation to the influence of current maintenance management strategies have on the reliability of CME in hospitals?

[15] Chapter 3, Section 3.7.2: Qualitative research: Interview design and questions, p.146, and Appendix B: A pilot study; interview and survey questionnaires forms, p. B1-B18.

1.1 Is there an apparent correlation between the type of maintenance strategy used and the availability of CME?

1.2 Is there an apparent correlation between the type of maintenance strategy used and the failure rates of CME?

1.3 What are user opinions of the magnitude of downtime of failed CME and how do current maintenance management strategies affect this?

Q2. What are the likely major factors that influence the selection of maintenance strategies for CME in hospitals?

Q3. What kind of maintenance management strategies could potentially be used to increase equipment availability and decrease costs while achieving the desired level of patient outcomes?

1.8 Research Methods

This study will use Reliability-Centred Maintenance as a methodology to measure the status of CME that have a high risk level. Reliability-centred maintenance is the application of quantitative measures appropriate to the nature of the data collected. It is also provides data on the probability of failure of CME through the adoption of Failure Mode and Effect Analysis (FMEA). The measures available that can be relied upon in the analysis of results include; Mean Time Between Failures (MTBF), Mean Time to Repair (MTTR), Failure Rate (FR), and Availability (A). Reliability-Centred Maintenance is discussed in chapter two[16], as well as in research methodology in the third chapter of the thesis.

The collection of data required by this study has involved using the following procedures;-

- survey/questionnaire to collect information regarding current maintenance strategies for selected CME;
- interview to collect qualitative and quantitative data on the reliability of selected CME;
- form to use in the interview process to analyse daily maintenance activities and failure rates of selected CME;

[16] Chapter 2, Section 2.2: Reliability-Centred Maintenance, p. 59.

- Personal observation of the daily maintenance activities carried out on the CME selected; and
- Discussion of the data analysis.

1.9 Contribution of the Study

This study contributes to the development of appropriate maintenance strategies by conducting an analytical study that examines recognised factors of measurement and linking them to hospital performance using appropriate statistical methods. The findings will provide hospitals with information about how the quality of maintenance strategies used impacts on their competitive advantage and ability to achieve strategic objectives. High quality maintenance activities will be shown to increase the availability and reliability of CME which contributes to the overall efficiency of the operating system. The measurements used in this study will contribute to the operational availability of CME and reduce sudden breakdown time. This study will also contribute new approaches that will assist hospitals in using and applying suitable maintenance strategies. It has moved from the theoretical to the practical approach depending on the analysis of failure time distribution, specifically in CME. In addition, it has used different measures[17] to obtain data on the current maintenance strategies in use for CME. These measures include: analysis of failure, reliability, repair and replacement theory. At the same time, this study will determine the risk related to patient as a result of sudden breakdown of CME during the health care delivery.

1.10 Motivation to the Study

The motivations considered for this study are:

- This type of research is new in Area Health Services (AHS) in Australian Public Hospitals. Maintenance management strategies for CME are a significant issue in providing high quality and safe healthcare and improving patient outcomes. As a result the performance of CME and thus hospital care will improve.
- Maintenance management strategies have been researched briefly in the Australian healthcare sector but not many researchers have paid attention to a

[17] Chapter 1, Section 1.8: Research Methods, p. 34.

comparison between maintenance management strategies and patient outcomes, as well as, improving performance of CME.

- In the Australian healthcare sector it is critical to carry out careful research in the area of CME and risk based maintenance in relation to patient outcomes due to the sensitive nature of the area and privacy of individual patients.
- Despite its limitations, the literature review shows that there is a lack of studies in the Australian healthcare sector in general, and in maintenance management strategies and reliability of CME in particular. This study may be a basis for future studies in maintenance management strategies in these areas.

1.11 Organisation of the Thesis

This study consists of 7 chapters:

- Chapter 1: The introduction provides the rationale for the study; its aim and objectives; its contribution to the field study; a brief description of the study design; and an overview of the thesis design.
- Chapter 2: The literature review examines the literature on maintenance strategies for CME in hospitals. This includes a critical review of major research works, published and unpublished.
- Chapter 3: The research method outlines and justifies the research methodology and outlines the plan and procedure of the proposed study.

  It describes the methods used for data collection, data sources, hypotheses and the plan of analysis. It also, presents the design principles of survey questionnaires, explains the types of questions selected for this study, and describes the interview form.
- Chapter 4 describes the field study with personal observations and field notes on the reliability of current maintenance strategies used for CME.
- Chapter 5 is a qualitative analysis of the survey questionnaire questions discussing why particular CME has been selected and how it was classified in the study sample to focus on critical types of CME.
- Chapter 6 is a quantitative analysis of the data from the survey questionnaire using SPSS.

- Chapter 7: Discussion, Conclusion and Recommendations: This chapter discusses the issues surrounding the identified maintenance strategies of CME used and applied in the selected hospitals. It focuses on the availability of the equipment and the level of risk relevant with sudden failure. In addition, summarises the findings of this study. Also, it includes outlines of the proposals and recommendations for application in hospitals and for further research.

1.12 Resources Statement

The following resources were used in this study:

A. Electronic library in the University; books, articles, previous studies, periodic reports for hospitals, scientific conferences, theses with a focus on recent publications.
B. Field study: Access to (1) hospital data and departments such as Biomedical Engineering, Kidney Dialysis, Cardiac Diagnostics and Operations/Surgery in order to collect data and interview staff; (2) technical and technological documents (catalogues) for the CME in the study sample; (3) analysis of current maintenance activities for medical devices; (4) documents, reports and Statistical data published on the annual evaluation of the performance of hospitals by New South Wales Government Health (NSWGH); (5) statistical software programs, e.g. Monkey Survey website, SPSS for Windows and Microsoft Excel to analysis the data and information collected by the survey questionnaire.

1.13 Summary

Critical medical equipment plays a vital role in the health care delivery system. Therefore maintenance management strategies are a major branch of hospital management. Ensuring availability of CME and predicting possible sudden failure depends on the skills of the engineering maintenance department. Finding a maintenance strategy which can be devised to predict maintenance problems can help to prevent recurrent failure of CME in the provision of health care. This study is an attempt to analyse the relationship between basic variables that play a vital role in identifying the optimal maintenance strategy for CME through Fault Analysis, Reliability Theory, Repair and Replacement. It also focuses on improving

performance measures in the hospital, which leads to reducing the risk to patients as a result of breakdown of CME during health care delivery. This will be reviewed in detail in the next chapters, which will focus on the practical issues associated with CME assessment in the hospitals studied and a presentation and discussion of the field study.

CHAPTER 2: LITERATURE REVIEW

2.0 Introduction

This chapter has two purposes. The first is to provide an overview of the various maintenance management strategies in use for hospital equipment which is of critical importance. The second is to compare these various strategies using Reliability Theory. This comparison will be used to establish an optimal maintenance strategy that can reduce failure rate and increase the availability of Critical Medical Equipment (CME).

2.1 Maintenance Definition

Maintenance is defined from a theoretical perspective as those activities that protect the original or operational condition of equipment or facilities "as-built" (Pintelon and Gelders 1992; Brook 1998; Reason 2000; Dhillon and Liu 2006). However, this definition focuses on maintaining equipment design characteristics and does not acknowledge how performing repairs at intervals can extend the useful life of equipment by ensuring system reliability and reducing idle time (Endrenyi *et al.* 2001; Dhillon and Liu 2006; Muchiri *et al.* 2011). In 1995, 'maintenance' was defined by The *Maintenance Engineering Society of Australia (MESA)* as, "the achievement of required asset capabilities within an economic or business context"(Muchiri *et al.*, 2011).

One strategic and effective approach that has been implemented in numerous organisations is that of Total Productive Maintenance (TPM), which is integrated within the concept of Total Quality Management (TQM). This is a continuous improvement methodology that aims to optimize the availability and effectiveness of existing equipment by minimizing input and reducing life cycle costs (Medhat *et al.* 2008; Pintelon and Parodi-Herz 2008). This approach tends to be used more in industrial than service organisations because of its emphasis on the need for continuous improvement of productivity.

Terotechnology is another approach to the continuous development of productive maintenance, which has been developed by the UK Department of Trade and Industry. This is defined as a combination of management, financial, engineering and other allied practices applied to physical assets in pursuit of economic life-cycle costs (Checkland 1979; Levery 1998; Shahanaghi and Yazdian 2009), which are

concerned with the specification and design for reliability and maintainability of plant, machinery, buildings and structures, their installation and replacement, feedback of information on design, performance and costs (Pintelon and Gelders 1992; Levery 1998; Belak 2004; Belak and Cicin-Sain 2005). A Terotechnology model was devised by Coetzee and Studdert (2004) and reproduced by Salonen (2011). This is shown in Figure 2-1 below.

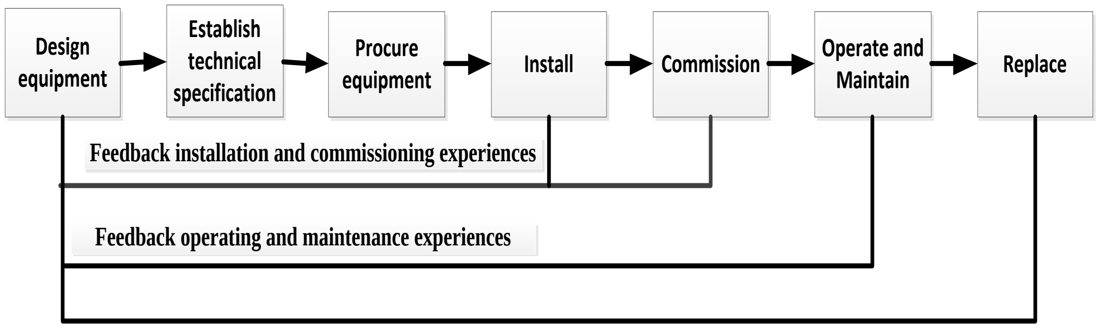


Figure 2-1: Terotechnology Economic Life-Cycle Maintenance Model (Coetzee 2004; Salonen 2011)

The concept of terotechnology has emerged over the past thirty years and is based on solving problems through the Analysis Theory System. It is still very new and therefore its application in the health industry is rare. However the concept has many applications eg the introduction of a system for life cycle management by companies in the USA and UK. Countries like Romania need to improve the life-cycle of their industrial equipment by integrating terotechnology into their operational management systems. The technical life-cycle of each machine is a series of particular events from its conception to replacement. The common denominator for all machines is the cost of their maintenance over their life-cycles (Drăguţoiu 2009). The efficient maintenance of an organisation's equipment is just one component of an integrated terotechnology system. Many US organisational experts use their own methods for evaluating the life-cycle of machinery but terotechnology has a better scientific basis, founded in its interdisciplinary analysis (Drăguţoiu 2009).

Although this concept covers all functions and activities related to maintenance strategy improvement, it is only applied in a few industrial organisations. No healthcare organisation has applied this integrated system in its maintenance strategy. As medical equipment has different structures, manufacturer's designs require

different maintenance strategies for each piece of equipment. The majority of health-care organisations widely adopt the practice of outsourcing their maintenance. For this reason there is a lack of feed-back of maintenance information on the life-cycle of medical equipment. Maintenance strategy in a hospital equipment scenario is defined here as *‘all activities that ensure the continuous provision of medical equipment functions to reduce the risks related to sudden failure; and lead to maximising the value of a healthcare organisation through its timely provision of health services to patients.’*

2.1.1 Maintenance Management

In general, a maintenance management strategy has number of goals (Endrenyi *et al.* 2001; Ratnayake and Markeset 2010; Muchiri, Pintelon, Gelders and Martin 2011; Salonen 2011; Salonen 2011; Mutia *et al.* 2012). These include:

- Extending equipment lifetime by replacement, repair, the mean time to the next failure whose may be too costly;
- Reducing the frequency of service interruptions and the many undesirable consequences of such interruptions;
- Improving component and system reliability;
- Enhancing equipment capability quantitatively and qualitatively;
- Improving safety, health and environmental factors in the expectation that such improvements will contribute to better quality and higher profits and
- Reducing maintenance costs by increasing system capacity, reinforcing redundancy and employing more reliable components.

Benefits include:-

- Improving the utilization of medical equipment;
- Ensuring that medical equipment is always in the best technical condition;
- Ensuring the integrity rate of equipment usage;
- Improving equipment reliability;
- Improving the economic benefits to the hospital;
- Reducing hospital operating costs, optimizing the financial structure and improving the ongoing costs of medical equipment;

- Reducing hospital dependence on sub-contractors, which is the main factor in increasing maintenance costs and low maintenance performance and
- Reducing the cost of maintenance by having an effective spare part inventory.

2.1.2 Factors Affecting Maintenance Performance

Maintenance performance impacts on all departments of an organisation and encompasses a number of factors. Parida (2007) highlights seven main criteria for the measurement of maintenance performance. These are: (1) process-related maintenance, (2) maintenance costs, (3) maintenance activities, (4) customer satisfaction, (5) quality maintenance, competitive growth, training and innovation, (6) health, safety and environmental issues, and (7) staff satisfaction. Kumar *(2006)* divides maintenance performance into two categories, Internal and External. Internal effectiveness factors gauge maintenance activities, based on their performance during the manufacturing process. External effectiveness factors concern the issues after a product is sold as shown in Figure 2-2 below, which illustrates the divisions of total maintenance effectiveness and common factors affecting it.

Internal effectiveness factors include productivity, costs and profit and are therefore directly related to maintenance operations. As maintenance is undertaken by people, it needs to be measured so as to eliminate unnecessary maintenance mistakes. The reliability and efficiency of Resource-Utilisation is also a major factor for consideration (Samat *et al.* 2011). External effectiveness covers customer satisfaction, and needs to be measured to counter inadequate internal factors. Service quality, timeliness of delivery, health, safety and environmental issues are highlighted. The monitoring of the long-term effects of maintenance also ensures effective manufacturing, which results in reliable products (Samat *et al.* 2011).

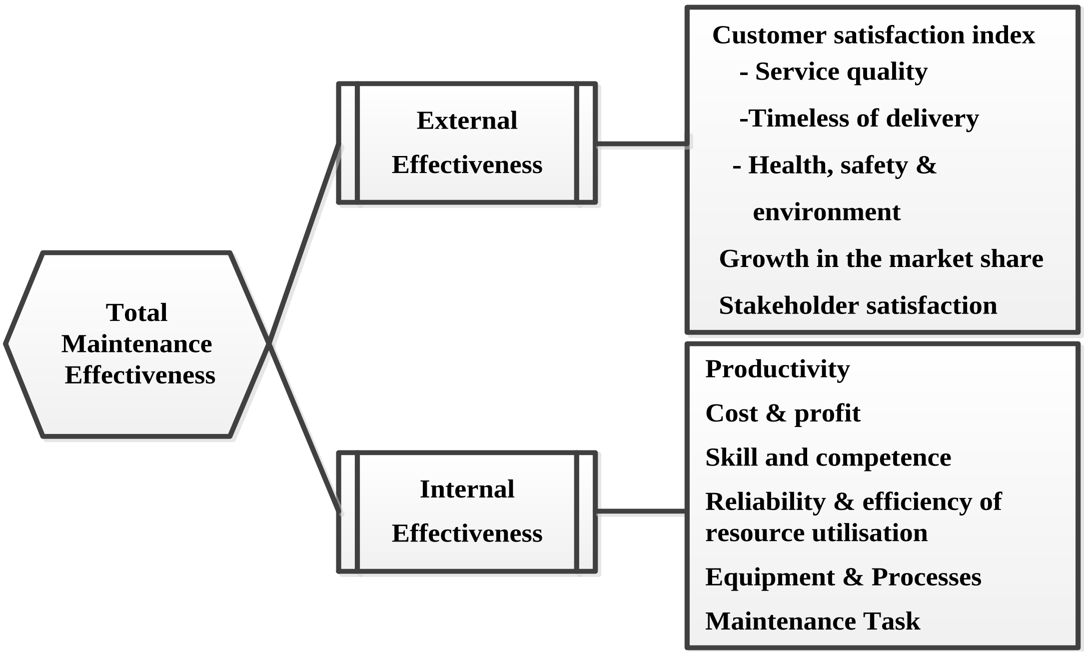


Figure 2-2: Total maintenance effectiveness based on an organisational effectiveness model (Kumar, 2006)

Successful maintenance management is dependent on a number of important factors, as summarized by Cholasuke *et al.* (2004) in Figure 2-3.

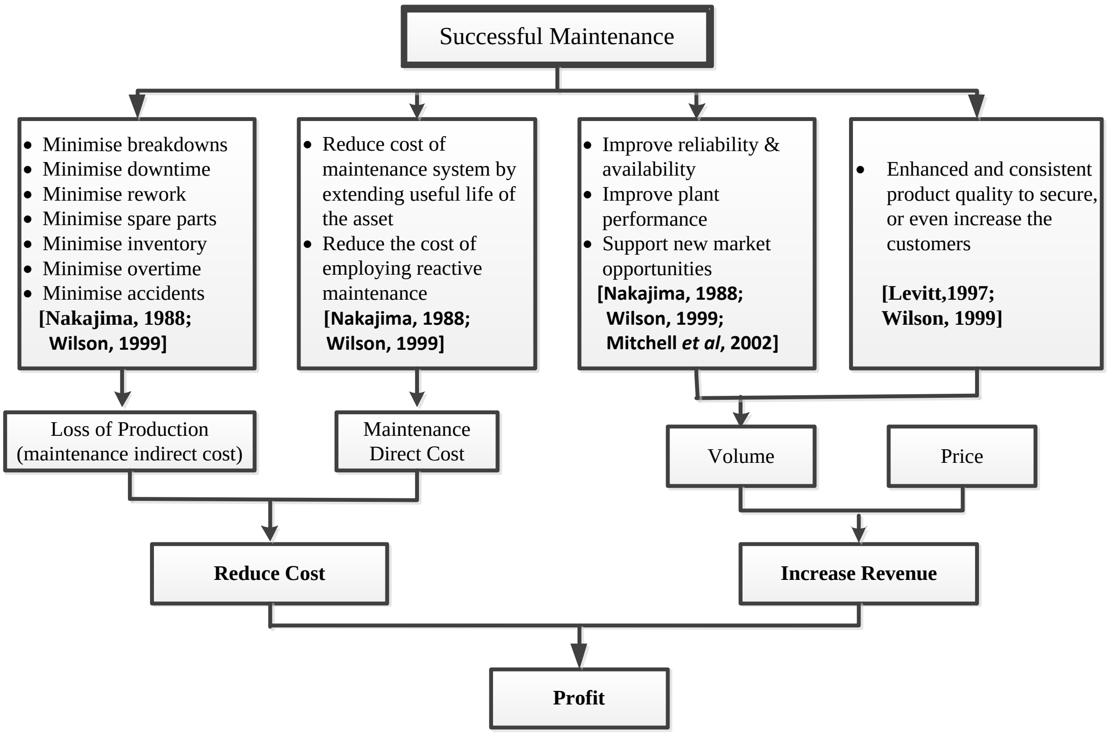


Figure 2-3: The key to successful maintenance management leading to maximised organisational profit (Cholasuke *et al.* 2004)

In Figure 2-3, the main goal of successful maintenance in industrial organisations is the maximisation of profit. In contrast, healthcare organisations are concerned more with improving patient outcomes and reducing total costs.

2.1.3 Maintenance Management Strategies

Maintenance management strategies fall into two categories. The first involves unplanned activities such as repair and replacement. The second involves planned activities which include proactive and reactive strategies. Proactive activities include scheduled replacement, predictive (or on-condition) maintenance and scheduled discard. Reactive activities include failure-finding tasks, recalibration, and redesign (Wang *et al.* 2006). The type of maintenance management selected by any organisation will depend on its operational system, its resources and the skill of its employees. To develop an appropriate maintenance strategy, it is necessary to identify and apply 'effective ways of managing unavailability of the hospital equipment' (Lo 2004). There are, however, many types of maintenance strategies: Reliability Centred Maintenance (RCM), Total Productive Maintenance (TPM) and Mixed Maintenance Management Strategies.

The majority of organisations that apply TPM or RCM gain the benefit of a reduction in machinery failure. This is because technical infrastructure is maintained in a proper condition which promotes production continuity. There is also a sizeable reduction in machine maintenance costs (Stadnicka and Antosz 2013). TPM is directly aligned to a lean manufacturing philosophy, which is considered to substantially improve productivity in enterprises, by the integration of processes not considered to be value-adding to the product (Shahanaghi and Yazdian 2009; Stadnicka and Antosz 2013). But RCM authored by engineers; Tom Matteson, Stanley Nowlan and Howard Heap, and Stadnick and Antosz (2013) working for United Airlines argued that actions recommended, in particular to Technical Machines Park Supervision (See Table 2-1), have resulted in a reduced failure rate, and an automatic boosting of equipment capacity because of the significantly reduced down-time. 71% of companies studied chose to implement TPM because 41% experienced low machine capacity and 34% reported high failure rates as shows in Figure 2-4. Thus TPM appears to be an advanced maintenance strategy involving equipment users in day-to-day maintenance of that equipment. This is a rather

foreign concept in hospital equipment maintenance but it may have potential in terms of productivity, economics reliability and ultimately patient outcomes.

Table 2-1: Modern Strategies for Machine Maintenance

Supervision method	Actions performed by maintenance services	Actions performed by an operator	Action performed automatically	Use of additional tools
Total productive Maintenance (TPM)	Machine maintenance, Inspection and repair, according to a schedule	Autonomous service regular assessment of technical condition and discrepancy identification	Reducing machine work time	Machine work schedule
Reliability Centred Maintenance (RMC)	Analysis of the technical condition machines and continuous monitoring of their condition	Regular analysis of the incorrect technical operation	Collection and analysis of data considering technical parameters of the machine (e.g. vibration, noise, processing accuracy)	Designing a maintenance process for the newly installed machines with account of technical, organizational and economic condition
Outsourcing (O)	Tasks performed by external services	Regular analysis of technical condition		

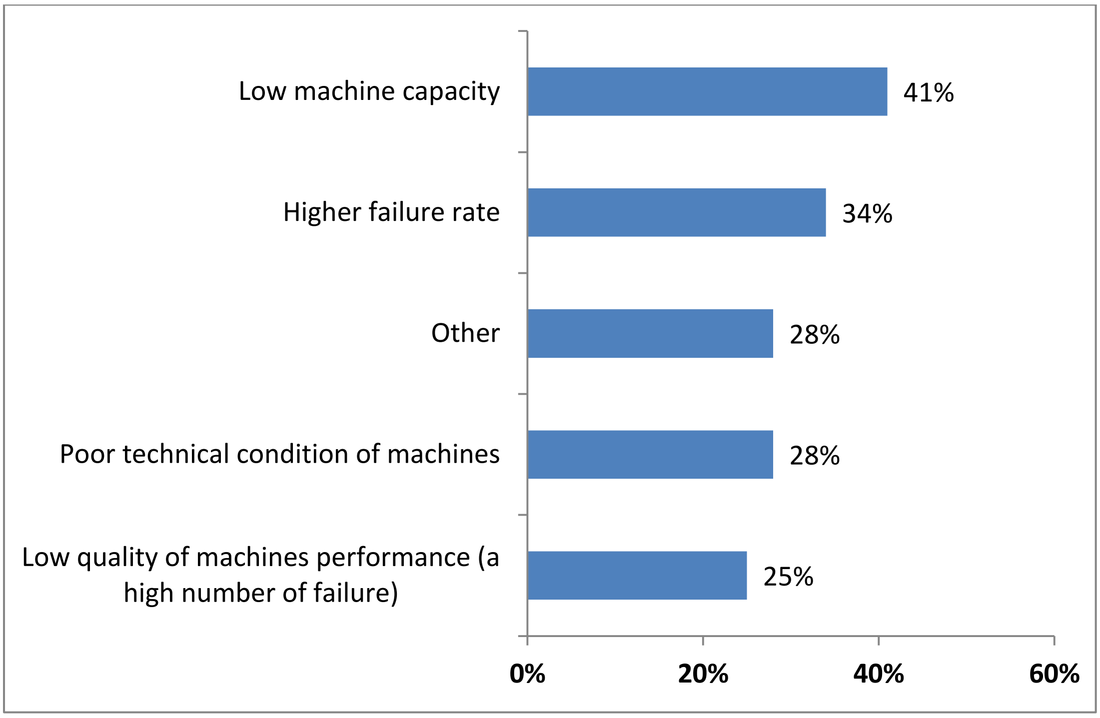


Figure 2-4: The reasons for TPM implementation in a company
(Stadnicka and Antosz 2013)

TPM objectives are; zero unplanned downtime, zero machine capacity losses, zero defects, zero accidents, minimum lifecycle asset care cost (Peters 2007) in addition to increased employee morale and job satisfaction. These objectives can achieved by eight key foundations which illustrate the TPM structure presented by the Japan Institute of Plant Maintenance (JIPM): individual improvement to eliminate major losses and improve production system effectiveness, an Autonomous Maintenance Program (AMO), a planned maintenance program, education and training aimed at increasing skills of operations and maintenance, early equipment management, quality maintenance, office TPM in administrative and support departments, safety, health and environmental management (Ahuja and Kamba 2008).

In healthcare organisations operational failures of medical equipment can obstruct employees, delay patient care, waste hospital resources, increased risk to patients, decrease productivity and the quality of healthcare. Most operational failures resulted from delay in the supply of materials and information and poor maintenance system used (Tucker 2004). Although healthcare organisations applied various quality improvement tools and industrial engineering techniques to improve services quality and productivity such as method improvement and work simplification, staffing, scheduling, queuing and simulation modeling, optimisation, and quality analysis and improvement (Sahney and Kachhal 2001), none of these methods focuses on the implementation of TPM in the healthcare organisations (Chompu-inwai *et al.* 2008). Thus, the implementation of TPM in similar facilities require different approaches and require completely different solutions (Hartmann and Charles 2001). Nevertheless, Chompu-inwai *et al.* (2008) attempted to implement and evaluate TPM in the dental units in the Dental Hospital, Faculty of Dentistry, Chiang Mai University, Thailand to increase dental unit utilization and availability, and decrease unplanned equipment downtime. This was a first pilot study that applied basic TPM theory in one major area of healthcare.

The strategies selected here for study are:

Maintenance Management Strategic (MMS) which views maintenance as a multi-disciplinary activity. This approach overcomes some of the deficiencies of Reliability Centred Maintenance (RCM) and Total Productive Maintenance (TPM) approach which do not contend with issues such as the operating load on the equipment and its

impact on the degradation process and long-term strategic issues and outsourcing of maintenance. These two approaches, to a large degree, are qualitative or at most semi-quantitative. The maintenance management strategic approach is more quantitative than productive management, involving the use of mathematical models that integrate technical, commercial and operational aspects from a business point of view. As a result, MMS views maintenance from a perspective that is wider than that of RCM or TPM (Murthy *et al.* 2002; Garg and Deshmukh 2006).

In the context of hospitals, advancing medical technologies mean that traditional maintenance is no longer sufficient to ensure that medical equipment is being maintained in the best possible manner (Khalaf *et al.* 2010). Clinical engineering professionals need to continually review and improve their management strategies in order to keep up with developing technology as well as with the rising demands of health care organisations. This requires the development of risk-focused maintenance management plans (Wang *et al.* 2006) .

However, it is not sufficient to focus on risk caused by the failure of individual pieces of equipment to individual patients. The emphasis should be on the impact of equipment failure on larger groups of patients, particularly when dealing with 'one of a kind', delicate pieces of equipment that are required to provide timely and accurate diagnoses for immediate therapeutic decisions or surgical interventions (Wang *et al.* 2006). For this reason, healthcare organisations are responsible for ensuring that their medical equipment is available and can be used safely and efficiently. This requires maintaining equipment in a condition that enables it to achieve the functions for which it was planned while complying with the related health and safety standards (Tarawneh and El-Sharo 2009). The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) suggested using different strategies for different parts, as appropriate. For example, different strategies can be employed for defibrillators used in emergency departments and intensive care units as well as those used in general patient care areas or clinics (Wang and Levenson 2000; Wang, Eliason, Richards, Hertzler and Moorey 2006).

Flexibility needs to be built into maintenance management strategies because medical devices have different characteristics and therefore a variety of maintenance strategies are needed to avoid sudden failure (Slack *et al.* 2005; Wang *et al.* 2006).

Some parts of medical equipment may require scheduled inspection and/ or regular maintenance. Further, hospitals could, for example, employ different strategies for defibrillators used in emergency departments and intensive care units to those used in general patient care areas or clinics. This provides flexibility when a scheduled maintenance activity cannot be performed at the appropriate time due to uncontrollable factors such as equipment in use on a patient or devices cannot be located (Wang *et al.*, 2006). Healthcare organisations must analyse their spare part inventories in order to have "effective, safe, and reliable operation." at all times. Evidence suggests, that there are many reasons why healthcare organisations need to use Mixed Maintenance Management Strategies (MMMS), as proposed by Wang *et al.* (2006).

2.1.4 Mixed Maintenance Management Strategies

This comparison of strategies is used more than any other type in order to achieve higher benefits (Slack *et al.* 2005; Wang *et al.* 2006) because it recognizes that:

1. Medical equipment includes different levels of risk. Some high-risk (e.g. critical-care monitoring) equipment requires little maintenance, unlike some low risk equipment (e.g. x-ray film processors) that needs frequent attention.
2. Preventive maintenance often does not increase reliability, and actually may introduce failure, a notion well documented in industrial maintenance (Wang *et al.* 2006).
3. Identical pieces of equipment used in different circumstances may need different maintenance strategies.
4. The majority of sentinel events have been traced by Root-Cause Analysis to communication, user orientation and training and patient assessment rather than equipment malfunction or missed maintenance actions (Wang *et al.* 2006).

2.1.5 Maintenance Management Strategies Classification

The application of effective maintenance strategy is essential for managing the availability of medical equipment in hospitals (Lo 2004). The same medical equipment, as explained by Wang (2006), requires different maintenance strategies

depending on its use. There are a number of maintenance strategies that need to be used in hospitals.

Maintenance Management Strategy (MMS) can be both qualitative and quantitative. The qualitative strategy includes TPM and RCM while Quantitative Strategy incorporates various deterministic/stochastic models (Garg and Deshmukh 2006). A number of studies classify MMS into various types, e.g. Chelbi *et al. (2008)*, Eti *et al.* (2006) and Ratnayake and Markeset (2010). Dhillon (2002) and Pintelon *et. al.* (2006) identify preventative, corrective and predictive strategies. Endrenyi *et al.* (2001) identify manufacturer's specifications, replacement, scheduled maintenance and predictive maintenance, as shown in Figure 2-5. Swanson (2001) identifies three types of maintenance strategies namely: (1) reactive strategy (CM), (2) proactive strategy (PM and PDM), and (3) aggressive strategy (TPM). Garg and Deshmukh (2006) identify ten types of maintenance strategies, as shown in Figure 2-6.

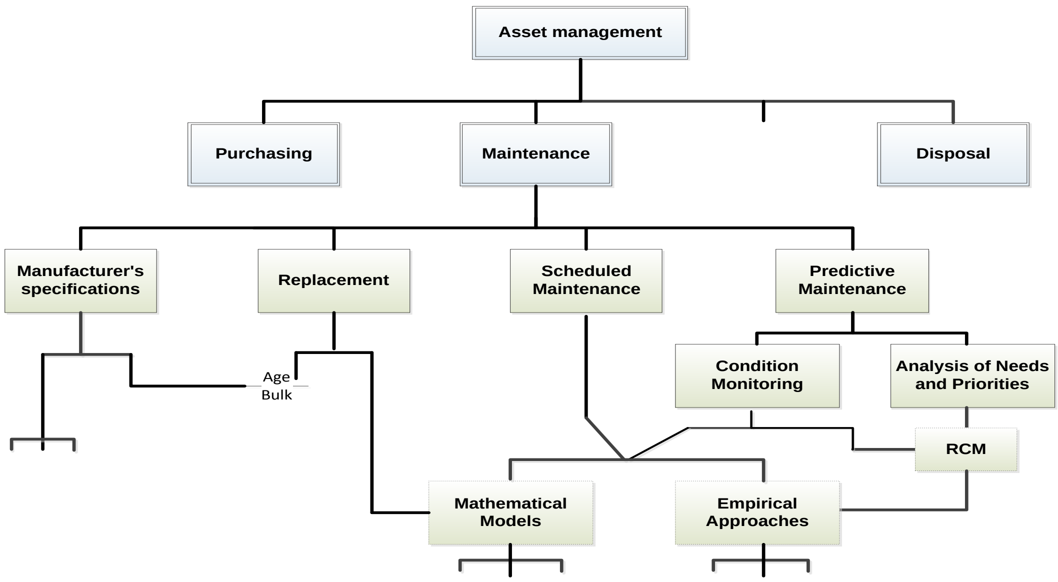
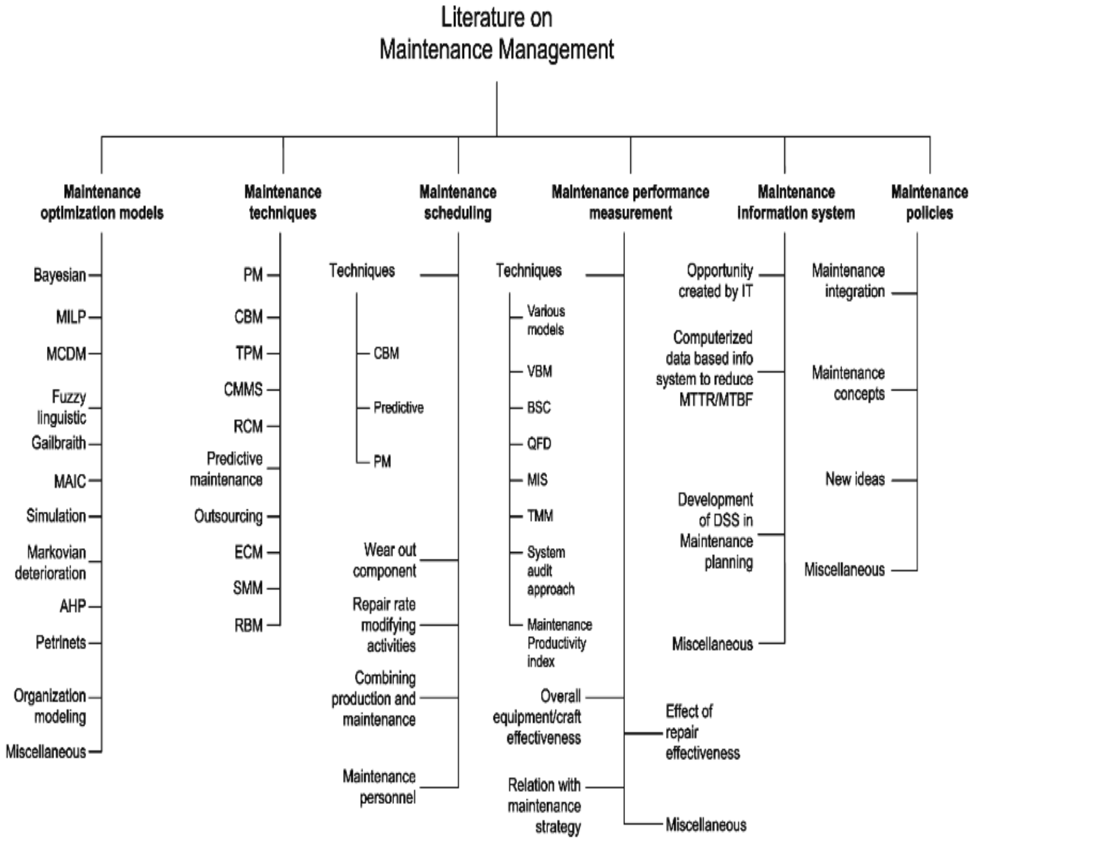


Figure 2-5: Maintenance Classification Strategies proposed by Endrenyi *et al*. (2001)



Notes: MILP: Mixed Integer Linear Programming; MCDM: Multiple Criteria Decision Making; MAIC: Materially per Apparecchiature de Impiariti Chemiei; AHP: Analytic Hierarchy Process; PM: Preventive Maintenance; CBM: Condition Based Maintenance; TPM: Total Productive Maintenance; CMMS: Computerized Maintenance Management Systems; RCM: Reliability Centered Maintenance; ECM: Effectiveness Centered Maintenance; SMM: Strategic Maintenance Management; RBM: Risk Based Maintenance; VBM: Vibration Based Maintenance; BSC: Balanced Score Card; MTTR: Mean Time to Repair; MTBF: Mean Time Between Failure; QFD: Quality Function Deployment; MIS: Maintenance Information Systems; TMM: Total Maintenance Management; DSS: Decision Support Systems; ECM: Electronic Counter Measures

Figure 2-6: Maintenance Classification Strategies proposed by Garg and Deshmukh (2006)

In the current study, the five maintenance strategies identified by Garg and Deshmukh (2006) have been selected to identify the extent of availability and the rate of failure of medical equipment in hospitals. These are: (1) preventive (2) corrective (3) predictive (4) condition-based maintenance and (5) mixed maintenance strategy.

2.1.5.1 Preventive Maintenance (PM)

Preventive maintenance can be defined as all these actions carried out on a planned, periodic, and specific schedule to keep equipment in its original working condition through the process of checking and reconditioning (Dhillon and Liu 2006; Wang *et al.* 2010) in order to prevent or minimize breakdowns and depreciation rates (Shahanaghi and Yazdian 2009). PM was first developed at General Electric in the

1950s (Thun 2004), and currently adopted by most organisations to achieve their objectives, which include: maintaining the condition and reliability of operating equipment; minimise interruptions to production and major breakdown; and keep production continuously running (Shahanaghi and Yazdian 2009). PM is also referred to as scheduled maintenance or planned maintenance (Endrenyi *et al.* 2001; Wang *et al.* 2010; Stadnicka *et al.* 2014).

Despite the fact that PM is widely used in organisations, there is significant variation in the activities it is used for and there are competing ideas about its effectiveness. Lo (2004) argues that unified PM strategies can provide an optimum maintenance strategy for managing equipment failure and the associated risks of unavailability of medical equipment. However, Wang *et al.* (2006) suggests that the PM of equipment may not only reduce its reliability, but can also 'introduce failure'. Endrenyi *et al.* (2001) argue that planning maintenance (routines) might be ineffective because it is expensive in the long term and may not extend component lifetime as required. This suggests that despite the popularity of PM, its use should be related to the condition of the equipment.

The PM of medical equipment includes more than safety and performance inspection activities, Wang *et al.,* (2006). It also includes risk analysis and other criteria that reflect the needs and reality of the healthcare organisation. Examples of other criteria that should be considered are: mission criticality or operational impact; the ability to detect failure, "hidden failures" and their respective severity; equipment hazards and recall history that occur outside the healthcare organisation; reliability including failure patterns and statistics and availability of medical equipment and spare parts (Wang *et al.,* 2006).

In relation to the relative importance of PM and medical equipment issues Ridgway (2008) noted that US hospitals continued to allocate approximately US$300 million per year to PM when there was still no collaborative consensus on the definition of PM, no identification of equipment maintenance activities, no rational process for the definition of a non-critical item of equipment and no efficient method for the justification of the regularity of PM intervals. It is indicated that PM does not prevent all facets of equipment failure, but only addresses failures resulting from the degeneration in a device's non-durable parts which cause failure. Furthermore,

Ridgway (2009) discusses the extent to which PM improves the reliability of equipment in consideration of downtime and safety. He discovered that PM does have an impact on the reliability of some equipment items, and has a beneficial impact on the equipment's uptime. Ridgway argued that a properly executed PM program brings to an organisation increased safety, reduced downtime and fewer expensive repairs. However, as medical equipment becomes more complex, it is argued by Pintelon and Parodi – Herz (2008) that PM activities become less relevant. This is because PM, in their review, is only concerned with inspection and scheduled maintenance activities, which do not take into consideration age-related failure. For this reason, PM is of limited use in improving the reliability of complex items.

2.1.5.2 Corrective Maintenance (CM)

Corrective Maintenance can be defined as unscheduled repairs on reported failures (Dhillon and Liu 2006), or replacement of parts to restore equipment to working condition (Lo 2004; Pintelon and Parodi-Herz 2008; Wang *et al.* 2010). CM is also known as Repair and Replacement (R&M), (Endrenyi *et al.* 2001), Run-to-Failure, Failure-Based Maintenance, Fire-Fighting Maintenance or Breakdown Maintenance (Ratnayake and Markeset 2010). R&M activities are carried out only after an equipment breakdown (Slack, Chambers, Harland, Harrison and Johnston 2005; Pintelon and Parodi-Herz 2008; Ratnayake and Markeset 2010; Stadnicka and Antosz 2014). The reason, according to the authors, is that it is complicated and difficult to predict stochastic and unforeseen equipment failures and breakdowns. CM involves the repair of stalled motors, repairs to ruptured pipelines or even the replacement of a failed light bulb (Pintelon and Parodi-Herz 2008). In 1957 the system called CM was developed, to include all measurements to improve the reliability of equipment (Thun 2004). This method is used particularly where the failure of equipment and appliances does not result in undue risk, does not violate the rules of work safety and does increase investment costs (Stadnicka, Antosz and Chandima Ratnayake 2014).

CM may be a good strategy where the failure rate is normal and the cost of breakdown is low (Pintelon and Parodi-Herz 2008). In the long term however it is more expensive than Preventive Maintenance (PM) because, for example, a sudden breakdown in the case of medical equipment creates idle time waiting for spares

parts, haphazard troubleshooting scenarios and unplanned interruptions of services operations (Lo 2004). In US manufacturing industries, over US$300 billion is spent each year on the maintenance of manufacturing operations. Of this amount, about 80 percent is spent in the correction of chronic equipment failure, production operations and workers' wages (Dhillon and Liu 2006). Therefore, while CM can be useful, it is usually an expensive option if used in isolation.

2.1.5.3 Predictive Maintenance

Predictive Maintenance (Pr. M) can be defined as the application of mathematical models to diagnose the condition of operating equipment (Dhillon and Liu 2006). It can be applied to improve outage scheduling, operating flexibility, equipment performance efficiency, better fuel use and more efficient spare part management (Endrenyi *et al.* 2001). Predictive Maintenance activities are performed as needed, and inspections should be carried out frequently to initiate maintenance before equipment break-down (Endrenyi *et al.* 2001). These maintenance activities are included in the healthcare organisation's medical equipment management plan and should be performed even if it takes place beyond the established inspection time. For example, a quarterly inspection period may possibly have a one-month grace period while an annual inspection period may possibly have a two-month grace period (Wang *et al.*, 2006). Predictive maintenance routines also involve a group of programs called Reliability-Centred Maintenance (RCM) (Endrenyi *et al.* 2001). This will be further discussed in section 2-2.

In contrast to preventative and corrective maintenance strategies, predictive maintenance actively utilises diagnostic methods in order to avoid the risk of breakdown Endrenyi *et al.* (2001). Diagnostic methods include visual and optical inspections; temperature, vibration, neutron, lubricant and magnetic flux leakage analysis; radiography; ultrasonic and eddy current testing and acoustic emission monitoring. Each of these methods has advantages and limitations. By using continuous inspection, or condition monitoring, of operating equipment, the detection of abnormalities indicative of future failure can be identified. Condition monitoring is preferable where it is not possible to expect wear-out trends through periodic inspections with reasonable accuracy, for cost effectiveness, where off-line

inspections are not desirable and where the criticality of a failure justifies keeping a constant vigil on medical equipment or services process.

When applying predictive maintenance to medical equipment, it is important to be flexible in the planning and scheduling of maintenance activities. This is because it is often difficult to perform planned maintenance activities at a suitable time due to its use on patients and other external control factors. For this reason, Wang *et al.* (2006) suggest use of a grace period (or slippage) for determining when an item of medical equipment must be considered overdue for a planning inspection or maintenance action.

It is argued that predictive maintenance is more advanced than other maintenance strategies because it focuses on inspection, condition and risk-based techniques Pintelon and Parodi-Herz (2008). Predictive maintenance was, and currently still is, limited to those applications where it is both technically practicable and cost-effective. Encouraging this trend was that condition monitoring equipment became more accessible and cheaper. In the past, these techniques were reserved for high-risk applications only, such as aircraft or nuclear power plants. Health organisations, however, should consider applying this strategy to their operations.

2.1.5.4 Condition Based Maintenance (CBM)

Condition Based Maintenance (CBM) is undertaken as a result of periodic monitoring of equipment by the use of non-invasive checking. It is performed at a critical time when the equipment requires overhaul, and includes diagnostic information and the making of effective maintenance decisions (Slack *et al.* 2005; Sethiya 2010; Stadnicka *et al.* 2014).

These maintenance activities are concerned with the condition of a machine component that may be found during observation and analysis rather than by occurrence of failure “Corrective Maintenance” or by following a strict maintenance time schedule “Preventive Maintenance” (Blechertas *et al.* 2009). CBM assists in identifying incipient faults before they become critical, which enables more accurate planning of preventive maintenance. For this reason, CBM is also known as Predictive Maintenance (Blechertas *et al.* 2009; Sethiya 2010). “CBM strategy reduces the probability of sudden random failures with the aid of diagnostics and timely intervention. In order to achieve an effective implementation of “zero-failure”

strategy the condition control helps to discover causes of failure, potential failures and mechanisms of failure. For instance spectral analysis, one of the most useful fault diagnostic tools, provides a basis for identification of failure mechanisms, causes of failure and failure modes in mechanical systems, such as rotating and reciprocating machines" (Temple-Bird *et al.* 1995).

The main advantage of CBM is that it promotes cost-effective production because it can be performed without stopping equipment or processes (Slack *et al.* 2005). CBM also reduces the number or extent of maintenance activities and false alarms, eliminates scheduled inspections, predicts useful remaining life, detects incipient faults, enables autonomic logistics and diagnostics, enables information management, enhances reliability, and consequently reduces life cycle costs (Blechertas *et al.* 2009; Sethiya 2010). For these reasons, it is considered an effective strategy for asset maintenance, and is becoming more commonly used by US manufacturers and the US military. There are many factors contributing to the incremental use of CBM, including the need for improved equipment availability; protection against failure of critical equipment and reduced maintenance and logistics costs (Thurston and Lebold 2001).

The use of CBM in asset management is not a new strategy. In fact, condition monitoring and analysis has been used for the last seventy years to improve technology, equipment and practices (Mitchell 2007). However, over the last two decades there has been a quickening in the pace of technological development and this has had an impact on the relevance and usefulness of maintenance strategies (Blechertas *et al.* 2009). The technological development that has occurred over the past two decades involve many advantages; it has made data collecting and analysis hardware much more compact, stronger and less expensive, enabling improved reliability of critical machinery like military rotorcraft, civilian vehicles, medical equipment, energy electronics, automotive and oil and gas production industries. However, because of the high cost of CBM, the more traditional maintenance strategies of Corrective and Preventive Maintenance are often used at the same time as CBM.

Because CBM is concerned with monitoring and replacing parts and equipment before the end of their operation lifetime, Ghasemi *et al.*, (2008) tried to find a model for an optimal replacement policy and observation interval. They applied several

models, including the Proportional Hazards Model (PHM) which models a system's failure rate. PHM is used to calculate the optimal replacement policy and long-run average cost for a system which lacks information but is used extensively in medical studies. Ghasemi *et al.* (2008) found that CBM can assist in finding the optimal observation interval of an operation process based on the total long-run average cost, as well as the corresponding replacement policy that optimizes the total long-run average cost of the replacement observations. Stadnicka and Antosz (2014) found in their survey that one company used the strategy based on failure rate. 65 precent of companies surveyed showed the most common maintenance strategies utilised were planned inspections. 63 percent of companies implemented a technical condition assessment by an operator prior to work commencement. 77 percent of the companies implemented monthly machine cleaning, and their general inspections are as shown in Figure 2-7.

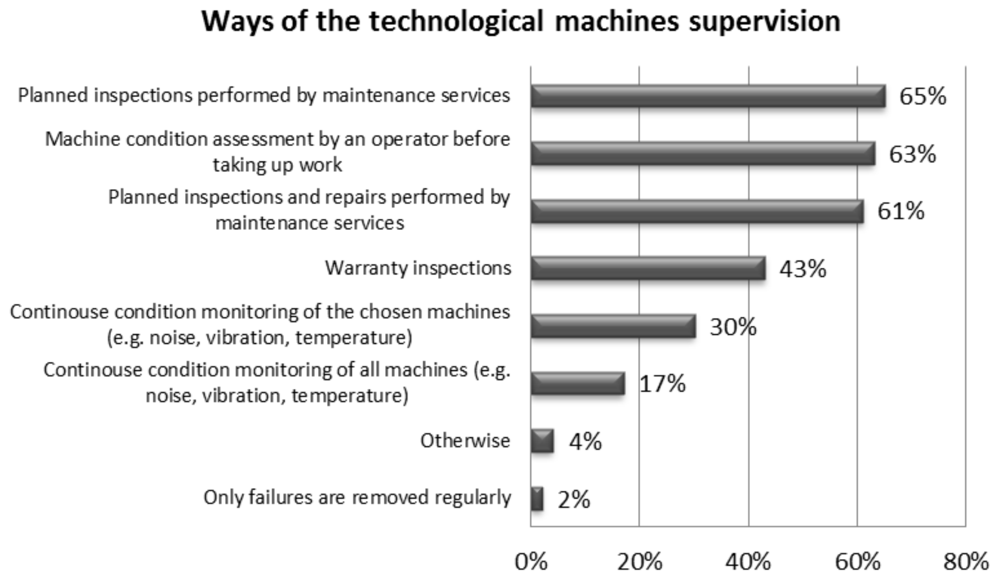


Figure 2-7: Machine maintenance supervision methods

In the context of Health Asset Management; Blechertas *et al.* (2009) has proposed used the Condition-Based Maintenance (OSA-CBM) standard, condition monitoring and diagnostics of machines ISO-13374. CBM application requires an integration of many functional levels. These levels include data acquisition, data manipulation, state detection, health assessment, prognostics assessment and advisory generation as shown in Table 2-2. Data acquisition, data manipulation and state detection levels involve the Condition Monitoring system, which is the basis of CBM. A more

efficient CBM program also involves diagnosis, prognosis, and advisory generation levels, which incorporate a broader range of new technologies (Blechertas *et al.* 2009).

Table 2-2: Functioning Hierarchical Components of CBM
(Blechertas *et al.*, 2009)

<table>
<tr><td>Data Acquisition</td><td rowspan="3">Condition monitoring</td><td rowspan="5">CBM</td></tr>
<tr><td>Data Manipulation</td></tr>
<tr><td>State Detection</td></tr>
<tr><td>Health Assessment</td><td>Diagnostics</td></tr>
<tr><td>Advisory generation</td><td>Prognostics and Health Management</td></tr>
</table>

Blechertas *et al*. (2009), cites He and Bechoefer (2008), Luo *et al*. (2003) and Jaw (2005) suggesting that the application of asset management (medical equipment) in healthcare organisations requires a CBM strategy that adopts both diagnostic and prognostic approaches because diagnostics focuses on identification of an individual component's condition, which includes early fault detection, isolation and identification (e.g. current crack location and size) and prognostics describe a process to predict the remaining useful life (RUL) of a component and system (how fast and to what extent the diagnosed fault will progress), as shown in Figure 2-8. Prognostics are critical in order to further improve reliability, minimize life cycle costs and realize automated logistics. Currently, CBM is dominantly diagnostic, since machine condition prognosis is relatively new and by definition has a high level of uncertainty and complexity with many remaining challenges (Blechertas *et al.* 2009). CBM is, however an optimal strategy for health organisations to reduce the total cost of maintenance and service operation.

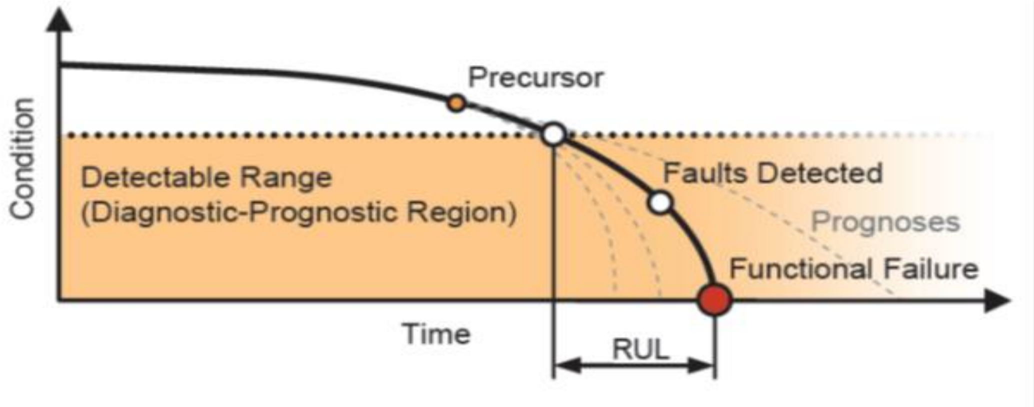


Figure 2-8: Schematic Diagram Curve of a machine component's lifetime, related to condition and prognosis (Blechertas *et al.,* 2009)

As can be seen in the Figure 2-8, diagnostics is focused on identification of individual component faults detected (Blechertas *et al.* 2009).

2.1.5.5 Mixed Maintenance Strategy:

This subject is discussed in section Mixed Maintenance management strategies[18].

2.2 Reliability-Centred Maintenance (RCM)

Reliability-Centred Maintenance originated in the 1960s in the North American aviation industry. Later it was adopted by the US Military and has since been implemented in high risk industrial plants, e.g. nuclear power plants. The contribution of RCM in industry has been illustrated by a number of researchers including: Nowlan and Heap (1978), Anderson and Neri (1990), and Moubray (1997), Pintelon and Parodi-Herz (2008).

The main objective of RCM is to maintain the reliability and safety of the operation system with minimum resource utilisation. RCM is also referred as proactive maintenance, as it can detect, reduce or control problems before complete failure occurs (Cheng *et al.* 2013). The fundamental principles of proactive maintenance are increasing the operation life of the equipment through improving external factors, such as decreasing the occurrence of failure and enhancing its inherent reliability (Cheng, Rong and Liu 2013). A variety of organisations have adopted proactive maintenance philosophies like RCM since these strategies are devoted to long-term progress of maintenance management (Cholasuke *et al.* 2004). One example is the

[18] Chapter 2, Section 2.1.4: Mixed Maintenance management strategies, p. 27.

Consolidated Edison Company of New York (Endrenyi *et al.* 2001) which used RCM to improve maintenance; system identification and the listing of critical components and their function; failure mode and the effects of analysis for each selected component; the determination of failure history and the calculation of Mean Time Between Failures (MTBF); the use of appropriate flow charts to categorize failure effects and determine possible maintenance activities; and maintenance activities assignment and program evaluation, including maintenance cost analysis (Endrenyi et al. 2001). RCM is a maintenance orientated procedure. Its main task is to promote equipment efficiency and reliability, and is one of the main acceptable models of reliability management of choice, when selecting and exploiting the operation of equipment and technical systems (Stadnicka and Antosz 2013). RCM can be defined as “a process used to determine what must be done to ensure that any physical asset continues to fulfil its intended functions in its present operating context” (Agrawal and Gandhi 1997; Moubray 1997; Shahanaghi and Yazdian 2009; Stadnicka and Antosz 2013). A concise and rigorous pro-active approach to the maintenance of equipment prevents serious downtime-maintenance-problems (Jardine and Tsang 2006).

In an RCM, various alternative maintenance strategies can be compared and the most cost-effective one should be chosen for sustaining equipment reliability. RCM programs have been installed by several electric utilities as a useful management tool. In the last ninety-nine years, many utilities have replaced their fixed-interval maintenance schedules with more flexible programs based on an analysis of needs and priorities or on a study of information obtained through periodic or continuous condition monitoring (Endrenyi *et al.* 2001; Stadnicka and Antosz 2013). RCM has now been adopted and incorporated into a variety of industries, viz. the power, gas, oil, chemical, farming, water, mining and pharmaceutical industries (Stadnicka and Antosz 2013). It has been determined that the first step in the application of RCM in an organisation, is to apply an ‘Asset Criticality Analysis’ approach, in respect of a great variety of equipment, where the failure-rates require clarification (Taghipour *et al.* 2011). In addition, Khalaf *et al.* (2013) has determined RCM as “based on condition monitoring, analysis of failure causes and investigation of operating needs and priorities”. Smith (2004) indicated that in 1982 medical equipment used by the

US Navy had six basic patterns of failure-identification, based on industrial experience. Very little data is available for medical equipment (Khalaf *et al.* 2013).

- 42 per cent in pattern E (random failure); constant probability of failure at all ages (exponential survival distribution).
- 29 per cent in pattern F (infant mortality); very slow increasing failure probability (particularly applicable to electronic equipment).
- 17 per cent is due to wear-out failure (pattern B); constant or gradually increasing failure probability, followed by a pronounced wear-out region.
- 6 per cent is the initial failure in the initial use (pattern D).
- 3 per cent is a combination of infant mortality and wear-out failure (pattern A).
- 3 per cent is due to expected wear and tear over time (pattern C).

Troyer (2006) has noted that "the majority of common system reliability parameters encompasses the MTBF and the MTTF, where the difference between both is the repair time. The MTBF is applied to system failure and the MTTF is applied to element failure*"* (Khalaf *et al.,* 2013).These parameters are useful for systems in frequent operation such as medical equipment where the exponential survival function MTTF equals the inverse frequency of the failure rate (λ) (Khalaf *et al.,* 2013). Furthermore, Keil (1997) has indicated that *MTBF* can be longer than the average useful life of certain medical equipment. Moubray (1997) suggested PM be only considered when age-related failure patterns become apparent; within this realm, maintenance tasks are technically feasible and not costly (Khalaf *et al.,* 2013). Endreyi *et al.* (2006) proposed the use of the RCM stringent maintenance program's critical elements to highlight equipment failure and financial waste (Khalaf *et al.,* 2013). Ridgway (2009) provides concise guidelines for the maintenance management of medical equipment to address methods used previously in the industrial world – such as RCM (Taghipour *et al.,* 2011).

Pintelon and Parodi-Herz (2008) argue that RCM is a valuable maintenance concept because it covers all of an organisation's functionality in addition to the equipment maintenance actions. There are many advantages as well as limitations in its use. For example, it increases the equipment's lifetime and establishes more effective and efficient maintenance activities, reduces individual error, provides more and better

historical data and analysis and exploitation of expert knowledge. It also improves reliability and safety and environmental integrity, which are considered to be more significant than cost. On the other hand, the standard decision charts and forms used in RCM are useful but are far from perfect. Its scientific basis is also questioned; for example the Failure Mode and Effects Analysis (FMEA), which is the heart of RCM, is often performed on a rather ad hoc basis. Often available statistical data is insufficient or inaccurate, and there is a lack of insight into the equipment degradation process (failure mechanisms) and the physical environment (corrosive or dusty) is ignored (Pintelon and Parodi-Herz 2008).

The following describes the applicability of FMEA and highlights the potential for its use as part of a RCM system applied to critical hospital equipment. FMEA defined by Teng and Ho (1996) as “a technique that identifies the potential failure modes of a device or product, determines the effects of these failure ‘before the event’ and assesses the criticality of the failure”(Sinha *et al.* 2004; Chin *et al.* 2009). FMEA defined as “an analysis technique for defining, identifying and eliminating known and/or potential failures, problems, errors from systems, design, processes, and/or services before they reach the customers*”*(Adachi and Lodolce 2005; Slack *et al.* 2005; Yang *et al.* 2011; Kutlu and Ekmekçioğlu 2012). FMEA can facilitate the identification of possible failures in the design or process of products or systems. This can assist designers to utilise recommended actions to reduce the probability of failures, decrease the probability of failure rates and avoid hazardous accidents (Wang *et al.* 2009; Yang *et al.* 2011). FMEA can also be extended to failure mode, and affects the criticality analysis (FMECA), (Chin *et al.*, 2009). Teng and Homodel’s model is shown in Figure 2-9 (Teng and Ho 1996; Teng *et al.* 2006; Hekmatpanah *et al.* 2011).

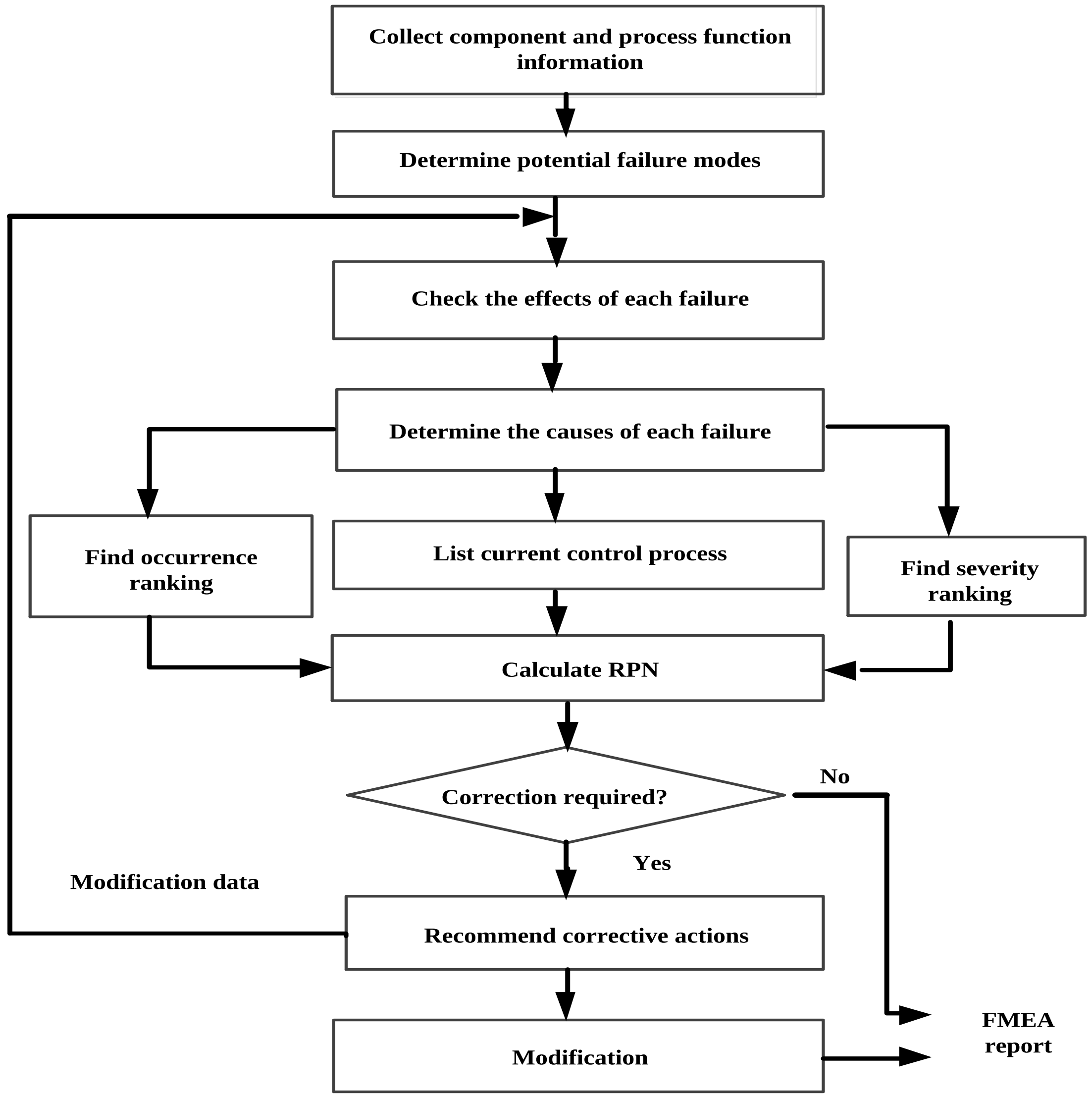


Figure 2-9: A Failure Model and Effects Analysis flowchart by Teng and Ho

FMEA has been extensively used in manufacturing, for example in structures operating in the power, aeronautics and astronautics industries (Wang *et al.* 2009; Yang *et al.* 2011) and is also a feature of quality management systems (Chin *et al.* 2009). FMEA can identify a possible failure mode and determine the effect of each failure. While there can be various failure modes, their risks and effects are different (Yang *et al.* 2011). A significant issue of FMEA is the determination of risk priorities in failure modes (Chin *et al.* 2009). Failure modes can be evaluated using three factors: severity, likelihood of occurrence and the difficulty of detection of the failure mode (Kutlu and Ekmekçioğlu 2012). Yang *et al.* (2011) introduced *FMEA* for rotor blades of aircraft turbines. Rotor blades are a major factor in the reliable

operation of aircraft turbines. The Failure Mode risk-priority is essential for the design and maintenance processes for rotor blades as they are the crucial operating component of an aircraft turbine.

FMEA was designed to provide information for decision-making under the auspices of risk-management (Pillay and Wang 2003). FMEA was initially developed as a formal design methodology by NASA in 1963 for its reliability requirements. It was then adopted by the Ford Motor Company in 1977 (Chin *et al.* 2008). It has developed into a powerful tool for the testing of safety and a reliability analysis for products and products in wide-ranging industries (Gilchrist, 1993; Sharma *et al.* 2005; Kutlu and Ekmekçioğlu 2012) viz: aerospace, the nuclear and the automotive industries. Therefore, *FMEA* has the potential to induce reductions in medical errors, and to increase improvements in the quality of the health care sectors. Medical errors detrimentally affect patient well-being through the sudden failure of medical equipment (as reported by the Institute of Medicine on the safety of the health care system), and have the potential to be catastrophic (Adachi and Lodolce 2005). For example, there are approximately 7000 patient deaths each year in the United States because of medical errors; and projected estimates have increased hospitalisation costs attributed to preventable Adverse Drug Events to US$2 billion (Adachi and Lodolce 2005). The *Joint Commission on Accreditation of Healthcare Organisations (JCAHO)* - expects health care institutions to conduct pro-active risk-management activities: to identify system weaknesses, predict outcomes of these weaknesses and adopt system changes to minimise a potential for patient harm; one such risk-management activity is failure-mode, and its affects-analysis (Adachi and Lodolce 2005).

Adachi and Lodolce (2005); employed a multi-disciplinary medication safety team, to conduct an FMEA to identify and reduce common medication errors such as incorrect dosages dispensed in the Good Samaritan Hospital located in San Jose, California. In 2002 incorrect dosages comprised 17% of the total medication errors at the Good Samaritan Hospital (59 of the 347 errors). Incorrect programming of an IV infusion pump accounted for 41% of these medication errors. However, these errors were reduced after conducting an FMEA, and implementing process changes as shown in Table 2-3.

Table 2-3: Causes of Errors at the Good Samaritan Hospital in 2002

Cause of Error[a]	No (%) Errors
Infusion-pump related	24 (41)
Epidural- pump related	3(5)
PCA _pump related	3(5)
TPN-pump related	2(3)
Drug-concentration related	7(21)
Oral related	9(15)
other	11(19)
Where N = 59 *PCA = patient-controlled analgesia* *TPN = Total potential nutrition*	

Apkon *et al.*, (2004) utilized *FMEA* to examine the effects of process changes on the reliability of delivering improved drug infusions: for patient safety, efficiency in the work-flow for medical staff, hemodynamic stability for patients during infusion modifications and overall efficiency in the use of medical resources.

Cheng *et al.* (2013) designed a system of RCM *Analysis Decision System* focused on pro-active maintenance as shown in Figure 2-10. This Figure shows the function of the RCM Analysis Decision System is to project manage fault and effect analysis (FMEA) and RCM logical decision-making, combining work functions, output tabling, systems management and various other auxiliary functions. Currently there are three main types of FMEA in use: System FMEA, Design FMEA, and Process FMEA (Ron Pereira, 2007).

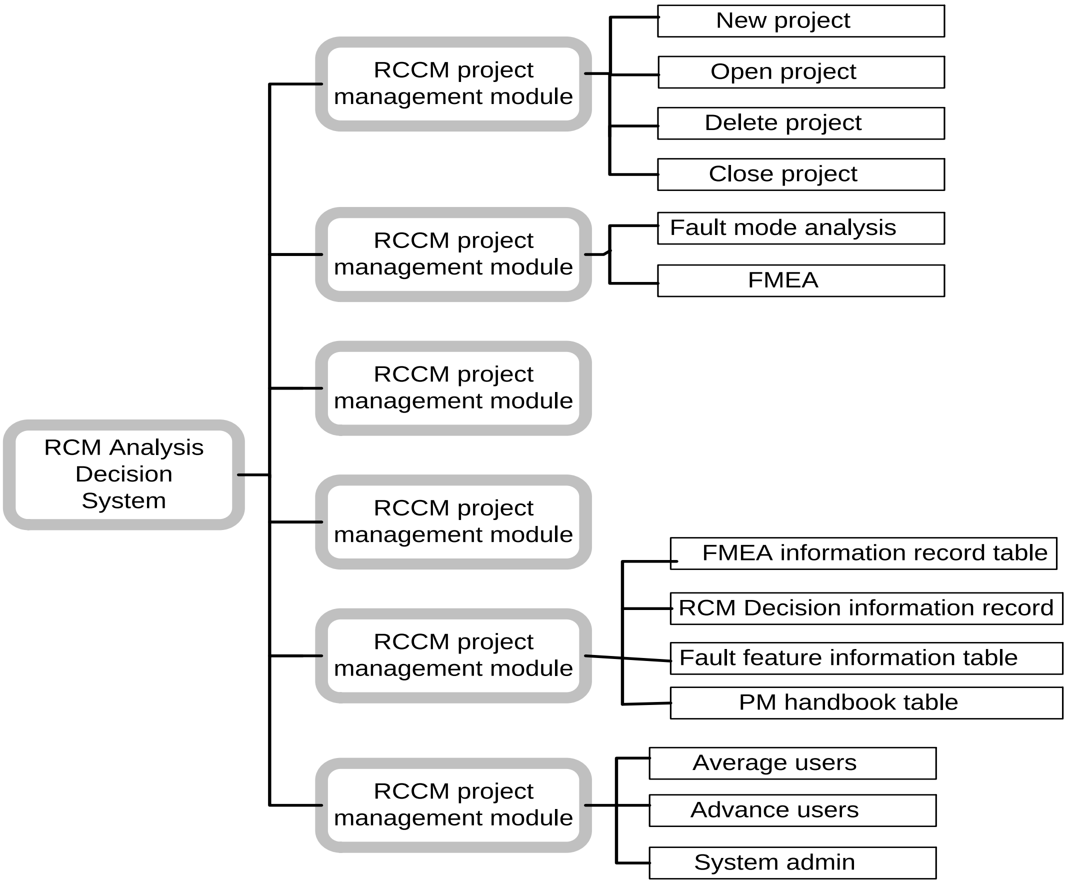


Figure 2-10: The functional modules of the RCM Analysis Decision System

According to Estorilio and Posso (2010) FMEA is defined by "The QS 9000FMEA Manual" as "A group of activities aimed at recognizing and evaluating the potential failure of a product/process and its effects, identifying actions that may eliminate or reduce the likelihood of a potential failure mode occurring and documenting the analysis process" (Hekmatpanah *et al.*, 2011).

Teng and Ho (1995-1996), proposed linking quality and reliability tools to the process of FMEA, where a comprehensive maintenance structure is used for process control, reliability prediction and product design (Teng and Ho 1996) and to eliminate the misuse of FMEA as listed by Raheja (1981). Additionally, Teng *et al.* (2006) discuss procedures for an integrated *FMEA* approach in a collaborative environment, targeting product reliability and satisfying *ISO/TS 16949, QS 9000* and *ISO 9000* requirements (Teng *et al.* 2006). Overall, the salient benefits of FMEA implementation promote customer satisfaction (Hekmatpanah *et al.* 2011). As an outstanding example, De Souza and Carpinetti (2014) proposed the application of

FMEA for the reduction of waste during production. Hekmatpanah *et al.* (2011) found that by applying FMEA, but modifying it against the studies of Sawhney *et al.* (2010), (De Souza and Carpinetti 2014) there was a reduction leading to an increase in production and an improvement in quality on the Four Litre Production Line of the Sepahan Oil Company (a key-player in Iran's oil industry). Wastage was reduced from *50,000* to *5,000 ppm*, and the percentage of oil wastage was reduced from 1 to 0.08 percent (Hekmatpanah *et al.* 2011).

Ayadi *et al.* (2013) indicates human action is a key factor in failures and numerous researchers have endeavoured to work within performance groups to solve decision-making problems found in maintenance management to minimise the risk of human error. Additionally, (Ayadi *et al.* 2013) presents a multi-criteria analysis for the classification of causes due to human actions, through the application of multi-criteria FMEA. Taghipour (2011), presents a multi-criteria decision-making model to prioritise medical equipment by criticality. His model uses AHP in the identification of the most critical equipment in the Medical Equipment Management Program (MEMP). The proposed hierarchical structure highlights six criteria in assessing criticality of medical equipment: (1) Function, (2) Mission Criticality, (3) Age, (4) Risk, (5) Recalls and Hazard Alerts, and (6) Maintenance Requirements. FMEA utilises RCM logic to find a number of functional failures. Ridgway *et al.*, (2009c) highlights nine codes in the analysis of equipment repairs captured on a database. In the study of three contrasting facilities, consisting of 14 hospitals totalling 2,598 repair-calls over three months during 2009, some interesting findings were:-

- 46.3% service calls were due to random or unpredicted failures associated with the inherent reliability of the device
- 18.2% were due to equipment management issues such as accessories, physical stress and environmental stress
- 13.7% were related to inadequacy of the pm (set-up and uncategorised repair-calls)
- 14% were user related or human interference related
- 7.8% of repaircalls were related to battery failure

(Ridgway 2009) identified widespread interest in the reduction of unproductive PM work finding that very few calls were attributed to the failure of items that should

have been replaced or restored during routine PM. Further investigation of these calls tended to reflect a poor formulation of PM procedures rather than unprofessional execution of them. It was determined acceptable and less costly for the device's non-durable parts to wear out. This expectation would see a higher level of Category 7 repairs when RCM is applied, and a run-to-failure strategy adopted for medical equipment. Regular monitoring would provide a check-and-balance for maintenance strategies such as run-to-failure.

RCM, however, does play an important role in measuring availability and reliability of aircraft in the airline industry. Nowlan and Heap (1978), for example, describe situations where equipment is 'over maintained'. As a result availability becomes lower due to the time spent on maintenance. Further, they showed that aircraft are most likely to experience failure immediately after maintenance and reliability deteriorates as a direct result of that maintenance. They postulate ways of optimising maintenance strategies to maximise availability and reduce unnecessary maintenance. Surprisingly, this usually results in an overall need for less maintenance due to a more systematic and less arbitrary approach to scheduled and on-condition maintenance. This notion may well be applicable to medical equipment in healthcare organisations where there appears to be a lack of knowledge of actual equipment maintenance needs and failure probability. Arbitrary decisions to carry out scheduled maintenance, whether condition and probability of equipment failure is known or not, could actually be reducing availability and increasing cost. Increasing probability of failure as an immediate result of maintenance could also endanger patients' wellbeing. Therefore, RCM should be given consideration as a potentially useful maintenance strategy for medical equipment in healthcare organisations. Tarawneh and El-Sharo (2009), explore the issue of the assessment of the condition of medical equipment in respect to their Down Time (DT). This is one of the most important factors in determining medical equipment status, and is defined according to the British standard (BS 4778 section 3.1 and 3.2), as "the total time period between the time equipment fails and the time the time it is returned to its re-operative state". DT can be calculated by using the following formulae:

$$A\,(\%) = \frac{\text{MTBF}}{\text{MTBF+MTTR}} \text{ x } 100\% \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\text{E1}$$

$$DT (\%) = 100\% \_ A (\%) \ldots\ldots E2$$

Where;-

A (%) = availability;

DT (%) = Down Time;

MTBF = Mean Time Between failures; and

MTTR = Mean Time to Repair.

$$MTTR = \sum T_r / N \quad \ldots\ldots E3$$

T_r= Repair Time; and

n = the number of failures during a specified period of time and

$$MTBF = R_t / N \ldots\ldots E4$$

R_t= The Required Time determines the time interval over which the user requires the equipment to be in a condition to perform a required function (Da Silva *et al.* 2008; Tarawneh and El-Sharo 2009).

A better understanding of downtime can help to improve maintenance planning by evaluating maintenance activities and service processes of all existing medical equipment (Tarawneh and El-Sharo 2009). Furthermore, Khalid *et al.,* (2006); argued that the overall healthcare system performed, even when one of the sub-systems failed. Although, the failure of any one part had some effect on the overall successful effectiveness, it was obvious that the complexity of the medical system played an important role in the variation to repair periods; which consequently affected equipment availability (A) for each of the medical sub-systems in place during 2005. Despite the general increase in availability (A) of medical equipment, there was still a considerable Mean Time To Repair (MTTR) for the recorded failure. This MTTR varied according to the type of equipment and its complexity as shown in Figure 2-11 below (Khalid *et al.* 2006).

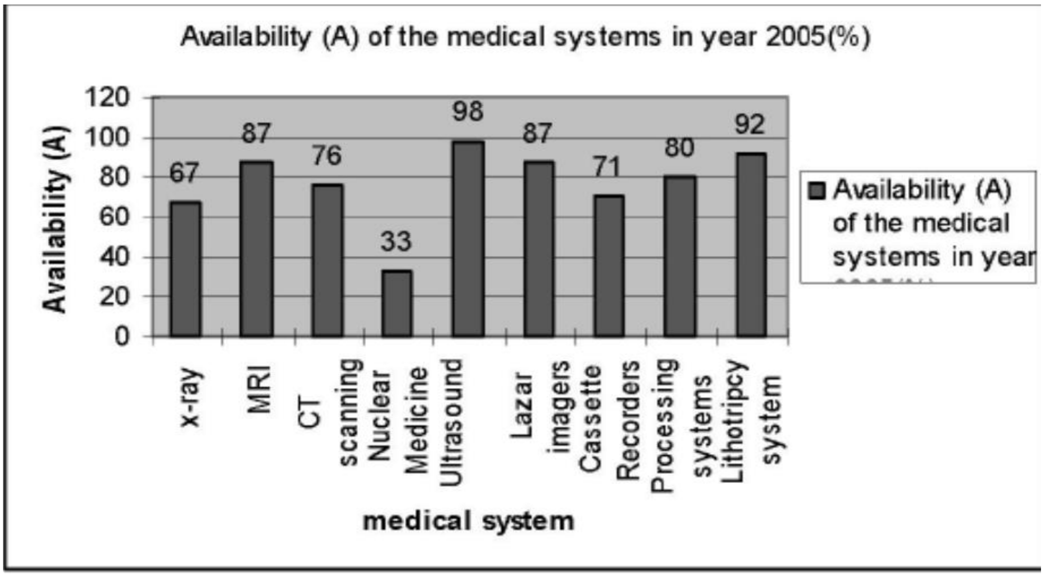


Figure 2-11: Availability of medical equipment in the King Abdullah University Hospital in Jordan during 2005 by (Khalid *et al.*, 2006)

Another advantage is the cost effectiveness of maintenance. This was found by Lo (2004a) who compared maintenance costs of equipment items in 13 hospitals by using the quantitative measures of reliability (in terms of the number of failures) and availability (in terms of the probability that a system is operational at a particular time), (Lo 2004) as shown below:

Reliability is a measure of the frequency of equipment failure;

$$\frac{\text{Equipment required day}}{\text{number of failures}}$$

Maintainability is a measure of the ability to fix equipment;

$$\frac{\text{Equipment down day}}{\text{number of failures}}$$

$$\text{Availability} = \frac{\text{Equipment required day} - \text{equipment down day}}{\text{Equipment required day}}$$

In another study, Lo (2004b) established the critical factors (*Cf*) to evaluate the direct maintenance cost, as:

$$Cf = \frac{(\text{ML} * \text{MC})}{(\text{UA} * \text{AC})}$$

Where,

C*f* = *C*riticality factor

ML = Percentage of the manufacturer-required maintenance level

MC= Maintenance cost

UA = 1- Availability

AC= Equipment acquisition cost

In the continuous improvement of healthcare service quality, these factors play an important role in evaluating and measuring the performance of medical equipment. Medhat *et al.,* (2008) support this idea in their study when they applied these measures to the quality performance of five types of medical equipment: pulse oximeter, ventilator, syringe pump, infusion pump and monitor at the Neonatal ICU department, Ahmed Maher teaching hospital in Cairo, Egypt. Their results are shown in Table 2-4 and 2-5 below:

Table 2-4: Measurement of efficiency of a baby incubator in the Neonatal ICU Department at the Ahmed Maher Teaching Hospital in Cairo, Egypt 2008

Outputs	Result
Total downtime	620 min/month
Total operating time	30775 min/month
Total uptime	44020 min/month
Total time = 1month	44640 min/month
Failure rate	1%

Table 2-5: The percentage efficiency of the baby incubator Ahmed Maher Teaching Hospital in Cairo, Egypt 2008

Detail	Results
The outputs performance	70%
Availability	99%
Quality rate	99%
Overall equipment effectiveness	69%
Reliability	98%
Failure probability	2%
Mean Time Between Failures (MTBF)	76.93 min

The effectiveness of this medical equipment was measured using the following equations:

$$\text{Equipment Availability} = \frac{(\text{Loading time} - \text{down time})}{(\text{Loading time})}$$

Where

Loading time = planned time available per day (or month) for production/services operation.

Downtime = idle time for many reasons such as: setup/adjustment requirements, equipment failures, exchange of dies and other fixtures.

Availability can be expressed as the ratio of actual operation time to loading time.

$$\text{Performance efficiency} = \frac{(\text{Total time} \times \text{operating time})}{(\text{Uptime})}$$

Where;

Total time = Loading time= Uptime + Downtime.

Downtime = time of equipment failure + maintenance time + inspection time + repair time + calibration time + lack of consumables.

Uptime = operation time + standby time (Medhat, Samy, Wahed and Mohamed 2008).

Antosz and Stdnicka (2014), their studies found that the common information gathered facilitated particular actions to identify individual-machine-related failures (72%) as shown in Figure 2-12.

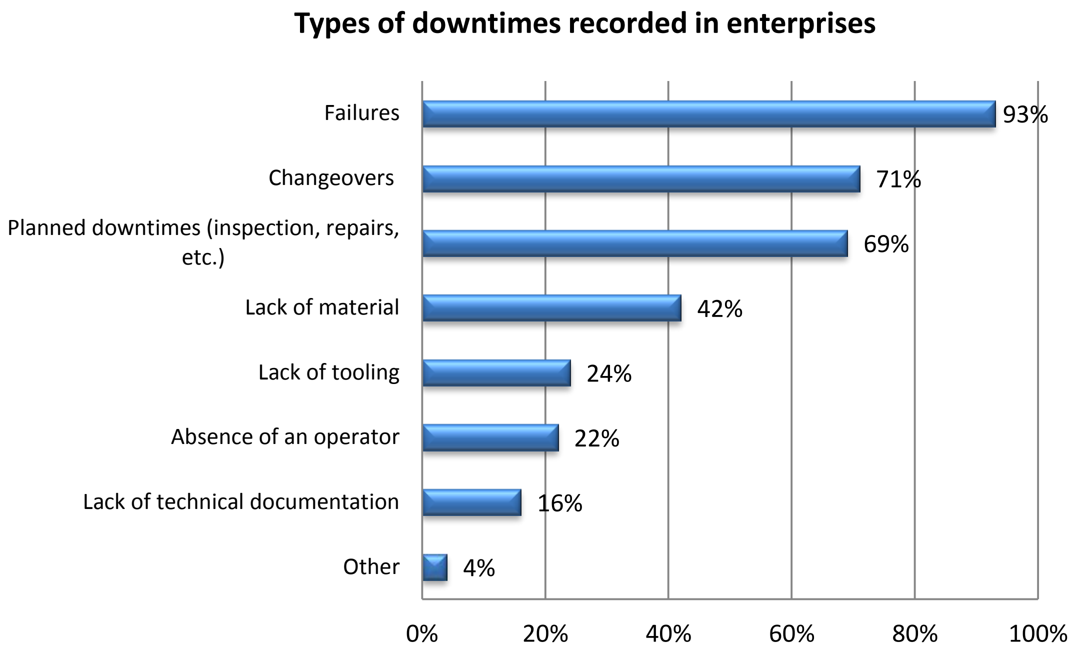


Figure 2-12: Reasons for machine downtime

Dos Santos and V.R. Almeida (2010), have studied the reliability of 161 cardiac treatment medical equipment in a large hospital in Rio de Janeiro, Brazil They developed four indicators for this equipment using condition and failure predictors and coordinating with the equipment manufacturer for one year. The results of this predictive model and The MTBF were identified as show in Table 2-5 below: (Dos Santos and V.R. Almeida 2010).

Table 2-6: Predictive model results for cardiac equipment

Intensity of use	Cardiac Equipment (%)	Failures (%)	Failure Rate	MTBF in days (95% CI)
Inactivated	8 (5)	-	-	-
Low	38(23.6)	3(3)	0.0082	121 (41.5-588.4)
Average	22(13.6)	24(27)	0.0659	15.2(10.2-23.7)
High	93(57.8)	63(70)	0.1731	5.8 (4.5-7.5)

Where:

MTBF is defined according to (Anderson and Neri 1990; Bloom 2006) as "the average time of failure (in days)"(Dos Santos and V.R. Almeida 2010).

$$\mathrm{MTBF} = \frac{1}{\lambda}$$

Reliability is;

$$\mathrm{R(t)} = \exp^{(-\lambda t)}$$

The competition between healthcare organisations requires them to develop and apply suitable maintenance strategies like RCM to continue improvement in healthcare service quality.

2.3 Assessment of Current Maintenance Strategies

In general, the major objectives of traditional maintenance strategies, such as CM and/or PM are to reduce the length of the outsourcing of servicing for medical equipment; to extend the cycle time between consecutive turnarounds; to ensure a high level of reliability (Bevilacqua *et al.* 2009); to keep plant machinery and equipment from breaking down and to improve maintainability and availability to maximize production (Khan and Darrab 2010). However, Ratnayake and Markeset (2010) found that the aim of a maintenance strategy exceeds these objectives. The current aim is to improve quality and boost higher productivity; to achieve faster and more dependable throughput; to reduce inventory and to lower operating costs. Maintenance strategies have been developed to improve the quality of production and services in time as shown in Table 2-7. This Table by Pintelon and Parodi- Herz (2008) indicates the historical development of maintenance strategies and identifies their main strengths and weaknesses. Also, Sethiya (2010) represent the strengths and weaknesses of different maintenance strategies, and identifies a relationship between the failure rate of equipment and changes in maintenance strategies as shown in Figure 2-13.

Table 2-7: Generational Maintenance Concept Descriptions
(Pintelon and Parodi-Herz 2008)

Generation	Concept	Description	Main strengths	Main weaknesses
1st	*Ad hoc*	Implementing FBM and UBM policies; rarely CBM, DOM, OBM	Simple	*Ad hoc* decisions
1st → 2nd	Q&D	Easy-to-use decision chart. It helps to decide on the "right" maintenance policy	Consistent, Allows for priorities	Rough questions, and answers
2nd	LCC	Detailed cost breakdown over the equipment's lifetime helping to plan the maintenance logistics	Sound basic philosophy	Resource and data intensive
	TPM	Approach with an overall view on maintenance and production. Especially successful in the manufacturing industry	Considers human/technical aspects, fits in kaizen approach. Extensive tool box	Time consuming implementation
	RCM	Structured approach focused on reliability. Initially developed for high tech/high risk environment	Powerful approach, Step-by-step procedure	Resource intensive
2nd → 3rd	RCM-based	Approaches focused on remediating some of the perceived RCM shortcomings Example: streamlined RCM, BCM, RBCM	Improved performance through *e.g.* use of sound statistical analysis	Sometimes an oversimplifi-cation
3rd	Customized	In-house developed; cherry-picking from existing concepts Examples: CIBOCOF, VDM	Exploiting the company's strengths and considering the specific business context	Ensuring consistency and quality in the concept developed

In planning and implementing maintenance strategies efficiency and effectiveness play a critical role in an organisation's success, survivability, economic and profitable production system (Rajagopalan and Cassady 2006; Khan and Darrab 2010) Increasing productivity and reducing significant costs can be achieved as a result (Rajagopalan and Cassady 2006). Hence, implementing a better maintenance strategy can increase productivity by up to 30 percent as indicated by Cassady and Nachlas (1998). But intense competitive pressure triggers many organisations to look for every achievable source of competitive advantage (Pintelon, Pinjala and Vereecke 2006). It is argued by Khan and Darrab (2010) that the objective of maintenance strategy is to become more efficient and achieve zero breakdowns and failures, zero accidents and zero defects.

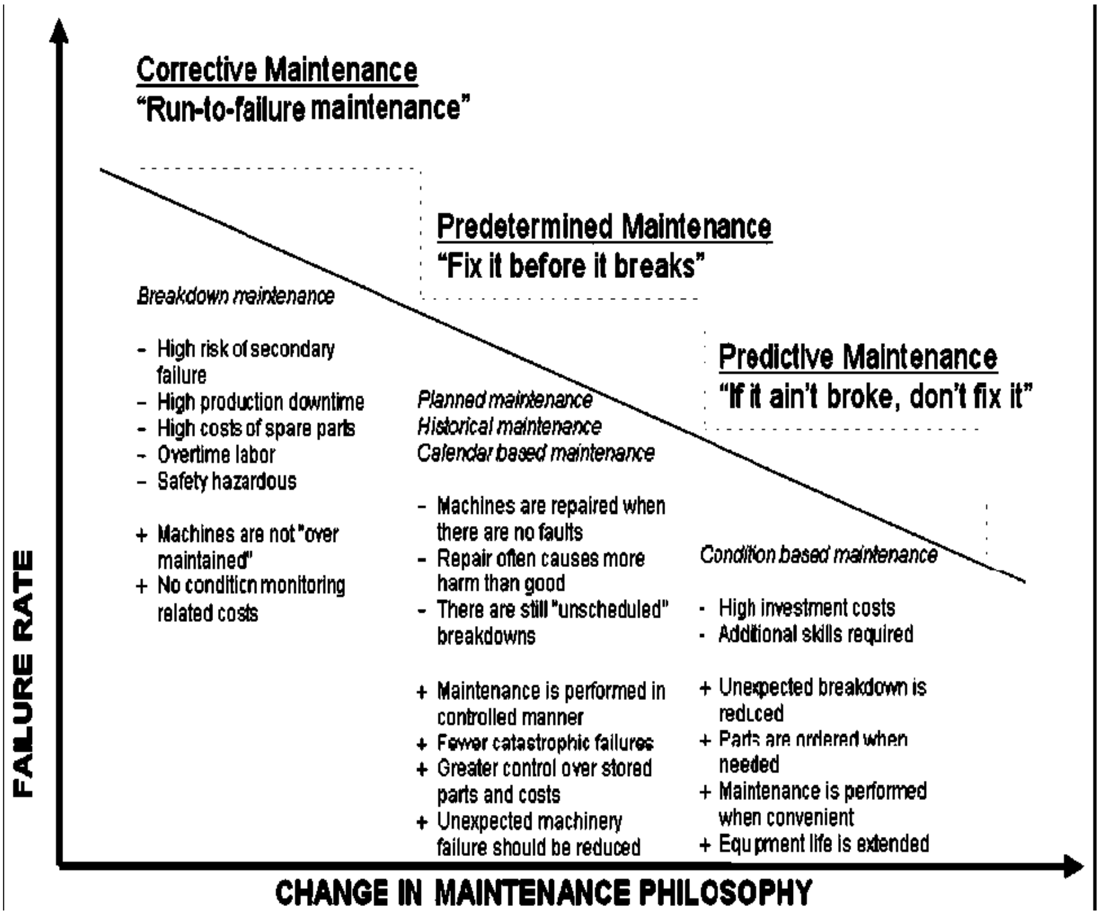


Figure 2-13: Relationship between change in maintenance strategies and failure rates (Sethiya 2010)

There are a number of factors which play a role in evaluating maintenance strategies and these can influence the performance of the maintenance activities (Pun *et al.* 2002) or assist an organisation to select the most efficient form of maintenance strategy, to provide a safe and effective service to patients (Temple-Bird, Mhiti and Bloom 1995). Tsang (2002) cited in Alsyouf (2006) identifies four strategic dimensions relevant to maintenance function as: "the choice between in-house capability and outsourced service, organisation of the maintenance function and the way maintenance tasks are structured, the selection of maintenance policies, and design of the infrastructure that supports maintenance" (Pun, Chin, Chow and Lau 2002).

An effective maintenance strategy can increase the availability and reliability of medical equipment, increase healthcare service productivity and reduce failure rate and reduce life cycle cost (Pun, Chin, Chow and Lau 2002; Mutia, Kihiu and Maranga 2012). In addition, Temple-Bird suggests it is significant to

> *Ensure continuity of patient services, accuracy of diagnosis and treatment, and safety of patients and staff. Unreliable or inaccurate equipment is often worse than no equipment at all. For example, an autoclave has to be hot enough to sterilize its contents, and an X-ray machine must produce diagnostic quality radiographs. Users of faulty equipment, and patients, can be at risk of exposure to radiation or electric shock (Temple-Bird, Mhiti and Bloom 1995).*

Parida and Kumar (2006) describe some of the significant factors behind demands on maintenance performance measures e.g. the measuring value created by maintenance; justifying investment; revising resource allocations; health and safety and environmental (HSE) issues; adapting to new trends in operation and maintenance strategy; focusing on knowledge management; and organisational structural changes (Rajagopalan and Cassady 2006).

In the present study, the evaluation factors for effective maintenance strategies selected are asset management (medical equipment) issues, type of maintenance service, life cycle cost for maintenance strategy, Risk Based Maintenance and Computerized Maintenance Management Software (CMMS).

2.3.1 Asset Management (Medical Equipment) Issues

The Pan-American Health Organisation has defined a Safe Hospital as "a healthcare facility which remains accessible, and continues to operate at full capacity within its infrastructure, even after the occurrence of natural disasters*"*(Licona *et al.* 2009). Asset Management can be defined as 'managing extensive amounts of maintenance, repair and replacement of equipment, renewal work and capital reinvestment in order to maximise the effect of expenditures and to maximise the value of the asset over its service life' (Lemer 1998). This includes reducing risks and delivering reliable support services (Alexander 1996), and is used for long-term strategic planning for the use of an organisation's assets (Vanier 2010). Further, it integrates the management functions of planning, organisation and control of a company's assets 'to efficiently and equitably distribute resources between valid and competing goals'

(Barrett 1995; Danylo and Lemer 1998; Barrett and Reardon 2000; Barrett 2000; Nelson and Alexander 2002; Shohet and Lavy 2004; Pantelias 2005; MacGregor *et al.* 2007; Barrett and Baldry 2009; Too 2010). Asset management plays an important role in healthcare organisations to achieve medical goals. Asset management in healthcare organisations (Turchetti *et al.* 2010) is also referred to as health technology asset management or biomedical engineering, but Health Technology Asset Management is defined according to the Institute of Medicine as

> *any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended* (Turchetti et al. 2010).

The Federal Highway Administration (FHWA, 1999) defines Asset Management as "A systematic approach to maintaining, upgrading and operating physical assets cost effectively". Asset Management combines engineering principles with sound business practices and economic theory utilising these tools to facilitate a more organised and logical approach to decision-making for short and long-term planning". Asset Criticality has been defined by Vellani (2005, 2006) as a "function of the operational impact to the organisation's mission and the loss, damage or destruction of an asset" (Vellani and CPP 2006; Taghipour *et al.* 2011; Saetang and Haider 2014). Dekker *et al.*(1998) defines equipment criticality as a function of the use of equipment, rather than of the equipment itself and explains the reason why one particular device may be deemed "critical", while another is defined as "auxiliary"(Kleijn and Dekker 1999; Tsakatikas *et al.* 2008; Sadeghian *et al.* 2011; Taghipour *et al.* 2011; Taghipour and Banjevic 2012).

Health care is a process that provides data and information about policy alternatives available which are required to make suitable decisions (Turchetti *et al.* 2010). In the healthcare sector this process requires 'analytical methods contributing to decision-making and the design and formulation of policy [focusing] on specific problems of safety, quality or the cost of health care services (Kachieng'a 2001). It is often focus on acquisition, economic, benefit, managing risk and cost over their operation life and its maintenance as indicated by the government of Victoria,

Australia (Kostic 2003). For this reason, decision support tools are required to assist managers in strategic asset management (Vanier 2010).

Biomedical engineering is one of the most important departments in the hospital. It is organisationally structured as a section of the clinical department, the Department of Medical Physics, rather than an engineering placement or part of the traditional facilities (Frisch *et al.* 2003). Biomedical engineering is identified by International Federation of Medical and Biological Engineering (IFMBE) as

> *"*Assessment, planning and acquisition of biomedical equipment to replace those outdated, based on the cost-effectiveness, operating costs, costs of consumables and other incidental expenses, based on the adequacy of the equipment to perform this or any task requested in compliance with safety standards and evaluating the reliability and the assistance services offered*"*(Tchokodjeu 2011).

Biomedical engineering has also been defined by Enderle *et al.* (2001) and Patterson *et al.* (2002) as a set of application engineering and managerial skills to healthcare technology in order to support and advance patient care (Da Rocha *et al.* 2005). Another definition by Nebeker (2002) is 'the use of principles and techniques of engineering to solve problems in biology and medicine' (Turchetti, Spadoni and Geisler 2010).

The Biomedical Engineering Department is an integral part of the patient care support team in a hospital (Logan et al. 2011). In this study, the term biomedical engineering is preferred because the term biomedical technology includes engineering and a variety of other sciences such as mechanical engineering, biology and materials science. Biomedical engineering can be classified either by kind of technology or its function in the delivery of healthcare services. Figure 2-14 shows the structure of a biomedical engineering department (Turchetti *et al.* 2010). Biomedical Engineers need to include in their skills and expertise, the adoption of a methodology for short-listing users of medical equipment, to improve the match between hospital needs, budget projections, medical equipment performance, inventory levels and cost of ownership (Buyer, 2014b).

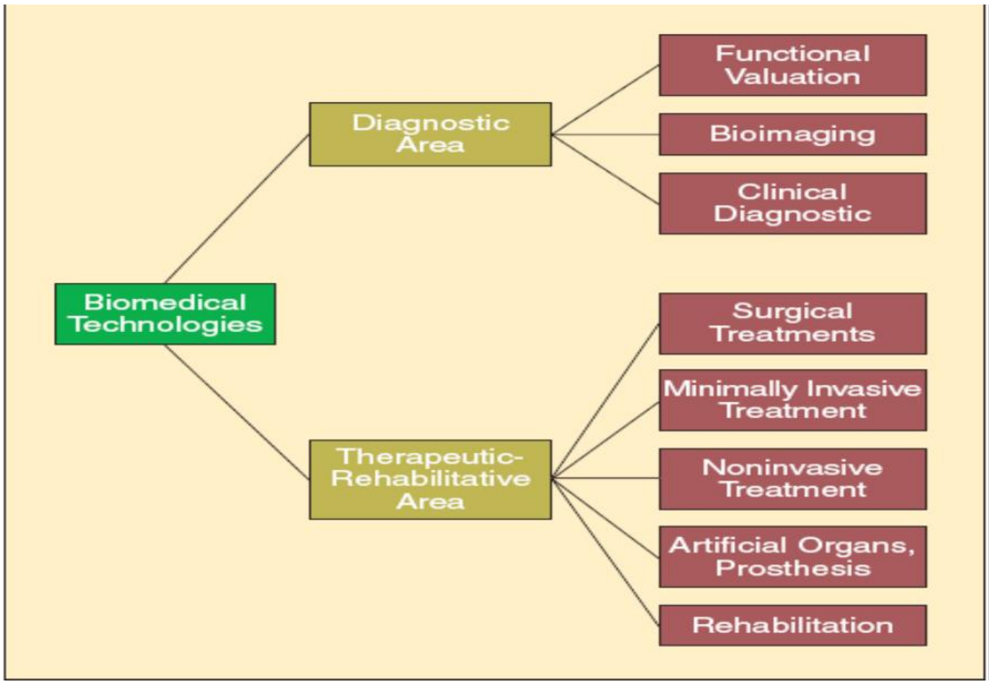


Figure 2-14: Biomedical Technology structure in the healthcare system (Turchetti *et al.*, 2010)

Figure 2-14 shows the four levels with diagnostics and therapeutics as the main categories.

The biomedical engineering department is significant to a healthcare organisation's success in achieving its goals in planning, research and development of equipment and the control and evaluation of medical equipment maintenance. It also ensures safety for patients and minimisation of equipment failure. Furthermore, the performance of maintenance activities by biomedical engineering has economic benefits to healthcare organisations because the engineers can determine which maintenance activities are unnecessary or routine (Da Rocha *et al.* 2005; Taghipour *et al.* 2011; Masmoudi *et al.* 2014). Thus biomedical engineering provides the means for improving healthcare services in both the diagnosis and treatment of diseases. These tools include medical imaging, instrumentation, and medical devices for example cardiac pacemakers, artificial limbs,, devices for the visually and hearing impaired, and dialysis instrumentation (Turchetti and Geisler 2010). There are several complex tasks carried out by biomedical maintenance in addition to corrective and preventive maintenance activity included: quality control, assessment of equipment performance, planned precisely, selection and monitoring contracts

with suppliers, subcontractors, and service companies, contributed in making purchasing decision for devices, and staff training (Masmoudi *et al.* 2014).

Healthcare organisations need to compare the advantages and disadvantages of types of maintenance services, such as in-house or outsourced before making decisions (Da Rocha *et al.* 2005). It is of the utmost importance to note feedback from centres of medicine (hospitals, healthcare communities, medical centres, private practice etc.) using critical and auxiliary medical equipment, noting the ease-of-use, ruggedness and the responsiveness to operating issues by the vendor. In hospitals or other centres of medicine where operating time on the same equipment by different operators is common, the chances of breakdown are high (Medical Buyer 2014).

Many healthcare organisations have serious issues because of the lack of asset management according to (Mages 2006). Vanier (2010) has suggested that many organisations have too many assets to inspect, let alone repair and so many are not given any maintenance, with the result that future maintenance outcomes are uncertain. For example a large hospital can have as many as 5,000 devices that must be inventoried, maintained and monitored. Between 10 and 20 percent of those devices will need to be replaced in any given year. Because of the number of devices, many hospitals have difficulty monitoring both their high-end items and the smaller pieces in each department. This is evidenced in a study conducted by Mages (2006) who found that a typical hospital inventory record can be 60 precent inaccurate with as many as 20 percent of items missing from the list, 25 percent listed with errors and 15 percent removed entirely.

Asset management, therefore, requires sophisticated tools for managing information in order to select the optimum maintenance strategy. While there are many existing tools and techniques that can be used, there is no one tool that can solve all the information issues (Vanier 2001). Further, there are few standards for data collection and many organisations are collecting enormous amounts of electronic data that can only be used in limited arenas such as computerized maintenance management (Vanier 2010). The asset life of medical equipment plays a role in the planning and selection of the type of maintenance strategy adopted. Figure 2-15 identifies the key maintenance stages in the life of an asset while Figure 2-16 shows an asset life cycle (Levery 1998; Mutia *et al*. 2012; Kumar and Srinivas 2014).

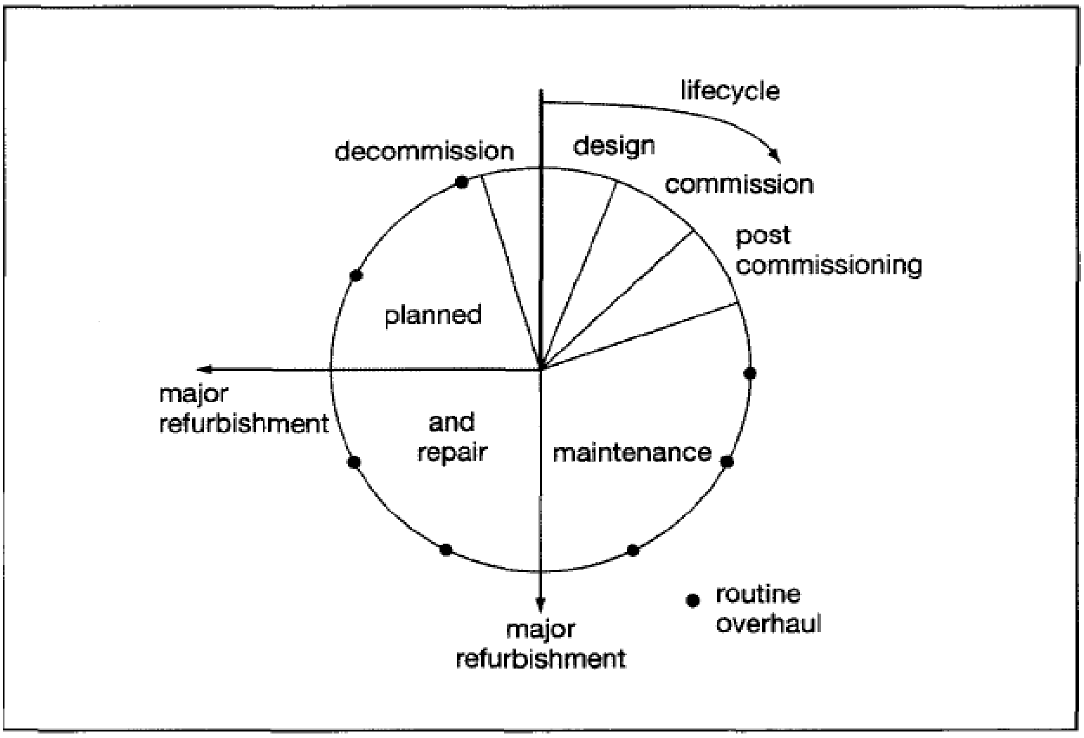


Figure 2-15: Asset Maintenance Life Cycle (Levery 1998)

In Figure 2-15, the maintenance life cycle of an asset shows that maintenance has a significant role to play in the design, installation and commissioning of an asset and is instrumental in driving post-commissioning improvements (Levery 1998). This lifecycle can help in planning and selecting maintenance services for all medical equipment. However, Vanier (2010b) has found that lifecycle analysis is unfortunately not a standard part of infrastructure management.

Each asset has a performance life cycle beginning with the ‘effective stage’ called Service Life (Vanier, 2010b). According to Vanier (2010), the service life of an asset, as defined by CSA (1995), is the useful operating lifetime of an asset or any of its parts without unexpected costs of disruption for maintenance and repair during the effective stage. The service life of an asset can be classified into two types: technical service life and economic service life (Vanier 2010). The last stage in the asset life cycle is ‘capital renewal’, the replacement of an asset because of issues relating to obsolescence, advances in technology, economics or compatibility (Vanier 2010).

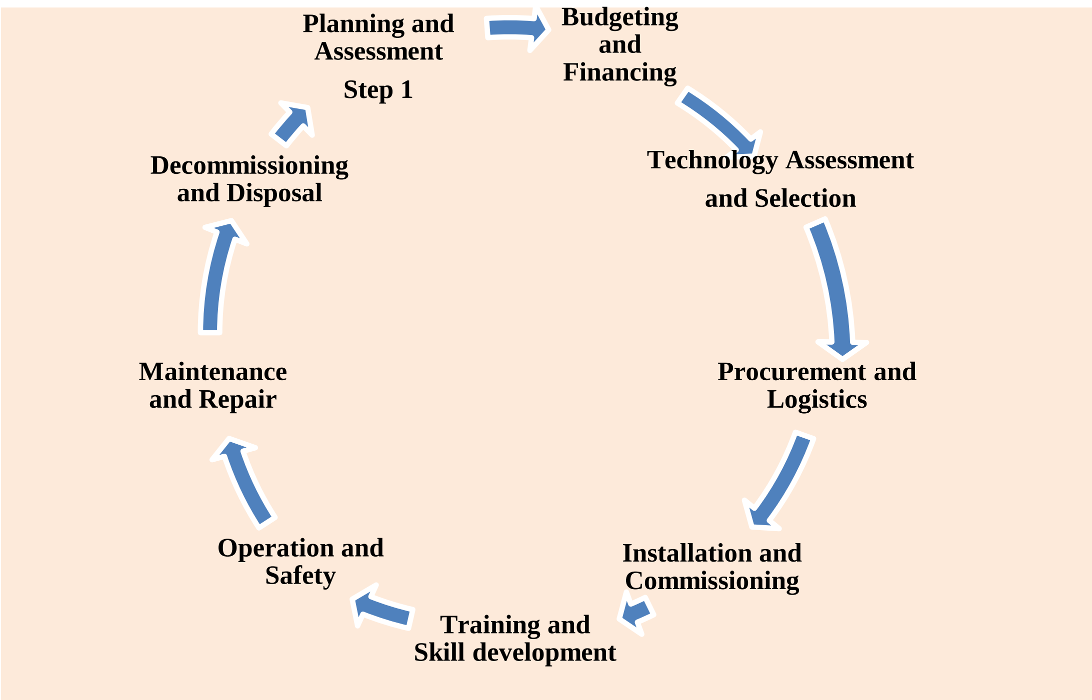


Figure 2-16: Asset Life Cycle (Kumar and Srinivas 2014)

Figure 2-16, illustrates the performance profile of an asset. This assists in targeting appropriate maintenance at particular times and, in addition, in reducing non-important activity in future maintenance plans. This was argued by Kumar and Srinivas (2014), in regard to the technical specification criteria of 'Life-Cycle-Asset' to assist health care organisations in their selection of suitable medical equipment.

When planning maintenance strategies and replacing equipment; the value of an asset needs to be determined. According to Vanier (2010, p. 3) the value of an asset can be determined by one or a combination of the following:

- The historical value, which is the original "book value" of the asset;
- The appreciated historical value of an asset, which is the historical value calculated in current dollars, taking into account annual inflation or deflation;
- The capital replacement value, which is the cost of replacing an asset in current dollars term;
- The performance in use value, which is the value of the asset for the user (Lemer 1998);

- The market value, which is the value of the property if it were sold on the open market today; and

- The deprival cost, which is the "cost that would be incurred by an entity if it were deprived of an asset and was required to continue delivering programs/services without the asset. The value is measured by the replacement cost of the benefits currently embodied in the asset. Deprival value may also represent an opportunity value i.e. the cost avoided as a result of having control of an asset" (Vanier and Rahman 2004; Vanier 2006; Smith 2010; ANAO 1996, p. 68).

In practical terms when maintenance strategies are too costly, it is prudent for affected companies to reclassify their equipment, in order to optimise return for their expenditure. Generally, most companies incorporate consistent criteria when collecting data for prioritizing equipment performance, e.g. machine work time, its failure frequency etc., or the classification of equipment according to prediction processes, company procedures, delivery delays and the quality of the product including: personnel, societal, environmental and safety issues (Stadnicka *et al.*, 2014). Classification criteria are used to optimize reliable data for identifying necessary equipment (Swanson 2001; Stadnicka *et al.* 2014).

In summary, asset management is the integration of all the efforts of the health care organisation in order to provide facilities and medical equipment which supports health care services to patients.

2.3.2 Maintenance Strategies for Medical Equipment

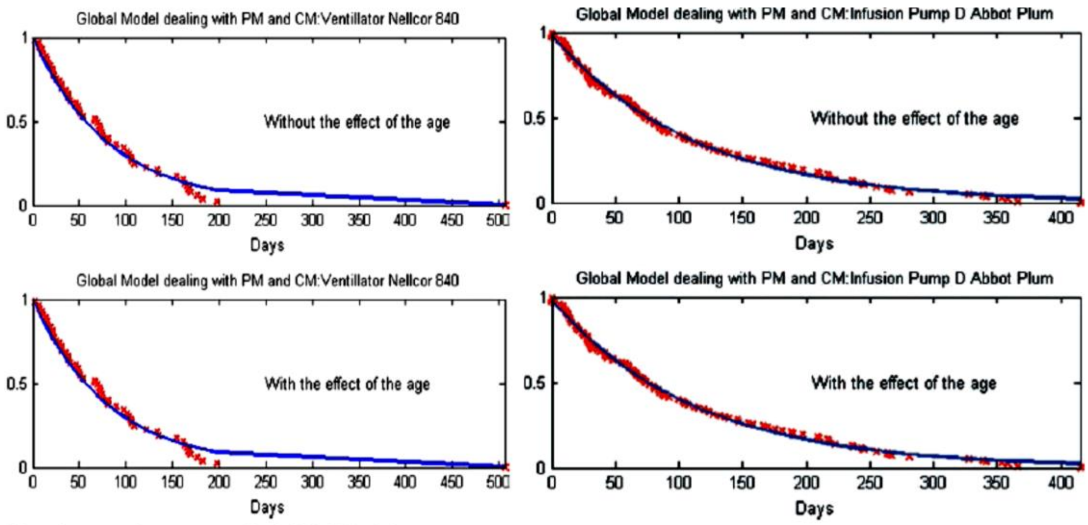
Dieffaga *et al.* (2013) proposed a method of problem resolution through quality improvement, productivity improvement of larger medical equipment and the maintenance issues in the Gabriel Touré Hospital in 2004. The most prolific maintenance issues listed in this study are related to a lack of maintenance information, knowledge, resources, financial records and information about medical equipment management. Table 2-8 shows the main results that were obtained from the 38 persons surveyed (Dieffaga *et al.* 2013). Cheng (1995) discussed the maintenance strategies used for medical equipment in developing countries: He recommended the *Pyramid Model* as a suitable strategy for solving issues of medical

equipment maintenance (Cheng 1995). The Center for Medicare and Medicaid Services (CMS) has approved a new risk-based PM strategy for medical equipment in hospitals and is a culmination of the extended efforts by the American Society for Healthcare Engineering (ASHE) and The Joint Commission that allows its accredited hospitals the option of using a risk-based strategy when it comes to PM activities on medical equipment (HCPRO 2014).

Table 2-8: Maintenance Issues' from 38 medical stakeholders surveyed (Dieffaga *et al.*, 2013)

Persons /Percent	The maintenance issues
2 doctors	could operate the ecrograph
3 (7.89%)	able to select the right parameters when using of the equipment
14 agents	carried out their work badly
8 (21.05%) agents	were operating medical equipment after work time
18 agents	did not check the material after use

Khalaf (2013) found through analysis using the survival approach that when conducting PM on selected medical equipment, there was a positive impact on the survival of the equipment. In contrast, the manufacturer's intervals for PM did not correlate to the failure rate encountered by users of the equipment. This study has directly contributed to the debate on the recommended intervals of PM stipulated by manufacturers, in relation to maintenance strategies implemented by hospitals and Clinical Engineering (CE) practitioners. In the main the study revolved around infusion pumps and ventilator machinery *as* shown in Figure 2-17 below (Khalaf *et al.* 2013)**.**



Notes: Parameters for upper curve: $\lambda = 0.0123$, $S(0) = 1.0$; parameters for lower curve: $\beta = 0.0000025$, $\lambda = 0.0123$, $S(0) = 1.0$

Notes: Parameters for upper curve: $\lambda = 0.0090$, $S(0) = 0.9838$; parameters for lower curve: $\beta = 0.00000016$, $\lambda = 0.0090$, $S(0) = 0.9839$

Figure 2-17: Global model for dealing with PM and CM for infusion pumps and ventilator machines

1. Infusion Pumps

The simplest infusion device was an IV bag with tubing connected to an IV catheter. This was the first type of infusion equipment used only from the 1900s (Levine and Vemest in Ehrenwerth *et al.* 2013) It regulated the desired flow-rate removing the necessity to clinically monitor the drip-rate. The benefits of this class of device is its lower cost, smaller size and the need for a single clinician to monitor several infusions at a time (Levine and Vemest in Ehrenwerth *et al.* 2013). Figure 2-18 shows the timeline of development of the infusion pump.

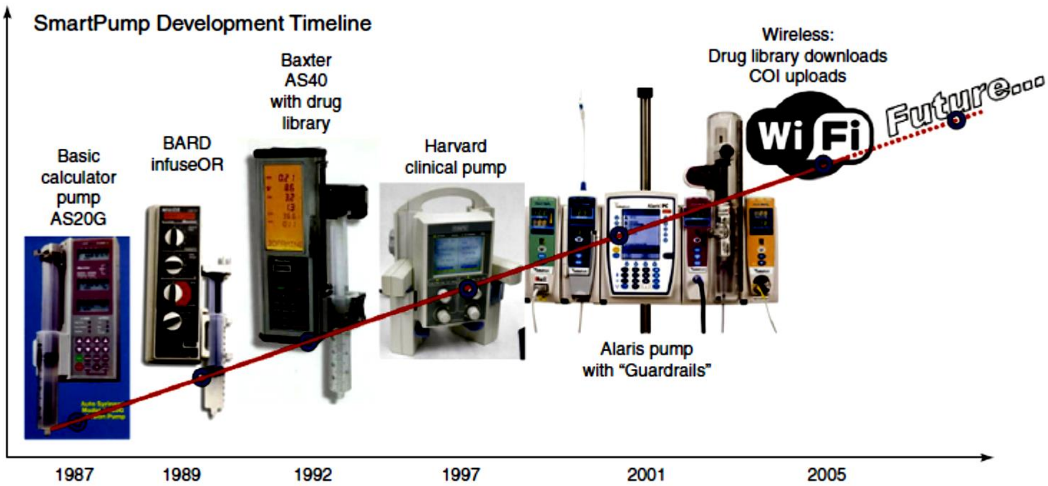


Figure 2-18: Infusion Pump Development Timeline

1987: The Baxter AS20G (Baxter, Deerfield, IL), the first calculator pump, which could be be programmed directly in mg/kg/min or μg/min rather than mL/h, eliminating the need for conversion tables. 1989: The Bard Infuseor (Bard Medical, Covington, GA), the first "Smart" pump, used different magnetic face plates for each drug which put dosing limits on the rate at which a drug could be infused. 1992: The Baxter AS40, the first pump with software drug libraries. This pump was pulled from the market for off-label use only 3 months after it was introduced. 1997: The Harvard Clinical 2 (Instech Laboratories, Inc., Plymouth Meeting, and PA) was the first pump introduced with clinically developed drug libraries. Hospitals were responsible for setting the hard and soft limits on their pumps, removing the liability from the pump manufacturer. 2001: Alaris was the first manufacturer to hit the mainstream market with drug libraries. They successfully trademarked "Guardrails," this became a very popular pump in the market and forced many manufacturers to follow suit in introducing drug libraries. 2005: Many pumps begin to incorporate Wi-Fi to allow the downloading of drug libraries and uploading of quality control information so that an administrator can see how often clinicians exceed soft limits or operate outside the drug libraries. Future: remote programming or verification of computerized entires of a doctor's presciption, uploading of current pump information to automated charting systems, automated syringe identification (bar code or radiofrequency identification).

The Joint Commission on Accreditation of Healthcare Organisation (JCAHO) recommends the use of PM (Scheduled Maintenance Approach and Performance Inspection) as the best maintenance strategy to effectively address risks associated with infusion pump devices. The majority of problems with maintenance occur, because of 'human error', e.g. user neglect and abuse (broken latches, frayed chords etc.). Importantly, manufacturers recommend PM to cultivate a culture where 'interval-based inspections' are supported, because a 'run to fail' strategy is inappropriate for life-supporting equipment (JCAHO 2006). Ridgway (2009) reported that 31,463 PMs were performed in 169 healthcare facilities during 2008 by Master-plan staff for 28,389 infusion pumps (56% were from four main infusion pump manufacturers, the balance being 74 miscellaneous models). These initial statistics are suspected to be under-reported because Master-plan has yet to standardise generic ASHE procedures to facilitate more complete and accurate

documentation (Ridgway 2009). Table 2-9 shows PM findings for infusion pumps (Ridgway 2009).

Table 2-9: Preventative Maintenance Findings for Infusion Pumps

	# of PM Finding Reported	Indicated MTBF (Days)	MTBF Used In Risk Analysis	LOF used In Risk Analysis
P3 Battery worn out	197	144	1-2 Years (Occasional)	3
S7.Damaged control /switch	60	473	1-2 Y Ears (Occasional)	3
S1. Line cord damaged	34	835	2-5 Years (Uncommon)	2
S9. Flow rate out of space	28	1,014	2-5 Years (Uncommon)	2
P2. Illegible labelling	11	2,580	>5 Years (Re-mote)	1
S4. Battery charger defected	8	3,549	2-5 years (Uncommon)	2
Where: (LOF) is the Likelihood of Failure				

2. Oxygenation Devices

JCAHO (2006) has defined oxygen devices as life-support equipment; additionally a ventilator is utilised because of its convenience and enhancement qualities recommended under Clinical Engineers' (CEs') and Bio-medical Equipment Technicians' (BMETs') definitions. Interestingly, a heart-lung by-pass monitoring machine is not considered life-support equipment although its failure could cause a patient's death (JCAHO 2006).

3. Haemodialysis Devices

McCarthy (2012) has presented the majority of maintenance issues for the haemodialysis equipment to Clinical Engineering (CE). The chronic nature of haemodialysis treatment follows that it cannot be skipped or avoided, because it is considered to be life-sustaining treatment. Maintenance issues associated with haemodialysis equipment were shown to be: (1) Difficulties in scheduling PM for haemodialysis equipment because of unplanned emergencies The repairs or planned maintenance activities would most probably need to be performed after work hours if no backup equipment was available. Standard PM for haemodialysis equipment takes 3-5 hours (depending on the age of the equipment).

(2) Confusion concerning the appropriate PM procedures to follow when maintaining haemodialysis equipment when there is a lack of biomedical engineering knowledge. (3) The high purchase price of haemodialysis equipment. (4) Lack of backup equipment which can lead to higher maintenance costs, e.g. overtime, and (5) The necessity to use purified water when servicing haemodialysis equipment to eliminate contamination problems (McCarthy 2012). Figure 2-19 shows a Haemodialysis Device.

Figure 2-19: Haemodialysis Devices

4. Maintenance of Anaesthesia Machines

Anaesthesia machines are considered a critical technology because malfunctions can cause patient deaths (LOGAN, *et al.* 2011). Over the last 30 years manufacturers have developed temperature compensated vaporizers which are made up of extruded anodized aluminium and fibre with guaranteed vapour pressure (incorporated heaters in desflurane vaporizers). At the same time a modern ventilator to deliver anaesthesia with respiratory variations has been incorporated. Latest advancements in extensive monitoring features are scrutinized by the World Federation of Societies of Anaesthesiologists (level 1, 2 and 3). Today there is a full range of monitors displaying hemodynamic, blood gas, respiratory parameters and inhaled and exhaled anaesthetic for maintaining specific MAC values (anaesthesia depth, temperature etc). Today's anaesthesia machinery is practical as well as functional. The addition of ventilators with a wide-range of monitors makes anaesthesia machinery compact and allows the delivery of modern general anaesthesia with full-range monitoring, which contributes significantly to patient safety. Technology has progressed with touchscreen delivery and with alarm systems to monitor the smallest discrepancies.

With the advent of robotics in the industry the human element is becoming less important (Buyer, 2013).

5. Defibrillator

The use of the Automated External Defibrillator (AED) can make the difference between life and death (Brady 2013). It is referred to as a '*Life Support Equipment'*. According to the *American Heart Association (AHA) and European Resuscitation Council (ERC)*, defibrillation or other terms such as manual defibrillator, Automated External Defibrillator (AED), defibrillator can be used by a trained bystander to stop ventricular fibrillation (VF), an often-fatal heart condition leading to Sudden Cardiac Arrest (SCA) (Brady 2013). The American Heart Association has also provided significant data as following;

- A victim's chances of survival are reduced by 7 to 10 percent with every minute that passes without CPR and defibrillation. Few attempts at resuscitation succeed after 10 minutes.
- The sooner the defibrillation shock the better because each minute the brain goes without oxygen diminishes the likelihood the victim will return to a "normal life" even if resuscitation does occur within 10 minutes. As time is precious in an SCA emergency, this equipment is critical.
- The average call-to-shock time for a "typical community" is 9 minutes (Mosesso Jr *et al.* 1998).
- Median response time is 6.6 minutes for emergency medical services in mid-sized urban communities (Braun *et al.* 1990)
- Connecticut Senate Bill 981 was inspired by the sudden cardiac death in 2007 of 15-year-old Larry Pontbriant after collapsing during an annual race. The Connecticut AED in Schools legislation mandates at least one automated external defibrillator (AED) and at least one trained AED responder provided that the school has money in its budget *(www.cardiacscience.com)*.

6. Maintenance of ECG Machine

(Medical Buyer 2014) has argued that manufacturers are focusing on improving system accuracy, reducing errors, and providing additional clinical capabilities to enhance workflow. Changes in the medical profession from acute intervention to preventive care has laid a strong foundation for ECG diagnosis in identifying a

variety of problems related to the heart. The exceptional rise in managed care services and the ensuing cost-control measures have facilitated the expansion of sub-acute care with features enabling the attachment of an ECG record to the patient's electronic medical record (EMR) in the form of a PDF and wirelessly acquiring ECG data for analysis. In this way the hospital's workflow is effectively streamlined. High-risk patients need to be continuously monitored during diagnostic as well as patient care stages. The rising incidence of cardiovascular diseases has necessitated uninterrupted monitoring of cardiac patients, which substantially enhances the demand for cardiac monitoring equipment and associated supplies (Medical Buyer 2014).

The following Figures 2-20 and 2-21 show some examples of CME, Ventilator, BIPAP-Vision and Respironics-CPAP machines.

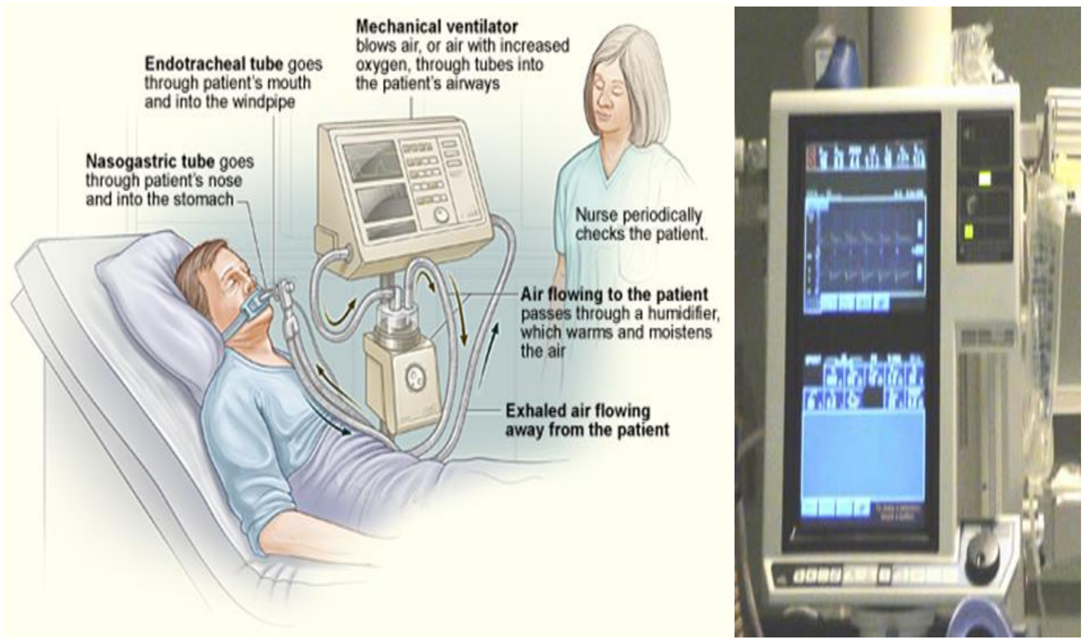


Figure 2-20: Ventilator machine

BIPAP-Vision machine Respironics-CPAP machine

Figure 2-21: BIPAP-Vision and Respironics-CPAP machines

2.3.3 Type of Maintenance Service

The effectiveness of a maintenance strategy will depend on the type of maintenance service used by the healthcare organisation. Maintenance services can be classified into three types: using an in-house biomedical engineering service department, outsourcing all the maintenance services to independent companies and mixing in-house with outsourced services (De Vivo *et al.* 2004). The in-house biomedical engineering service is used in order to ensure patient safety and quality control of medical equipment (Brook 1998). In-house maintenance services can offer several benefits for healthcare organisations including greater economy, an increase in the skills of technical staff and engineers, the ability to compile service manuals and ensure the timely availability of spare parts (Wickesser,1994 in; Olaiya 1999).

Outsourced services tend to involve negotiated contracts with the Original Equipment Manufacturers (OEM) who take responsibility for the medical equipment they have provided and employ contractors, distributors and consultants who provide competence, knowledge and manpower in maintaining the equipment. This kind of outsourced service is a popular approach to maintenance and support requirements. Over the past decade, several manufacturers and suppliers have offered a total performance guarantee of their products or have supplied a functional product and are taking full responsibility for the equipment maintenance and provision of spare parts (Patterson *et al.* 2002). Many organisations depend on this type of maintenance service in order to achieve minimum operating costs including labour. However, the

equipment may be individually designed, with few, if any standby facilities, limited spares and a shortage of skilled and experienced maintenance engineers (Levery 1998). In spite of this, a significant issue is that long-term contract maintenance service may not be useful for healthcare organisations for many reasons: it is difficult for top management to monitor maintenance procedures; the fixed costs of the contract cannot be changed; there may be difficulty in cancelling the contract and in the long term these types of contractual services can result in poor administrative control and financial problems for the health care organisations, as indicated by (Bluemke 1995; Olaiya 1999).

Outsourcing is a concept utilised by enterprises to streamline their activities. External service providers specialising in particular tasks and processes are given responsibility for these areas. In recent times the frequency of outsourcing has increased in providing ‘technical infrastructure management’ (Stadnicka and Antosz 2013). Approximately 77% of companies surveyed had implemented, to some extent, the concept of outsourcing (Stadnicka and Antosz 2014).

Each type of service has advantages and disadvantages as shown in Table 2-10, and places different demands on management (De Vivo, Derrico, Tomaiuolo, Capussotto and Reali 2004). To reduce the effect of these disadvantages, most organisations use a combination of in-house and outsourced maintenance services (Levery 1998).

The decision whether to select an in- house or outsourced maintenance service is affected by the maintenance cost of each type of critical medical equipment. The cost of maintenance service depends on all maintenance activities necessary (Da Rocha, Sloane and Bassani 2005). In order to reduce the significant costs related to service contracts, some of healthcare organisations have attempted to change their maintenance service from outsourced to in-house. For example, Memorial Sborrow Kettering Cancer Center has a supporting in-house biomedical service together with an insurance based (Kemper) equipment management program (Frisch *et al.* 2003). ‘Approximately, 40% of the institution’s medical equipment is serviced directly by the Biomedical Engineering staff, 59% (5800 devices, medical and non-medical) is supported through a time and material / insurance service model, the remaining 1% is supported through service contracts. Of the 5800 devices serviced by the time and materials / insurance methodology, 94% are exclusively time and materials with 320

devices (5.4 Oh) based on capped service cost insurance. The overall service model has reduced service costs by more than US$ 2M annually maintaining response time and service quality at an acceptable level. The user departments utilise the service provider of their choice with service costs documented and closely monitored by Biomedical Engineering (Frisch *et. al.*, 2003).

Table 2-10: Advantages and disadvantages of strategic maintenance services (De Vivo *et al*., 2004)

	Advantages	**Disadvantages**
In-house	- Fast response possible for breakdowns. - Technical staff can work closely with professional users; - On-site repairs can lead to short down times. - Often less costly than an outside organisation for a given level of service.	- Special tools and test equipment may not be available or may need additional costs (E.g. Calibration by the manufacturer). - Hard to maintain adequate stocks of spare parts across a wide range of devices. - Training costs high and manufacturers are sometimes reluctant to provide. - In-house staff are typically generalist rather than specialist.
Manufacturer	- Predictable costs. - Same build standard as the original device with modification and updates incorporated - Assures access to spare parts. - Remote diagnostics via computer network sometimes available. - No problems with warranty/ liability. - Availability of training for professional users.	- Contracts with many separate manufacturers need to be negotiated and updated. - Staff need to administer the maintenance system. - Quality control must be monitored. - Response time may be longer, depending on the contract.
Third party	- Often cheaper than manufacturer. - Possible to have an on-site engineer. - Few external organisations to deal with.	- May only be available for certain devices. - Manufacturers are usually reluctant to train personnel. - Possible liability problems.

In order to select which type of maintenance service is effective for medical equipment, Da Rocha *et al.* (2005) designed a framework to be used by the biomedical engineering group of the public health system of the Universidade Estadual de Campinas located in Brazil to support the choice of maintenance services

for each type of medical equipment as shown in Figure 2-22. Their findings have assisted hospital managers in making decisions about maintenance strategies for different kinds of equipment because they show the cost and performance related to each type of maintenance service. The final results of their study found that the maintenance costs of third party maintenance services are greater than in-house maintenance service. Examples of this are shown in Table 2-11 and Figure 2-23 for 4 Radiographic units and 1 Ct (Da Rocha *et al.,* 2005).

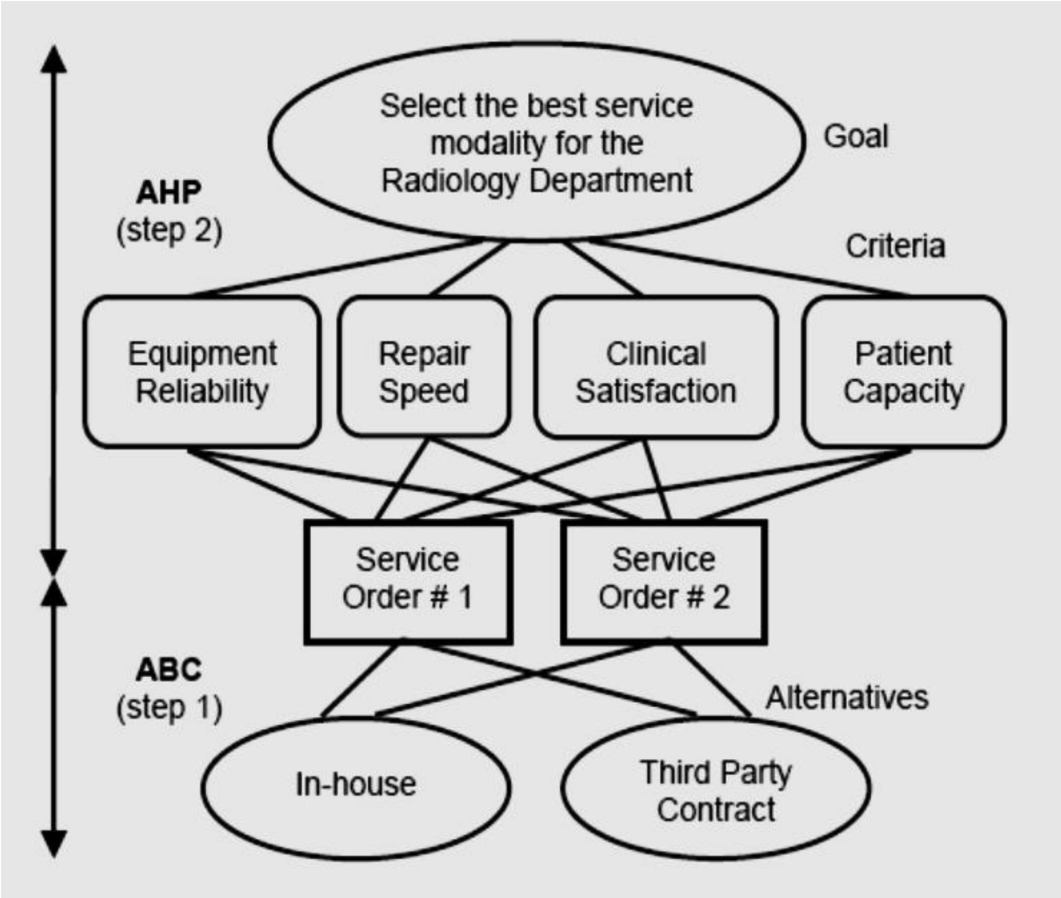


Figure 2-22: Cost model for selecting the best maintenance service
(Da Rocha *et al.,* 2005)

Table 2-11: Maintenance Costs for In-House and Third Party maintenance services (Da Rocha *et al.*, 2005)

Equipment	Cost of the maintenance service (R$)	
	In -house	Third Party
4 Red. Units	83.51	551.60
1 CT	74.45	1,969.80

The result of applying the cost model to select the best maintenance service is shown in Figure 2-23, which demonstrates that in-house maintenance services are more economical than contracted services.

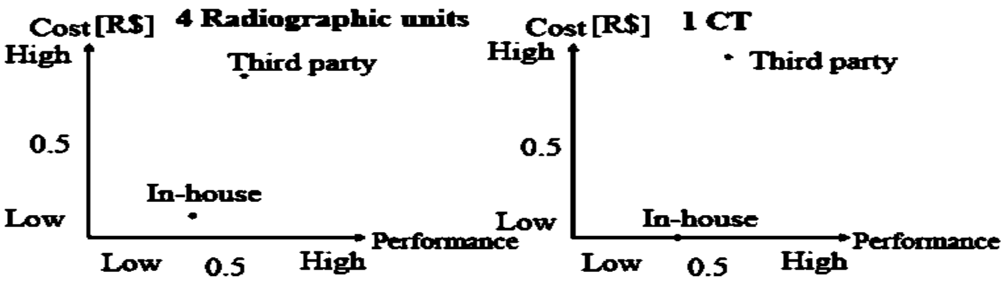


Figure 2-23: Cost and performance model for the best maintenance service (Da Rocha *et al.*, 2005)

Likewise, Figure 2-23 shows the final results of the cost and performance of this model for selecting the best maintenance service model for 1 CT and 4 radiographic units in the Radiology Department. This suggests that the relative benefit of in-house servicing the CT is about 4 times greater than servicing the Radiographic Units (Da Rocha *et al.*, 2005).

In addition, De Vivo *et al.* (2004) found that when the hospital gradually replaced outsourced maintenance with an in- house service, the number of repairs needed was drastically reduced, as shown in Figure 2-24. It was noticed that during this gradual change between 2002 and 2003, maintenance costs were reduced, as shown in Figure 2-25 (De Vivo *et al.*, 2004). This shows that before purchasing equipment the financial implications of outsourcing maintenance should be studied. There are far-

reaching implications. Issues in the investment cost of assets such as medical equipment are often a result of poor performance of equipment and high costs of maintenance (Levery 1998).

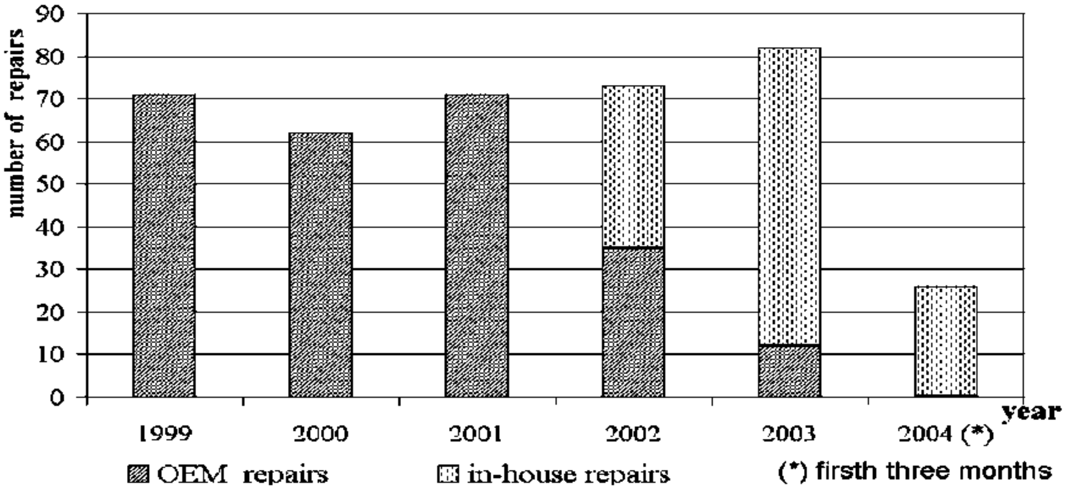


Figure 2-24: Outsourced vs in-house repairs 1999-2004 by (De Vivo *et al.* 2004)

Figure 2-24 shows a scenario of changing maintenance service from contracts with the original manufacturers to in-house maintenance.

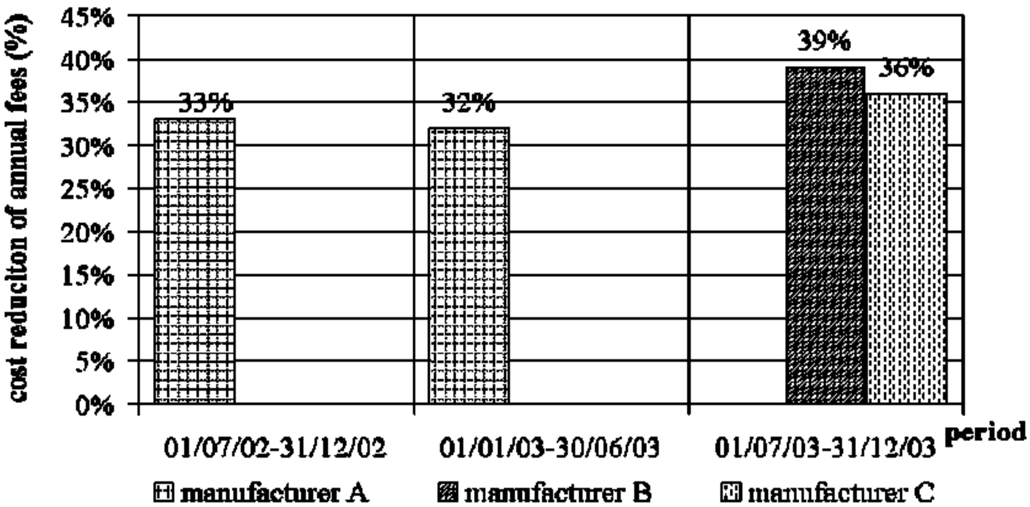


Figure 2-25: Percentage reduction of annual maintenance fees 2002-2003 (De Vivo *et al.* 2004)

Figure 2-25 shows the benefits that have been obtained by hospitals (including the re-education) in contractual maintenance fees after the application of in-house maintenance service 2002-2003. In summary, in-house maintenance service has been shown to be most effective for hospitals because it is economical, extends the life of medical equipment and reduces the number of failures.

2.3.4 Life Cycle Costs of Maintenance Strategies

Healthcare institutions rely heavily on biomedical equipment to provide diagnosis, treatment and monitoring in patient care (De Vivo *et al.* 2004). For this reason, the role of biomedical maintenance engineers in selecting the most efficacious and cost effective maintenance strategies is vital to ensure that medical equipment meets appropriate standards of safety, quality and performance (De Vivo *et al.* 2004).

In general, the costs of maintenance activities can be classified into two types: direct and indirect (Salonen 2011). Direct maintenance costs include: labour, spare parts, repairs and maintenance services, inspection and other costs that clearly are directly linked to maintenance activities. Indirect maintenance costs include the cost of recovery due to lost production (from equipment failures) and the cost of reduction in the quality of service (Salonen 2011).

In general, Corrective Maintenance (CM) is less expensive than PM in the short term (Pun *et al.* 2002), but in the long term, overall maintenance costs are very expensive (Temple-Bird *et al.* 1995). There are many reasons for this. Firstly, when a CM requirement occurs, the capacity of the production operation is reduced, workers are idle and this causes direct labour costs to rise. Secondly, in the case of an emergency, breakdown maintenance crews must be called in and the necessary spare parts acquired (Nicholas 1998; Walker 1999; Moayed and Shell 2009). Thirdly, a lack of activity leads to sudden failures usually also related to high maintenance costs (Temple-Bird *et al.* 1995). Therefore, CM is only suitable for non-critical areas with low capital costs, slight consequences of failure, no safety risk, quick identification of failure and fast repairs (Starr, 1997 in Sharma *et al.*, 2005). In contrast, in PM, the overall maintenance costs are less than CM because spare parts are available, worker and machine idle time tends to be reduced and maintenance procedures and manuals are always available (Wireman 1998; Walker 1999; Moayed and Shell 2009) The costs include maintenance employees costs, spare parts inventories kept for

maintenance procedures and lost time when equipment is down for repairs (Wireman 1998; Walker 1999). Pun *et al.* (2002) has reviewed the effective maintenance cost by comparing different maintenance strategies e.g. proactive maintenance, TPM, RCM, product maintenance, approach profit-centered maintenance, and continuous maintenance as shown in Table 2-12.

The increasing demand world-wide for high quality and low risk healthcare services makes reduction in expenditure on "non-core" activities, such as maintenance and operations necessary (Briggs *et al.* 2006). A number of studies have found that the adoption of new technologies is a major reason why the cost of maintaining equipment has increased. For example, Hay *et al.*, (2001) found that new medical technology contributed 19% of the increase in inpatient healthcare spending in the United States between 1998 and 2002. In a study conducted by the University of California, Berkeley researchers discovered that for computer-based systems, the first three years after the acquisition of equipment currently represents between 3.6 and 18.5 times the initial cost of hardware and software (De Vivo *et al.*, 2004). In UK manufacturing maintenance costs range from 12-23 percent of the total factory operating costs (Tsang 2002; Emmanuel 2010) (Cross, 1988 Tsang, 2002). In the Swedish mining industry, which is highly mechanised, maintenance accounts for 40-60 precent of the operating costs (Danielson 1987; Myeda *et al.* 2011; Stenström 2013). In refineries up to 30 percent of the total staff are involved in maintenance of production equipment and structures (Dekker 1996; Tsang 2002; Rajagopalan and Cassady 2006). In Europe, the total value of maintenance budgets has been estimated to be approximately US $1500 billion per year. A third of these costs are due to poor planning, overtime costs, and inefficient use of preventive maintenance (Salonen 2011).

Table 2-12: Comparison between different maintenance strategies
(Pun *et al.* 2002)

Criteria	Proactive maintenance	Total product maintenance	Approach Profit-centred maintenance	Reliability –centred maintenance	Continuous maintenance
Maintenance cost reduction	By improving the life cycle management of the system	By improving overall equipment effectiveness and resolving equipment related problems once and for all	By optimizing the physical function of maintenance and resolving recurring maintenance problem	By optimizing the required maintenance interval	By addressing the problematic and technical aspects of maintenance
Equipment or maintenance productivity	By focusing on proven corrective and preventive maintenance technology; by identifying equipment maintenance processes	By increasing added value per person; increasing the time of operation and reducting equipment breakdown	By reducing the need for maintenance and reducing breakdown	By improving the reliability of equipment	By maintaining and improving readiness with fewer resources
Overall equipment effectiveness (OEE)	By emphasizing equipment and system effectiveness	By improving OEE by attacking the six losses : breakdown, set up and adjustment; idling and minor stoppages; speed and yield reduction from start-up and defects	By emphasising decision-making based on value; re-engineer the administration of maintenance and using available maintenance information.	By emphasizing a systematic approach using appropriate run-to- failure, planned, preventative and condition based strategies according to the consequence of failure of the system	By emphasizing the measuring of maintenance performance and making use of both readiness and total related maintenance costs
Continuous improvement	By having a consideration of continuous improvement	By achieving continuous improvement by extensive use of standardization of workplace organization and visual management	By emphasizing continuous administrative improvement and optimization	By emphasizing a proactive approach to achieve continuous improvement	By achieving continuous improvement by incorporating RCM and PAM techniques
Anticipated duration of implementation	1-3 months	1-3 years	1-3 years	3-6 months	3-6 months

In order to cope with the challenges of global competition, many healthcare organisations need to re-engineer their current maintenance strategies by adopting cost effective and reliable strategies (Temple-Bird *et al.* 1995; Rocha and Bassani 2004; Wu and Liu 2010). A life cycle costing analysis is dependent on equipment reliability and maintainability of data input. Much of this data can be estimated using experience, service reports, spare parts and warranty data, comparison with similar equipment and product databases (Patterson *et al.* 2002). Therefore reducing the life cycle cost of maintenance requires the managers of healthcare organisations to understand the overall management process, input and output, and strengths and weaknesses in the performance of existing maintenance in order to develop their maintenance strategy. Figure 2-26 is a basic example which shows the relationship between maintenance strategy with production operation, input and output resources in any organisations as proposed by (March 2003).

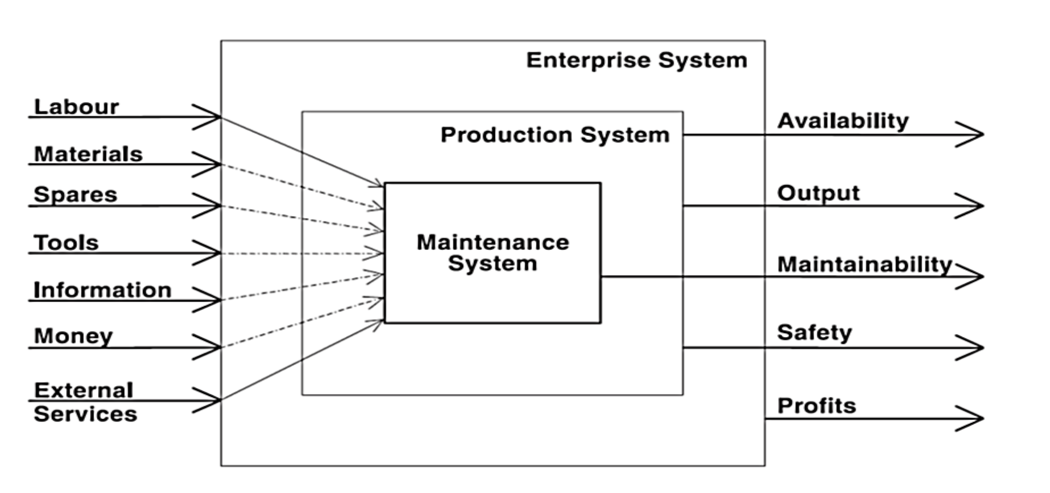


Figure 2-26: Input and output model for organisational maintenance systems (March, 2003)

Figure 2-26, illustrates that the maintenance system in any organisation includes input, the maintenance process and output. An input resource includes labour, materials, spares, tools, information, money and external services. Output includes availability, maintainability, safety and profits. The maintenance process converts inputs to actual outputs. The cost of the effective maintenance life cycle depends on managing this maintenance process efficiently during use and working to achieve maintenance goals.

In health care organisations effective maintenance strategies can save on the maintenance costs of medical equipment without impacting on its availability and performance safety in relation to patients' lives. For example, Wu and Liu (2010) attained savings on maintenance costs of medical equipment of over RMB7,000,000, (approximately US$1,000,000) during the implementation of a quality control program for medical equipment from 2007 to 2009. They identified a small failure in an X-ray machine that is difficult to detect during maintenance as one of the problems endemic to this medical device. Figure 2-27 shows the results of savings in the cost of medical equipment maintenance (Wu and Liu 2010).

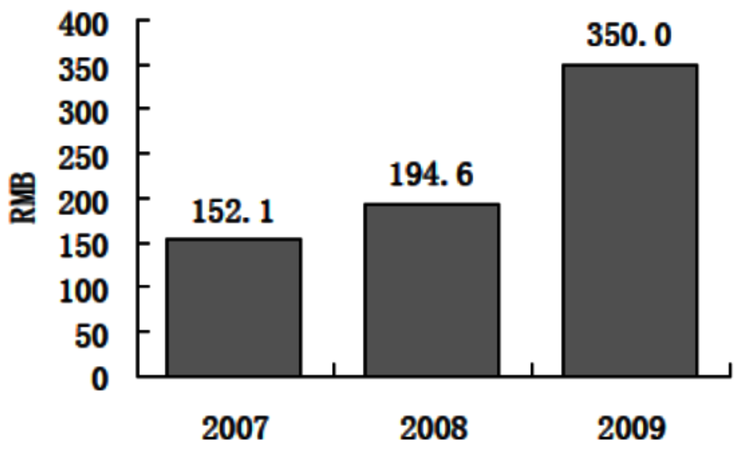


Figure 2-27: Maintenance cost saving (Wu and Liu, 2010)

2.3.5 Risk Based Maintenance

A risk-based maintenance approach has been incorporated into continuous-type production systems to classify equipment within production and processing facilities, based on the risk of failure of equipment, which can cause financial, staffing and environmental challenges for the asset owner (Stadnicka *et al.* 2014). Risk as defined by Dyro (2014) highlights the combination of probability and severity of harm. Risk Management in healthcare is explained in the 'American Society of Health Care Risk Management' as the process of making or carrying out decisions in the prevention of adverse consequences and to minimise these effects on patients, on the quality of performance of the operators and on the productivity of the organisation (Tchokodjeu 2011; Kumar and Srinivas 2014).

As mentioned above, traditional maintenance strategies are no longer enough to ensure that medical equipment is receiving the best possible maintenance because of the rapid progress of medical equipment technologies and the invention of thousands of types of devices (Khalaf *et al.* 2010; Wu and Liu 2010). It must be recognised that in all healthcare organisations, the effectiveness and efficiency of the maintenance of medical equipment must ensure the provision of healthcare services to patients without any risk (Khalaf *et al.* 2010). In a healthcare organisation , risks to the patient include death, injury, and misdiagnosis (Khalaf *et al.* 2010). All medical equipment and facilities related to a patient's life should be effectively verified in calibration safety and reliable operation (Wang *et al.* 2006; Avendaño *et al.* 2010; Wu and Liu 2010).

An error in the performance of medical equipment when providing healthcare service can become a source of serious harm for the patient (Avendaño *et al.* 2010; Wu and Liu 2010), For this reason, hospital management needs to understand the risk to patients' lives of medical equipment failure during the provision of healthcare service to patients' lives by closely monitoring the use of medical equipment and selecting a suitable maintenance strategy (Wu and Liu 2010).

Despite the development of medical equipment, according to Khalaf *et al.,* (2010), no medical device is one hundred percent safe and no one has unlimited resources. Khalaf *et al.,* (2010) argued that traditional maintenance strategies focus mostly on safety and inspection activities, because of this, it often cannot ensure the reliability of medical equipment (Wang *et al.* 2006). Therefore, maintenance strategies should focus on risks caused by medical equipment failure rather than on the device with maximum maintenance demands (Wang *et al.* 2006). Risk analysis is "a technique for identifying, characterizing, quantifying, and evaluating the loss from an event" (Khan and Haddara 2003). Risk evaluation is integrated with reliability, safety and minimizes the probability of medical equipment failure and its consequences. It also assists hospital management to select the most suitable maintenance strategy and maximise the value of capital investment (Khan and Haddara 2003).

There are a number of factors that increase the impact of medical equipment failure on patients' lives.

1. Medical equipment can be connected directly or indirectly to the patient's body when providing treatment, especially with biomedical equipment. For example, some medical equipment, such as EKG, EEG and EMG, is connected the patient's body in order to pick up biological signals; some apply energy to the patient, such as X-rays, diathermy, U. Violet; etc., while others verify vital conditions in the patient, such as Clinical Laboratory Tests (Avendaño *et al.* 2010; Mutia *et al.* 2012).
2. Increasing breakdowns of medical equipment can be caused by either poor maintenance or mistakes in implementation (Amuasi and Crawley 2002; Chompu-inwai *et al.* 2008).
3. The lack of centralised information about medication errors and medical equipment failures. For example, in US hospitals, possibly 1 in every 200 patients admitted dies due to medical errors (Segal *et al.* 2001).
4. Human error in the use of medical equipment. For example in 1971, before safety measures were applied world-wide, "in the United States, at least three patients were accidentally electrocuted each day and the total number of electrocutions yearly was about 1200". Figure 2-28 shows the current frequency and electrical risk to a patient's heart which leads to death (Avendaño *et al.* 2010). Moreover, Lardner and Fleming (1999) indicated that 80 per cent of accidents are due to a combination of both human and organisational causes (Ratnayake and Markeset 2010).
5. Medical equipment management ensures machinery is planned and budgeted for effectively prior to procurement for the effective operation of an organisation (Mutia *et al.* 2012). 'Human Factors Engineering' (HFE) is utilised to influence the procurement of medical devices for hospitals. The process ensures that the safest and most efficient and effective machinery is purchased. *HFE*, applied to the design and evaluation of medical devices, is frequently cited as an important method for the reduction of medical errors and adverse events and for increasing patient safety (Mutia *et al.* 2012; Kumar and Srinivas 2014).

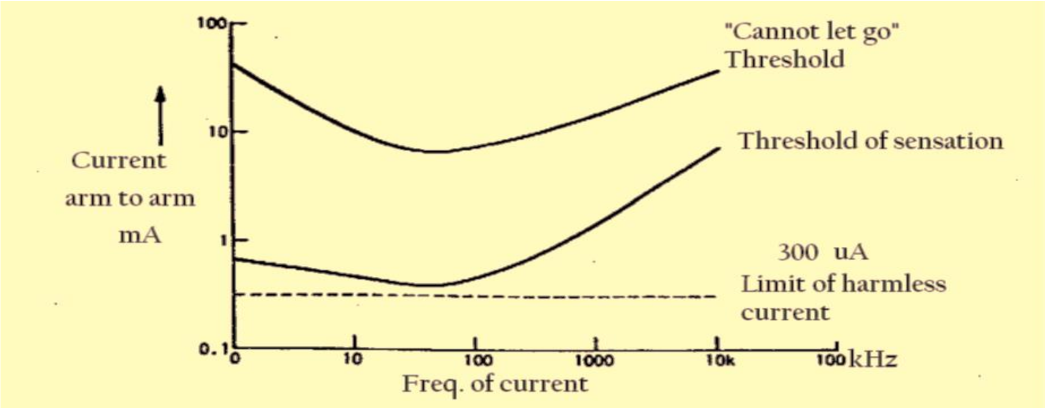


Figure 2-28: Current frequency of electrical risk from machines
(Avendano *et al.*, 2011)

6. Technical causes of equipment. In general, 20-30 percent of large-scale accidents are due to technical causes as indicated by (Turner, 1994 in Ratnayake and Markeset 2010; Lardner and Fleming, 1999;Ratnayake and Markeset 2010).
7. *Kalra (2011)* found that medical errors are either human or mechanical, and usually result in procedure-revision and/or regulatory action. These influences add to the complexities of medical processes, and can inadvertently introduce new opportunities for failure in the system (See Figure 2-29).

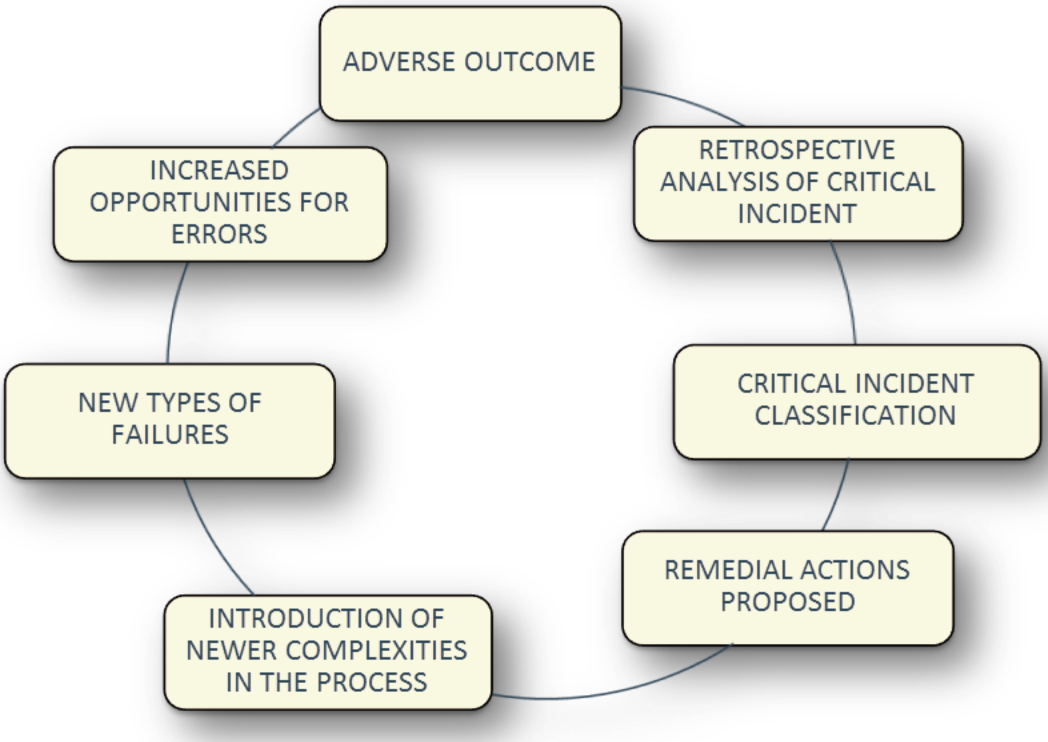


Figure 2-29: Cyclic behaviour of error-generating propogation
(Kalra 2011)

For all these reasons, failure of medical equipment can have serious consequences in diagnosis, therapy, monitoring, and simulation, analysis of graphs, curves or data (Avendaño *et al.* 2010). If medical equipment is outside the normal operating range, it may cause:

1. Direct damage by interaction with the patient (current leakage, accelerated electrons, X-rays in unacceptable doses, infusion of drugs in excessive amounts).
2. Indirect damage by measurement error (values in blood cellcounts, hematocrit, blood pressure and body size, magnitudes of neoplastic structures, size of the gestational sac and foetus).
3. Damage by calculation error in elements of application such as; dimensions, mechanical prosthesis, miscalculation of doses of accelerated electrons, therapy planning (Avendaño *et al.* 2010).

Risk to the patient can be classified into three levels: high, medium and low (Khalaf, *et al.*, 2010; Wang, *et al.*, 2006). Table 2-13 shows an example of the classification of medical equipment according to these risk levels (Khalaf *et al.* 2010). This classification is proposed by ECRI (1995) as explained below (Wang and Levenson 2000).

1. High risk level: devices which are used as life support, key resuscitation, critical and other devices whose failure or misuse is reasonably likely to seriously injure patients or staff.
2. Medium risk level: Devices, including many diagnostic instruments, whose misuse, failure, or absence (out of service with no replacement available) would have a significant impact on patient care, but would not be likely to cause direct serious injury.
3. Low risk level: Devices, whose failure or misuse is unlikely to result in serious consequences (Wang and Levenson 2000).

Table 2-13: Examples of equipment classification by Wang B (Khalaf *et al.*, 2010)

		Level of Risk's into Patient		
		High	Medium	Low
Mission Criticality	Critical	Anaesthesia Ventilator Radiotherapy	MRI, CT scanner, Cath lab, autochem. Analyser	Electron microscope
	Important	PCA pump Infant incubator Defibrillator Telemetry System	Infusion pump, ESU, Hypo/Hyperthermia Physiological Monitor, Scanner blood gas Analyzer, Ultrasound	Special procedure Table, lab Microplate reader, Cine projector, Flat-panel detector
	Necessary	Bariatric patient Lift, laminar Airflow	Enteral feeding Pump, ECG, Pulse oximeter	Patient scale, Examination Light, Treadmill

Risk measurement for asset management (medical equipment and facility) can be quantitative or qualitative (Khan and Haddara 2003). Quantitative risk measurement is cost impact per unit time. The results of this type of measurement can assist hospital management to determine the risk probabilities and evaluation of consequences. Qualitative risk measurement is less careful and the results are often shown in the form of a simple risk matrix where one axis of the matrix represents the probability and the other represents the consequences (Khan and Haddara 2003). Both of these types can be defined as a set of duplets for a particular failure scenario. Risk is calculated using the equation: Risk = probability of failure × consequence of the failure (Khan and Haddara 2003; Bevilacqua *et al.* 2009).

In Preventative Maintenance (PM) "risk-based criteria" are used including equipment management (EM) factors, which are calculated using the equation: EM = function + physical risk + maintenance requirements. Examples of equipment management for certain equipment are shown in Table 2-14. All equipment with EM ≥ 12 is included in equipment management planning (Khalaf *et al.* 2010).

Table 2-14: Risk management-based criteria (Khalaf *et al.*, 2010)

Device	Function	Risk	Maintenance	EM #	PM
Ventilator	10	5	5	20	6m
Defibrillator	10	5	4	19	6m
Infusion Pump	9	3	2	14	12m

In order to establish the quality control and quantitative risk evaluation of medical equipment, Wu and Liu (2010) proposed that after three years of application, a six-dimension risk model be used. Practice and performance analysis confirmed the effectiveness of the risk quality control. This study in four famous hospitals in China (General Hospitals of the People's Liberation Army) evaluated ten types of high risk medical equipment, such as ventilators, anaesthetics equipment, ECG monitors, infusion pumps, syringe pumps, defibrillators and high frequency surgical equipment. The results of this study showed an increase in of high-risk medical equipment from 10% to 40%. Figure 2-30 pre- and post-implementation quality control to high risk medical equipment (Wu and Liu 2010).

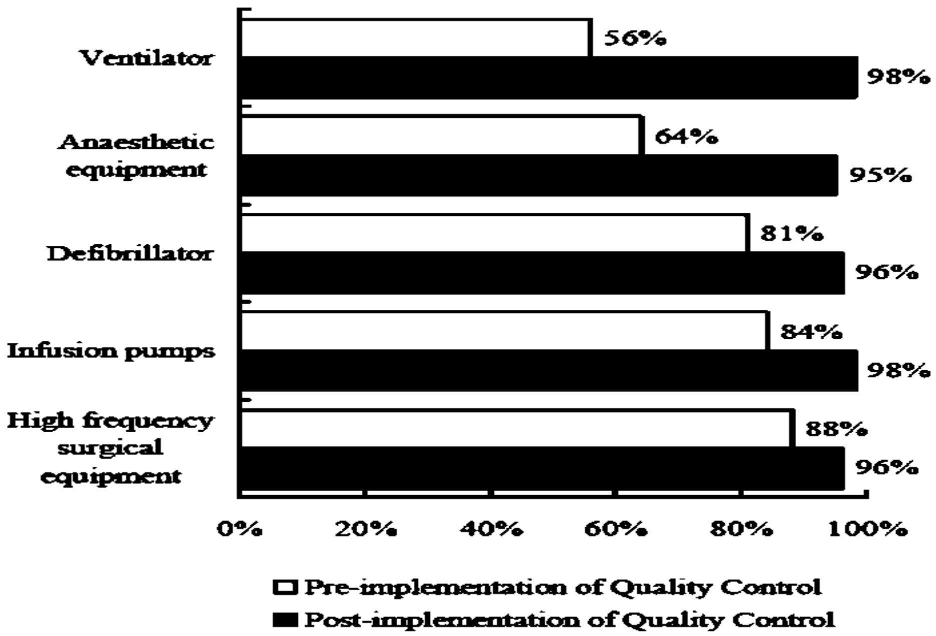


Figure 2-30: Pre- and post-implementation quality control for high risk medical equipment (Wu and Liu, 2010)

Despite the limited number of studies which refer to accidents, injuries and death of patients due to errors from medical devices there are some studies which indicate the occurrence of accidents.

1. Derfel (2012) indicated that the JGH had come forward with more details concerning medical accidents that may have caused the deaths of three people during 2010-11 along with additional information concerning other errors that permanently harmed patients revealing that a problem with diagnostic tests "may have caused or contributed" to the death of a patient. Also, two patients were highlighted as suffering "permanent harm" after falls at the hospital were disclosed by Markirit Armutlu, the Quality Program Coordinator at JGH. Furthermore, hospital staffs were involved in the application of life-saving procedures to save the lives of five patients due to errors in the dispensing of medications in hospitals and the health of two patients was compromised due to the malfunction of hospital medical equipment. Vanheuver Zwijn indicated, "it should have been 0.004, or a total of 75 deaths across Quebec" (Derfel 2012).
2. Derfel (2012) noted that Montreal's McGill University Health Centre and the Jewish General Hospital have publicly confirmed that medical accidents "contributed to or resulted in" the deaths of at least 10 patients in 2010. The hospitals also revealed that "medical accidents" or the government term, "errors", caused permanent disabilities in 16 patients, which ranged from a hip fracture and permanent hearing loss to cardiac arrhythmia. The disclosures contradict the Quebec government's first "Medical Error Registry Report" in December of 2010, which concluded that no patients died in 2010 in The McGill University Health Centre and did not provide the exact circumstances of its seven reported deaths (the same number as in 2010, and up from three in 2009). However, it did reveal some details. With one patient there was an "overdose of narcotics, resulting in respiratory depression and subsequent death". With another: "a client sustained a very bad fall in hospital and was transferred to the Intensive Care Unit where he subsequently died and in yet another instance there was an undetected malfunction of CME leading to cardiac and respiratory arrest resulting in the patient's death". (Derfel 2012).

3. The IOM, in their 2006 report *Emergency Care for Children: Growing Pains*, acknowledged the risk to pediatric patient safety, and the need for more proficient data systems, research and procedures to ensure safe high quality care and implored the United States' Department of Health and Human Services to fund studies in pediatric pre-hospital safety (Meckler *et al.* 2014).

2.3.6 Computerised Maintenance Management Software (CMMS)

The effectiveness of a maintenance strategy will depend on the Computerized Maintenance Management System (CMMS) used by Biomedical Engineering in a healthcare organisation. Cohen (2003) suggested that Biomedical Engineering needs data and information in order to solve maintenance issues; to plan and control the performance of maintenance activities; to control cost; and evaluate the quality of maintenance performed on medical devices and other equipment. For these reasons, Biomedical Engineering Departments need to collect, store and analyse data by using the Computerized Maintenance Management System (Acevedo *et al.* 2005; Vanier 2010; Acevedo-Garcia *et al.* 2012). CMMS is a tool that can be used to record which assets are owned (Vanier 2010) and which maintenance activities are carried out. The use of CMMS significantly improves the management of maintenance activities by providing an efficient information system (Chien *et al.* 2010).

Cohen (2003) indicated that CMMS has a number of benefits in the management of maintenance strategy. One major benefit is the ability to manage and control the inventory of all medical equipment (Acevedo, Fuentes and Enderle 2005; Acevedo *et al.* 2006). Using CMMS each medical device requiring tracking is labelled with a unique control number. Without an accurate inventory system it is impossible to track maintenance and repairs, alerts and recalls, scheduled work orders and many of the other technology management functions (Acevedo *et al.*, 2005). However, Vanier (2010) argues that while CMMS is excellent for storing data, its analytical capabilities for risk analysis and life cycle costing are not particularly advanced. Currently these systems are not able to assist the manager in analysing data or offering scenarios for long-term system readiness, capability or performance. Despite this, CMMS has become an essential tool for asset managers in the new millennium (Vanier 2010).

Despite the limited analytical capabilities of CMMS, it can still be used for the management of work order control. According to Acevedo *et al.,* (2005), Work Order Control (WOC) is used:

- To schedule inspections and track the status of work orders, prioritize work orders, monitor service response times and equipment downtime and balance technician workloads;

- To standardise documentation, inspection and preventive maintenance procedures;

- To track medical device recalls and alerts;

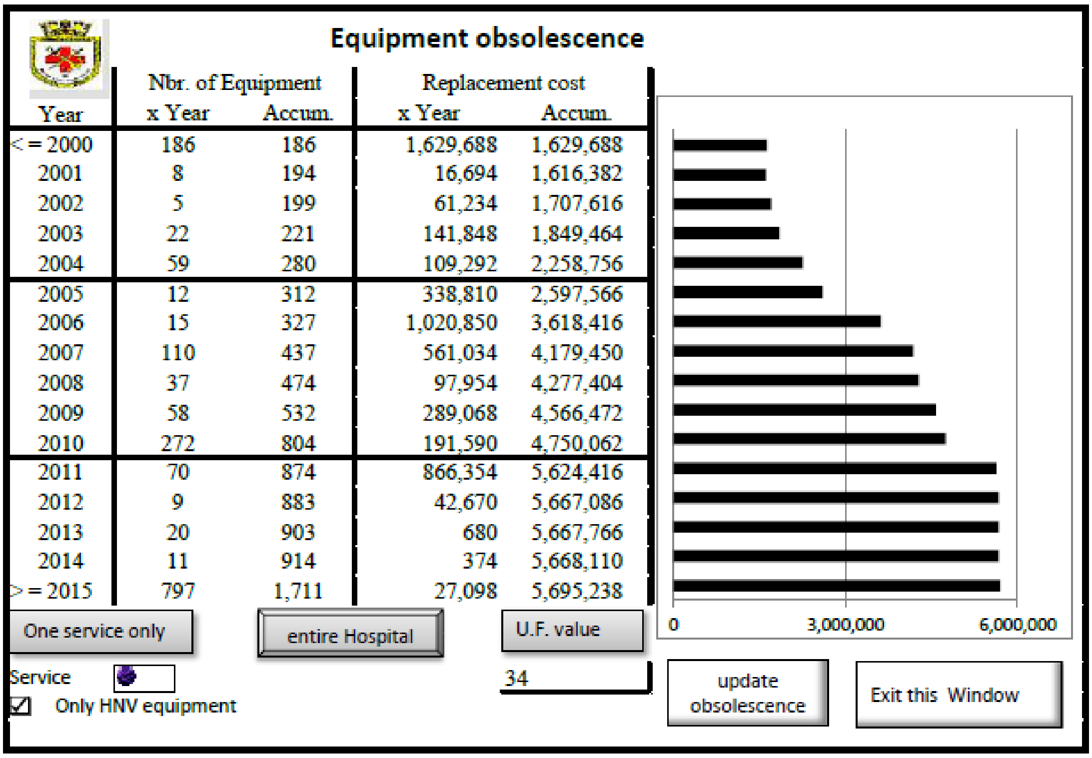
- To provide cost and productivity reporting by technicians, customer departments, and vendors.

Thus CMMS can assist the asset manager to determine both the present backlog of deferred maintenance in calculating the probable levels of maintenance in the future (Vanier 2010).

One of the most commonly used CMMS is a relational database. Usually a relational database simply maintains the most recent information in its records. It can save data about wages, repair dates and scope as well as contract specifications and drawings. This data is stored and used to extract the trends over the past years on issues like deferred maintenance and recurring maintenance scenarios. It could be also used to establish trends for strategic planning of maintenance (Vanier, 2010b).

The use of CMMS in biomedical engineering departments is important if the medical devices are to perform their functions safely. A number of authors have explained the importance of applying and using software maintenance programs in hospitals in order to improve the reliability of medical equipment and make maintenance activities more efficient (Kusinitz 2004; Mock *et al.* 2005; Schrenker 2005; Williams 2006; Schrenker 2010). One example of the use of CMMS in a Biomedical Engineering Department comes from Acevedo *et al.* (2005) who designed and implemented CMMS in the Chilean Naval Hospital. Their system was designed to meet the specific requirements of this military facility and followed the Generic

Clinical Engineering Maintenance Management System suggested by the Union for the Development of Medical Instrumentation. Figure 2-31 shows the CMMS equipment obsolescence screen for decision makers in the Biomedical Engineering Department (Acevedo *et al.* 2005).



Year	Nbr. of Equipment x Year	Nbr. of Equipment Accum.	Replacement cost x Year	Replacement cost Accum.
<=2000	186	186	1,629,688	1,629,688
2001	8	194	16,694	1,616,382
2002	5	199	61,234	1,707,616
2003	22	221	141,848	1,849,464
2004	59	280	109,292	2,258,756
2005	12	312	338,810	2,597,566
2006	15	327	1,020,850	3,618,416
2007	110	437	561,034	4,179,450
2008	37	474	97,954	4,277,404
2009	58	532	289,068	4,566,472
2010	272	804	191,590	4,750,062
2011	70	874	866,354	5,624,416
2012	9	883	42,670	5,667,086
2013	20	903	680	5,667,766
2014	11	914	374	5,668,110
>=2015	797	1,711	27,098	5,695,238

Figure 2-31: CMMS Equipment Obsolescence screen, Chilean Naval Hospital (Acevedo *et al.*, 2005)

In addition Chien *et al.* (2006) illustrated the design principles and structure of an information management system as shown in Figure 2-32. This figure shows the five functions required for building information management system to manage the maintenance of medical equipment. These functions were: Request List, Borrowed list, Data Query and History, Stock List.

The authors explain the advantages of using this database in managing the maintenance of medical equipment. The major advantage is in reducing the hospital's budget by reducing the rate of break-downs and borrowing of medical equipment by 75%. They reported that after applying this system for over six months, the usage rate of three types of medical equipment doubled, as shown in

Figure 2-33. Further, the rate of breakdowns and borrowing was significantly reduced

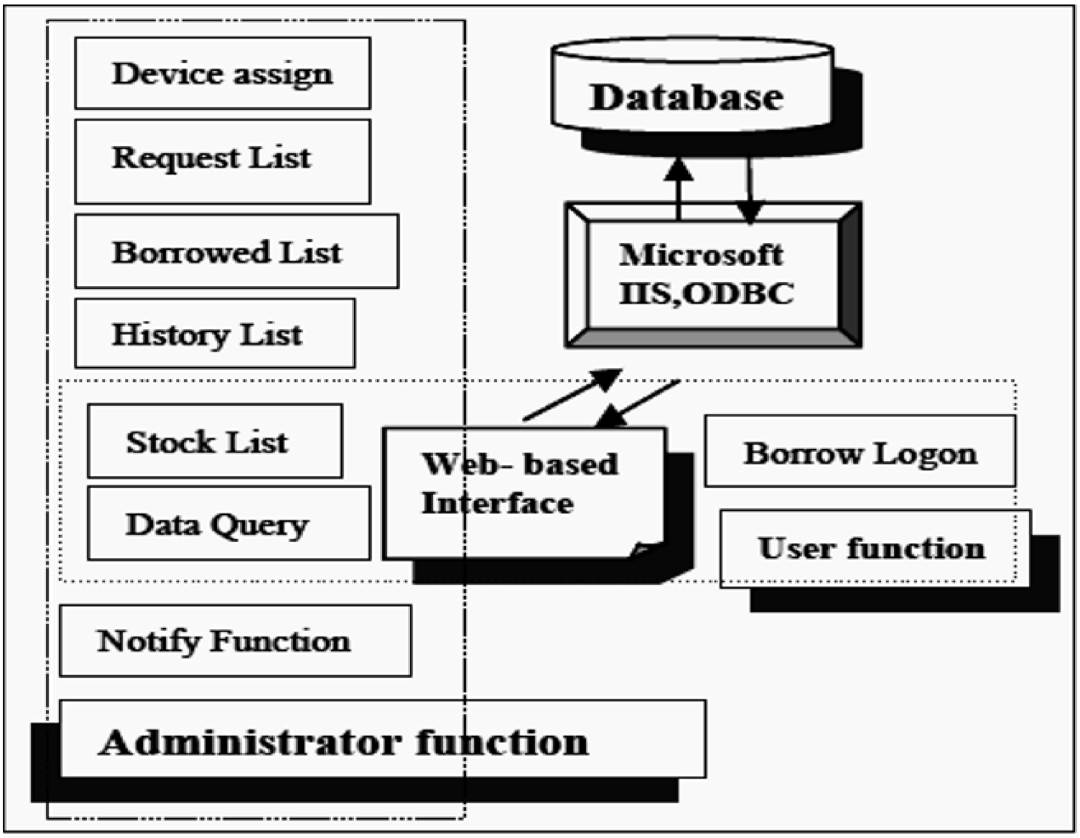


Figure 2-32: Framework of an information system (Chien *et al.* 2006)

In order to improve the performance of medical equipment in the National Taiwan University Hospital, (Chien *et al.*, 2010) also designed a web-based medical equipment management system for use in in-house clinical engineering departments. This system integrates clinical engineering and hospital information system components. The results showed only a few examples in the error analysis of medical equipment by the maintenance sub-system. This information can be used to improve work quality, to reduce the maintenance cost, and to promote the safety of medical devices used on patients by clinical staff (Chien *et al.*, 2010). The major elements of the medical equipment management system are illustrated in Figure 2-34. These elements contain ten sub-systems such as basic information, maintenance, preventative maintenance, procurement, discard, acceptance, warranty inspection, installation verification, and contract management (Chien *et al.*, 2010).

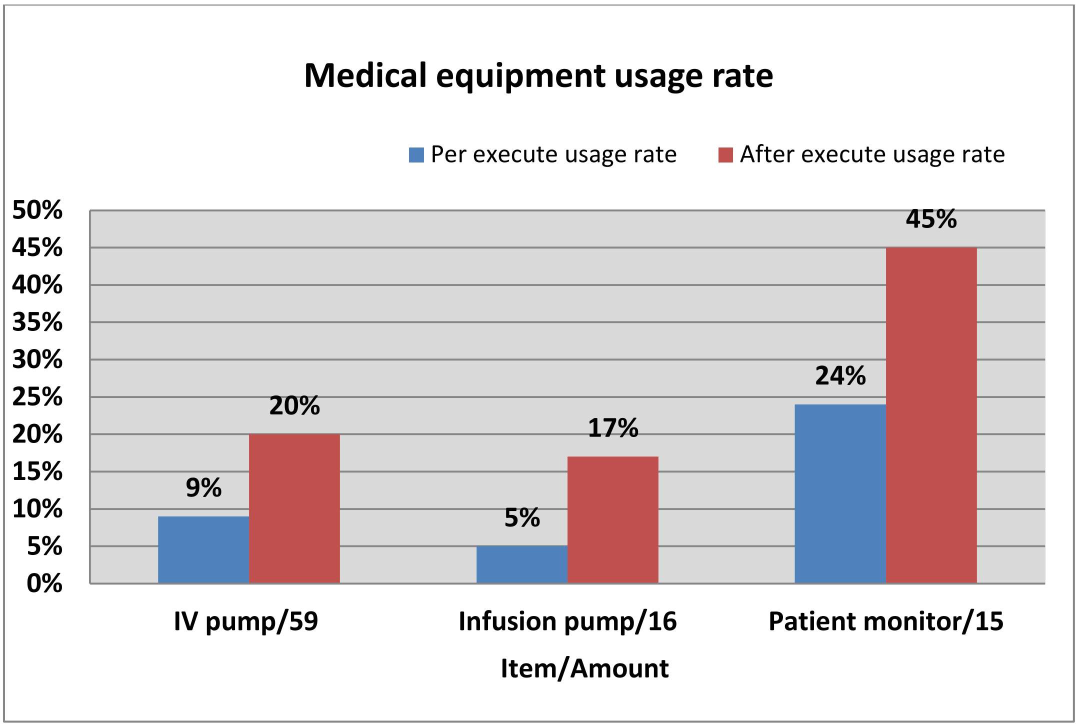


Figure 2-33: The usage rate change of using the system (Chien *et al.* 2006)

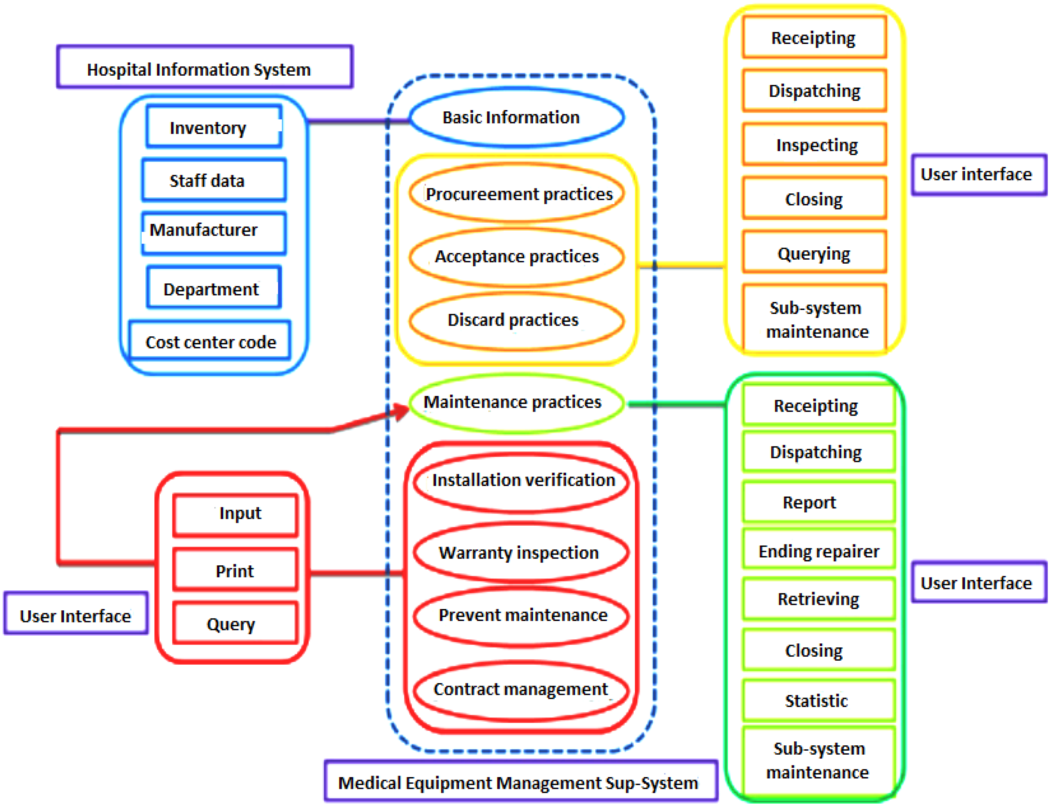


Figure 2-34: The relationship between the modules of the medical equipment management system (Chien *et al.* 2010)

2.4 Summary

This section has outlined the current maintenance strategies to demonstrate the main factors that impact on maintenance practices and medical equipment reliability on patient outcomes by classifing the type of maintenance management used in CME. Focus is on RCM and Failure Mode and Effects analysis and evaluating the economic cycle life of CME due to maintenance issues and medical equipment errors.

2.5 Maintenance Issues in Hospitals

Generally there are a number of maintenance issues concerning medical equipment in hospitals. These issues are world-wide and are generally relevant to Research Question 1, which considers the relationship between reliability of medical equipment and maintenance strategy choices.

2.5.1 Medical Equipment Error

Recently, there has been an increased focus on the causes and prevention of medical errors, particularly in surgery. "Medical Errors" can cause catastrophic injuries to patients.. Although maintenance errors are inherent in human nature, many mistakes can be attributed to the size and vulnerability of health care systems and resulting complexity in CME maintenance requirements (Cooper and Makary 2012). The unintended consequence of these errors is the potential harm to the patient. Wang *et al.*, (2013) has indicated that is there are no data specific to "equipment management" that is obtainable in hospitals.. The data on sentinel events caused by maintenance omissions covers a wide range of failures and inefficiencies. This study and other research has found that it is difficult to collect data that can show thatharm to patients is caused as a result of the medical equipment failure and/or maintenance errors.

- Cooper and Makary (2012) discovered that the Institute of Medicine (IOM) published one of the first and most important documents raising awareness of injuries due to medical errors *To Err is Human: Building a Safer Health System* in 1999. This report concluded that in American hospitals between 44,000 and 98,000 deaths and one million injuries occur each year due to medical errors, amounting to more deaths in hospitals from medical errors than from motor vehicle accidents, breast cancer, and AIDS combined.

- Kalra (2011*), Quality of Australian Health Care Study (QAHCS)*, reported more than half of the adverse events recorded in their study were associated with surgical operations. The *Harvard Medical Practice (HMP) Study II* identified particular areas of health care that they consider high-risk areas for patient safety. Their analysis identifies operating rooms (anaesthetic/ surgical), in-patient rooms, emergency rooms, and intensive-care units.
- Kalra *(2011)*, indicated that Emergency Departments (EDs) and Intensive Care Units (ICUs), have a higher rate of mistakes compared to operating theatres. In addition, there is a high dependence on clinical laboratories making the focus of studies on laboratory testing and reporting of the utmost priority, because of their influence on clinical decision-making. Table 2-15 summarises medical errors in EDs, ICUs and laboratories.
- Khoury *et al.* (1996) undertook a study of the error-rates in Australian chemical pathology laboratories. They reported error-rates as high as 39% for transcriptions and 26% in analytical results in five states of Australia – which has the potential to compromise patient identification data (*Kalra 2011).*
- Kalra (2011) found that the introduction and implementation of a zero tolerance policy to address labelling errors in 1999 led to a decrease in errors from 100% (43/43) in 1998 to 64% (16/25) in 2002.
- In 2010 6% of patients in the NSW health system who had a medical test in 2008-2009 reported experiencing a delay in receiving results and 5% reported being given the wrong medication by a healthcare professional (BOHI, December 2010, p.7).
- In 2008-09 10% of patients in NSW were of the opinion that a medical mistake was made in their care, although the extent of harm was not assessed. In this area NSW has a comparatively low ranking (BOHI, December 2010, p.7).

Table 2-15: Historical Overview of Medical Equipment Errors revealed in Clinical Diagnostic Laboratories, Emergency Departments and Intensive Care Units

	Author/'s /Year	Years	% of Errors Reported and found
Clinical diagnostic laboratories	McSwiney and Woodrow	1969	2% to 3% reported at a clinical laboratory
	Chambers *et al.*,	1986	0.3% detected a blunder in a large biochemistry laboratory
	Boone	1990	1 Error/1,000 Laboratory events
	Kazmierczak and Catrou	1993	9.36% of 438 results of replicate creatinine analysis
	Khoury *et al.*,	1996	39% for transcription and 26% of analytical results **in Australian chemical pathology laboratories**
	Bonini *et al*-,	2002	0.60% and 0.039% due to human errors
Emergency Department	Gratton *et al.*,	1990	3% errors made in an emergency medicine residency program involved the interpretation of radiographs
	Chin *et al.*,	1999	3% errors of all adverse events occur in the emergency department indicated in the HMP Study II
	Rothrock *et al.*,	1995	33% of the women with appendicitis in a initially misdiagnosed
Intensive Care Units	Abramson *et al.*,	1980	145 patients adverse that the mortality of patients with an incident report filed during their Intensive Care Units (ICU) admission was 41%, whereas the rate for all ICU patients was 21%.
	Giraud *et al.*,	1993	63% of incidents [Abramson *et al.*, (1980), reported that 63% of incidents were a duo to human error].
	Stambouly *et al.*,	1996	
	Wright *et al.*,	1991	80% of critical events indicated due to human error
	Giraud *et al.*,	1993	31% of the total of 400 admissions
	Donchin *et al.*,	1995	at least 20% of the errors were potentially life threatening
	Bracco *et al.*	2001	31% of errors indicated due to human error
	Donchin *et al.*,	2003	1.7 Errors/Patient/Day were caused by human errors in ICUs

Mkalaf, Khelood A, by Source; Karla, Jay. Patient Safety: Medical Errors and Patient Safety: Strategies to reduce and disclose medical errors and improve patient safety. Berlin, DEU: Walter de Grunter, 2011, pp 45.

- Landrigan *et al.*, (2010) indicated in their study that 10 hospitals in North Carolina reported patient harm from 2002 to 2007. This was shown as 25.1% of all inpatients sustaining a form of preventable harm due to a medical mistake (Cooper and Makary, 2012).

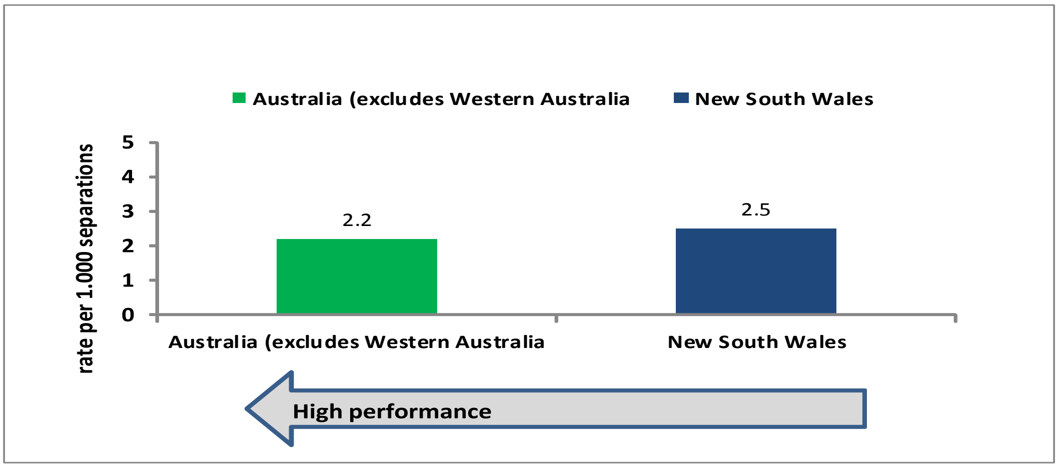


Figure 2-35: Falls resulting in patient injury in a NSW healthcare setting 2007-08[19]

2.5.2 Biomedical Engineering Department Requirements

a. Kanpur (1989) and Tchokodjeu (2011) found poor maintenance conditions due to absence of a management system for maintenance, inadequate rules on labour requirements, untrained operators, lack of spare parts, erratic power supply and adverse environmental conditions. Kanpur (1989) estimated that biomedical equipment costing US $ 6-8 billion was affected.

- The World Health Organisation (2008) indicated around 50-75% of medical equipment is out of service. In addition to 95% of medical equipment is imported into these countries.
- Judd *et al*., (2004) and Molalla and Froze (2008) indicated that in some African Nations up to 80% of medical equipment in use is donated.
- Lynch (2013) found that in the developing world, countries such as Cuba, Rwanda, Honduras and Guatemala have received donations of medical equipment from first world countries. However there are problems with these well-meaning donations:

[19] 86 - BOHI December 2010, *Healthcare in Focus: How NSW compares internationally'*, Annual performance report: December 2010, Bureau of Health Information, Sydney, NSW, Australia.

1. There is a shortage of well-trained Biomedical Engineering Technicians (BMETs).
2. There is a shortage of spare parts for the donated medical equipment.
3. New equipment is invariably delivered without operating manuals.
4. The *BMETs* in these countries are not versed in PM procedures.
5. Medical equipment such as: electrocardiograph simulators, pressure meters, safety analysers, ultrasound phantoms, defibrillator testers and electrosurgical analysers are often unavailable in medical practices.
6. A lack of repair supplies (heat-shrink, electrical tape, solder-less connectors, lubricant sprays, duct tape, Teflon tape, AC plugs, screws, nuts, bolts, chemicals, glues, adhesives etc.) is the norm. Outlets for these supplies are limited.
7. The availability of hand-tools (soldering-guns, oscilloscopes, multimeters, temperature-meters) is limited. Screwdrivers and pliers are often the only repair tools available to work on medical equipment.
8. Sophisticated support mechanisms and networks are limited for BMETs in developing nations.
9. Mutia *et al.,* (2012) indicated that it is good policy for companies to ensure they have original spare-parts in stock for repairs to their equipment, even though the actual repair work is outsourced. Theoretically, repairs can be done on equipment until spare-parts are no longer available.
10. Mutia *et al.*, (2012) found that obsolete medical equipment has been discovered in medical practices, which has not been utilised from the time of its installation. For example the East African Standard reported in 2003 that Kenyatta National Hospital had been burdened with three X-ray machines, a sterile processing unit (SPU), an embalming machine, laundry equipment and dental facilities, among numerous others non-functional equipment.

Table 2-16 shows condition of donated equipment upon arrival and Table 2-17 shows the lack of biomedical engineering staff in some developing countries as revealed by (Mullally and Frize 2008).

Table 2-16: Condition of donated equipment upon arrival (% of response) (Mullally and Frize, 2008)

Resource	None %	<25%	25-50%	50-75%	>75%	All
New(n=65)	41.5	18.5	3.1	4.6	10.8	2.5
Used(n=61)	44.3	16.4	14.8	8.2	11.5	4.9
Refurbished (n=60)	60.0	18.3	10.0	5.0	6.7	0
Obsolete (n=58)	65.5	17.2	5.2	8.6	3.4	0

Respondents reported that the majority of their equipment had been procured through a formal acquisition process (an average of 77%), while donations accounted for (on average) 18.6% of the base and leases, rentals and borrowings another 10%. Donated equipment often arrives without resources. The following resources never accompanied donations (n=63): spare parts (58.7%); user manuals (29.7%); maintenance manuals (42.2%); user training (50.2%); and maintenance training (61.3%). Often, there is little or no consultation with recipient hospitals when equipment is donated (Mullally and Frize2008).

Table 2-17: Total respondents who had difficulty finding qualified staff locally (by % of regional responses), (Mullally and Frize, 2008)

Staff	Africa	Latin America	Asia	Middle East and Eastern Europe
Engineers	79.35%	79.4%	56.5%	83.35%
Technicians	705%	77.6%	60%	60%

Table 2-17 shows that in most developing countries clinical engineers and technicians are in short supply. Sixty percent of departments reported having inadequate staff for their workload. Previous studies by both Glouhova *et al.* (2000) and Cao (2003) found similar results (Mullally and Frize, 2008).

2.5.3 Knowledge and Skills required

Makin and Keane (2010) found six domains of knowledge were required to accomplish 99% of the repairs; installation or user training (25%), plumbing (19%), mechanical (18%), electrical (18%), power supply (14%) and motors (5%).

Applying this knowledge has assisted in returning to service 66% of the out-of-service equipment included in their study (Malkin and Keane, 2010).

In resource-poor settings more than 50% of medical equipment is out-of-service (WHO Guidelines for Donated Medical Equipment) due to a lack of Biomedical Engineering Technicians (BMETs), a lack of other highly trained technicians and a lack of spare parts. Malkin and Keane (2010) found during their studies from 60 resource-poor hospitals located in 11 nations in Africa, Europe, Asia, and Central America that there were 2,849 equipment repair requests (of which 2,529 were for out-of-service medical equipment). Moreover, the repair of medical equipment was attempted by using locally available spare parts. Generally, 89% of engineering requests in resource-poor hospitals are for medical equipment (Malkin and Keane, 2010).

Kachieng'a (2001) has referred to previous studies, like Kachieng'a (1999), which indicated that in South Africa, medical equipment maintenance budgets represent less than 3% of the capital stock whereas 10% is considered optimal by the World Bank (1995). For this reason Medical equipment failed prematurely because of inadequate, infrastructural support and insufficient maintenance budgets. Furthermore, the public health sector technologies suffered from different issues such as poorly managed, planned and under-utilized or non-functional (Kachieng'a, 2001).

2.5.4 Increasing Health Care Expenditure

Turchetti *et al*. (2010) reported that in the 2009 Centre for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group report:

- The biomedical industry has been the greatest rising sector of the United States economy and new medical technologies have been one of the drivers of the rise in health care costs.
- Since 1970, health care spending has grown at an average annual rate of 9.8%, about 2.5% points faster than the economy, as measured by the nominal gross domestic product.
- Annual spending on health care increased from US$75 billion in 1970 to US$2. 2 trillion in 2007, and it is estimated to reach US$4.3 trillion in 2018.

- As a share of the economy, health care costs have more than doubled over the past 35 years, rising from 7.2% of gross domestic product in 1970 to 16.2% of gross domestic product in 2007, and it is projected to be 20.3% of gross domestic product in 2018.
- Health care spending per capita increased from US$356 in 1970 to US$7,421 in 2007 and is projected to rise to US$13,100 in 2018.

2.5.5 Capital Investment

Capital investment in new medical technologies is very costly for many reasons.. Firstly, project costs associated with developing and adopting new technologies for a new 250 bed hospital are immense (Kumar and Srinivas 2014). Kumar and Srinivas (2014) indicated that medical equipment is responsible for approximately one third, to one half of the total cost of a particular project. (Kumar and Srinivas 2014). These new pieces of medical equipment and services are developed by complex processes of testing and approval by regulatory bodies in order to include added functions and improvements in quality, safety, and clinical performance.

Secondly, there is a positive correlation between the adoption of new medical technologies and increased overall health care costs as a result of the impact of the level of demand for healthcare services. New medical technology such as minimally invasive surgeries, imaging and transplantations which are commonly used are improving clinical outcomes, reducing mortality and morbidity rates with a corresponding increase in life expectancy. As patients live longer they suffer from more age-related illnesses such as cancers, diabetes and cardiac and respiratory diseases which are expensive to treat (Orszag and Ellis, 2007).

Finally, there are many other factors that drive the cost of healthcare delivery. Ginsburg (2008) found that medical technology is a more powerful driver of costs than administrative costs or the increases in staff costs. For example, about 18% of the rise in the cost of health care services is as a result of the impact of hospital expenditure or physicians' salaries. This can lead to the economic unsustainability of the health care services system, then to the rationing of health care and cuts in expenditure and investment as indicated in Geisler and Heller (1989) in (Turchetti *et al.*, 2010). Table 2-18 shows the type drivers of cost identified by Ginsburg (2008).

Table 2-18: Cost drivers from Ginsburg (2008)
(Turchetti *et al.*, 2010)

Studies estimating contributions of Selected Drivers			
Drivers of Cost	**Smith *et al.* (25)**	**Cutler (26)**	**New house (27)**
Aging of the population	2%	2%	2%[1]
Changes in third party payments	10	13	10[2]
Personnel income growth	11-18	5	<23
Prices in health care service	11-22	19	*
Administrative costs	3-10	13	*
Preventitive medicine and supplier –induced demand	0	*	0
Technology-related changes in medical practice	36-62	49	>65
Note: amount represents the estimated percentage share of long-term growth that each factor accounts for. [1]Represents data for 1950-1987, [2]Represents data for 1960-1980, * Not estimated. Source: congressional Budget Office, 2008 based on Smith *et al.*, Cutler and Newhouse.			

This may not have much direct relevance to this work but it is important to understand that these factors also have an influence on equipment reliability and maintenance requirements.

2.5.6 Ownership Costs

Cost of ownership is another maintenance issue. The cost of ownership includes all costs related with the use of a medical asset over the whole of its useful life, such as: maintenance costs, software and hardware upgrade costs, purchase price, installation and testing, cost of site works, labour and training costs, supply spare parts and consumption expenditures such as energy. Decision makers can decide whether to maintain an existing strategy or replace it with a new one by analysing the cost factors. The cost of ownership is very important especially when maintenance is outsourced, in assisting future planning. Also, when capital investment is being proposed, it is necessary to consider the on-going costs for medical equipment for example consumables (whether single- or multiple-use) and reprocessing costs for multiple-use items (Brown *et al.* 2001).

Wang *et al.,* (2013) estimated error-incidents caused by medical equipment maintenance omissions by using a number of databases acquired from The Joint Commission (TJC). The estimates ranged from 0.14 to 0.74 in *2011*, which translates into .00011 to .0006 per million equipment uses. These extremely low values were confirmed by a survey conducted by *AAMI*, in which 1,526 participants reported no-known patient incidents traceable to maintenance practices. (Wang, Rui and Balar 2013) reported that:

1. An analysis of the TJC Sentinel (unexpected) Event data (Figure 2-36) showed that the classification of 2011 Sentinel Events reviewed by the TJC as a percentage of the 1,242 events reported in 2011. Medical equipment-related events totalled 39 (3.1%), and represented the 10th highest category. These values are consistent with previous years. 176 events related to medical equipment in the period from 2004-2011, which represents 2.9% of the grand total of 6,093 events - the 11th highest category.

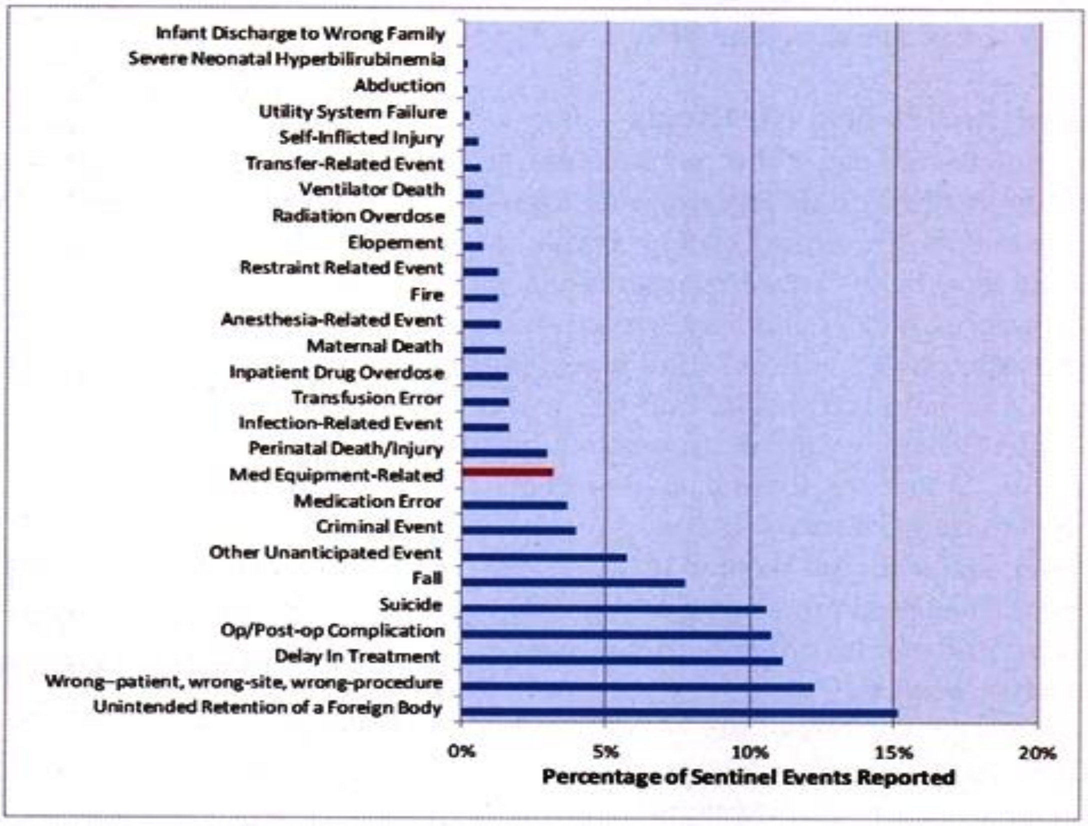


Figure 2-36: Percentage of sentinel events reported to the TJC in 2011[20]

---

[20] Each category is a percentage of the total number of events reported in 2011 (1, 241).

2. Figure 2-37 shows the root cause of medical equipment-related events, as determined by the TJC for the medical profession from 2004-2011. 620 causes were identified.
3. Wang *et al.*, (2013) has indicated there are no data specific to "equipment management" that can be obtained by the approximation of sentinel events caused by maintenance omissions known as "physical environment" which covers a wide range of failures and inefficiencies.
4. The estimation method (percentage of root causes of sentinel events) caused by medical equipment maintenance omissions was due to equipment management and medical equipment failure. The final assessment in their study was that from 2004 to 2011 18% (111 / 620 causes) of medical equipment was the focus of related events due to equipment failure. Table 2-19 shows the event data estimates of patient incidents, caused by maintenance omissions.

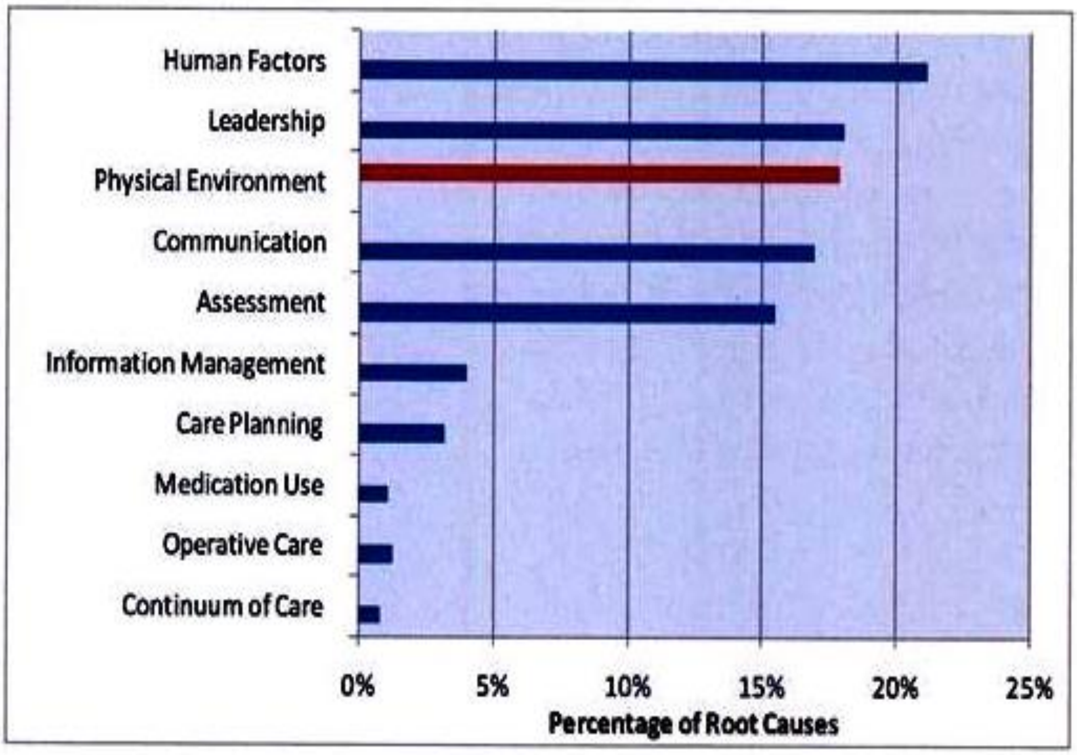


Figure 2-37: Root causes of sentinel events, related to medical equipment 2004-2011

Figure 2-37 shows the percentage of the total number of cases identified (620) for 176 events. Each event is assigned to a group of possible multiple causes, because individual causes seldom result in negative outcomes in isolation.

In the Australian health care industry, medical technology is a valuable asset that is strategically significant for the provision of healthcare services (Brown *et al.,* 2001). It represents a major asset in the healthcare sector and its use increasingly determines the efficient provision of health care. Medical technology has a significant role in all health care specialisation and requirements. Several aspects of the health care value chain depend on technology. Medical care is very human resource costly. Health care organisations must carry expensive service costs in the event of any technical error (Brown *et al.,* 2001). Biomedical engineers are very important personnel in health care organisations because they are involved in the technology and health and management issues across a wide range of technology used in health care organisations. For this reason many biomedical engineers have become involved in the management planning process (Brown *et al.,* 2001) but it would seem that in general there is great deal of potential to improve outcomes by greater encouragement of this trend across health care industry and lend further information to assist in answering research question 2.

Table 2-19: TJC sentinel event data and estimates of patient incidents caused by maintenance omission

DATA	2011	2004-2011
Total # sentinel events	1242	6093
# of events related to medical equipment	39	176
# of multiple causes related to medical equipment	N/A	620
# of multiple causes of 176 incidents due to physical environment	N/A	111
ASSUMPTIONS AND CALCULATIONS	ESTIMATION METHOD A	ESTIMATION METHOD B
Assumed % physical environment issues caused by equipment failure	100%	100%
Estimated # events caused by equipment failure	7.0	24.6
Assumed % equipment failure under CE control (maintenance omission)	2%	3%
# events could have been caused by maintenance omission	0.14	0.74
# In-patient days in community hospitals in 2010	189,595,000	189,595,000
# Out- patient visits to community hospitals in 2010	651,424,000	651,424,000
Estimated equipment uses in 2011	1,220,203,000	1,220,203,000
# Sentinel events per million equipment uses	0.00011	0.00060

From previous studies, (Brown *et al.*, 2001) have pointed out many maintenance management issues in the Australian healthcare sector. One of these issues is the high cost of replacement of medical equipment. For example, the estimated current replacement value of medical equipment in all Victorian public hospitals to be $740,260,000 (Brown *et al.*, 2001). Figure 2-38 and Figure 2-39 show the estimates and extrapolate this to other states on the basis of population.

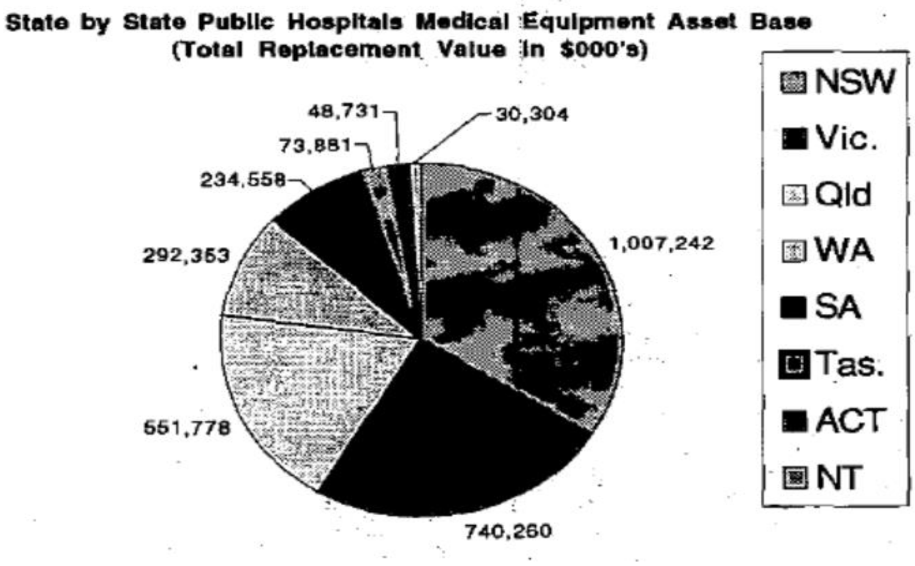


Figure 2-38: Replacement value of medical equipment by state (Australian Demographic Statistics 3101) by (Brown, *et al.*, 2001)

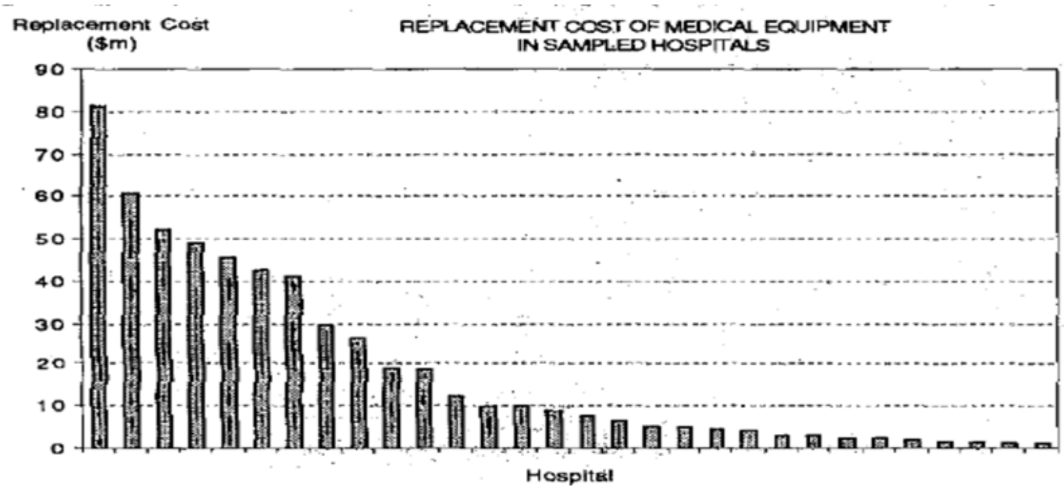


Figure 2-39: Replacement value of medical equipment in Victorian hospitals (Brown *et al.*, 2001)

These figures show the distribution of medical equipment across the 30 Victorian hospitals. The seven largest hospitals each have in excess of $40M worth of equipment. Also shown is the distribution of medical equipment by replacement value in the sample of Victorian public hospitals. Not shown here is equipment worth less than $50K which is estimated to have an aggregate replacement value of more than 50% of the total replacement cost of medical equipment in these hospitals (Brown *et al.*, 2001).

Table 2-20: Replacement value of medical equipment in sampled Victorian hospitals, (Brown *et al.*, 2001)

Medical equipment profile by Replacement Value category for Sampled Hospitals				
Repl. Val category	Replacement Value		No of Items	
	($000)	(%)	(n)	(%)
>$500k	169,135	45%	135	7%
$200-500k	78,204	21%	283	14%
$100-200k	56,470	15%	424	21%
$50-100k	72,732	19%	1,158	58%
Total ≥$50k	376,541	100%	2,000	100%

According to NSW Bureau Heath Information (2011), expenditure on healthcare (public and private) was AU$41 billion. Hospitals are the most resource intensive component of the healthcare system and consumed AU$15 billion (40% of the healthcare budget). Public hospitals spent AU$12.6 billion of the total medical budget.

There were approximately 765,000 overnight admissions (11% of the population), to public and private hospitals. About 85,000 patients (1% of the population) were re-admissions (at least three admissions). This group accounted for approximately 43% of the total bed days in NSW hospitals for the year.

These statistics show that the hospital equipment has to be operational (or at least on standby) for nearly half the admissions (overnight stays) in NSW hospitals. Add to this the fact that this same medical equipment has to be available for the other half of the population that fall into the category of day-admissions. These statistics show how important it is for hospital administrators to select the best machinery available to undertake particular tasks. The maintenance procedures have to be the very best and the training for operators must be thorough to ensure optimum outcomes for medical providers.

Schoen *et al.*, (2009) has indicated that the error margin of the test sample in the 'IHP 2010' was approximately ± 2% for Australia, Canada, Sweden and the United States. It is estimated to be ± 3% for other countries where the confidence level in the medical systems is at 95%.

Health in Focus: Technical Supplement, (December 2010, P9). (*www.bhi.nsw.gov.au*): reported problematic issues with medical equipment in hospitals from a survey of 11 countries compared with NSW hospitals. Table 2-21**,** a report of medical mistake occurrences in 2010, is a concise survey, having a 95% participation rate.

Table 2-21: Reported occurrence of medical mistakes survey 2010[21]

Country	In the past two years;			
	Was there a time you thought a medical mistake was made in your treatment or care?	Have you experienced delays in being notified about abnormal test results?	Have you been given incorrect results for a diagnostic or lab test?	Have you ever been given the wrong medication or wrong dose by a doctor, nurse, hospital or pharmacist?
Canada	8 (6, 9)	10 (8, 11)	4 (3, 5)	6 (5, 7)
France	6 (4, 8)	3 (2, 4)	3 (2, 4)	9 (6, 11)
Germany	6 (4, 8)	5 (3, 7)	2 (1, 3)	2 (1, 3)
Netherlands	5 (3, 6)	4 (2, 5)	3 (2, 4)	4 (3, 6)
New Zealand	6 (4, 7)	6 (4, 9)	2 (1, 4)	5 (3, 6)
Norway	11 (8, 13)	9 (6, 12)	3 (2, 5)	8 (6, 10)
NSW	10 (8, 11)	6 (4, 7)	3 (2, 4)	5 (4, 6)
Rest of Australia	8 (6, 9)	5 (4, 7)	2 (1, 3)	4 (3, 6)
Sweden	6 (5, 7)	8 (6, 10)	2 (1, 3)	5 (3, 6)
Switzerland	8 (6, 10)	2 (1, 4)	3 (2, 5)	5 (3, 7)
United Kingdom	3 (2, 4)	6 (4, 8)	3 (1, 4)	2 (1, 3)
United States	10 (8, 11)	9 (7, 10)	5 (4, 6)	6 (5, 8)

Table 2-21 shows that medical equipment malfunction in NSW hospitals is 25% higher than those in the other Australian states. Programs need to be implemented in NSW hospitals, to decrease equipment issues that are creating unfavourable medical performance so that the quality of patient care improves.

The most important maintenance costs in NSW public hospitals are reported in *Bureau of Health Information*: *Financial and Corporate Report* (2012/2013), p49,

[21] *HEALTHCARE IN FOCUS: Technical Supplement, (December 2010), p.9, www.bhi.nsw.gov.au.*

showing that plant and equipment costs increased from $275,000 to $354,000. See Table 2-22.

Table 2-22 Financial position for plant and equipment 30 June 2013[22]

Parent	13	Consolidation	
Actual 2013 ($000)	27	Actual 2013 ($000)	27
Budget (unaudited) 2013 ($000)	(75)	Budget (unaudited) ($000)	(75)
Actual 30 June 2012 ($000)	28	Actual 30 June 2012, ($000)	28

Servicing and repair costs can include maintenance contracts, new/replacement equipment under $10,000, repairs (maintenance/non-contract), maintenance expenses for contract-labour and miscellaneous expenses. Table 2-22 shows maintenance servicing costs for plant and equipment (Information 2012/2013).

Table 2-23: Maintenance costs for plant and equipment

		Parent		Consolidation	
Plant and equipment	Notes	2013 $000	30 June 2013 $000	2013 $000	30 June 2012 $000
Maintenance contracts		**0**	**0**	**0**	**0**
New / replacement equipment under $10,000		**114**	**11**	**114**	**11**
Repairs maintenance / non-contract		**39**	**0**	**39**	**0**
Maintenance expense – contract labour and other	**5**	**153**	**11**	**153**	**11**

Establishing sound audit and risk management practices is a major objective for boards in the NSW public health system. (Information 2012/2013). This section has clear implications for research question 2, pointing to major limitations in choice of maintenance strategies and possible non-optimal spending on new and replacement medical equipment.

[22] 85 - Information, B. o. H. 2012/2013, *Health In Focus: Financial and Corporate Report;Timely, accurate and comparable information about the performance of the NSW public health system'*, Annual performance report, NSW Ministry of Health Corporate Governance and Accountability Compendium, Sydney, NSW, Australis.

2.5.7 Implications for research questions from this section:

From this section, the reader should note that there are many sources that can lead to poor medical outcomes. However, for the purposes of this research the main points that this section identified that are continually coming to the fore are those that relate to choice of maintenance strategies and lack of knowledge amongst those who procure, use and maintain this equipment. The statistical evidence in this section provides further evidence of this point. For example, it seems that there is evidence to suggest that hospitals are unsure whether to invest in new equipment or continue to maintain existing equipment. It seems clear that replacement costs of medical equipment are enormous and rarely questioned. A better appreciation of the true cost of ownership which is intrinsically part of maintenance strategy choices is also a clear need. All of which will have major influence on the efficient use of and life of equipment and more particularly patient outcomes. In presenting this information it can be seen that it as relevance in the consideration of Research Question (1) influence of maintenance strategy on reliability of CME and (2) Selection of maintenance strategy. These factors and further gaps in literature are discussed in more detail in 2.6 below.

2.6 Gaps in the literature and possible future directions

The studies carried out of developing world hospitals (e.g. South-East Asia, Africa, Western Pacific, Middle East, Eastern Europe and Latin America) tend to focus on reasons for poor performance due to lack of planning, organisation, finances and resources. For these reasons, some of the issues raised are not applicable within the Australian context. In the Australian context the issues surrounding the quality of health-care maintenance often relates to the types of maintenance services and the systems used in managing the processes.

Furthermore, most study reviews focus on two types of maintenance strategies: preventive or corrective. However, neither of these strategies avoid the sudden failure of medical equipment or increase reliability. This is because the focus is on scheduled inspection times. Therefore, Wang *et al.,* (2006) suggest an effective and efficient maintenance management strategy focusing on risks caused by medical equipment failures, rather than increasing demand for maintenance activities. They suggest a mixed maintenance strategy approach. Additionally, most tools and factor-

measurements used to evaluate the performance of medical equipment ignore the impact of equipment Down-Time as being a significant factor to determining medical equipment status; as indicated by Tarawneh and El-Sharo (2009).

One approach might be to include the equipment Down-Time factor in measuring the status of medical equipment in Reliability-Centred Maintenance (RCM); which applies complex mathematical models to organisations (Endrenyi *et al.,* 2001) for many reasons, such as: component reliability for example might also depend on installation factors or changes to the use of profiles in equipment, or lack of reliable and accurate data collected from organisations or poor communication (Wu *et al.,* 2010). Thus, RCM remains just a theory and is difficult to apply in practice as indicated by (Endrenyi *et al.,* 2001). Medhat *et al.,* (2008) have applied RCM in a hospital in Egypt in order to assess the quality of the performance of medical equipment when using Total Productive Maintenance (TPM). They suggest applying this measurement in all departments throughout hospitals, in order to improve the quality performance of CME and healthcare services.

This is a first attempt to assess the current maintenance strategy of CME used in New South Wales Public Hospitals across Australia; to investigate whether hospitals are using RCM to assess the availability of critical medical equipment when providing their health care services. This study has focused on the risk of sudden failure of CME and its impact on the outcomes of hospitalisations. It has proposed to use software maintenance management as a significant step to programming maintenance activities, and for predicting early occurrences of sudden failure in medical equipment. This present study is as attempt to adopt a maintenance strategy which could assist hospitals to move from dependence on contract maintenance servicing to use of in-house maintenance services.

In conclusion, according to previous studies, and with the background of the practical application of critical medical equipment maintenance strategies in Australian Public Hospitals; the results of this study show that a new maintenance strategy is necessary for hospitals in general, because of the inefficiencies in preventing sudden failures. The large dependence on outsourced maintenance strategies for solving maintenance problems is very costly, and those costs can, and must be reduced.

CHAPTER 3: RESEARCH METHODOLOGY

3.0 Introduction

This chapter focuses on the research design and methodology used. It includes research aims, primary and secondary research questions and the theoretical and conceptual framework designed to investigate the relationship between the variables, choice of methodology, data collection methods, data analysis, ethical conduct and limitations.

3.1 Research Aims

The aim of this study is to investigate the relationship between the reliability of Critical Medical Equipment (CME) in a group of Public Hospitals in New South Wales and Current Maintenance Strategies (CMS) and the effect upon patient health care. This research also identifies the types of CME and the current maintenance strategies used for both in-house and outsourced maintenance services in the context of Failure Rate (FR), the Mean Time To Repair (MTTR) and at the same time, the impact on patient health care in terms of the probability of harm to patients in the event of unpredictable CME failure. This research aims to determine current strategies and then to analyse them in relation to best practice and to examine maintenance strategies used for CME (both in-house and outsource) to achieve improved service to patients, to reduce downtime and maintenance costs and offer an alternate model to improve the overall availability of equipment to patients.

3.2 Research Question

i) Primary research question

Q1. What are the opinions of users and maintainers in relation to the influence of current maintenance management strategies on the reliability of CME in hospitals?

ii) Secondary research questions

Q1.1: Is there an apparent correlation between the type of maintenance strategy used and the availability of CME?

Q1.2 Is there an apparent correlation between the type of maintenance strategy used and the failure rates of CME?

Q1.3 What are user opinions of the magnitude of downtime of failed CME and how do current maintenance management strategies affect this?

Q2. What are the likely major factors that influence the selection of maintenance strategies for CME in hospitals?

Q3. What kind of maintenance management strategies could potentially be used to increase equipment availability and decrease costs while achieving the desired level of patient outcomes?

3.3 Theoretical and Conceptual Framework

Before determining the research methodology and model, it was necessary to describe the dependent and independent variables of both in-house and outsourced maintenance management strategies of CME to be investigated in this study. A conceptual framework was devised to clarify the factors that impinge upon the research aims and questions (Mkalaf and Gibson 2012). This is illustrated in Figure 3-1 below.

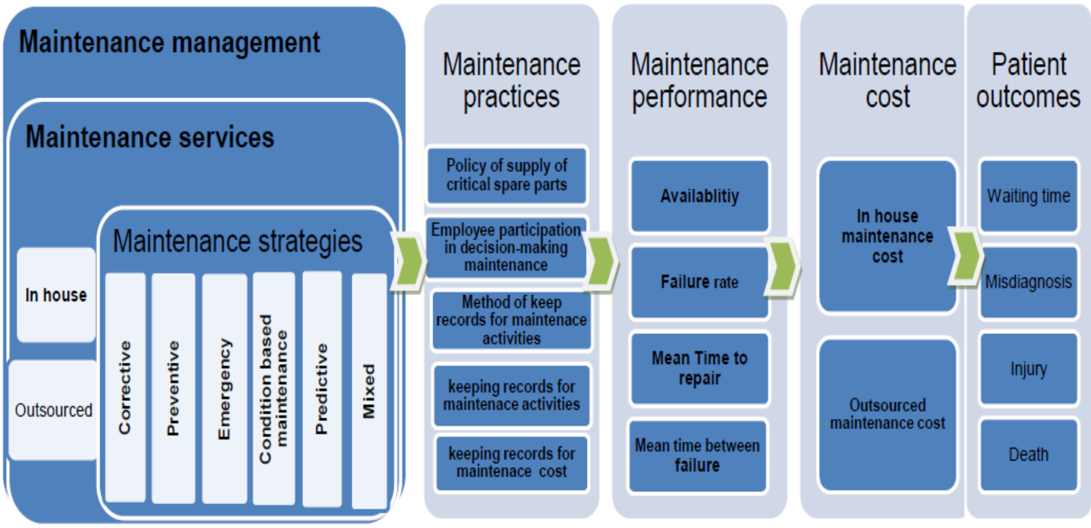


Figure 3-1: Conceptual framework of the variables affecting patient outcomes (Mkalaf and Gibson 2012)

Referring to Figure 3-1: the conceptual framework of the dependent and independent variables that influence patient outcomes are featured below:

1. Maintenance services variables include in-house and outsourced maintenance services. Both these services cover different maintenance management strategies: Corrective Maintenance (CM), Preventive Maintenance (PM), Emergency

Maintenance[23] (EM), Condition Based Maintenance (CBM), Predictive Maintenance, and Mixed maintenance strategy.

2. Maintenance practice variables include staff participation in decision-making, availability of critical spare parts, use of maintenance management software, methods for keeping records of maintenance activities and maintenance costs.
3. Maintenance performance and/or critical medical equipment reliability variables cover failure mode and reasons for failure, availability, Mean Time to Repair and Mean Time Between Failures.
4. Maintenance cost variables refer to both in-house and outsourced maintenance services.
5. Patient outcome variables include waiting time, the quality of medical service provided, death, injury and misdiagnosis. Figure 3-2 below demonstrates the relationship between variables.

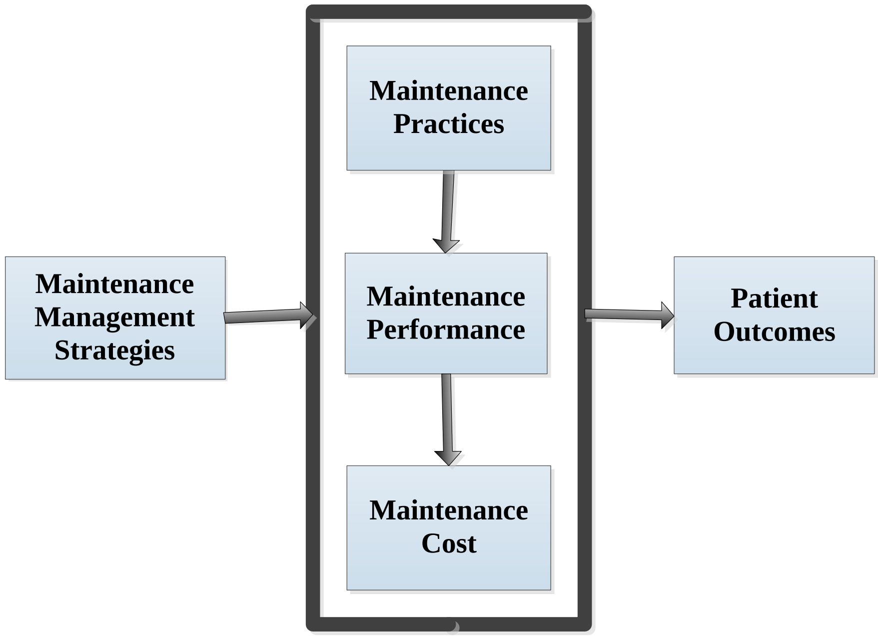


Figure 3-2: Theoretical framework showing the relationship of the concepts described in Figure 3-1

[23] **Corrective and Emergency maintenance** that must be carried out immediately, or with the shortest possible delay, after condition monitoring detects a danger of imminent failure (emergency), or after a failure is corrected (corrective) (Endrenyi *et al.* 2011; Kostic 2003)

The variables in this study that can lead to improved patient outcomes are maintenance management strategy, maintenance services, maintenance practice, medical equipment reliability and maintenance costs. Statistical analysis is also used to find the correlation among the dependent and independent variables. The research questions and the objectives of this study have been designed from conceptual and theoretical frameworks, and the variables that affect patient outcomes, which also influence the hypotheses.

3.4 Scope of Study, Sampling and Pilot Study

The aim of this section is to identify the scope of the study; the sampling of critical medical equipment and an explanation of the pilot study.

3.4.1 Scope of Study

This study examines the maintenance management strategies of critical medical equipment in Public Hospitals located across 17 Local Health Districts and Health Services in NSW, Australia. In total 116 (55%) hospitals of 212 hospitals invited to participate in this study responded. From these 84 hospitals responded to the survey questionnaire, which included: 68 Public Hospitals, 13 Community Health Services plus 3 Medical Centres as shown in Figure 3-3. Reasons for exclusion participation included: the size or type of hospital, a lack of a maintenance management department, and/or non-availability of the CMEs elected for study.

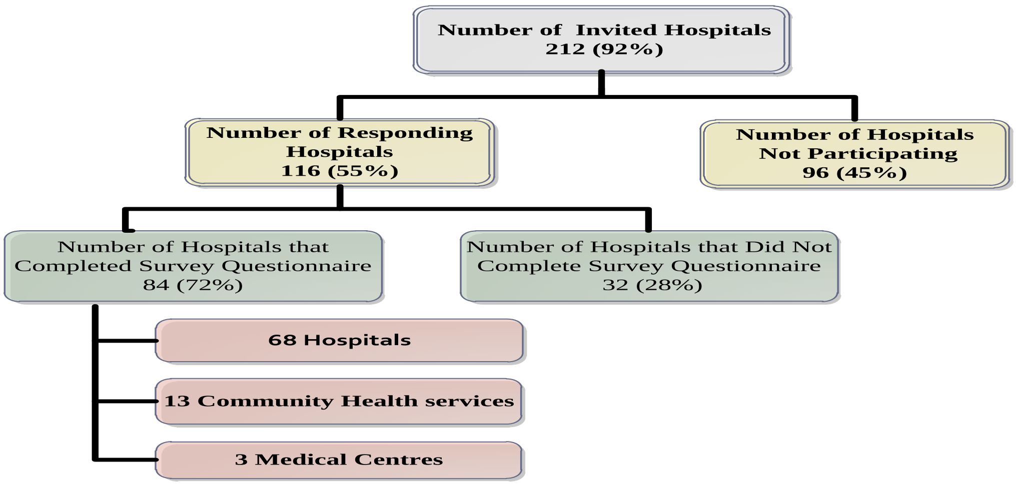


Figure 3-3: Participating hospitals[24]

[24] Where; 212 (92%) is a number of hospitals invited from Total Public Hospital found across NSW, Australia.

Four different hospital departments are targetted: Biomedical Engineering, Surgical Operations, Cardiac Catheterisation and Kidney Dialysis.

3.4.2 Sampling

This study focuses on CME where failure or non-availability poses a high level of risk to patients. The criteria for judging the criticality of equipment includes the risk failure or breakdown poses to patients, the average usage time per patient, average number of patients serviced by these devices per month, the average operational life of CME and the availability of alternatives in case of CME failure.

The scope of this study was limited to examining 14 types of CME used in hospitals, in which data for a total of 5769 devices were collected using a questionnaire. These were Kidney Dialysis (151), Cardiac Catheterisation (16), Anaesthesia (191), Defibrillator (487), Defibrillator Manual (152), Diathermy (246), Respironics – BIPAP and CPAP (247), Ventilator (268), Infusion Pump (3051), ECG (267), Electrosurgical (162), Respironics Nebuliser (287), Oxygen Concentrator (106) and other Critical Medical Equipment (138) devices, as shown in Figure 3-4. From the average total number of CME in use 6% were new, 59% had had one to five years of use, and 35% had had over than five years of use (Mkalaf *et al.* 2013).

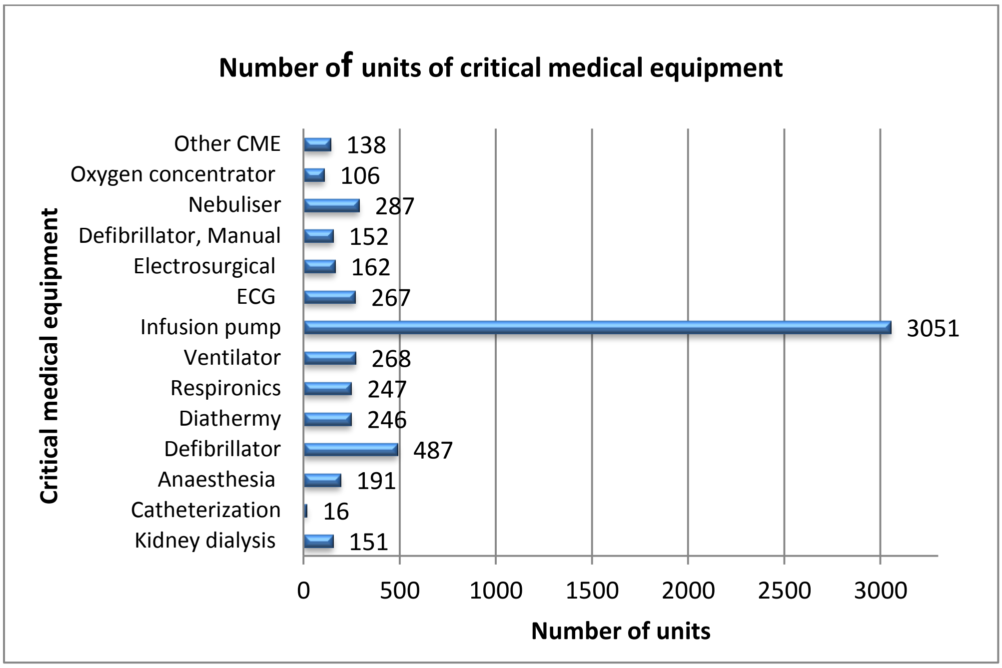


Figure 3-4: The total number of critical medical equipment examined in this study

Although a variety of CME were looked at in this study, only the results of the six most significant are provided as this shows greater statistical variation. The six items of CME used were Kidney Dialysis, Anaesthesia, Defibrillator, Ventilator, Infusion pump and ECG devices. Although other critical items of medical equipment as shown in Table 3-1 are also significant to patient outcomes, it is recommended these could be considered in future research. However they are outside the scope of this study.

Table 3-1: Other critical medical equipment which could be considered in future research

1. Reliance EPS	8. Respironics/Exsuffator	15. ABG Machine
2. BIS Monitor	9. Bladder scanner	16. Autoclave
3. Insufflators	10. Olympus control unit	17. Electronic Tourniquet
4. Respironics-light	11. Vision BIPAP	18. SCDS
5. Trans illuminator	12. Respironics-Humidifier	19. Olympus Flushing
6. PICCO machine	13. INR machine	20. Surgical Laser
7. Monitor	14. Respironics-Continuous positive Airway pressure units	

3.4.3 A Pilot Study

In a pilot study of 3 hospitals, five types of critical medical equipment were examined. These had a high non-availability rate and risk level to patients. Chosen were Kidney Dialysis, Anaesthesia, Defibrillators, Diathermy and Cardiac Catheterisation machines. Preliminary interview and survey questionnaire forms were designed and used to collect data at this stage[25]. In addition researcher observations of maintenance activities were undertaken including emails, telephone calls and meetings with hospital staff and some survey questionnaires were posted. The data and information collected in the pilot study was used to assess current maintenance strategies of critical medical equipment.

3.5 Recruitment and Participants

This section provides a description of the recruitment method and assessing of participants and their profiles.

[25] Chapter 3, Section 3.7.2: Qualitative research: Interview design and questions, p.146, and Appendix B, pp. B1-B18.

3.5.1 Recruitment Method

After ethics approval was granted the names of the NSW public hospitals, District Unit Managers, Managers of Biomedical Engineering and District Nurse Unit Managers (NUM) were retrieved from hospital websites and the Ethical Community and Research Governance Officer in each of Local Health Districts and Health services. After telephone calls, emails and face-to-face meetings, potential departments, facilities and units were given information and consent forms as well as access to the research to answer any questions directly related to the research.

3.5.2 Assessing Participants

Initial enquiries began in July 2011 and official meetings with hospital staff began in September of the same year. After ethics approval was granted meetings were held to discuss the research aims and objectives as well as develop research credibility and rapport. These meetings were important to establish trust and gain access to the names and contact details of possible participants. Invitations were made to the potential participants by mean of email, face to face meetings and by mail. In total (157) research information forms were sent out and all agreed to participate. 101 forms were completed fully and returned, the others were either incomplete or unable to be used as their internal ethics department restricted their participation. Table 3-2 show a total number of the hospitals staff who participate in the survey questionnaire.

The researcher conducted the pilot study and interviews on site. However, during the course of the survey questionnaire access to participants was stopped by one local Health District Hospital's Ethics Committee because the survey questionnaire did not include the version number and date of the amended survey questionnaire generated from the pilot study. This occurred during April 2012. Fortunately, all additional requested information was provided to the ethics committee and the restriction was lifted as the survey questionnaire was updated to feature the required reference numbers, identified that it was version 5 dated 1 May 2012. An unexpected positive outcome from this was that other hospitals became aware of this research and requested to participate.

Table 3-2: Hospital staff participating in the survey questionnaire

Details	Number of Forms	Notes
Total Number of survey questionnaires distributed to hospitals	157	
Total number of survey questionnaires completed and collected	103 (66%)	
Total number of responses where the questionnaire was completed	102 (99%)	74 hospital staff filled in 1 form
		4 hospital staff filled in 2 forms
		4 hospital staff filled in 3 forms
		2 hospital staff filled in 4 forms
Total number of responses where no questions were attempted	1 (1%)	
Total number of survey questionnaires not completed or collected	54 (34%)	

3.5.3 Participant Profile

This study targeted four different hospital departments: Biomedical Engineering, Surgical Operations, Cardiac Catheterisation and Dialysis. The study focused on specific hospital staff in the survey questionnaire including directors of Bioengineering Departments, directors and managers of nursing units, and other users of critical medical equipment including medical and nursing staff. Interviews and meetings were held with district managers of hospitals, District Nurse Unit managers, managers of Biomedical Engineering Departments, Staff Medical Officers (SMOs) and nurses or other users of CME. A breakdown of participants in this study comprised biomedical engineering facilities 78 %, surgical or operations units 9%, kidney dialysis or renal units 5%, cardiac catheterisation or cardiac diagnostics units 2%, Intensive Care Units 2%, Staff Medical Officers (SMO) 3%, and medical centre laboratory facilities 1%, as shown in Figure 3-5.

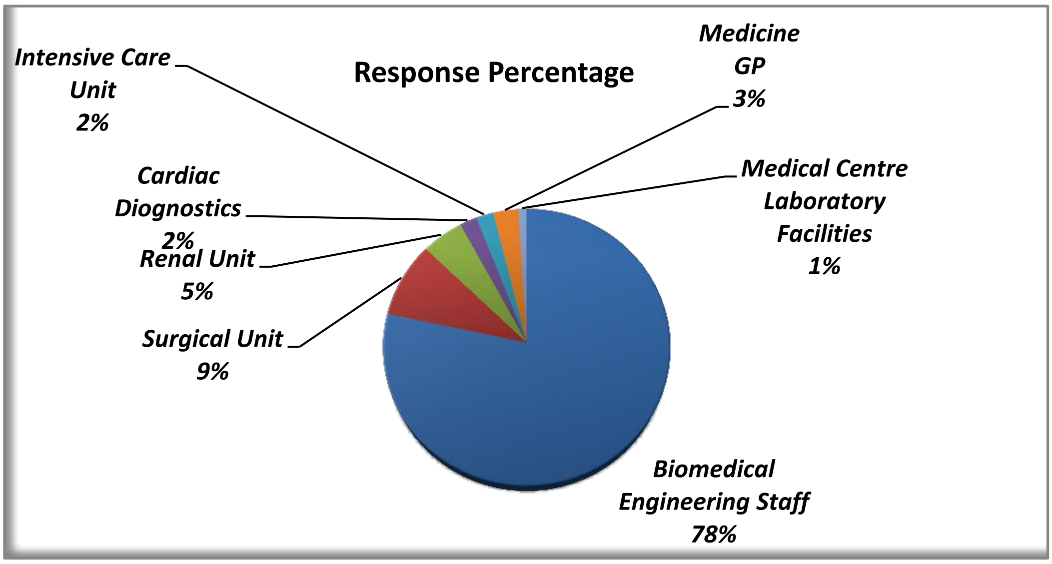


Figure 3-5: Response percentage

3.6 Choice of Methodology

An approach involving quantitative and non-quantitative statistical methods was chosen to analyse the relationship between the reliability of critical medical equipment and current maintenance management strategies and its effect upon patient outcomes. The benefits of quantitative research methods are supported by the qualitative research findings as both methods complement each other and provide a greater depth of knowledge and understanding. This, together with the triangulated data, shows a greater degree of statistical reliability.

3.7 Improving the Structure of the Questionnaire

The information from the pilot study[26] was used to design the final questionnaire which was divided into eight key sections[30] as described in sections A-H below.

Section A: General information about the critical medical equipment: The first section aimed to identify general information about the CME available in hospitals, total number of units, operational life, the average usage time per patient, average number of patients who were serviced by this device, alternative methods used when the CME is out service and how often these alternatives were used. This was assessed in questions 1-10.

[26]Chapter 3; Section 3.5.3: Participant profile, p. 141.

Section B: Maintenance management strategies (MMS): This involved identification of the types of maintenance management strategies for both in-house and outsourced services used in hospitals, a description of particular maintenance issues that affect patient outcomes and staff practices in decision-making regarding maintenance policy. This was assessed in questions 11-18.

Section C: Repair and Replacement Policy: This is to identify the specific parts of a device that are critical or that commonly fail. Also if there are spare parts readily available and whether there is a policy for spare parts storage. This was assessed in questions 19-22.

Section D: Equipment Failures: This was to identify the number of failures of critical medical equipment when providing health care to patients and the reasons for failure. This was assessed in questions 23-26.

Section E: Maintenance Costs: This aimed at identifying maintenance costs of both in-house and outsourced maintenance services and the type of method used to record this data and how often data was used for decision making. This was assessed in questions 27-31.

Section F: Risks: This was to identify whether duplicate equipment was available, and if not whether there were any adverse patient outcomes. Also how often the biomedical engineering departments needed to substitute equipment and to identify whether there were any cases in hospitals where patient outcomes had been affected by the breakdown of critical medical equipment. It was also important to identify a level of risk in relation to patients if a medical device fails or breaks down while in service. These risks were categorised high, middle, low and very low. This was assessed in questions 32-36.

Section G: Availability of Equipment: This was to identify the number of hours of unavailability for each device used in hospitals. It was also to identify how patients access the health care service. This was assessed in questions 37-41.

Section H: Reliability Centred Maintenance (RCM): This section consists of two parts. The first part discusses whether hospitals used RCM factors to evaluate the reliability of their maintenance management strategy using Availability (A), Failure Rate (FR), Mean Time Between Failure (MTBF) and Mean Time To Repair (MTTR). The second part evaluates maintenance practices, the methods used to

keep maintenance records and any maintenance management software programs. This was assessed in questions 42-54.

These eight sections were covered in 55 closed and open-ended questions. The questionnaire was designed according to the research objectives outlined in chapter 1 and provided recommendations for best practice. The survey was available both online and as hard copy. The eight sections were used to design a theoretical and conceptual framework of the methodology with the hypotheses explicitly identified to verify the research questions. The conceptual framework proposed five variables and associated factors that can affect patient outcomes: (1) Maintenance Management Strategies (MMS) and Maintenance Service (MS), (2) maintenance performance or Reliability-Centred Maintenance (RCM), (3) maintenance practice (4) maintenance cost and (5) patient outcomes. The relationship between these variables and the research hypotheses are identified in Figure 3-6: below.

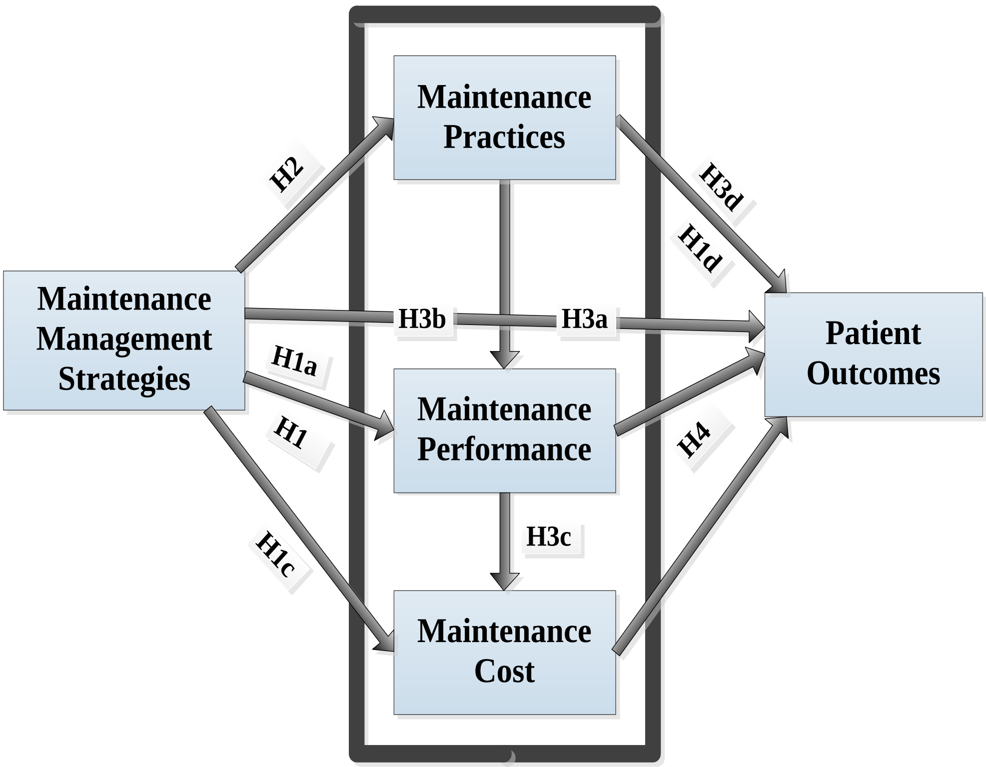


Figure 3-6: Theoretical and conceptual framework of the methodology.

Research Hypotheses

H1: That the current maintenance management strategies for critical medical equipment have an influence on reliability and patient outcomes.

H1a: That failure rate of critical medical equipment is influenced by the type of maintenance management strategies.

H1b: That downtime of failed critical medical equipment is influenced by type of maintenance management strategies.

H1c: That cost of ownership of critical medical equipment is influenced by the type of maintenance management strategies.

H1d: That outcomes for patients serviced by the critical medical equipment is influenced by the type of maintenance management strategies.

H2: That the selection of current maintenance management strategies for critical medical equipment is the result of (i) lack of knowledge of 'state of the art' maintenance management strategies and (ii) practices used in other industries. (Both are considered).

H3.1: That computerized maintenance systems based on condition-based maintenance have the potential to improve reliability and patient outcomes.

H3a: That computerized maintenance systems based on condition-based maintenance have the potential to reduce failure rates.

H3b: That computerized maintenance systems based on condition-based maintenance have the potential to improve the availability of equipment.

H3c: That computerized maintenance systems based on condition-based maintenance have the potential to improve economies of operation/ownership.

H3d: That computerized maintenance systems based on condition-based maintenance have the potential to improve patient outcomes.

H3.2: That patient outcomes serviced by the critical medical equipment are influenced by maintenance performance (equipment reliability).

3.7.1 Variable Measurements

The survey design and questions that correlate with the variables are presented in the conceptual and theoretical frameworks. Table 3-3 shows the variables and their correlation with questions in the survey questionnaire.

Table 3-3: Variables and their correlation with questions in the survey questionnaire

No	Variables	Questions number/s on survey questionnaire
1	Machine properties and usage	Q4, Q5, Q6 and Q7.
2	Maintenance management strategies	Q11,Q12, and Q13
3	Maintenance practices	Q18, Q19, Q20, Q22, Q27, Q29, Q36, Q42, Q43, Q44, and Q5
4	Maintenance Performance	Q10, Q23, Q24, Q25, Q26, Q33, Q37, Q38, Q40, Q41, Q46, Q 47, Q48, Q49, and Q53
5	Maintenance costs/ Cost of ownership	Q30,Q31, and Q54
6	Patient outcomes	Q16,Q32,Q33,Q34,Q35,and Q39

3.7.2 Qualitative Research: Interview Design and Questions

In the pilot study the interview form was used to gather qualitative research data. Interviews were structured into three questions[27]:

Q1: General information about the critical medical equipment such as function of equipment, serial number, level of importance (critical, important and necessary), level of risk in relation to patient health (high, middle and low). The data from this question was used to classify and identify the CME which have a high risk level in relation to patient outcomes. This was measured through 5 questions generated from the objectives from Question 1.

Q2: The data from this question were used to statistically analyse performance tests in this study and to measure the reliability of critical medical equipment selected at this stage including kidney dialysis, cardiac catheterisation, anaesthesia and the defibrillator. This covered the type of current maintenance strategies and services used in hospitals, reasons for equipment failure, reliability, unavailability, repair and replacement policy, maintenance costs and the effect on patient outcomes.

[27] Appendix A: Survey Questionnaire Form, pp. A1-A30.

This was assessed through 38 questions generated from the objectives from Question 2.

Q3: The data from this question was used to find the major reliability factors of critical medical equipment: Failure Rate (FR), Availability (A), Mean Time between Failure (MTBF) and Mean Time to Failure (MTTF). This was measured using the objectives of Question 3.

The aim of the interview was to identify and select that critical medical equipment which has a high level of risk in relation to patient outcomes and to ensure control over the survey questionnaire and avoid ambiguity. Interviews were carried out by meeting staff face-to-face, email, and telephone. The total number of hospital staff interviewed was 32. their roles were district managers of hospitals 9%, district nurse unit managers 63%, managers of Biomedical Engineering departments 3%, Staff Medical Officers (SMOs) 19% and nurses or users of critical medical equipment 6%.

The data collected at this stage was used to improve the design of the final questionnaire[28]

3.7.3 Rationale for a Mixed Method

The benefits of quantitative research are that it is able to generate objective numerical measures and values in order to provide useful statistical information. Qualitative research however offers subjective and more in-depth information to explain phenomena using descriptive attributes that acknowledge the complexity of the data being measured. This combination allows for triangulation of quantitative and qualitative data, adding to the reliability and validity of each research method Together these research methods produce a more comprehensive understanding of the research findings (Jick 1979; Guion 2002).

3.7.4 Quantitative Research: Survey Design and Questions

A survey questionnaire was designed for this study. Each hospital was sent between 1 to 4 copies of this questionnaire depending on the number of relevant departments and the type of maintenance used. In total, 101 questionnaires were completed and

[28] Appendix A: Survey Questionnaire Form, pp. A1-A30.

submitted to the researcher. Ethics approval was obtained from the responsible authority for each hospital

A survey questionnaire was sent out in two phases. The initial phase used in the pilot study was the draft survey questionnaire.[29] Then improvements were made to the survey questions and structure and the secondary phase used the updated survey questionnaire[30] to collect data from 84 hospitals. Data collected in both these phases were used together in the final results. The basic survey questionnaire form was divided into 18 questions. In this questionnaire all questions were designed to identify the type of current maintenance strategies used in hospitals and how these maintenance strategies impact on the availability and reliability of critical medical equipment when providing health care for patients. In the initial pilot study hospitals completed forms related to critical pieces of medical equipment: kidney dialysis, cardiac catheterisation, anaesthesia and the defibrillator and any other critical medical equipment proposed by the hospitals which has a high level of risk to patients[29.]

3.8 Research Design

This research design is based on its aim of improving the current maintenance management strategies used with critical medical equipment in hospitals. The basic research method employed analytical theory development based on previous findings obtained from the literature review. To further validate the hypothesis and research questions surrounding current maintenance management models and the reliability of critical medical equipment, both qualitative and quantitative methods were used to investigate the six variables; Maintenance Management Strategies (MMS) and Maintenance Service (MS), maintenance performance or Reliability-Centred Maintenance (RCM), maintenance practice, maintenance cost and the patient outcomes, which were identified in the conceptual framework[31] and were associated factors that can affect patient outcomes.

The research design was staggered over several activities throughout the duration of this study. After the research proposal was approved an extensive literature review was conducted and updated throughout the length of the study. When ethics

[29] Appendix B: A Pilot Study: Interviews and Survey Questionnaire Forms, pp.B1-B18.
[30] Appendix A: Survey Questionnaire Form, pp. A1-A30.
[31] Chapter 3, Section 3.4, Scope of Study: Sampling and Pilot Study, pp.137-139.

approval was for granted the pilot study, fieldwork observations, interviews and the survey questionnaire were conducted over a 12 month period as the study required hospital consent. This study used a parallel investigation of qualitative and quantitative data. It was also a longitudinal study, as this method is best for understanding changes over time. Logistics was difficult as an extensive area was covered in the data collection period and in total 84 hospitals located over 17 Local Health Districts and Health Services were visited. Prior to entering the field the research thesis and questions, and survey questions were approved by the primary supervisor, who also worked collaboratively with the data analysis and triangulation of the qualitative and quantitative results to ensure greater validity and reliability. A new model of best practice and recommendations were then generated with the research results.

- **Research Model**

Figure 3-7 below illustrates philosophical approaches and identifies the conceptual model that guided this study

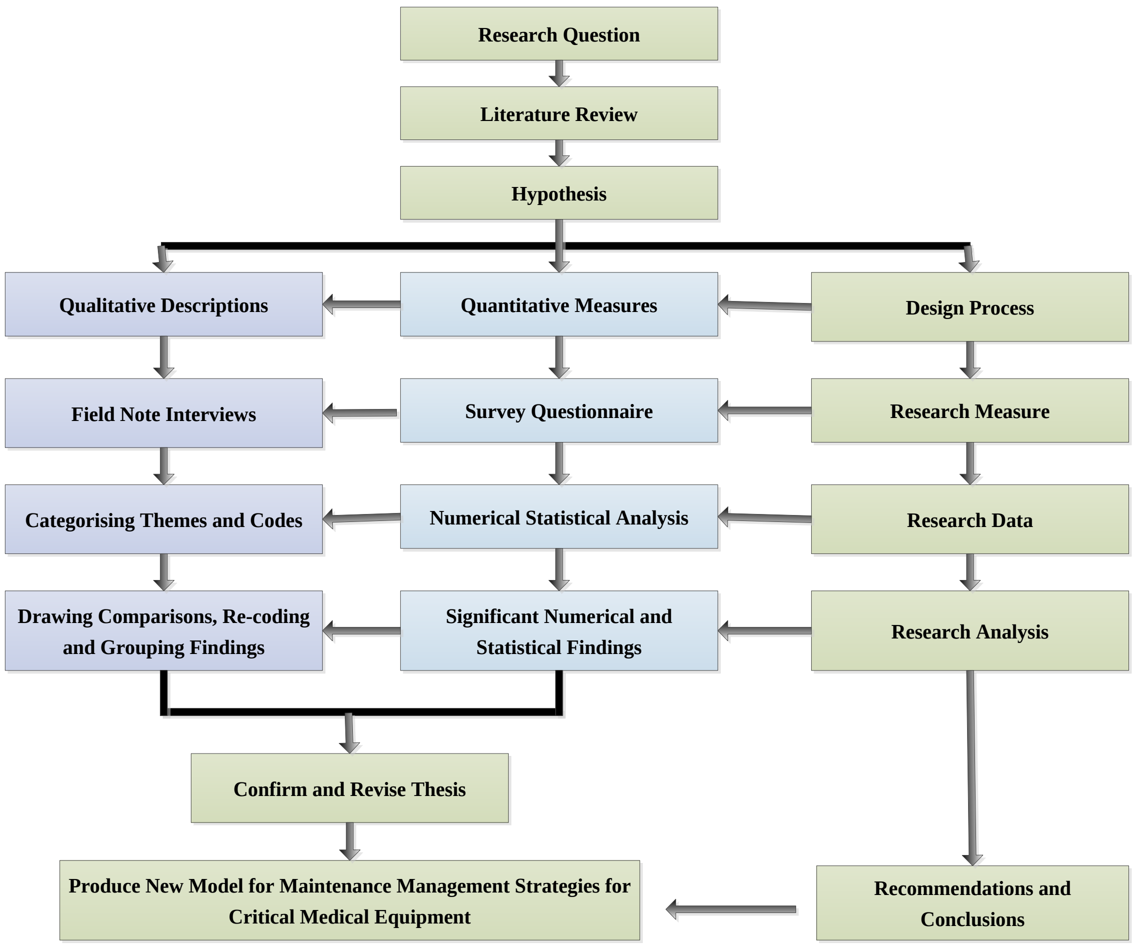


Figure 3-7: Research Model for project

3.9 Data Collection Methods

Emails, telephone calls, hospitals visits, personal observations and staff meetings were used in the data collection process. In total 10 hospitals and 1 medical centre were visited personally to enable the researcher to make observations of maintenance equipment activities, conduct interviews, issue and collect survey questionnaires and achieve rapport with the participants.

3.9.1 Field Notes

Field notes included recording all observations with respect to the medical device under consideration, the name of equipment, time of visit, start time of personal observation, device operating hours, sterilisation time needed for the device, notes on the effectiveness of staff performance within the maintenance department.

3.9.2 Observation Phase

Personal observations were conducted in 10 hospitals for 2 days a week. The duration was usually a six hour session for 11 months, from July 2011 to June 2012, with the aim of collecting the following information:

- Personal observations of the operation from set up stage, sterilisation and maintenance activities of critical medical equipment from different units including kidney dialysis machines in renal units, anaesthesia machines and laparoscope in surgical units, cardiac catheterisation, defibrillator and monitors in cardiac diagnosis units and infusion pumps and monitors in Invacare units.
- Information about major and minor components of this equipment which had a failed repeatedly or randomly.
- Internal catalog of parts to identify the most crucial parts in this critical medical equipment which cannot be observed.
- The activities of daily maintenance and current policies in order to note strengths and weaknesses to allow the researcher to better develop a more effective maintenance strategy model.

3.9.3 Data Management

Data management of the qualitative and quantitative data was an ongoing process throughout this study in line with security and ethics requirements. As ethics approval restricted formalised structured interviews, recording of interviews via electronic devices were not permitted. Instead the researcher was allowed to take field notes during the 11 month observation phases. A notebook was used to manually record conversations with the hospital staff that provided qualitative descriptions of the information surrounding the research questions. A large proportion of staff provided information, however only the most significant 32 interviews will be included in this study. To manage the data from the field notes each participant was coded to de-identify them and to deal with the volume of data received. The code consisted of four parts Hospital: Unit: Position: Interview Number.

The data management of the qualitative findings was both manual and electronic. The hard copies of the survey questionnaire forms collected was entered manually into a Monkey Survey website and stored on the researcher's personal computer and USBs, sent to the research supervisors, manually printed out and securely stored in a locked filing cabinet at the University of Wollongong along with the original completed survey forms.

3.10 Data Analysis

3.10.1 Qualitative Analysis

Qualitative data was generated from the pilot study, field note interviews, observations of maintenance activities and long answer responses from the survey questionnaire. After all qualitative data was collected it was coded, themes and meta-themes generated and comparisons made before analysis was generated to record the results. The initial coding required the data to be read several times in order to identify emerging topics that were given sub headings throughout the transcripts. These were then compared to make associations and generate the essential information to code. The second phase required making relationships between the codes to identify commonalities and generate themes that made larger associations with the findings. The themes were then arranged into meta-themes to produce links between the themes and merge the related themes. After all the information had been

coded and thematically arranged it was continually decontextualised and recontextualised with the research questions reiteratively to ensure there was alignment with the findings and the research aims. This process was initially conducted under the supervision of the primary supervisor, who also maintained contact over the data analysis period to ensure it was performed with accuracy and consistency.

3.10.2 Quantitative Analysis

The quantitative data findings obtained during the survey phase were analysed using the Monkey-Survey website (Ishida *et al.* 2014), SPSS 21.0 for Windows and Microsoft Excel, which allowed the relationship and the degree of correlation between variables to be investigated (Manning and Munro 2007; Polisena, Jutai and Chreyh 2014). Each variable was given a standard unit measurement and the data was examined for validity and reliability. Descriptive statistics of the means and frequencies (Cannesson *et al.* 2011) were generated in order to obtain significant numerical and statistical relationships. A significance test was performed using a Fisher Exact test.

3.10.3 Bracketing

It is expected that researchers acknowledge their own preconceptions, assumptions and prejudices that may influence or interfere with the research. Before beginning this study the researcher acknowledged that prior knowledge and experiences as a biomedical engineer, researcher and lecturer in this field, could sway the data collection and analysis process. Hence prior to commencing the project the researcher bracketed personal beliefs and assumptions by discussing them with the primary supervisor and recording them in the researcher's personal research reflection journal, as an act of conscience to minimise the risk of bias influencing the research process.

3.11 Ethical Conduct

Ethical conduct was maintained throughout the research process as required in the actions of using best practice research behaviour that follows all the ethical requirements bracketing research assumptions, ensuring professional research

conduct in the field, maintaining participants' confidentiality and securely storing data.

3.11.1 Ethics Approval

Human Research Ethics Committee (HREC) approval, with the reference number HE11/318 was given to the researcher in consecutive stages for each Local Health District prior to the distribution of the questionnaires to participants. During 2011, the first HREC approval was issued on 2 September 2011 for 3 hospitals, 21 November 2011 for 4 hospitals, 28 November 2011 for 32 hospitals, 5 April, 2012, 2 approvals were received for 40 hospitals and the final approvals were received on 3 May 2012 for 87 hospitals

3.11.2 Informed Consent

Two different informed consent forms were produced, one for the facility unit in the hospital and the other for the hospital staff who participated in this study. Prior to issuing these informed consent forms an introductory meeting was held and/or email was sent to make initial contact. These forms were then either distributed by hand, email or posted with the survey questionnaire to all respondents. Signed approval was required[32].

3.11.3 Confidentiality

All participants' personal information and responses were managed under the strict codes of confidentiality required by the HREC ethics approval that governs this study. The names of the participants were de-identified and coded and the information provided was not discussed with others outside this research study to ensure the privacy of the participants was maintained and their confidentiality respected.

3.11.4 Validity and Reliability

In both qualitative and quantitative research methods, validity and reliability are important to justify and to demonstrate that the researcher is aware of and has conducted quality research. To ensure theoretical sophistication an extensive review

---

[32] Appendix A: Survey Questionnaire Form, pp. A1-A30.

of the current literature was undertaken. As well regular supervisory meetings were held to test the methodological rigour of each phase as designed and approved by the supervisor before commencing. A pilot study was undertaken and reviewed. This involved the content validity of the survey design and questions used in the instrument, firstly by comparison with the literature and then using expert feedback of quality for the supervisor and HREC ethics community. Suggestions were generated from the pilot study. However, the two most important aspects of precision were validity and reliability.

3.12 Summary

The methodology described in this chapter comprehensively identified the process by which the researcher carried out this research with professional integrity. The 10 sections covered were (1) research aims (2) research questions (3) theoretical and conceptual framework (4) scope of study, sampling and pilot study (5) recruitment of participants (6) choice of methodology (7) research design (8) data collection methods (9) data analysis (10) ethical conduct. The following chapter presents the findings of this study. Chapter 4 provides the qualitative results and Chapter 5 the quantitative results from this study.

CHAPTER 4: FIELD SURVEY AND RESULTS

4.0 Introduction

The results of this research project are presented in chapters 4, 5 and 6. Chapter 4 describes the activities and findings of a field survey involving 10 hospitals and one medical centre. By means of this field survey the researcher sought to gain familiarity with the operation and maintenance problems of critical medical equipment in a functioning hospital. This involved observations and interviews with a wide range of staff from six different hospital departments. All participants in the field survey were asked to complete and comment upon a draft questionnaire in preparation for the final design of the questionnaire to be administered to a larger number staff from hospitals and medical centres in New South Wales (NSW)..

Chapter 5: "Qualitative and Descriptive Results" presents descriptive statistics summarising responses to the quantitative questions which are included in the final version of the questionnaire. Also, presented is an analysis of responses to open-ended questions about users' perceptions of the current maintenance strategies employed and the performance of current maintenance systems as reflected in the reliability and availability of critical medical equipment as well as suggestions for improving maintenance practices.

Chapter 6: "Quantitative Analysis of Questionnaire Responses and Suggested Causal Models" also discusses correlations of measures of equipment reliability with other system variables included in the questionnaire responses and proposes tentative causal models for failure rates and unavailability of critical medical equipment.

4.1 Field Survey

The following sections present (1) field observations, (2) participant de-identification, and (3) field study results. The aim of the personal observations and field notes in this study was to; (1) identify the maintenance strategies currently used with CME in public hospitals and medical centres in NSW and (2) to determine how sudden failure of critical devices influences patient outcomes. The observations were conducted in 10 hospitals and one medical centre for two days a week over a 10 month period from September 2011 to June 2012. Each session usually lasted six hours. A total of 32 hospital staff participated in the field survey.

The breakdown of participants from different hospital departments is shown in Figure 4-1 below and the staff functions are shown in Figure 4-2. As far as can be determined, this is the first such field survey to be carried out in Australia.

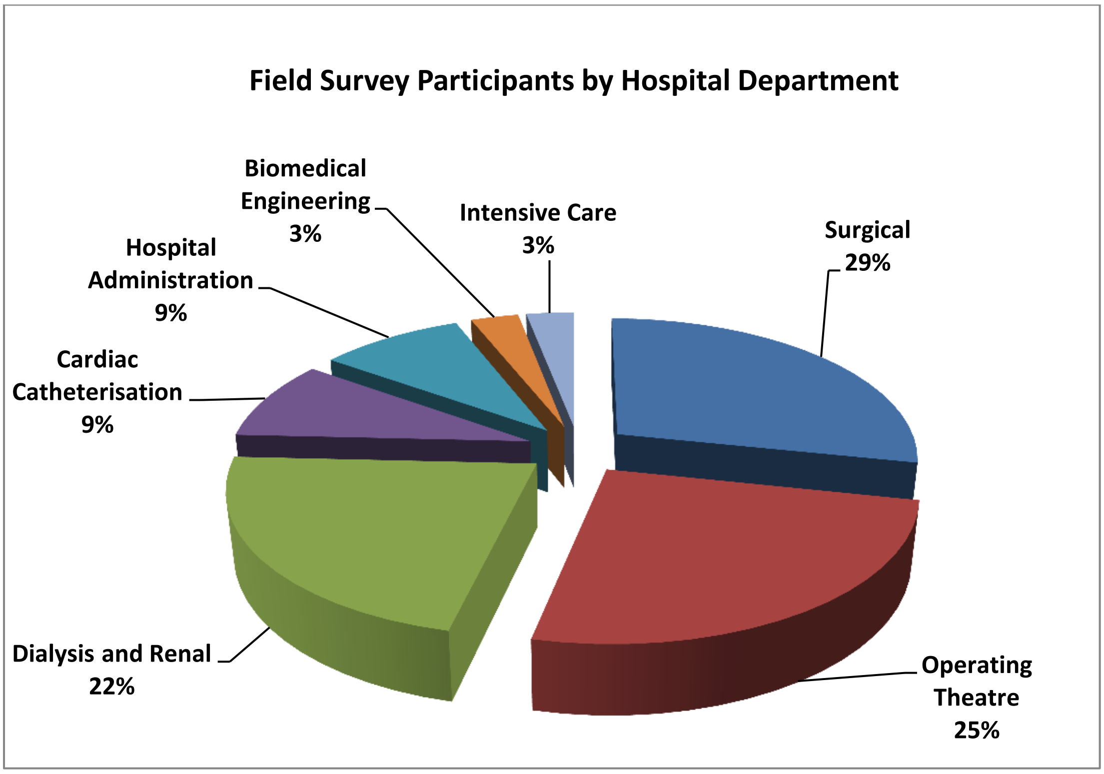


Figure 4-1: Field Survey Participants by Hospital Department

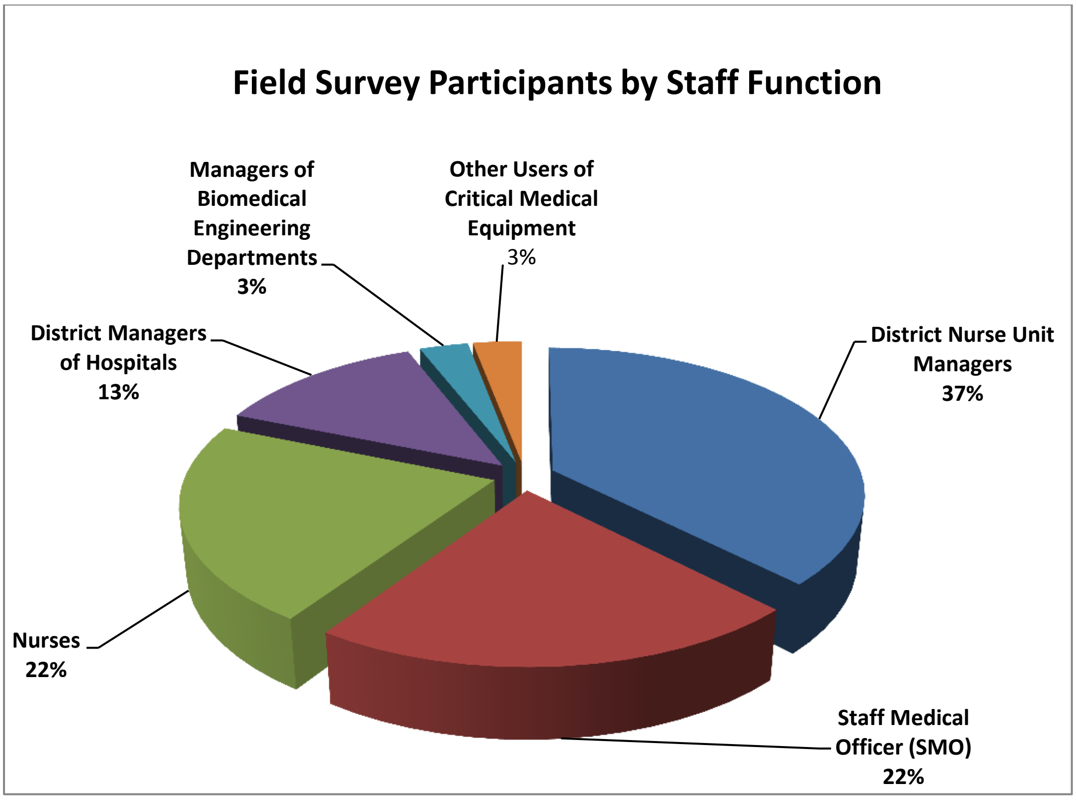


Figure 4-2: Field Survey Participants by Staff Function

4.2 Participants of Hospital Staff

Six of the 32 participating hospital staff were medical doctors, referred here as Staff Medical Officers (SMOs). Each of these was interviewed for one hour about problems with the CME involved in their area of responsibility and their perceptions of current and available maintenance strategies. It was intended that, in addition to interviews with and observation by the researcher, the remaining 26 staff would be asked to complete the draft questionnaire[33]. However, that decision required the approval of the ethics committees at the University of Wollongong (UoW) and the individual hospitals involved. After only two participants, representing one hospital had completed the draft questionnaire, members of the ethics committees required the researcher to develop the final version of the questionnaire to be approved by all the ethics committees and to be used for all future data gathering. That was a long

[33] Appendix B, initial interview and questionnaire forms; this is the draft questionnaire designed by Mkalaf, Khelood, pp. B1-B18.

iterative process because, before the researcher could formally invite a hospital or medical centre to join the research project, the relevant ethics committee at UOW required the researcher to personally establish contact with the organisation concerned and then obtain approval from the ethics committee to formally invite the organisation to participate. Before the revised questionnaire could be sent to any hospital or medical centre it also had to be approved by the ethics committees of all participating hospitals. Some ethics committees required changes to be made to the final questionnaire, for example eliminating a request to estimate the degree of risk of death or injury to a patient resulting from an in-service failure and substituting a version of the question that simply asked if there was any risk of such outcomes from an in-service failure. The final questionnaire was thus a compromise document, including parts of the initial draft questionnaire, improvements as a result of interviews with hospital staff and changes required by the ethics committees. During that process, qualitative interviews were continued with 26 hospital staff members. The results are reported in this chapter. They include information provided by the two staff members who completed the draft questionnaire. The SMOs had not been asked to complete the questionnaire in either draft or final form, although one did so voluntarily.

In each of the six hour sessions at the hospitals the researcher accompanied hospital staff and observed their work with CME. This included learning the function and operation of each item of CME and observing when problems occurred with the equipment.

In some cases, any failures were of a minor nature and could be remedied by the operator but in other cases expert technical assistance had to be sought either through in-house or outsourced maintenance personnel. In those cases the researcher documented the action taken by the operator and the resultant outcomes.

4.3 The Vital Roles of District Managers and other Staff

As shown in Figure 4-2, in this field study, the district managers of hospitals made up 13% of participants. They played a crucial role in solving problems and making decisions about whether to continue with the current maintenance strategy or investigate alternative solutions to machine failure and maintenance strategies and

whether to repair or replace equipment. Because it is costly to investigate alternative maintenance strategies and there is a great deal of pressure to remain within narrow budget constraints, these managers are often restricted in how much time and money they are able to use in evaluating and auditing the total quality of the maintenance strategies used. Further, vital information about the performance of equipment can be gained from other staff members in different departments. For instance, the managers and staff of the Biomedical Engineering departments have highly valuable information regarding the performance and failure of equipment. Also, the daily users of this equipment, who included district nurse unit managers, doctors and nurses, offered first-hand expert information about using the equipment and its functionality and impact upon patients during sudden failures and repair downtime.

The Biomedical Engineering department was deemed the most crucial department, because it is responsible for maintaining surgical units, operating theatres and intensive care units. From the 17 Local Health Districts and Health Services, there were 264 NSW Australian Public Hospitals and health services. Personal observations and field notes revealed some highly significant data that correlates with genuine reasons why certain maintenance strategies are superior to other methods. Most alarming was the fact that there are only 13 Biomedical Engineering Departments in NSW or approximately 1 for every 20 hospitals. This is a critical factor in this study as the majority of the staff from the departments using CME stated that the best practice is to have a Biomedical Engineering Department within the hospital for in-house maintenance. Yet few exist and often there are not enough biomedical engineers employed to service all the machines needed to provide adequate health services. Further, the main recurring theme from the field notes was that when the outsourcing of maintenance is an inferior management strategy. This was attributed to the long wait time and poor efficiency of returning equipment. Outsourced maintenance was held to be a far poorer option compared to the access to speedy repairs and shorter downtime when equipment was managed by an in-house Biomedical Engineering department. The departments most impacted by outsourcing repairs were Renal Dialysis and Cardiac Catheterisation. Most of these departments are serviced by outsourced maintenance companies.

4.4 Field Observations

During the 10 month field study a wide range of interactions with CME was observed including (1) the set up stage and (2) the sterilisation and maintenance activities of critical medical equipment from different units. The machines observed in each unit included kidney dialysis machines in renal units, anaesthesia machines, Reliance endoscope processing system and laparoscope in surgical and operating theatres, cardiac catheterisation, defibrillator and monitors in cardiac diagnosis units and infusion pumps and monitors in Intensive Care units. Information about the major and minor components of this equipment which had failed repeatedly or randomly was obtained. A selection of internal catalogues of the parts of the machines was gathered to identify the most crucial parts of the critical medical equipment which cannot be observed externally. Records of daily maintenance activities and current policies were collected in order to note the strengths and weaknesses, and to allow the researcher to better understand the operations in order to develop a more effective maintenance strategy model from this research.

4.5 Participant De-Identification

In order to encourage participants it was necessary to assure the hospitals and medical centres that individual hospitals and participating staff would remain anonymous in reporting data to the researcher. To distinguish but still de-identify the participants the following coding system was devised, and the resultant code was added at the end of each response in brackets, e.g. (H: D: P: No of R), where:

H is Hospital: codes for the 84 hospitals featured in this study from H1 to H84;

D is Department: codes for the hospital departments or units;

DB is Biomedical Engineering, DS is Surgical, DO is Operating Theatre,

DC is Cardiac Catheterisation, DIC is Intensive Care and DD is Dialysis or Renal

P is Position: codes for the participant's position in the hospital,; PM is District Managers of Hospitals, PNUM is District Nurse Unit Managers, PB is Managers of Biomedical Engineering Departments, PSMO is Staff Medical Officer, PN is Nurses and PU is other users of CME.

No of R is Number of Response: the number code allocated for the participant who provided qualitative data from the field note observations and individual meetings. These numbers are in chronological order of interviewing and observing the respondent.

4.6 Field Study Results

4.6.1 Summaries of Staff Interviews and Observations

The following presentations of results are sequenced chronologically. Staff interviews and observations were conducted over a 10 month period. The 26 participants are individually numbered from 01 to 26, and number 27 is a collation of the responses from individual meetings of the researcher with the six participating SMOs. Because some ethics committees would not permit the use of audio recordings, the following summaries have been prepared from the researcher's hand-written field notes made during interviews with and observations of hospital staff.

H7: DS: PNUM: 01

Participant 01 found their Surgical Unit used 18 CME. The importance of this equipment in administering health services and level of risk to patients is identified in Table 4-1 below. The major issues of the maintenance strategy used were discussed. The machines considered were anaesthesia, diathermy, infusion pumps and AET electronic tourniquet machines. The maintenance of this CME was outsourced to a larger hospital, which uses a combination of CM, PM and EM strategies. With the current method maintenance is performed during annual testing or repair after equipment failure. Surprisingly the participant also indicated that there were no records kept of the costs for maintenance carried out by the manufacturers of these devices. This occurred because the machines were leased and access to costing was only provided at the conclusion of a long-term contract of five years.

Therefore, the researcher could only access historical records and this made it difficult to compare the costing of maintenance between current in-house and outsourced maintenance in order to evaluate maintenance cost efficiency. Most in-house maintenance activities were preventative methods for the setup of CME and included the cleaning and sterilisation of those machines. An example of the type of failure was leaking and pressure issues for the AET electronic tourniquet machine

and the frequency of failures which occurred every couple of months. However, this device does not fall within the parameters of this research project. Participant 01 stated that the total number of failures in the surgical unit in 2011 was only two, which is relatively low as an annual figure and suggests the equipment is reliable and well maintained in H7. The reason for these two failures was that the cycle did not start on the AET electronic tourniquet machine when the start touch pad button was pressed. The cause and correction of these failures could be from any of 13 possible problems, as suggested by the manual.

Table 4-1: General information about the critical medical equipment that served

Hospital Name: H			**Department: operation unit**						
N	**Medical equipment name**	**Function of critical medical equipment**	**Level of importance this machine in providing health care service**			**Level of risk upon patients**			**Number of equipment**
			C	**I**	**N**	**H**	**M**	**L**	
1	Anaesthesia machine	Anaesthesia	Y			Y			6
2	Diathermy	Electro surgery	Y			Y			8
3	Infusion pump	Drug infusion		Y		Y			5
4	Electronic tourniquet	Tourniquet	Y					Y	3
5	Light sources	Laparoscopies Surgery	Y				Y		5
6	Reliance Endoscope Processing System	Cleaning Endoscopy	Y					Y	2
7	Camera control unit	Lap Cases	Y					Y	5
8	Insufflators	Pump Co2		Y			Y		5
9	BIS monitor Anaesthesia	Anaesthesia	Y					Y	6
10	Olympus Control unit	Endoscopy	Y						
11	Olympus flushing	Endoscopy		Y					
12	The LCD mentoring	Visualized Lap surgical		Y					
13	Vitegra				Y			Y	6
14	Synthes E pen	Drifting		Y				Y	5
15	Calf compressors	Prevent DVT		Y				Y	5
16	H LED lighting	Lighting		Y				Y	4
17	Bair hugger	For keep patient warming		Y				Y	7
18	Printer	Print patient data			Y			Y	6
Where C is Critical, I is Important, N is Necessary, H is High, M is Middle, and L is Low.									

As can be seen in Table 4-1[34], this form was used in the field survey to assist the researcher to select the CME which has a high level of risk to patient lives.

[34] Table 4-1, designed by researcher Mkalaf, khelood A.

H7: DS: PNUM: 01 reported (1) the anaesthesia machine is classified as high level risk for patients. Participant 01 indicated there is a 5% risk to patients' lives if this equipment failed during treatment resulting in either patient death or injury. This device provides health care to 1200 patients yearly but was reported to only have failed once in the last five years (2007-2011). A 5% failure rate appears to suggest that around 60 patients per year are at risk of harm. The actual impact of the failure reported on this patient was not revealed but it is possible that death resulted. (2) The current MS used are CM, PM and EM, carried out in-house by Central Biomedical Engineering Department departments in Local Health District (LHD). Both the EM and scheduled maintenance activities of anaesthesia machines were performed as a minor 6 monthly maintenance activity per year. The conditions of anaesthetic machines are evaluated by continuous monitoring. (3) The Mean Time to Repair MTTR was 2 hours per machine per month. To improve the performance of MS used, H7 must reduce the MTTR and control the cost of spare parts. This is increasingly difficult because this hospital does not have a Biomedical Engineering department and depends on outsourcing maintenance to other hospitals. (4) The replacement policy governing spare parts was carried out using the following procedures. All parts or items were considered critical, as any may fail during use. Most of these critical parts were replaced after the machine broke down or when the anaesthesia machine was being serviced.

Reliability-Cantred Maintenance (RCM) began to be implemented with the anaesthesia machine in 2009, but it is only applied to evaluate the failure frequency. As a result, as part of RCM, Predictive Maintenance Strategies are applied 98% of the time for minor maintenance and 2% of the time for minor overhaul.

H7: DS: PSMO: 02

From observations by participant 02 the major issues for users of CME, who are predominantly doctors or nurses, are the solving of problems related to the failure of CME during treatment and how they would manage the failure in the patient's presence. Failure of CME such as the anaesthesia machine was managed by accessing a borrowed machine from another hospital within the same LHD or using a standby anaesthesia

machine. Participant 02 identified that the defibrillator and diathermy also had a high level of risk for patients if it failed while in use but the laparoscopy and ECG had a low level of risk. The researcher was surprised to discover the high level of risk to patient safety and potential risk of death that was possible during treatment with the defibrillator and diathermy. Further research and evaluative measures need to be undertaken with this equipment as there are potentially serious impacts including fatality during a failure.

H7: DS: PN: 03

Participant 03 provided information about a highly sensitive machine that is not part of this study. However, the results are included because it provides important information related to the implementation of MS for high risk devices. The Reliance endoscope processing system machine is a device that sterilises the surgical stomach telescopic device, the laparoscopy, though it does not connect directly with patients. PM and EM were used with a maintenance contract with the manufacturer of this device. The schedule of maintenance included minor maintenance every 4 months and there is an alternative, the Medivator Steris machine that can substitute if a failure occurs. In spite of this, it is a very important machine because it may cause injury or misdiagnosis for patients if the sterilisation process is not performed in the correct manner resulting in a 10% risk level of injury to patients. The frequency of failure was of concern as it was in regular use. (1) The frequency of failure was 4 times per year as well as minor breakdowns. From 2007 to 2011 this device had failed once per year during use in H7 (2) The mean time to repair MTTR was 2 hours (3) The replacement policy for spare parts and storage is important as all parts are deemed critical and most parts were able to be replaced before or after the breakdowns because there were ample in stock (4) The maintenance costs were extremely high at A$6,710.00 per year. Particiant 03 suggested that continuous monitoring is a good strategy to use for the ongoing evaluation of the condition of this machine. This example highlights that regular frequency of failure and maintenance strategies need to be regularly evaluated in order to assess the efficiency of the strategy employed and ensure the best outcomes for patients However a significant restraint is the high cost involved which is ongoing and impacts on the hospital as a whole.

H7: DD: PNUM: 04

Participant 04 pointed out that for the kidney dialysis machine the maintenance strategies used were CM, PM and EM. H7 had a maintenance contract with the manufacturer of this device. While most maintenance activities were in-house, they were mainly for the setup of medical devices before use and involved cleaning and sterilising the control system of the machine. Participant 04 suggested that a mixed maintenance strategy would be a better approach to use and would improve performance and increase reliability of the kidney dialysis machine. They also indicated that the major maintenance issue perceived was the lack of a Biomedical Department with engineering staff who could maintain and avoid sudden failure of this machine.

Participant 04 further explained why a Biomedical Department is essential for best practice of CME maintenance. (1) The kidney dialysis machine is a critical device with a high level of risk to patients. 04 stated that there is a 5% risk of death if this equipment fails during treatment. (2) It provides health care service to 7,200 patients yearly. (3) Failure is infrequent and reasons for failure included electronic, mechanical, human error and overuse. (4) The replacement policy for spare parts and storage were vital factors related to in-house servicing. All parts are critical, as any may fail at any time during health care. Maintenance can take between 5 and 6 hours and most critical parts were replaced after machine breakdown by the company's manufacturer, which can provide critical spare parts easily. (5) The major reason for unavailability is the high demand, which is greater than the availability of equipment in the health care system. Maintenance costs are approximately A$12,000 per annum according to the type of repair and replacement activities. The concerning factor for the kidney dialysis machine is the failure rate and potential risk to patients. The relatively low failure rate, access to an alternative machine and the low Mean Time to Repair demonstrate the efficiency of an in-house maintenance strategy.

H7: DS: PSMO: 05

Participant 05 identified important problems and reasons for CME failures in the operating/surgical room these devices: anaesthetic, diathermy, laparoscopy, Olympus control unit, LCD monitor, and Bair Hugger. The time of patient contact with a device during surgical service ranged between 15 minutes to 1 hour. Participant 05 regarded the laparoscopy as a critical device with direct contact with the patient's body low level risk in relation to a patient's life and for this reason it was not included in this study of CME. However, there were some interesting findings from the observations of the laparoscopy. There is a small hole in the machine which may harbour bacteria and disease that could be transferred between patients if it is not properly maintained and there is a lack of research about this device and the potential harm to patients during treatment. Further research into this factor is recommended. For this reason the only strategy offered for the maintenance of the laparoscopy is to replace it if it fails, as repairing may not fully guarantee its safety. This is a highly costly device to replace. This observation period also highlighted that for the anaesthetic and diathermy devices in H7, there are no alternatives for these pieces of equipment. This is a serious problem as it reduces patient access to health services, particularly when all stand-by machines are in use.

H5: DB: PM: 06

Participant 06 identified major maintenance issues for CME, particularly in the structure and functions of the the central Biomedical Maintenance departments in LHD sites. These included: (1) there is only one Biomedical Department in every LHD and it is responsible for overseeing the maintenance activities for all hospitals in that district. (2) There is a lack of biomedical and clinical engineering staff and a high turnover of skilled engineers. (3) Even with a biomedical department in a hospital, maintenance still needs to be outsourced, especially for the kidney dialysis and cardiac catheterisation machines. (4) There are no comprehensive records kept for the costs of outsourced maintenance. (5) The responsibility for holding maintenance reports in small hospitals falls upon the Biomedical Engineering department. However, often that department does not have an efficient computerised maintenance system to report on maintenance activities. (6) Maintenance is costly because of maintenance staff costs and the wide reliance on outsourced maintenance. In some cases new CME is turned off and stored for long periods before use and this

equipment has failed as there was no scheduled maintenance before use. As a result Biomedical departments are stretched and under-resourced to carry out all the maintenance required in each LHD, placing greater stress on staff. As these departments cannot service all hospitals this puts additional pressure on budgets from outsourced maintenance costs.

H5: DS: PN: 07

Participant 07 identified major maintenance issues related to CME used in surgical units including anaesthesia, defibrillator and diathermy machines. Participant 07 pointed out that certain factors relating to the choice of maintenance strategy impacted upon the CME., Many different types of maintenance strategies are used for the anaesthesia machine according to the characteristics of this equipment including preventive and emergency maintenance outsourced maintenance by the manufacturer. While preventive maintenance was also carried out in-house for the defibrillator machine, some maintenance was also outsourced. Most importantly, the problems associated with CME maintenance strategies, was the time delay for the biomedical department to respond to and repair failures. This was due to the large number of responsibilities they had and their heavy workload, as they look after a group of hospitals located within the LHD in addition to their work in this particular hospital. Participant 07 believed that preventive maintenance is an efficient strategy, particularly if the schedule of maintenance activities parts replacement is carried out before the equipment breaks down. The unavailability of CME was stated as less than 5%.

H5: DC: PN: 08

Participant 08 identified important maintenance issues for CME associated with cardiac diagnostics including cardiac catheterisation, defibrillator and monitor. According to participant 08 the maintenance strategy used with cardiac catheterisation is preventive and emergency maintenance is outsourced to the manufacturing company. This CME was described as new. Failures were thus attributed to human or technical errors. Cardiac catheterisation was also classified as a process rather than a machine because it included a group of different equipment that controlled the system. Participant 08 further stated that the defibrillator machine was available just one day per week for emergency cases, because this machine is shared between departments in hospitals.

H5: DD: PNUM: 09

Participant 09 identified major maintenance issues of CME in the renal unit including kidney dialysis and infusion pump. Mixed maintenance strategies were used with this equipment, adopting an outsourced maintenance contract with the manufacturing company. According to participant 09 kidney dialysis has a high impact on patient outcomes when it fails, because this is a life saving treatment and the health care service is unable to provide dialysis if this machine is not available. 09 also reported that it was a common occurrence for the kidney dialysis machine to fail while providing health care services to patients. Fortunately standby replacement machines were always available.

H10: DD: PNUM: 10

Participant 10 identified the major maintenance issues for kidney dialysis used in the renal units. It was found that H10 used outsourced maintenance for both preventative and emergency maintenance. Participants believed that preventative maintenance was the best strategy for this equipment to prevent emergency maintenance. During emergency maintenance the equipment is unavailable for some time as there are occasionally particular issues in keeping this device properly maintained and available. As maintenance is outsourced it may take several days to repair. Participants believed that hospitals need a study like this to improve performance and increase the reliability of CME, especially for hospitals that rely widely on outsourced maintenance and lack a Biomedical Engineering department.

H10: DS: PNUM: 11

Participant 11 identified the major maintenance issues for defibrillators and infusion pumps used in the surgery unit. Participant 11 reported that a variety of maintenance strategies were used both in-house and outsourced. Patient outcomes were sometimes affected by current maintenance strategies because the biphasic defibrillator may be replaced with monophasic which may lead to greater harm to a patient's heart. Manual infusions may sometimes be inaccurate and adversely affect treatment of the patient.

H12: PM: 12

Participant 12 identified major maintenance issues for all CME used in the hospital. It was found that the maintenance strategy used for CME was carried out by outsourced service through the Central Biomedical Engineering department located

in the LHD. For this reason there is a lack of recorded data for maintenance activities. Failure of the CME was managed by borrowing equipment or by calling on the Biomedical Engineering department.

H13: DIC: PNUM: 13

Participant 13 identified the major maintenance issues for the following equipment: defibrillators, ventilators, infusion pumps, ECG and oxygen concentrators which are all used in the intensive care units. It was found that H13 used mixed maintenance strategies from outsourced services through the Central Biomedical Engineering department that was located in the LHD. Preventive maintenance for the infusion pump was carried out under contract. There were particular issues in keeping this device properly maintained and available. Its availability was dependent on funding for routine and emergency maintenance and the replacement of obsolete equipment. Some items of CME remain turned-off for long periods beyond scheduled maintenance intervals, when they need to be replaced or repaired. This equipment has a high cost investment. Patient outcomes are affected by failure of this CME. Any issues associated with critical care medical equipment will relate to some form of increased risk to patients. What kind of equipment has an issue could determine whether a patient needs to be transferred to another facility, thus increasing the risk of an adverse outcome for the patient through delays inappropriate treatment and transport issues.

H13: DD: PN: 14

Participant 14 identified the major maintenance issues for kidney dialysis which are used in the renal units. It was found that H13 used mixed maintenance strategies carried out by outsourced services. There was a lack of data relating to maintenance activities and cost.

H15: DS: PNUM: 15

Participant 15 identified the major maintenance issues for CME used in the surgical units such as defibrillators, infusion pumps, ECG and nebulisers. Participants said that the hospital used a predictive maintenance strategy carried out by the Central Biomedical department located within the LHD site. The hospital managed the sudden failure of this equipment through borrowing similar equipment from other hospitals located in the same area. According to participants 15 patient outcomes are affected if this equipment fails while providing health care services. This equipment

has a high level of risk to the patients' lives. Results include death, injury or misdiagnosis.

H15: DO: PNUM: 16

Participant 16 identified the major maintenance issues for CME used in the operation unit such as anaesthesia and diathermy. According to participants 16 the hospital used corrective, preventive and emergency maintenance strategies carried out by Central Biomedical department located within the LHD site. It also used condition based maintenance for anaesthesia and corrective maintenance for diathermy carried out by outsourced services. Participants stated that two patients per year were affected by the sudden failure of an anaesthesia machine while in use. This equipment has a high level of risk for patients.

H15: DD: PN: 17

Participant 17 identified the major maintenance issues for kidney dialysis used in the renal unit. Participants 17 stated that hospital used corrective, preventive and emergency maintenance strategies all carried out by a central b

iomedical department located within the LHD site and used condition based maintenance under contract with the manufacturer that produces and supplies this equipment. The renal unit is newly introduced and has 9 kidney dialysis machines; the most common cause of failure is human error due to a shortage of skills and experience in the use of the device.

H41: DD: PNUM: 18

Participant 18 identified the major current maintenance strategy issues for the kidney dialysis and defibrillator machines used in the haemodialysis unit. According to participant 18 planned preventive maintenance and cleaning of the equipment before it fails prevents breakdown and ensures fewer interruptions to service. Particular issues in keeping this device properly maintained and available were identified as the technicians managed the schedule and made necessary alterations. Participants mentioned that the main problem affecting patient outcomes was time delay when the machines needed to be swapped around for repair.

H41: DS: PNUM: 19

Participant 19 identified the major maintenance strategy issues for CME used in the surgery unit. It was found that most maintenance activities were carried out by the

Biomedical Engineering department (in-house services). There are no particular issues in keeping this device properly maintained and available. Participants 19 believed that the current maintenance strategy used in hospitals helps to reduce sudden failure and to increase the availability of critical equipment. **H41: DO: PNUM: 20**

Participant 20 identified the major current maintenance strategy issues of CME used in the surgical unit. Maintenance of this equipment was carried out by the Biomedical Engineering Department (in-house services). The discussion in the meeting was to identify the level of risk of CME. Failure for most of this equipment has a high risk for patients particularly the anaesthesia, defibrillator and diathermy machines.

H41: DC: PNUM: 21

Participant 21 identified the major maintenance issues for the cardiac catheterisation machine in the cardio-respiratory unit. Maintenance of this equipment was outsourced. The major reason of the failure for this device was an over demand by health care services because it is the only unit available within the entire LHD.

H41: DC: PN: 22

Participant 22 identified the major maintenance issues for CME used in the cardiorespiratory unit such as defibrillator, ECG machine and respironics-nebuliser. It was found that hospitals used different maintenance strategies for each piece of equipment. For example, it used preventive maintenance for the defibrillator, while it used condition-based maintenance for other equipment. This maintenance was carried out by the Biomedical Engineering department located in this hospital. It was suggested that the best maintenance program was a mixture of preventive and condition based maintenance. It was found that the current maintenance strategy used affected patient outcomes. A major issue for preventive maintenance, according to the participant, was that patients would require re-booking for a respiratory test. This may incur extra expense (e.g., travelling time) for patients living in rural areas.

H25: DS: PN: 23

Participant 23 identified the major maintenance issues of all CME used in the surgical unit. Maintenance on all this equipment was outsourced through the

Central Biomedical Engineering Department located in the LHD. For this reason, there is a lack of any data recorded for maintenance activities and associated costs. The failure of CME was managed by using loan equipment or calling on the Biomedical Engineering department for assistance.

H28: PM: 24

Participant 23 identified the major maintenance issues for all CME used in the hospital. Maintenance on all this equipment was outsourced through the Central Biomedical Engineering Department located in the LHD. For this reason, there is a lack of any data recorded for maintenance activities and associated costs. The failure of CME was managed by using loan equipment or calling on the Biomedical Engineering department for assistance. Participants 24 suggested that the best maintenance strategy an aged-care hospital located in a small town is an outsourced service.

H29: PM: 25

Participant 25 identified the major maintenance issues of all CME used in the hospital. Maintenance on all this equipment was outsourced through the Central Biomedical Engineering Department located in the LHD. For this reason, there is a lack of any data recorded for maintenance activities and associated costs. The failure of CME was managed by using loan equipment or calling on the Biomedical Engineering department for assistance. 25 noted that there was a lack of Biomedical Engineering staff and that the hospital needs more support for the creation a unit for medical management.

H8: PU: 26

Participant 26 identified the major maintenance issues of all CME used in this medical centre such as the defibrillator, diathermy and autoclaves devices. The maintenance strategy used on this equipment is carried out by an outsourced service. The majority of maintenance issues discussed were outsourcing issues, availability of equipment and the waiting time to provide health care service to patients. The particular issues in keeping these devices properly maintained and available is the delay in the maintenance of the autoclaves devices which leads to disruption of the work of the medical

centre, which may in turn lead to delays in providing a health care services appropriately.

H: PSMO: 27

Six individual meetings were conducted during the fieldwork observations with Staff Medical Officers (SMOs) and their responses have been grouped. This was part of the interviews with the 32 participants during the 10 month field study. The six SMOs were all highly supportive of this study and assisted the researcher by (1) helping to select the CME where failure causes high risk to patients, (2) introducing the researcher to the departments, units and staff in the hospitals, and (3) explaining that alternative devices are available to manage sudden failure in surgical units.

4.7 Major Issues Identified from Field Survey

The following major issues were identified during the interviews and observations with participants in the field survey. In each case the description of the issue is preceded by a list of the respondents who raised the issue. Responses (R) were as follows:-

1. R1, R3, R4, R8, R9 and R14. Maintenance of these CME was outsourced with no local Biomedical Engineers department for major maintenance.
2. R1, R4, and R8. Most in-house maintenance activities were preventative methods for the setup of CME and included the cleaning and sterilisation of those machines.
3. R1, R3, R4, R10 and R16. Equipment maintained by a combination of CM, PM and EM strategies. The current method of maintenance is performed during the annual testing or repair after medical equipment failure. Neither,predictive maintenance or condition based maintenance has been used.
4. R4, R6 and R25. Insufficient in-house Biomedical Engineering staff is seen as a major maintenance issue.
5. R6, R7, R11, R13, R14, R23, R24 and R25. A central Biomedical Engineering department servicing all hospitals in the area does not have sufficient technical or human resources to adequately fulfil all its responsibilities. This leads to inadequate record keeping of maintenance activities.

6. R1. R6 and R14. No records kept of the outsourced maintenance costs carried out by the manufacturers of these devices. Maintenance costs are not available until the end of the contract period (typically 5 years).
7. R2. Doctors or nurses solve problems related to the failure of CME during the provision of health service to patients and have to manage the failure.
8. R2. Failures of critical equipment such as anaesthetic machines have to be managed by borrowing equipment because of a lack of spare units.
9. R1, R3 and R5. The desirability of having spare equipment to substitute in the event of failure during servicing patient.
10. R3, R4. High cost of outsourced maintenance.
11. R11. Use of unsuitable emergency replacement equipment can lead to adverse outcomes for patients.
12. R22. Excessive demand for cardiac catheterisation service causes overload of this facility. Unavailability of medical testing equipment may lead to patients having to re-book and incur extra travel expenses.

4.8 Adequacy of Sampling

Baker and Edwards (2012) edited a series of short papers by internationally renowned qualitative researchers addressing the perennial question "How many qualitative interviews is enough?" Basically the contributors all said "it depends on many factors" but some were more specific. Adler and Adler (2011) recommend that for a qualitative PhD research project "loosely around 30" interviews will suffice. Bryman (2012), presents evidence that in such studies a sample size of between 20 and 30 should suffice. The sample size of 26 interviews in this study satisfies these criteria.

There is also the concept of "saturation introduced in the pioneering work of Glaser and Strauss (2009) on Grounded Theory. Interviews are arranged chronologically and the most important issues are introduced early in the series of interviews with a few new issues being introduced towards the end. The researcher can claim that further interviews are unlikely to reveal important new issues. That is, "saturation" has been reached. An examination of the chronological sequence in which issues were discovered, as discussed in

section 4.5 above, reveals that "saturation" has been achieved relative to the major issues. It can thus be concluded that the sample of 26 interviews is adequate.

4.9 Conclusion

The field study discussed in this chapter achieved several valuable outcomes:

Firstly, by observing hospital staff in their daily activities over a period of ten months the researcher gained familiarity with the equipment concerned, its functions in providing health care and the risks to patients associated with equipment failure or malfunction during service provision.

Secondly, the researcher gained knowledge of the maintenance strategies in use at the various hospitals and the opinions of staff on the adequacy of methods currently employed.

Thirdly, the list of issues summarised above and discussions on the draft questionnaire allowed the researcher to refine the final questionnaire to be administered to a large number of hospitals and clinics.

Finally, the researcher was able to interview senior management personnel in the hospital management system's district managers of hospitals, district nursing nnit managers and one regional manager of Biomedical Engineering. This provided a rare opportunity to understand the problems faced by senior management in organising and funding the maintenance of critical medical equipment.

CHAPTER 5: SUMMARY OF QUESTIONNAIRE RESULTS

5.0 Introduction

This chapter provides a summary of the results based on the 102 usable responses to the questionnaire[35] that was administered to hospital staff in NSW during 2012. The process which led to the 102 usable responses is shown in Figure 5.1 below. In smaller hospitals the responses refers to the targeted hospital, but in some larger hospitals staff in specialist clinics e.g. renal haemodialysis and cardiac catheterization also provided separate responses relating to just the equipment used in a particular clinic. Thus, from the 84 responding hospitals a total of 103 responses were obtained. Of these, one response had been left blank for most of the critical fields. This reduced the total number from 103 to 102 responses available for further analysis. In the questionnaire form and in the chapters that follow, the generic term "hospital" is used to refer to the unit from which a response was obtained whether it was an entire hospital or a specialist clinic.

The categories under which the summary data are discussed are as follows:

- General descriptive statistics for each machine type providing the number of machines of each type in a hospital, average number of patient treatments per machine per month, average duration of a treatment and average time per month that a machine is occupied in treating patients.
- Possible maintenance location for each machine type in-house, outsourced or mixed.
- For in-house and outsourced locations, the most commonly adopted maintenance strategy, (Preventive Maintenance, Corrective Maintenance, Emergency Maintenance, Condition Based Maintenance, Predictive Maintenance and/or Mixed Maintenance).
- Availability and use of substitute machines in case of breakdowns,
- Procurement and inventory strategies for spare parts.
- Scheduling of patients for treatment by each machine type.
- Perceived risk to patients from equipment failure or unavailability.
- Failure rates for each machine type, measured as number of failures per thousand hours spent treating patients.

[35] Appendix A: Survey Questionnaire Form, pp. A1-A30.

- Perceived causes of machine failures or unavailability.
- User perceptions of current maintenance strategies and outcomes.
- User suggestions for improvements to current maintenance strategies.
- Cost of maintenance.

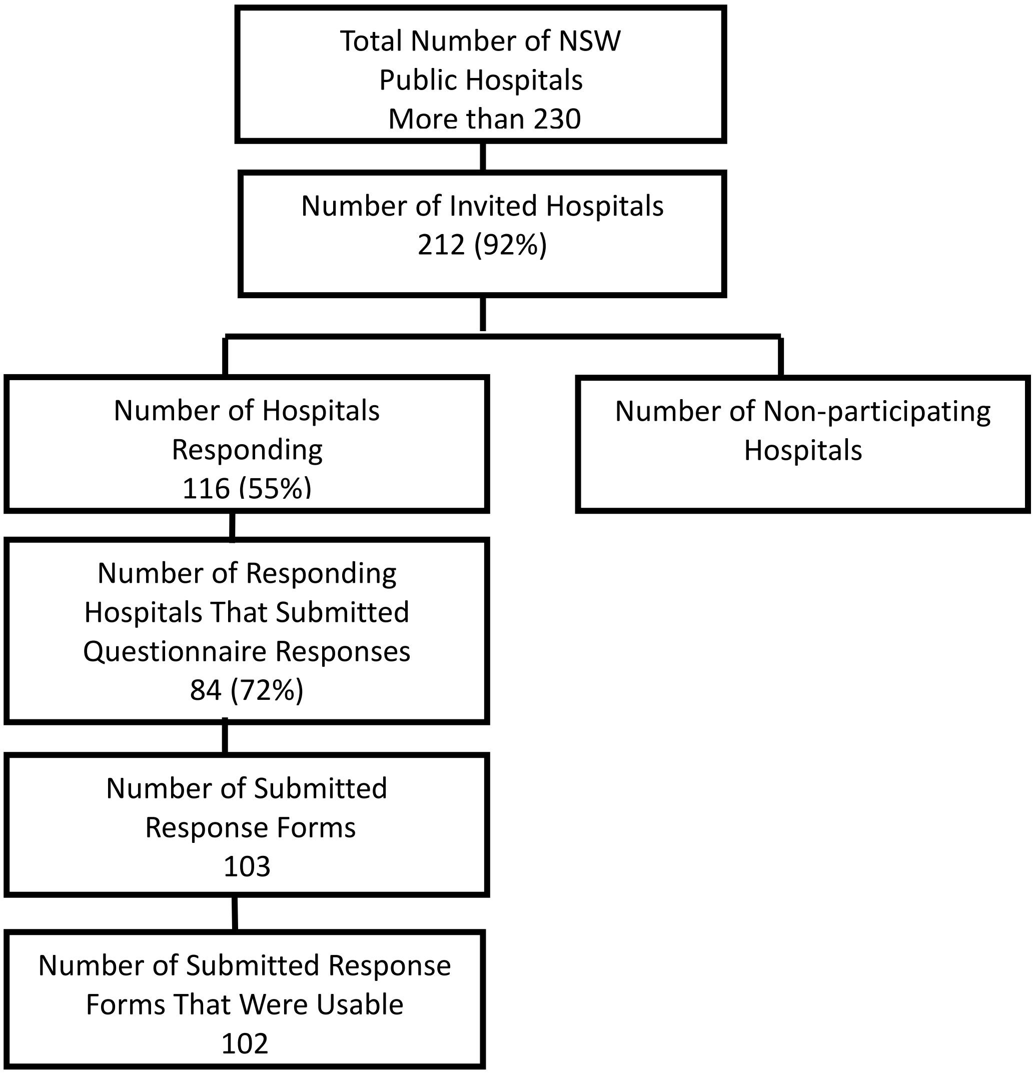


Figure 5-1: Provenance of 102 usable survey responses

5.1 General Descriptive Statistics for Each Machine Type

5.1.1 Number of Machines of Each Type

In the survey Question 2 was fully completed by 102 of the 103 respondents[36].

[36] Question 1 asked name of hospital and department or unit.

Q2. Do you have any or all of the following critical medical equipment?

Of the 84 hospitals surveyed (31) 37% have a combination of the 14 CME types that are the focus of this study. Of these hospitals, only 25 had kidney dialysis and renal departments. This is because these machines are costly and require specialised skills for their operation. For this question only 14 of the 25 hospitals responded, so only 48% of these departments are represented. These results have been generated from the data in Questions 2 and 3 in the survey questionnaire.

Table 5-2 below shows the summarised responses to Question 2 of the survey for each machine type. The Respironics Pump was included in the survey questionnaire based on the literature survey, but no respondents reported having that equipment. Only one respondent reported having an automatic transport defibrillator. Apart from the types of equipment mentioned, the least commonly held machine was the cardiac catheterisation machine, which was used by only 8 respondents. Renal dialysis machines were used by only 16 of the 120 respondents. Of these, all but one had more than one dialysis machine. The most commonly used machines were the automatic defibrillator (used by 70.6% of respondents) and the infusion pump (used by 69.6% of respondents).

Table 5-1: Summary of machine types held by respondents

Q2. Do you have any or all of the following critical medical equipment?					
Equipment	**Results from 102 forms**				
	Yes	**No**	**Total Responses**	**Response Rate**	**% Have Machine**
Dialysis	16	86	102	100.0%	15.7%
Cardiac Catheter	8	92	100	98.0%	7.8%
Anaesthesia	39	61	100	98.0%	38.2%
Defibrillator	72	30	102	100.0%	70.6%
Diathermy	19	80	99	97.1%	18.6%
BIPAP etc.	11	81	92	90.2%	10.8%
Ventilator	40	54	94	92.2%	39.2%
Infusion Pump	71	24	95	93.1%	69.6%
ECG	64	31	95	93.1%	62.7%
Electrosurgical	33	59	92	90.2%	32.4%
Defibrill. (manual)	1	0	1	1.0%	1.0%
Respironnics Pump	0	13	13	12.7%	0.0%
Nebuliser	33	58	91	89.2%	32.4%
Oxygen Concentrator	33	57	90	88.2%	32.4%

The distribution of CME within departments in NSW hospitals featured in this study is shown below in Table 5-2.

Table 5-2: Equipment used in hospitals in this study and in NSW hospitals

Equipment	Departments	Number of hospitals in NSW	Hospitals represented in this study
Anaesthesia	Surgical Specialties - Operating - Theater	150	33
Ventilator		150	37
Defibrillator	Emergency Departments Intensive Care units Aged Care and Rehabilitation Facilities	264	64
ECG		264	62
Infusion Pump		264	68
Kidney dialysis	Dialysis - Renal	25	11

Access to the departments shown in Table 5-2 above was more difficult as the equipment used is more directly connected to the patient. The nature of the work of these departments made it difficult to obtain further information from a wider range of hospitals because participants regarded this as being very sensitive information. However, although the survey responses represent a relatively small proportion of the actual numbers of departments in NSW hospitals, the results obtained are still important in showing the use of alternative equipment. For example, it was noticed by respondent H15:R3:IC that the anaesthesia machine is used as an alternative device when the ventilator breaks down.

The majority of NSW hospitals and healthcare service units have defibrillators, infusion pumps and ECG machines. These three CME types are broadly represented as information was more easily accessible and as such, the results are significant because they are closely aligned to the total number of devices in NSW hospitals.

Q3. Do you have any other critical medical equipment that is not listed in Q2 above? Please name these.

In the survey Question 3 was fully completed by 44 of the 103 respondents. In the process of collecting the data via the questionnaire, hospitals also suggested 23 other types of CME (137 devices in total) that should be considered in future research in this area. These are listed in Table 5-3 below. From the suggested list in response to Questions 3, the final survey questionnaire included 14 CME types in Question 2. There were 4 significant additions: the infusion pump, the ECG machine,

the B1PAP, and the ventilator machine. These were added to the list in Question 2[37].

Table 5-3: Other critical medical equipment to be considered in future research

Equipment	Equipment	Equipment
Infusion pumps	Surgical Laser	ABG machine
ECG machine	Bladder scanner	SCDS
B1PAP Ventilator	Insufflator	Reliance EPS
RESPIRONICS, Monitor	RESPIRONICS-light	PICCO machine
Trans illuminator Monitor	INR machine	Vision BIPAP machine
Electronic Tourniquet	BIS Monitor	Humidifier
Olympus control unit	Olympus Flushing	Autoclave
RESPIRONICS, Exsufflator	RESPIRONICS: Continuous positive Airway pressure unit	

5.1.2 Availability of Alternative Equipment (e.g. backup, duplicates, equipment borrowed from other hospitals)

This aimed to identify whether any alternative equipment is available to provide the required health services if the existing CME failed and what strategies were used when a CME was unavailable. These results have been generated from data from Questions 8, 9 and 10 in the survey questionnaire, which are linked to this subject[38].

Q8. If these devices break down, are there any alternatives that can do the same work and provide the required health services to patients?

In the survey Question 8 was fully completed by 101 of the 103 respondents. The data on the number of CME was also analysed according to availability in hospitals. This data is shown in Figure 5-2 below. In this figure the cardiac catheterisation, kidney dialysis and nebuliser have the lowest percentage of alternative devices available if failure occurs. This is a concerning result as there is a high risk associated to patients if these devices are not operational. Ventilators and infusion pumps have the highest percentage of failure making the failure of these machines a great risk of death to patients.

[37] Chapter 5, Section 5.1.1: Number of Machine of Each Type, p.177.
[38] The data obtain from Questions 4, 5, 6 and 7 were statistically analysed to obtain each of failure rate and MTBF, Section 5.3.1: Failure Rate, pp.194-197.

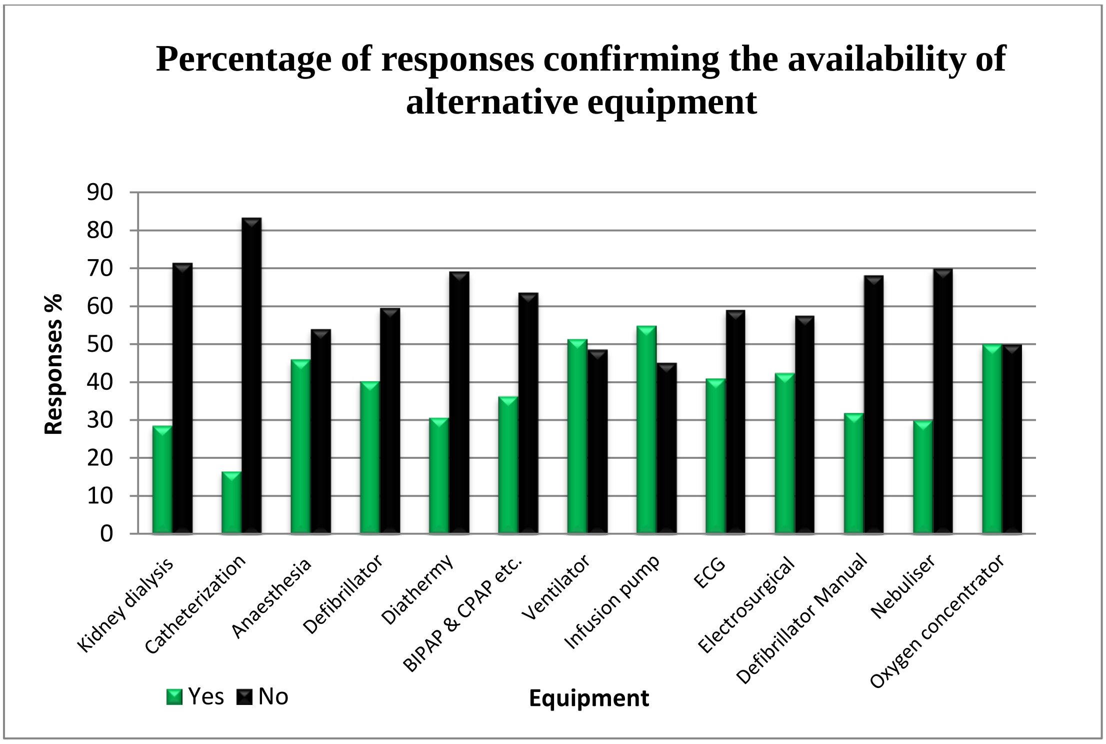


Figure 5-2: The availability of alternative devices in case of failure of critical medical equipment

Q9. If there are alternative to these devices, please supply their name.

In the survey Question 9 was fully completed by 85 of the 103 respondents. The alternative devices or strategies that were used when CME types were unavailable were using an alternate device if one existed, borrowing a machine from another hospital or restricting the use of all devices in order to have standby/duplicate machines as a backup in case of a breakdown.

All hospitals participating in this study had access to machines from other hospitals located in their Local Health District except for the kidney dialysis machine. All hospitals reported that they used the strategy of not using all CME items so they could have standby/duplicate machines as backups when breakdowns occurred. This was reported to be an effective strategy in managing patient care.

Table 5-4 below shows the percentage of hospitals that actually had access to alternative equipment.

- 74.1% access to infusion pump machines ,
- 65.9% access to defibrillator machines ,
- 58.8% access to ECG machines,
- 36.5% access to ventilator machines,
- 32.9% access to anaesthesia machines and
- 8.2% access to kidney dialysis machines

Table 5-4: Alternative methods and devices used in case of critical medical equipment failure

Equipment	*Borrowed machines	**Standby or Duplicate machines	Other alternatives
Anaesthesia	53%	6%	2% Nil
Defibrillator	62%	30%	Defibrillator manual devices 4%
ECG	46%	54%	Nil
Infusion Pump	39%	57%	2% Alaris device, 2% Timed measure by registered nurses.
Ventilator	58%	32%	10% for each of; puritan Bennett 840™ Ventilator, anaesthesia machines, and BAG/Mask ventilation devices.
Kidney dialysis	N/A	57%	29% peritoneal and haemodialysis machines. 14% Technician repairs ASAP

** Borrowed machines from other hospitals located in the Local Health District.*
***Standby/Duplicate machines: extra machines held as backup in case of critical medical equipment failure*

As shown, the availability of alternatives is not consistent among hospitals and the numbers using alternative devices are not high. The logistics of borrowing machines is difficult as they may also be in use . It is difficult to co-ordinate their use as not all alternative machines or devices are available in all hospitals. The strategy of not using all machines at once and thereby having standby machines was deemed the most practical and efficient strategy to ensure a back-up machine would be available.

Q10. How often are these alternatives used?

In the survey Question 10 was fully completed by 97 of the 103 respondents. The frequency in which an alternative device was used in the case of a machine failure is presented below in Table 5-5.

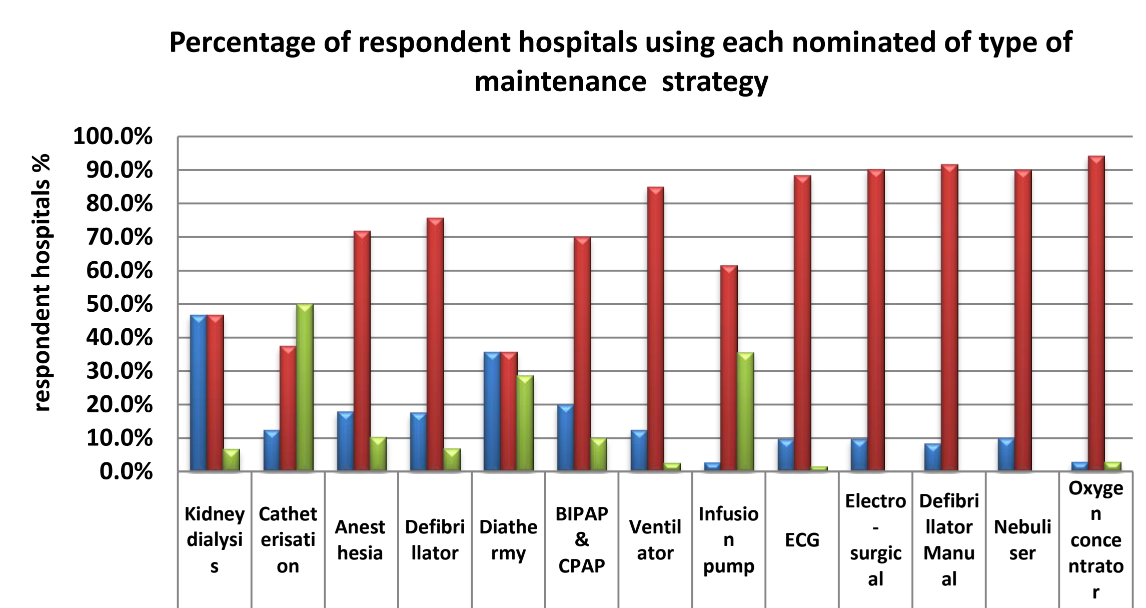
Table 5-5: Frequency of alternative devices used to replace critical medical equipment

Q10: How often are these alternatives used?						
Equipment	Very often	Often	Occasionally	Seldom	Never	Response %
Kidney dialysis	8.33%	8.33%	25.00%	33.33%	25.00%	100%
Catheterization	0.00%	0.00%	33.33%	33.33%	33.33%	100%
Anaesthesia	0.00%	2.86%	14.29%	60.00%	22.86%	100%
Defibrillator	0.00%	0.00%	10.29%	60.29%	29.41%	100%
Diathermy	0.00%	16.67%	25.00%	25.00%	33.33%	100%
BIPAP & CPAP etc.	0.00%	10.00%	20.00%	50.00%	20.00%	100%
Ventilator	0.00%	0.00%	5.26%	76.32%	18.42%	100%
Infusion pump	0.00%	1.43%	22.86%	67.14%	8.57%	100%
ECG	0.00%	0.00%	22.41%	63.79%	13.79%	100%
Electrosurgical	0.00%	0.00%	3.33%	76.67%	20.00%	100%
Defibrillator Manual	0.00%	0.00%	0.00%	63.64%	36.36%	100%
Nebuliser	0.00%	0.00%	24.14%	58.62%	17.24%	100%
Oxygen concentrator	0.00%	0.00%	14.29%	68.57%	17.14%	100%

As can be seen in Table 5-5, for the anaesthesia machine, the frequency of use of alternative devices was relatively low (17.2% for *often* and *occasionally*) suggesting the high reliability of this machine. The results for the defibrillator also suggest there are minimal alternative devices (10.3%) being used and the reliability of the machine is noted. Similar to the anaesthesia and defibrillator machines the ECG machine did not *often* need an alternative device. As indicated only 22.4% of the alternative machines were used. Alternatives for the infusion pump were only *seldom* used, as most of the time this device was functional. The findings for the ventilator machine showed the frequency of alternative machine use was only 5.3%. The frequency of alternate devices used for the kidney dialysis machine was of more concern. Of the six pieces of CME in this study the kidney dialysis machine was the machine in need of the greatest number of alternative devices. It also has the highest frequency of usage.

5.2 Maintenance Management Strategies

One objective of this study is "*to identify and document the type of maintenance management strategies used for critical medical equipment in NSW hospitals*". The survey responses indicated that, depending on the type of CME, maintenance management strategies fall into three groups: outsourced, in-house or mixed. Outsourced maintenance tends to be used more than in-house and mixed strategies, as shown in Figure 5-3, Table 5-6 and Table 5-7.



	Kidney dialysis	Catheterisation	Anesthesia	Defibrillator	Diathermy	BIPAP & CPAP	Ventilator	Infusion pump	ECG	Electro-surgical	Defibrillator Manual	Nebuliser	Oxygen concentrator
In house	46.7%	12.5%	17.9%	17.6%	35.7%	20.0%	12.5%	2.7%	9.8%	9.7%	8.3%	10.0%	2.9%
Outsourced	46.7%	37.5%	71.8%	75.7%	35.7%	70.0%	85.0%	61.6%	88.5%	90.3%	91.7%	90.0%	94.3%
Mixed	6.7%	50.0%	10.3%	6.8%	28.6%	10.0%	2.5%	35.6%	1.6%	0.0%	0.0%	0.0%	2.9%

Figure 5-3: Percent of respondent hospitals that use each nominated type of maintenance strategy[39]

As can be seen in Figure 5-3, 102 of the possible 103 respondents to Question 11 gave outsourced as the dominant type of maintenance strategy used for CME. The average use of outsourcing is 72.2%, compared to 15.9% in-house and 11.9% mixed strategies. A higher use of outsourced MS ranged between 61.6% for the infusion pump and 94.4% for the oxygen concentrator and the lowest use of this strategy was 35.7% for diathermy and 46.7% for kidney dialysis. Conversely the lowest used

[39] 129 - Mkalaf, K., A. , P. Gibson and J. Flanagan (2013), A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes, *International Journal of Management Science and Engineering*, France, Paris, World Academy of Science, Engineering and Technology

strategy was in-house maintenance ranging from 2.5% for the infusion pump to (46.7%) for kidney dialysis machine. The average use of mixed maintenance strategies was less than 50%.

Responses in relation to in-house maintenance identified six strategies: Corrective Maintenance (CM), Preventive Maintenance (PM), Emergency Maintenance (EM), Condition Based Maintenance (CBM), Predictive Maintenance (PrM) and Mixed Maintenance (MMX).

The following Table 5-6 shows the responses of 39 of the 103 respondents in answer to Question 12. The most common types of in-house maintenance strategies used for CME were corrective (27.77%), preventive (31%) and emergency maintenance (24%), while those rarely used were condition based maintenance (2%), predictive (0.5%) and mixed maintenance (14.75%).

Table 5-6: Percept of respondent hospitals that used each nominated type of In-House Maintenance Strategy

Q12. If maintenance is carried out in house, what type of maintenance strategy is used for each of the critical medical equipment nominated?							
Equipment	CM	PM	EM	CBM	PrM	MIX	Total
Dialysis	22%	39%	22%	0%	0%	17%	100%
Catheterisation	30%	30%	30%	0%	0%	10%	100%
Anaesthesia	22%	37%	26%	0%	0%	15%	100%
Defibrillator	19%	35%	23%	3%	3%	16%	100%
Diathermy	20%	35%	25%	0%	0%	20%	100%
BIPAP, CPAP	44%	22%	22%	0%	0%	11%	100%
Ventilator	29%	29%	29%	0%	0%	14%	100%
Infusion pump	43%	27%	19%	0%	3%	8%	100%
ECG	25%	25%	25%	6%	0%	19%	100%
Electro surgical	25%	38%	25%	0%	0%	13%	100%
Defibrillator Manual	29%	29%	29%	0%	0%	14%	100%
Nebuliser	33%	17%	17%	17%	0%	17%	100%
Oxygen Concentrator	20%	40%	20%	0%	0%	20%	100%
Average	27.77%	31%	24%	2%	0.5%	14.75%	100%

Similarly, Table 5-7 shows the most common types of outsourced maintenance strategies for CME are also corrective (31%), preventive (35%) and emergency maintenance (29%). Those rarely used included condition based maintenance (3%), predictive (0%) and mixed maintenance (2%). The highest use of outsourced

maintenance strategies types these were (CM, PM and EM) of most the CME selected.

Table 5-7: Percentage of respondent hospitals using each type of outsourced maintenance strategy

Q13. If maintenance is outsourced (maintenance is done by contract or another hospital), what type of maintenance strategy is used for each of the critical medical equipment nominated?							
Equipment	CM	PM	EM	CBM	PrM	MIX	Total
Dialysis	19%	31%	23%	19%	0%	8%	100%
Catheterisation	8%	38%	39%	0%	0%	15	100%
Anaesthesia	27%	39%	27%	6%	0%	1%	100%
Defibrillator	33%	35%	30%	1%	0%	1%	100%
Diathermy	42%	32%	21%	5%	0%	0%	100%
BIPAP, CPAP	39%	29%	29%	3%	0%	0%	100%
Ventilator	33%	38%	27%	1%	0%	1%	100%
Infusion pump	30%	38%	28%	1%	1%	2%	100%
ECG	33%	36%	30%	1%	0%	0%	100%
Electro surgical	32%	38%	29%	1%	0%	0%	100%
Defibrillator Manual	35%	32%	32%	1%	0%	0%	100%
Nebuliser	34%	32%	33%	1%	0%	0%	100%
Oxygen Concentrator	39%	32%	29%	0%	0%	0%	100%
Average	31%	35%	29%	3%	0%	2%	100%

The results presented in this section demonstrate that outsourced maintenance is the most frequently used strategy for the maintenance of CME and the types of maintenance strategies for both in-house and outsourced strategies used are corrective, preventive and emergency maintenance. As already discussed in the literature review (Endrenyi, *et al.*, 2001), these three types of maintenance strategy are incapable of avoiding sudden failure of equipment while in use. It is argued that increasing the efficiency and effectiveness of maintenance management requires a predictive strategy.

5.2.1 Best Maintenance Strategy

Q14 follows up the findings from Q12 and Q13.

Q14. Which of these do you suggest is the best maintenance strategy for critical medical equipment?

Questions 12 and 13 asked which of a number of specified maintenance strategies were adopted in the respondent's health organisation. Question 12 covered in-house maintenance and Question 13 covered outsourced maintenance. Maintenance strategies suggested were (1) corrective (2) preventive (3) emergency (4) condition based maintenance (5) predictive and (6) mixed maintenance.

5.2.1.1 Preventative maintenance (PM)

Only 40 health organisations responded to Q14. Identical responses were given by 13 hospitals because they used their regional biomedical engineering group for their responses. Thus, for all questions, identical responses from the 13 hospitals were counted as a single response. The response to Q14 from the 13 hospitals was:

- *Preventative maintenance (PM) which keeps the devices in their optimum operational condition as recommended by the manufacturer's specifications*.

Respondents were also aware of the need to maintain the manufacturer's operational standards to make certain that the machines are kept in the best working order.

A further 5 health organisations chose preventative maintenance with responses:

- "*Preventative maintenance"* [2 hospitals].
- *"Preventative maintenance carried out by using in-house [Biomedical Engineering Department] services".*

Another health organisation also chose preventative maintenance and explained it in terms of "Regular Maintenance" and "Planned Preventative":

- **[H1]** indicated, *"Regular maintenance is determined by regularly checking with the staff who use the equipment and asking about its performance"*.

This respondent identified that staff were also involved in providing first-hand information about the machine's performance and this is factored into the routine preventative maintenance strategy employed in their hospital.

- **[H10:R2]** indicated, *"Planned preventative [is the best strategy] as it prevents breakdown and the equipment cleaned up before it fails".*

In total 7 healths organisation explained why PM was used:

- *"Preventative maintenance avoids the equipment failing when it is needed".*

- [**H1**] indicated, *"Failure rate of equipment was reduced when PM is carried out, as regular cleaning and servicing reduces breakdowns"*.
- [**H80**] indicated, *"Preventative maintenance ensures the equipment does not fail when you need it"*.
- **[H7:R2]** indicated; "*This strategy [PM] helps to preventive emergency issues with equipment"*.
- **[H10:R1]** indicated, "*Preventative maintenance is the best strategy for this equipment as a means of avoiding emergency maintenance. If emergency maintenance is needed, the equipment becomes unavailable for some time"*.
- **[H73]** indicated; *"Preventive maintenance maintains equipment well [and] means safety for the patient and less breakdowns"*.
- **[H10:R2]** indicated, *"PM is to less interruption to service provision"*.

A reduction in critical emergency maintenance activities was also suggested when PM is regularly carried out. When machines break down this has a direct impact on their availability and may affect health care. An increased benefit was a higher degree of safety for patients, as PM minimises interruptions to treatment thus reducing direct impact on patients. Preventive maintenance is used because the regular maintenance of all types of CME is catered for in scheduled routine servicing which prevents machine failure (Dhillon and Liu 2006; Wang *et al*. 2010). PM is also an effective strategy for ensuring the longevity of machines and may be carried out before the machine is used or in some circumstance while it is still in operation (Slack *et al.,* 2004). From this survey it was found that one increased benefit to patients was a higher degree of safety because PM minimises interruptions to treatments.

The advantages of PM are (1) it is enhanced by staff input (2) it increases the availability of functional machines (3) it reduces failure rate and machine breakdowns (4) it reduces the frequency of emergency maintenance (5) it ensures the quality of functioning machines meets the manufacturers standards resulting in fewer interruptions to treatment. Overall, PM competently managed, is the optimum strategy in maximising health care outcomes.

5.2.1.3 Corrective Maintenance (CM)

Three hospitals responded "Corrective Maintenance":

- **[H1]** indicated, *"Resolved [breakdowns] quickly, as they are checked and the problems solved.* From this respondent's experience, CM was a positive strategy as repairs were completed quickly and machines were functional in a better turnaround time frame.
- **[H13:R2]** indicated, *"Corrective [maintenance is desirable] due to the lack of interruption to treatment".* As previously acknowledged in the PM results, CM was also described to be an efficient strategy to reduce interruptions to treatment and increase patient servicing outcomes.
- **[H5-R1]** indicated, *"Corrective Maintenance, that is, in-house maintenance has a quick turnaround".* It was identified that in-house CM could provide greater efficiency in reducing downtime and increasing machine availability to patients.

Corrective Maintenance as a secondary strategy to PM was advantageous as machines were reported to be repaired quickly. It also prevented interruptions to treatments and when carried out by in-house technicians ensured machines were efficiently repaired in time to reduce the impact on patient services. CM was identified as being used in this study but far less frequently than PM. CM is the irregular maintenance of CME determined by sudden machine failure while in use or during PM. This strategy is unplanned as it occurs despite PM being carried out and the machine is not operational until it is serviced (Slack *et al.*, 2005; Pintelon and Parodi-Herz 2008; Ratnayake and Markeset 2010). Although this is the least desirable strategy, it is unavoidable. In this survey strategies are in place to follow procedures for biomedical engineers or machine technicians to service equipment in the most timely way and to ensure the machine is completely repaired and back in service quickly.

5.2.1.4 Mixed Maintenance Strategy

A total of 8 hospitals and clinics responded "Mixed" and "Mixed maintenance". In terms of more efficient patient servicing, mixed MS was identified as essential to increasing the availability of machines and this was of particular concern for sensitive CME e.g. dialysis machines where high frequency of use is necessary.

- [**H13:R2**] indicated, *"Preventative and corrective [strategies are able to be used] because of lack of interruption to treatment".*
- **[H5:R1]** indicated, *"In-house corrective and preventative routine maintenance on our dialysis machines is paramount to ensure we have sufficient machines available every day for our patients".*
- **[H10:R1]** indicated**, "***A mixture of Preventative and Condition-Based Maintenance. Living in a rural area incurs extra expense (e.g. travelling time) for outsourced preventative maintenance from a company".* This was the only hospital that recommended Emergency or Predictive Maintenance. The factor determining the benefit for CBM was that this participant was situated in a rural hospital and CBM was deemed as an alternate method that further reduced maintenance costs caused by travel time for technicians.

Mixed Maintenance Strategy (MMS) is the terminology given when two or more of the above maintenance strategies are used collaboratively in conjunction eg PM, CM, EM, CBM, Pr.M, RCM or TPM. The whole question of the most effective maintenance of critical medical equipment needs to be resolved by the *NSW Health Department* using either in-house or outsourced maintenance strategies. In-house maintenance is used when the hospital has a department equipped with staff qualified to carry out maintenance on CME ie biomedical or clinical engineers and/or technicians. Outsourced maintenance uses external companies employed to carry out scheduled servicing and repairs on the machines.

5.2.1.5 Predictive Maintenance (Pr.M)

Predictive Maintenance (Pr.M) is similar to CBM as it predicts the expiry age of machines for serving to enhance efficiency. Predictive Maintenance employs mathematical predictions of failures and breakdowns when inspections are carried out frequently (Dhillon and Liu 2006). Two health organisations reported predictive maintenance to be the best strategy:-

- **[H73]** indicated*, "Predictive maintenance means well maintained equipment. This means safety for the patient and less breakdowns".* The combination of predictive maintenance is beneficial in increasing patient safety and in turn machine breakdowns.

Although Predictive Maintenance may also involve Reliability-Cantered Maintenance (RCM) and Total Productive Maintenance (TPM) (Endrenyi *et al.*, 2001) as was featured in the literature review, no participants in this study reported that either RCM or TPM was used.

5.2.1.6 Maintenance Services

Responses indicated "Maintenance Services" are best used for CME.

- *In house [maintenance services] for a quick turnaround*
- *Outsourced [maintenance services], and*
- *Critical medical equipment would be best serviced in-house [maintenance services].*

Currently maintenance is carried out in two ways, either in-house or outsourced. In-house maintenance occurs when the hospital has a department equipped with staff qualified to carry out maintenance on CME, which requires biomedical or clinical engineers and/or technicians. Outsourced maintenance on the other hand, involves external companies employing outside staff to conduct scheduled servicing and repairs on the machines.

5.2.2 Issues of Current Maintenance Strategies that affect the performance of CME

Q15. Are there any particular issues/ problems to keep this device properly maintained and available? If your answer is [Y] describe in box below?

In the survey Question 15 was fully completed by 99 of the 103 respondents. The results are presented in Figure 5-4. Only 15% of respondents reported that they had perceived problems in properly maintaining CME and keeping the machines available. While others pointed out:

"There are no problems maintaining equipment. If the equipment has a high usage, then it is only a matter of communicating with clinical staff to arrange a mutually convenient time to carry out service /maintenance of the device in question."

However, the vast majority of respondents complained of a lack of (1) funds, (2) service information and access to maintenance resources, (3) technicians both in-

house and outsourced, (4) time lost waiting for replacements, and (5) reduced service to patients.

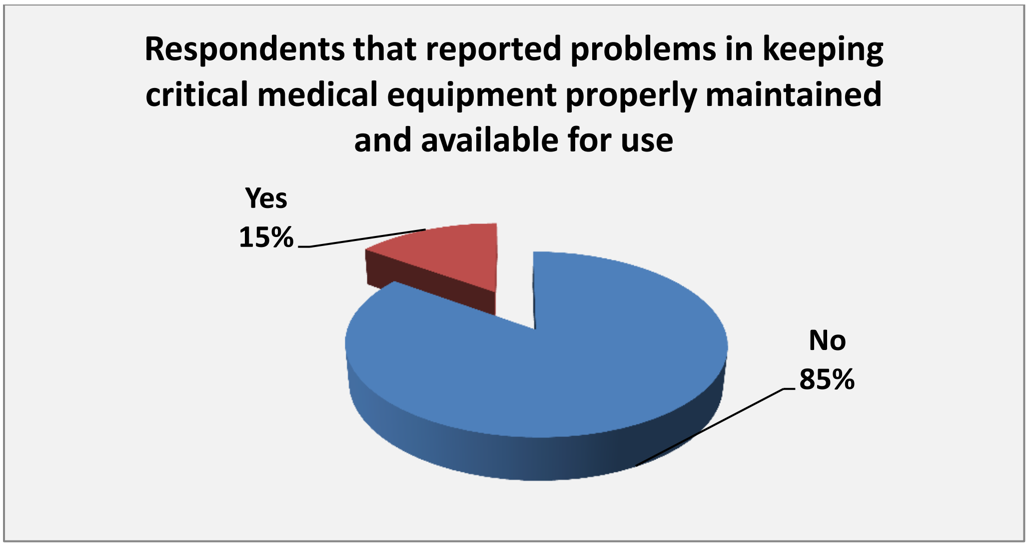


Figure 5-4: Respondents that reported problems in keeping critical medical equipment properly maintained and available for use

5.2.2.1 Funds

- *"Lack of budget to replace them with new ones when we start having issues with the performance."*
- *"Funding was available for routine, emergency maintenance and replacement of obsolete equipment".*

Funding was only referred to by two respondents as being a problem preventing proper maintenance being carried out.

5.2.2.2 Service Information and Access to Maintenance Resources

- *"Getting the information required to service equipment and the access to any specialised tools and software"*

It was also noted that accessing information and specialised equipment and software has hindered maintenance.

5.2.2.3 Technicians In-House and Outsourced

- *"If it [is] in-house there is a delay with biomedical engineering. They look after the entire hospital not only theatre equipment."*
- *"Requires contractor input for kidney dialysis and cardiac catheterisation machines."*

- *"As maintenance is outsourced it may take up to several days for repair."*
- *"Requires contractor input."*
- *"Service availability from both inside and outside providers can be a problem due to the staff resources and matching maintenance with low periods of theatre activity. We do not have a pool of these items so that we cannot replace an item while it is being serviced."*

The greatest problem associated with keeping the CME available for service and properly maintained was the accessibility and availability of technicians. This was due to a number of factors including the technician's availability, time for an outsourced technician to schedule a repair, the distance of the hospital from the technical support and coordinating times when the machine is available to be serviced and when it is required for scheduled use in theatre.

5.2.2.4 Time Lost Waiting for Replacements

- *"Machines are not easily replaceable when they need to be removed from the department to be serviced."*

There was also an issue associated with the availability of replacement machines.

5.2.2.5 Service to Patients

- *"Anaesthesia machines out of service-cancel service if can't be fixed in time."*

Surprisingly, only one respondent linked maintenance concerns to patient outcomes with reference to the cancelling of services due to service maintenance down time.
However, there were concerns about delays and access to resources for the most efficient and timely maintenance for CME.

5.3 Maintenance Reliability (Medical Equipment Reliability)

The aim of this section was to find out whether the final results established a relationship between the maintenance strategy, failure rate and availability of CME and improved patient outcomes. It is proposed that alternative maintenance strategies for specific CME be used to increase their availability and reliability. An evaluation of maintenance efficiency and medical equipment reliability must investigate all factors that affect the performance of CME, such as failure rates, reliability, availability and maintainability. Related to this aspect of the research, the

questions Q1, Q1.1, Q1.2 and Q1.3, and their Hypotheses; H1, H1a, H1b, H1c and H1d[40] need to be included.

5.3.1 The Failure Rate (FR)

The questionnaire examined the failure rate of CME and its causes. By this means the number of failures could be identified that occurred during the provision of health care to patients for each of the surveyed CME between 2011 and 2012. Where, FR and MTBR are found by the following equation; (Slack *et al.* 2005).

Where;

ATTPP = Average Treatment Time per Patient per Year by this Machine

ANOP (t) = 12 x Average Number of Patients each month (data from Q6)

AOTPP (t) = Average Operation Time per Patient (t=Hours, Minutes, Seconds), (data from Q7)

Annual Total Operating Time (ATOT) = (12 months x Number of Patients each month) x (Average Treatment Time per Patient)
ATOT= ANOP x ATTPP

The response to Q23 gives the number of failures per year (for the total number of each type of machines in the hospital concerned).

NF= Number of items of equipment that failed over one year (data from Q23)

FR = Failure Rate

MTBF= Mean Time between Failure

FR, measured as Failures per Thousand Operating hours, is calculated using the equation:

$$\text{FR} = \frac{1000 \text{ x Number of Failures per year}}{\text{Total Operating Time per year}}$$

$$\text{FR}\,\lambda = \frac{1}{\text{MTBF}} \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \text{E1}$$

[40] Chapter 3: Section 3.3: Theoretical and Conceptual Framework, p. 135, Figure 3-6, p.144, and Research Hypotheses, p. 145.

$$\lambda (t) = \lim_{n\to\infty} \left(\frac{1}{\Delta t}\right) P\,[t < t < t + \Delta t \backslash t < t] = \frac{F(t)}{R(t)}$$

$$R(t) = \int_{t}^{\circ} F(x) + d\,(x) \text{ …….. Where; } R(0) = 1,\ R(\infty) = 0\text{……………..E2}$$

$$T = \int_{t^\circ}^{\infty} F_{(t)}\ dt = \int_{t^\circ}^{\infty} R_{(t)}\ dt \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots E3$$

$$MTBF = \frac{1}{\lambda} \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots E4$$

So,

$$MTBF = \frac{\text{Total Operating Time per year}}{\text{Number of Failures per year}}$$

$$ATTPP_{(t)} = \frac{[ANOP_t \times AOTPP_t] \times 12 \text{ month}}{\text{Total Number of Equipment items}} \ldots\ldots\ldots\ldots\ldots\ldots E5$$

$$\sum_{i}^{t} n_1 + n_2 + n_2 + n_4 \ldots\ldots\ldots nn \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots E6$$

The following Figure 5-5 gives the total responses to questions [4, 5, 6, 7, 11, 23, 25 and 26]. These data were used to find FR and MTBF to compare with the reasons for the failures.

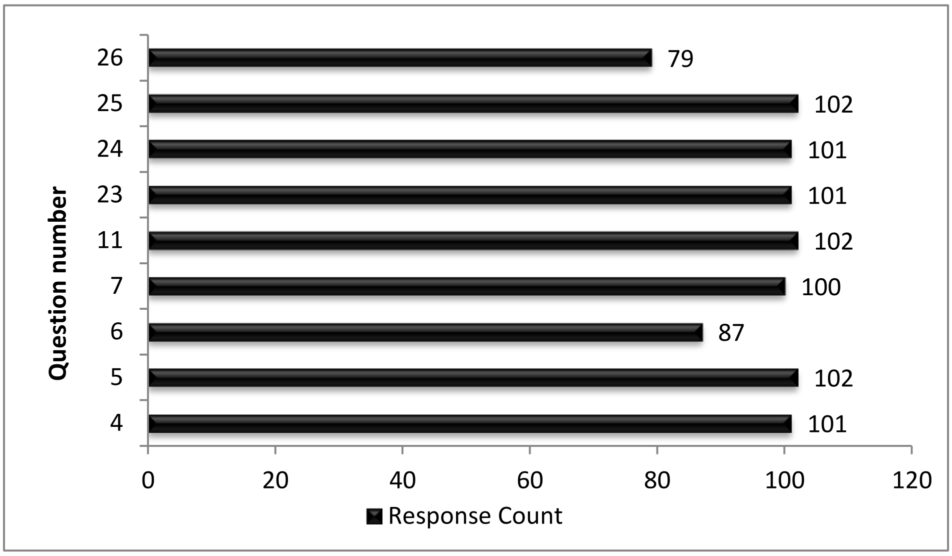


Figure 5-5: Number of responses counted for question shown

1. In this study, 13 types of CME were examined; this was a total of 4371 devices, in addition to the (137) of other CME. Of the total number 5.5% were new, 59% had been used for one to five years and 35.5% had been used for more than five years.
2. Respondents from all the hospitals that participated in this study indicated that, on average, for 58% of CME there were no alternatives or standby equipment to provide the required health services to patients in the event of breakdown or unavailability. Operating times of CME investigated ranged from 1 to 48 hours. This meant that the patient remained connected to the equipment during this period. The defibrillator and ECG equipment were deemed highly critical with potential high risk to patients, including misdiagnosis, injury and death (Khalaf, Djouani, Hamam and Alayli 2010).
3. Table 5-8 below shows high failure rates for kidney dialysis 725 of one thousand hours with a median MTBF of 1925 hours, followed by the infusion pump 58.87 of one thousand hours with a median MTBF of 17280 hours and the anaesthesia machine 0.35 of one thousand hours and a median MTBF of 2880 hours.
4. The reasons for high the failure rates of CME were classified in the survey into three types. From this it was determined that 44% were technical causes, 55% were human errors and 1%was due to overuse. Noteworthy from the results were the high percentages of FR attributed to the three classifications. For the 13 critical devices “Technical Causes” accounted for 90% FR with the defibrillator, “Human Error” 85% FR for the Respironics-nebuliser, 76% FR for the infusion pump, and “Overuse” 12.5% FR for the cardiac catheterisation machine.

Table 5-8: Median failure rate and MTBF of selected CME

No	Equipment	VNH	NE	Median TOT (Time)	Median FR per thousand hours	Median MTBF (Time)
1	Dialysis	14	183	26580 Hrs.	725.00	1925 Hrs.
2	Infusion pump	57	2743	69120 Hrs.	58.87	17280 Hrs.
3	Anaesthesia	25	158	5760 Hrs.	0.35	2880 Hrs.
4	Ventilator	25	226	394512 Hrs.	0.10	7200 Hrs.
5	ECG	45	200	24000 Sec.	83.33	12000 Sec.
6	Defibrillator	46	225	96 Sec.	10.42	66 Sec.

Notes: Time of all machines is measured by hours with the exception of the defibrillator and ECG machines which is measured by seconds.
Where: VNH Valid Number of Hospitals, NE, Number of Equipment, OT Operating Time, FR Failure Rate and MTBF Mean Time Between Failure.

5. Overuse of CME was calculated by examining the Average Treatment Time per Patient (ATTPP) per year by any of these machines compared with the total number of hours the CME was used for patient treatment as shown in Table 5-8 above. Comparitive results indicated that the ECG machine had a higher ATTPP (3568 patients: 1 machine) as shown in Table 5-9.

Table 5-9: ATTPP services by this critical medical equipment

Equipment	VNH	NE	NP/m	ATTPP
ECG	45	200	25484	713529
Dialysis	14	183	6475	24143
Anaesthesia	25	158	10089	55138
Ventilator	25	226	8219	89445
Infusion pump	57	2743	17527	666411
Defibrillator	46	225	407	60

Where: VNH: Valid Number hospitals, NE: Number of Equipment, NP/m: Number of patients per month, ATTPP: Average Treatment Time per Patient

6. Respondents claimed that in the last five years (2007-2011) only 660 failures had occurred, yet this current study (2012) has shown a 20% increase in FN (1534 failures) in this period. However results are inconclusive because they are not statistically reliable as the survey requested opinions, and accurate quantitative statistics were not available or accessed within the scope of this research. The failure number FN was analysed for each piece of equipment, to find the failure rate FR in 2012 (Mkalaf, Gibson and Flanagan 2013). The results are shown in Figures 5-6 and Figure 5-7.

7. Of the 13 CME deemed highly critical with potential high risk to patients, including misdiagnosis, injury and death, the highest were defibrillator-manual 100%, defibrillator 94.4%, oxygen concentrator 77% and ventilator 76.5%.

8. Respondents claimed that from their personal experiences there were some cases of patients who have been exposed to harm by the breakdown of CME (Question 35):

   I. cases of injury using the anaesthesia machine (2 hospitals)and one death (1 hospital),

   II. misdiagnosis using the defibrillator machine (3 hospitals) and one death (1 hospital),

   III. misdiagnosis using the ECG machine (1 hospital),

   IV. a case of injury through misuse of the ventilator machine (1 hospital),

   V. a case of injury using the infusion pump machine (2 hospitals) and one hospital claimed there had been death,

   VI. a case of death using the cardiac catheterisation machines (1 hospital),

   VII. cases of death through using the diathermy machine (2 hospitals).

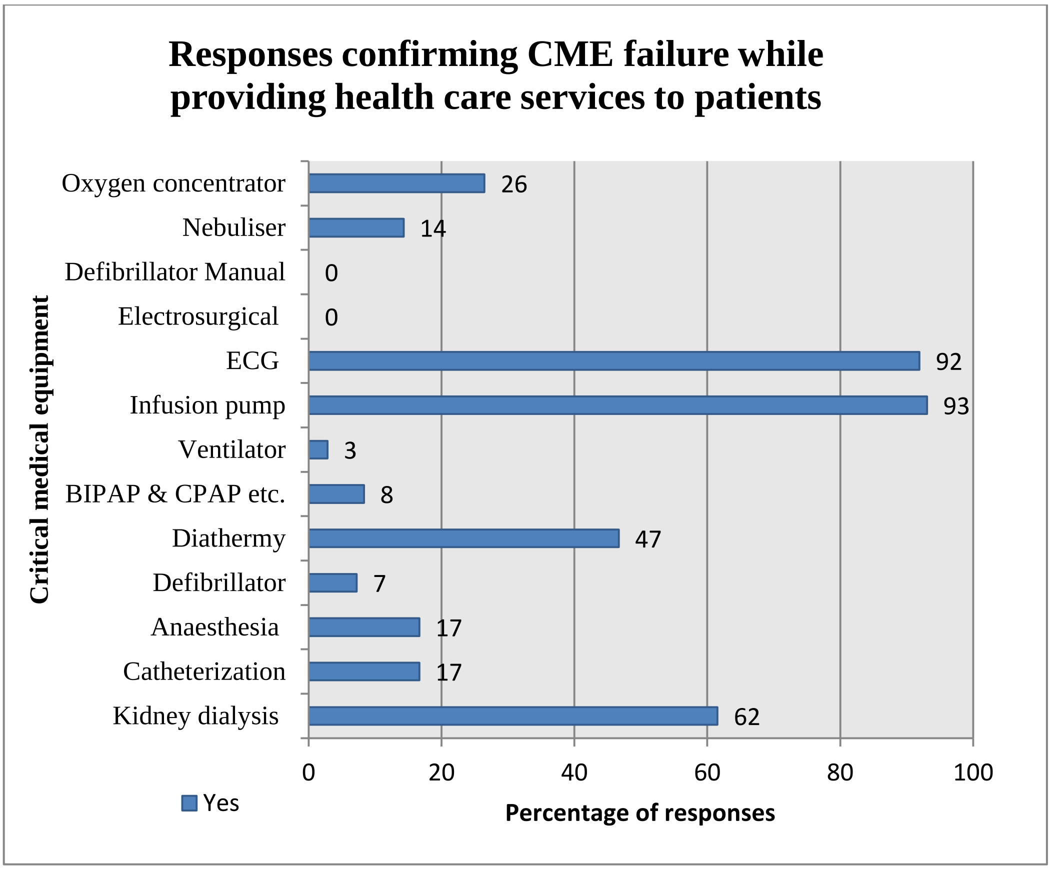


Figure 5-6: Percentage of responses confirming CME failure while providing health care services to patients

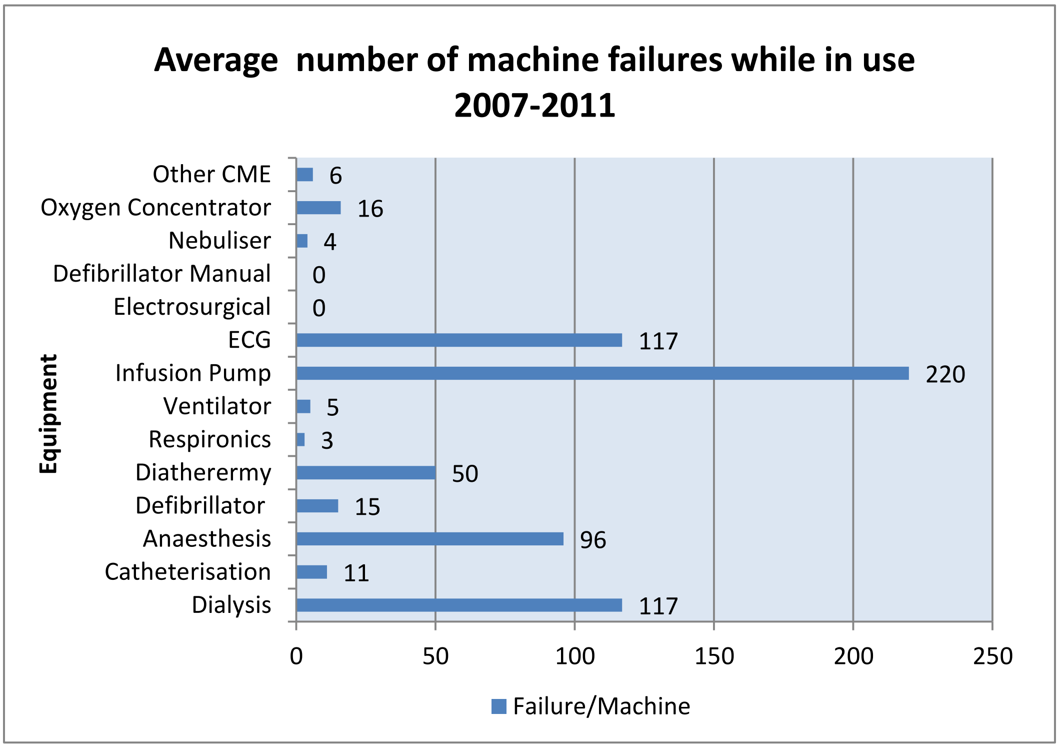


Figure 5-7: Average number of machine failures while in use (2007-2011)

5.3.2 Reliability

The questionnaire examined in (Question 46) whether the hospitals surveyed used the reliability and availability data to evaluate the performance of CME in terms of Availability (A), Failure Rate (FR), Mean Time to Repair (MTTR) and Mean Time between Failure (MTBF). In this question there was a total of 100 respondents but only a very small number indicated that they used such data to evaluate the performance of CME. For example only 2.82% indicated they used unavailability data to evaluate the performance, e.g. the kidney dialysis, anaesthesia and defibrillator machines. Similarly, only 12.83% indicated they used the FR data to evaluate the performance of most of the equipment surveyed. 1.4% of respondents indicated they used the MTTR and 3.7% indicated they use the MTBF for evaluation purposes. Results are shown in Figure 5-8.

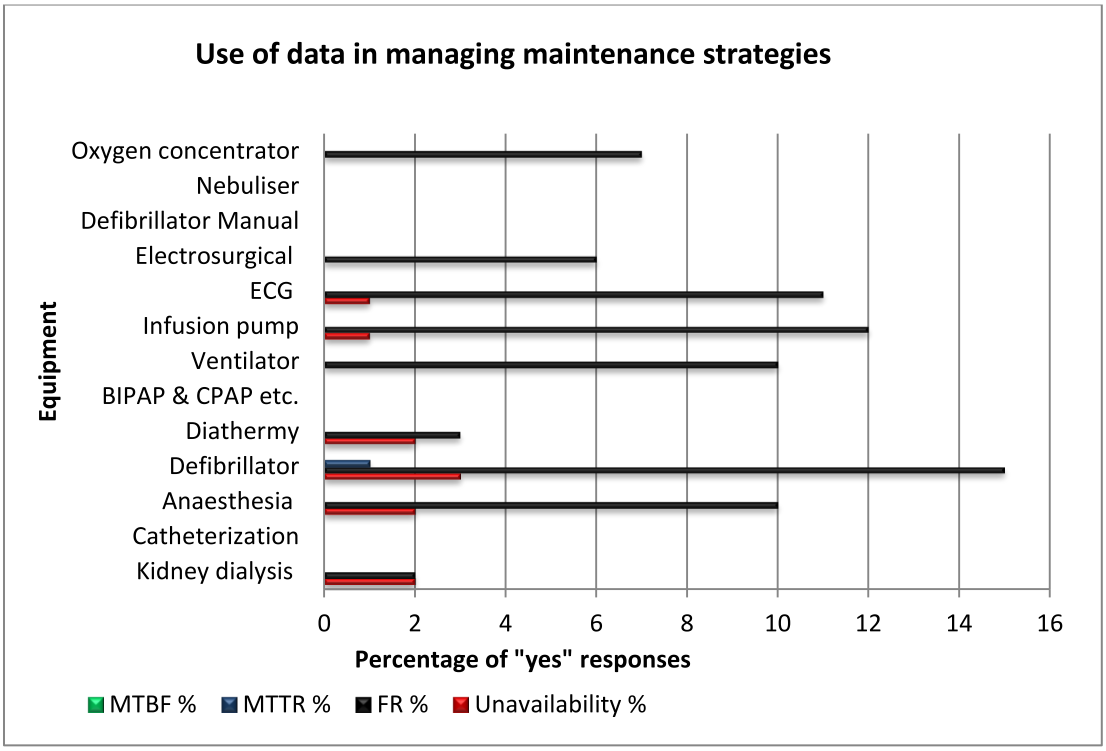


Figure 5-8: Percentage of responses confirming use of reliability measurements to evaluate maintenance strategies

5.3.4 Availability

Respondents confirmed that the reasons for unavailability of CME in this study were due to either the CME being limited in number (33.28% of respondents) or the device was out of service (66.72% of respondents). The results are shown in Figure 5-9. The unavailability of the surveyed equipment ranged between 96 and 360 hours per month. The defibrillator and infusion pump had the highest instance of unavailability at 360 hours per month followed by the diathermy and ECG machines at 336 hours per month and the kidney dialysis machine at 240 hours per month. Overall, the highest average availability of these machines per year ranged between 91% for the nebuliser and 96% for the anaesthesia and ventilator. The lowest availability rates were for the defibrillator at 89% and the infusion pump at 61% as shown in Figure 5-10 (Mkalaf, Gibson and Flanagan 2013).

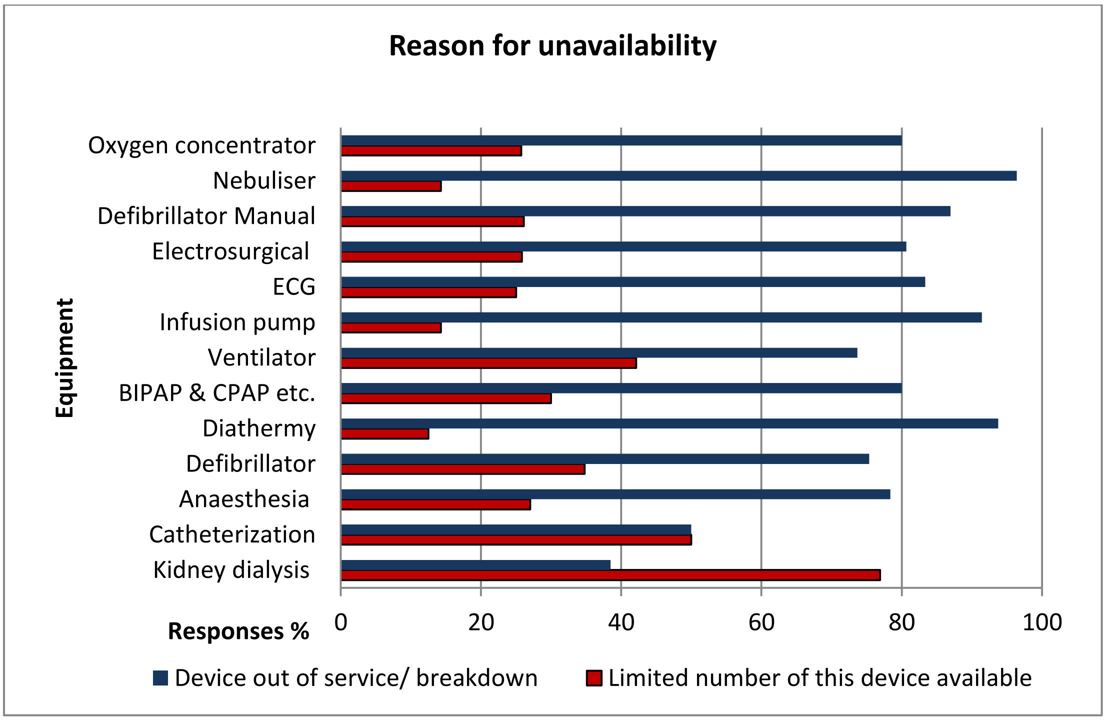


Figure 5-9: Reason for unavailability

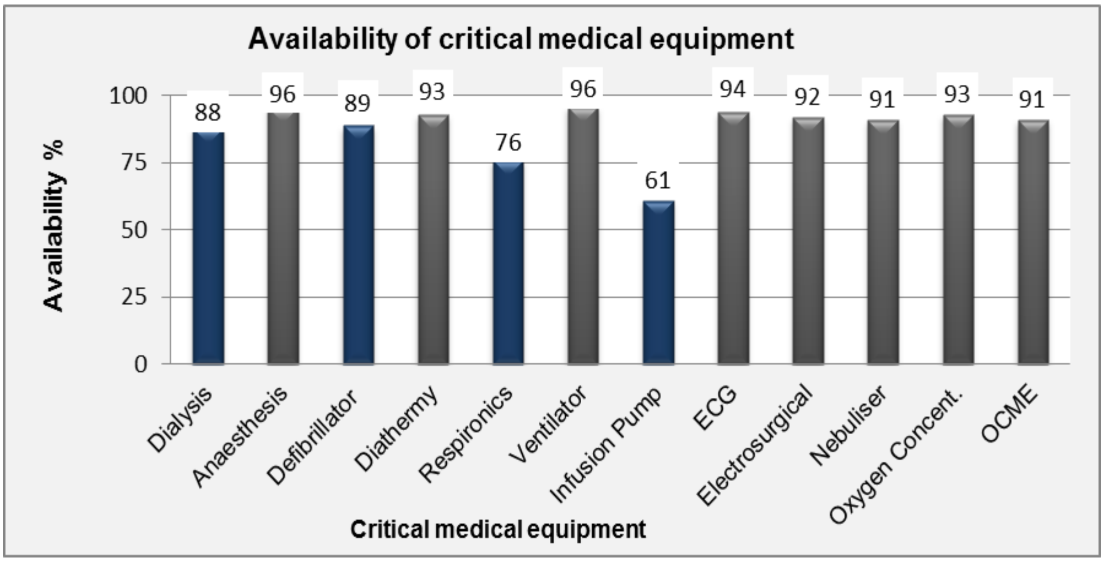


Figure 5-10: Overall average of availability of critical medical equipment 2011-2012[41]

As can be seen in Figure 5-10 above, the average availability of CME in the year 2011-2012 ranged from 61% to 96%. It can be seen, however, that the availability of all the surveyed CME was well below this standard, particularly in the case of the defibrillator, kidney dialysis, respironics and infusion pump machines. This lack of availability may be due to the maintenance services used.

5.3.5 Maintainability

In general, CME has three important stages in its operational life: initial age, useful life and obsolescence (depreciation). This survey attempts to determine the operational life stages of CME to assist hospitals in the selection of suitable maintenance management strategies for each type of equipment. Fourteen types of CME were examined, a total of 5769 devices. Of the total number of CME 5.5% were new, 59% had one to five years of use and 35.5% had more than five years of use, as shown in Figure 5-11.

[41] 129 - Mkalaf, K., A. , P. Gibson and J. Flanagan (2013), A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes, *International Journal of Management Science and Engineering*, France, Paris, World Academy of Science, Engineering and Technology

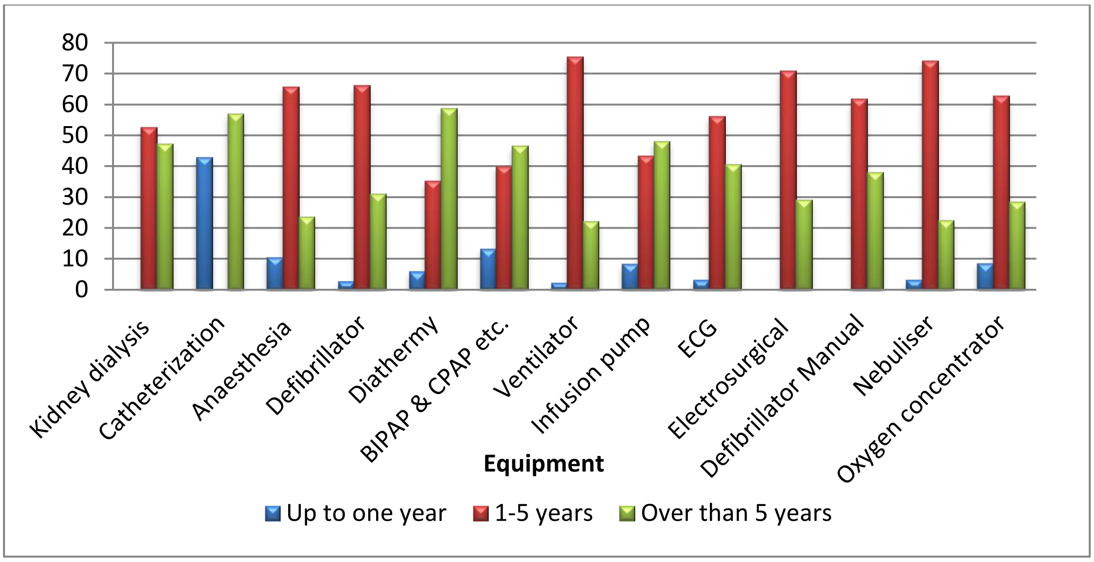


Figure 5-11: Percentage of respondents operating particular CME types and average age of equipment

As can be seen in Figure 5-11, most of the CME selected in this study are in the useful life stage. This is followed by the obsolescence stage. The highest percentage of CME which were within useful life stage were the oxygen concentrator machines (67%) and the ventilator (79%). The CME that in the obsolescence stage kidney dialysis (53%), and diathermy (63%).

The availability of alternatives in case of failure of this CME is one of the important reasons for selecting these types of equipment[42]. In some cases alternatives were not available to provide the same medical service to patients[43]. Often alternatives were not of the same quality or efficiency. On the other hand, the responses showed that the highest percentage of alternatives for these medical devices were Seldom (56.67%) followed by Occasionally (22.73%), Never (16.94%), Often (3.0%) and Very Often (0.64%).[44]

There are different ways of managing failure of CME to provide medical care including (1) duplicate equipment in-house (2) loans from other units or hospitals (3) suppliers and (5) in-house maintenance as shown in Table 5-10.

---

[42] Chapter 5, Section 5.1.2, Alternative equipment availability, e.g. back-up, duplicates and borrow machine from other hospitals, p. 180.
[43] Figure 5-2, p.181.
[44] Table 5-5, p.183.

Table 5-10: Management policy for failure of critical medical equipment						
Q36: When critical medical equipment does fail (break down), how is that failure usually managed?						
Equipment	Duplicate equipment	Call supplier	In-house maintenance	Borrow equipment	Other	Response %
Kidney dialysis	43.48%	34.78%	17.39%	4.35%	0.00%	100%
Catheterization	0.00%	100.00%	0.00%	0.00%	0.00%	100%
Anaesthesia	30.43%	10.87%	23.91%	34.78%	0.00%	100%
Defibrillator	47.93%	5.79%	11.57%	34.71%	0.00%	100%
Diathermy	18.18%	9.09%	27.27%	45.45%	0.00%	100%
BIPAP & CPAP etc.	50.00%	12.50%	18.75%	18.75%	0.00%	100%
Ventilator	42.00%	6.00%	16.00%	36.00%	0.00%	100%
Infusion pump	73.75%	12.50%	6.25%	7.50%	0.00%	100%
ECG	61.97%	0.00%	11.27%	26.76%	0.00%	100%
Electrosurgical	65.71%	0.00%	14.29%	20.00%	0.00%	100%
Nebuliser	70.27%	0.00%	13.51%	16.22%	0.00%	100%
Oxygen concentrator	69.70%	3.03%	6.06%	21.21%	0.00%	100%
Average	47.79%	16.21%	13.86%	22.14%	0.00%	100%

As can be seen in Table 5-10, on average 47.79% of the respondents reported that the "duplicate equipment" was recommended when the CME does fail, 22.14% used "borrowed equipment", 16.21% used "call the supplier" and 13.86% used "in-house maintenance". The highest percentage of duplicate equipment used was defibrillator (0.58) and nebuliser (0.81). The highest percentage of borrowed equipment was anaesthesia (41%) and diathermy (0.63).

The survey respondents were asked how often hospital staff needed to substitute duplicate equipment. The results obtained from Question 33 are shown in Table 5-11. In 101 of the 103 responses 80% claimed they needed substitute duplicate equipment 0.00% of the time, 15% claimed they needed it 25% of the time, 2% that they needed a substitute 50% of the time, 1% for 75% of the time and 2% they needed more than 75% of the time. The fact that that 80% of the respondents never needed substitute equipment may mean that those who responded to this question are not responsible for finding a substitutes.

Table 5-11: Frequency that hospitals need substitute equipment

Q33: How often do you need to substitute duplicate equipment						
Equipment	Zero% of time	25% of time	50% of time	75% of time	More than 75%	Response %
Kidney dialysis	46%	36%	0%	0%	18%	100%
Catheterisation	50%	33%	17%	0%	0%	101%
Anaesthesia	82%	13%	3%	3%	0%	100%
Defibrillator	89%	7%	1%	1%	1%	100%
Diathermy	69%	15%	8%	8%	0%	100%
BIPAP, CPAP etc.	100%	0%	0%	0%	0%	100%
Ventilator	87%	13%	0%	0%	0%	100%
Infusion pump	89%	10%	1%	0%	0%	100%
ECG	92%	8%	0%	0%	0%	100%
Electrosurgical	83%	17%	0%	0%	0%	100%
Defibrillator Manual	100%	0%	0%	0%	0%	100%
Nebuliser	87%	13%	0%	0%	0%	100%
Oxygen concentrator	72%	28%	0%	0%	0%	100%
Average	80%	15%	2%	1%	2%	100%

5.4 Relationship between Current Maintenance Strategies and Reliability Factors

This study investigated the relationship between the current maintenance strategies used in hospitals and the reliability factor in terms of: availability and FR. The results from questions: [41, 47, 48, 49].

The survey respondents were asked whether they perceived a causal relationship between the maintenance strategy used and the failure rate of selected CME. The results from Question 47 data are shown in Table 5-12. In total, 101 of the 103 responsed: 16 % Strongly Agreed, 13% Agreed, 52% were Indifferent, 5% Disagreed and 14% Strongly Disagreed. These results indicate that nearly 29% of the respondents agreed there is a causal relationship between the maintenance strategy used and the failure rate of selected CME.

Table 5-12: Perception of causal relationship between maintenance strategy and failure of critical medical equipment

Q47 Do you think the current maintenance strategy helps optimise the failure rates (breakdown) of this critical medical device?							
Machine	N	Strongly Agree	Agree	Indifferent	Disagree	Strongly Disagree	Total
Dialysis	13	53.8%	23.1%	7.7%	15.4%	0.0%	100%
Cardiac Catheter	6	16.7%	16.7%	66.7%	0.0%	0.0%	100%
Anaesthesia	41	56.1%	2.4%	9.8%	9.8%	22.0%	100%
Defibrillator	70	7.1%	11.4%	57.1%	5.7%	18.6%	100%
Diathermy	15	6.7%	20.0%	33.3%	26.7%	13.3%	100%
BIPAP& CACP etc.	10	0.0%	40.0%	50.0%	0.0%	10.0%	100%
Ventilator	41	53.7%	7.3%	12.2%	0.0%	26.8%	100%
Infusion Pump	72	2.8%	6.9%	70.8%	2.8%	16.7%	100%
ECG	63	3.2%	7.9%	66.7%	3.2%	19.0%	100%
Electrosurgical	30	6.7%	10.0%	60.0%	0.0%	23.3%	100%
Defibrillator Manual	23	0.0%	4.3%	91.3%	4.3%	0.0%	100%
Respironics PUMP	0	0.0%	0.0%	0.0%	0.0%	0.0%	100%
Nebuliser	29	0.0%	10.3%	86.2%	3.4%	0.0%	100%
Oxygen Concentrator	34	2.9%	2.9%	67.6%	0.0%	26.5%	100%

The survey respondents were asked whether, from their personal experience, the current maintenance strategy helps reduce the sudden breakdown of critical devices while in use. The results are shown in Table 5-13. Of the 103 responses, 102 fully answered Question 49: 22% Strongly Agree, 19% Agree, 57% Indifferent, 0% Disagree and 2% Strongly Disagree**.** These results indicate that nearly 62% of the respondents were indifferent to change.

Table 5-13: Responses to whether the current maintenance strategy helps reduce the sudden breakdown of this critical device.

Q49. Do you think the current maintenance strategy helps reduce the sudden breakdown of this critical device while providing medical service?							
Machine	N	Strongly Agree	Agree	Indifferent	Disagree	Strongly Disagree	Total
Dialysis	14	35.7%	57.1%	7.1%	0.0%	0.0%	100%
Cardiac Catheter	7	14.3%	71.4%	14.3%	0.0%	0.0%	100%
Anaesthesia	39	76.9%	15.4%	7.7%	0.0%	0.0%	100%
Defibrillator	72	21.9%	11.0%	65.8%	0.0%	1.4%	100%
Diathermy	17	17.6%	29.4%	35.3%	0.0%	17.6%	100%
BIPAP etc	9	0.0%	0.0%	100.0%	0.0%	0.0%	100%
Ventilator	40	35.0%	45.0%	20.0%	0.0%	0.0%	100%
Infusion Pump	73	17.8%	4.1%	76.7%	0.0%	1.4%	100%
ECG	63	20.6%	3.2%	74.6%	0.0%	1.6%	100%
Electrosurgical	30	23.3%	0.0%	73.3%	0.0%	3.3%	100%
Defibrillator-Manual	23	0.0%	4.3%	95.7%	0.0%	0.0%	100%
Respironics PUMP	0	0.0%	0.0%	0.0%	0.0%	0.0%	100%
Nebuliser	29	0.0%	3.4%	96.6%	0.0%	0.0%	100%
Oxygen Concentrator	35	28.6%	0.0%	71.4%	0.0%	0.0%	100%

Also, in Question 41, the survey respondents were asked whether, from their personal experience, the current maintenance strategy helps to increase the availability of this medical device to provide timely health care to patients. The results are shown in Table 5-14. Of the 103 responses, 102 fully answered Question 41: 27% Strongly Agree, 17% Agree, 56% Indifferent, 0.5% Disagree and 0% Strongly Disagree. These results indicate that nearly 56% of the respondents were indifferent as to, whether their current maintenance strategy used is helping to increase the availability of selected CME.

Table 5-14: Response to whether the current maintenance strategy helps increase the availability of this medical device

Q41. Do you think the current maintenance strategy helps increase the availability of this medical device to provide health care to patients in time?							
Machine	N	Strongly Agree	Agree	Indifferent	Disagree	Strongly Disagree	Total
Dialysis	14	42.9%	35.7%	14.3%	7.1%	0.0%	100%
Cardiac Catheter	7	14.3%	71.4%	14.3%	0.0%	0.0%	100%
Anaesthesia	39	82.1%	12.8%	5.1%	0.0%	0.0%	100%
Defibrillator	72	25.0%	16.7%	58.3%	0.0%	0.0%	100%
Diathermy	16	31.3%	37.5%	31.3%	0.0%	0.0%	100%
BIPAP etc	11	0.0%	9.1%	90.9%	0.0%	0.0%	100%
Ventilator	42	85.7%	2.4%	11.9%	0.0%	0.0%	100%
Infusion Pump	70	20.0%	7.1%	72.9%	0.0%	0.0%	100%
ECG	62	22.6%	6.5%	71.0%	0.0%	0.0%	100%
Electrosurgical	32	25.0%	6.3%	68.8%	0.0%	0.0%	100%
Defibrillator Manual	23	0.0%	13.0%	87.0%	0.0%	0.0%	100%
Nebuliser	28	3.6%	7.1%	89.3%	0.0%	0.0%	100%
Oxygen Concentrator	36	25.0%	8.3%	66.7%	0.0%	0.0%	100%

The survey respondents were asked whether, from their personal experience, the current maintenance strategy is one of the reasons for the unavailability of critical medical equipment. In total, 102 0f the 103 responses were: 0% strongly agreed, 2% agreed, 18% were indifferent, 8% disagreed and 73% strongly disagreed as shown in Table 5-15. These results indicate that nearly 73% of the respondents strongly disagreed that their current maintenance strategy reduces the availability of selected CME.

Table 5-15: Is the current maintenance strategy one of the reasons for the unavailability of critical medical equipment?

Q48, Do you think the current maintenance strategy is one of the reasons for the unavailability of this critical medical device?							
Machine	N	Strongly Agree	Agree	Indifferent	Disagree	Strongly Disagree	Total
Dialysis	15	0.0%	0.0%	26.7%	33.3%	40.0%	100%
Cardiac Catheter	6	0.0%	0.0%	50.0%	0.0%	50.0%	100%
Anaesthesia	38	0.0%	2.6%	13.2%	5.3%	78.9%	100%
Defibrillator	73	0.0%	1.4%	9.6%	8.2%	80.8%	100%
Diathermy	16	0.0%	6.3%	25.0%	18.8%	50.0%	100%
BIPAP etc	11	0.0%	0.0%	0.0%	18.2%	81.8%	100%
Ventilator	40	0.0%	0.0%	2.5%	5.0%	92.5%	100%
Infusion Pump	73	0.0%	1.4%	4.1%	4.1%	90.4%	100%
ECG	62	0.0%	0.0%	4.8%	1.6%	93.5%	100%
Electrosurgical	30	0.0%	0.0%	3.3%	0.0%	96.7%	100%
Defibrillator Manual	23	0.0%	0.0%	8.7%	0.0%	91.3%	100%
Nebuliser	**29**	**0.0%**	**10.3%**	**86.2%**	**3.4%**	**0.0%**	**100%**
Oxygen Concentrator	35	0.0%	0.0%	2.9%	0.0%	97.1%	100%

The survey respondents were asked how often their hospital or department attempted to optimise the amount of maintenance to avoid over-servicing. In total, 102 0f the 103 responses were: 62% very often, 25% often, 2% were occasionally, 3% seldom and 8% never. The results are show in Table 5-16. These results indicate that nearly 87% of the respondents attempted servicing maintenance to their CME.

Table 5-16: Optimising maintenance to avoid over-servicing

Q42: How often do you attempt to optimise the amount of maintenance to avoid over-servicing?						
Equipment	Very often	Often	Occasionally	Seldom	Never	Response %
Kidney dialysis	43%	14%	0%	7%	36%	100%
Catheterisation	38%	38%	0%	0%	25%	100%
Anaesthesia	54%	36%	3%	3%	5%	100%
Defibrillator	58%	31%	3%	3%	6%	100%
Diathermy	13%	53%	7%	13%	13%	100%
BIPAP, CPAP etc.	62%	15%	0%	8%	15%	100%
Ventilator	64%	31%	0%	3%	3%	100%
Infusion pump	75%	21%	3%	0%	1%	100%
ECG Machine	71%	24%	2%	0%	3%	100%
Electrosurgical	74%	26%	0%	0%	0%	100%
Defibrillator Manual	96%	0%	4%	0%	0%	100%
Nebuliser	93%	3%	0%	0%	3%	100%
Oxygen concentrator	68%	32%	0%	0%	0%	100%
Average	62%	25%	2%	3%	9%	100%

5.4.1 Summary

In conclusion the findings in this section are:

- The highest percentage of equipment with no alternative were; 83% for cardiac catheterisation and 64% respironics-BIPAP & CPAP.
- Of the 13 types of CME 5.5% were new, 59% had been used for one to 5 years, and 35.5% had been used for more than five years. Nearly 94.5% of equipment was within the phase of old, obsolescent or depreciated. This means that majority of hospitals needed to decide whether, if want to improve current maintenance strategies or to replace nearly 35.5% of this equipment.
- Substitute equipment is usually borrowed from other hospitals located within LHD.
- Approximately 79% of respondents reported a causal relationship between maintenance strategies and equipment failure.
- A lower rate of availability was found for Respironics: - BIPAP, CPAP at 76% and the infusion pump at 61%.
- The failure rate for some CME was quite high.
- The failure rate seems to be because of human error more than technical reasons or over-use. This is because most of the hospitals, 77%, used an outsourced maintenance strategy, which led to a lack of knowledge and experience of those using this CME.

5.5 Effect upon Patient Outcomes

This section aims to identify to what extent patient outcomes are affected directly and indirectly by CME maintenance management strategies. The results will present how effects range from lack of access or misdiagnosis to injury or death. These results have been generated from data from Questions 16 and 17 in the survey questionnaire. The final result in the Question 16 shows that the degree to which patient outcomes

were affected was 19 % often affected, 57% sometimes affected and 25% never affected[45](Mkalaf, Gibson and Flanagan 2013)

Q17. Please explain how patient outcomes are affected in the box below.

In the survey Question 17 was completed by 10 of the 103 participants. As with all surveys it is impossible to gain 100% completion for all questions. It is assumed that the nature of the question is very sensitive as respondents were asked to report on a topic that may expose malpractice and have a direct impact upon the hospital. As stated earlier in the Chapter 3 *Methodology*, the ethics approval required an amendment to Question 17 which was rewritten to meet the requirements. Despite confidentiality and ethical protection governing this research respondents were still reluctant to provide answers to this question. Further recommendations for research would be to ask this question in an individual or focus group interview. A researcher may be able to probe for more detailed answers in this way rather than using a survey where respondents have the choice of not answering some questions.

Respondents felt the impact on patient outcomes was (1) critical (life-threatening), (2) increased injury and (3) time delays and adverse outcomes, as are featured below:

5.5.1 Patient Lives and Critical Impact

> ***[H5: DD: R1]*** *"*If dialysis machines are not available, we are unable to treat patients. Dialysis is a life-saving treatment*"*.

A respondent from a Renal Unit in H5 was very concerned about the effects on patient's lives because if the dialysis machines are not properly maintained, then dialysis patients cannot be treated which potentially is life-threatening. This result could be transferable to other CME, yet, as described earlier reluctance to discuss patient outcomes has limited the amount of data gained.

[45] Chapter 5, Sections 5.2.2: The majority of issues of current maintenance strategy used that effect on performance of CME, p.191.

> ***[H3: MSMOs: R2]*** "It depends on the defect and machine type. It can be very critical."

Staff Medical Officers (SMOs) from H3 identified that the effects correlate with the machine type but added that it had a more general effect in exposing how critical the effects can be.

> ***[H15: DOS: R2]*** "Two episodes per machine per year affect two patients per year."

An operating suite respondent revealed that, from personal experience, 2 episodes per year on average will affect patients. This is a cause for concern as CME is critical when being used during operations.

5.5.2 Increased Injury

> ***[H10: DS: R2]*** "The Biphasic Defibrillator may be replaced with a monophasic, which may damage the heart more. Infusions measured by nursing staff may sometimes become inaccurate and either have little effect or overdose the patient."

A critical effect of CME failure is that may actually increase an injury to a patient. An example is the biphasic defibrillator as its replacement could potentially cause greater heart damage from this respondent's experience in the surgical unit of H10. An additional concern was human error with measuring infusions, as inaccuracies may lead to machine failure and in the worst case scenario, patient overdose which will increase injury risk to the patient.

> ***[H13: DIC: R3]*** "Any issues associated with critical care medical equipment will relate in some form to more risk to patients than if there were no issues. Depending upon the kind of equipment, unreliability could determine whether a patient needs to be transferred to another facility, thus increasing the risk of an adverse outcome for the patient through delays in appropriate treatment and transport issues."

An intensive care respondent suggested that all CME can potentially create a reisk of injury including delays in treatment and transport issues that hinder access to CME. These are factors exacerbating injury to patients.

5.5.3 Time Delays and Adverse Outcomes

> ***[H2: DCE]*** "[If] the unit [CME] is unable to be repaired [this] means that patient[s are] not treated and [their] discomfort is prolonged*"*.

CME repair time has a ripple effect on patients if they cannot be treated this only prolongs their discomfort and is a predicament for a hospital if patients are suffering when CME has not been properly maintained or repaired in a timely manner.

> ***[H41: DD]*** "Time delay if machines need to be swapped out for repair*."*

A respondent from the haemodialysis unit verified time delays also arise from poor CME maintenance management strategies.

> ***[H15:DIC: R3]*** "It slows provision of acute care results*"*.

When results are urgently needed to verify disease and diagnose treatment, an intensive care unit respondent stated that if CME are not fully operational it slows down health service which is critical in the unit.

> ***[H41: DC: R3]*** "Patients would require re-booking for a respiratory test*"*.

Further re-booking patients prolongs treatment time and has adverse outcomes as the patient is left to deal with a health issue for a longer period of time. This may be not only physically unpleasant but may also have negative psychological effects.

5.6 Maintenance Practices

The survey questionnaire examined management practices for the maintenance of CME to determine any effect on patient outcomes. The results in this section identify for biomedical engineers and their departments essential skills and practices in CME maintenance and an array of methods to manage CME failure and increase availability of equipment. This section includes the major finding for questions related to the maintenance practices used: (1) participation of staff in maintenance decisions, (2) strategies for storing critical spare parts, (3) record keeping of maintenance costs, (4) use of maintenance records to evaluate future maintenance decision making, (5) record keeping of maintenance and subsequent equipment reliability, (6) different methods of record keeping, (7) use of maintenance

management software programs, and (8) improvements in current maintenance management strategies.

5.6.1 Participation of Staff in Maintenance Decisions

In this study, the survey questionnaire asked respondents whether staff was involved in the making of maintenance decisions. These are the results are from Question 18.

*Q18.Are you involved in decision making regarding maintenance policy for critical medical equipment**?***

In this survey 88 of the 103 respondents stated they were involved in decision-making relating to maintenance policies for CME. The results are presented in Figure 5-12 below.

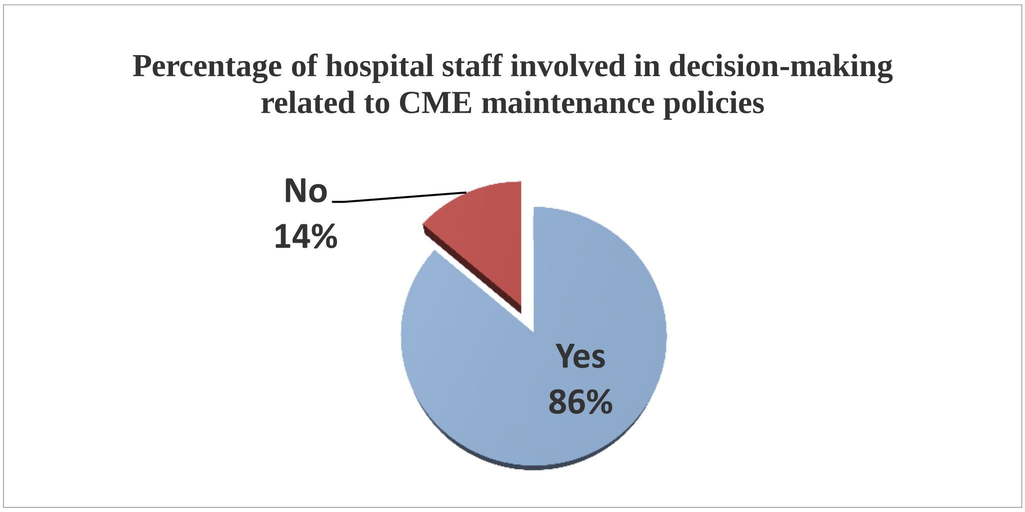


Figure 5-12: Percentage of hospital staff involved in decision-making related to CME maintenance policies

As can be seen in Figure 5-12, the percentage of hospital staff involved in decision-making maintenance was high. This may be attributed to the participants' demographics, as many were senior managers leading the maintenance departments in LHD. For this reason, the results may not be representative of the total distribution of staff across the spectrum working with CME in NSW hospitals. Hence, the contribution of a representative sample of staff involved in maintenance decision making cannot comprehensively be determined by this study.

5.6.2 Strategies for Storing Critical Spare Parts

This section presents results related to critical parts of CME and features the types of strategies used to store and manage critical spare-parts according to hospital requirements. These results have been generated out of data from Questions 19, 20, 21 and 22 in the survey questionnaire.

5.7 Classification of Critical Spare Parts

*Q19. Are there specific parts in this device that are critical and/or fail regularly***?**

In this survey, 102 of the 103 respondents fully completed question 19. The classification of critical parts of CME and those that fail regularly, which were generated from this question, are shown in table 5-17 below.

Table 5-17: Classification of critical parts of the critical medical equipment

Q19: Are there specific parts to this device that are critical and/or fail regularly?						
Equipment	All parts are critical and/or fail regularly	Most parts are critical and/or fail regularly	Some parts are critical and/or fail regularly	Parts are not critical and have redundancy*	Not critical and/or fail regularly	Response %
Kidney dialysis	64%	18%	9%	0%	9%	100%
Catheterisation	50%	38%	13%	0%	0%	100%
Anaesthesia	30%	13%	58%	0%	0%	100%
Defibrillator	17%	13%	26%	44%	0%	100%
Diathermy	53%	0%	27%	20%	0%	100%
BIPAP, CPAP etc.	20%	10%	10%	30%	30%	100%
Ventilator	12%	24%	56%	7%	0%	100%
Infusion pump	7%	13%	3%	75%	3%	100%
ECG Machine	11%	15%	2%	71%	2%	100%
Electrosurgical	11%	18%	0%	71%	0%	100%
Nebuliser	0%	0%	6%	90%	3%	100%
Oxygen concentrator	12%	21%	3%	64%	0%	100%
Average	24%	15%	18%	39%	4%	100%
*machine will still function after failure						

As can be seen the CME whose parts are all critical and most susceptible to fail regularly are kidney dialysis 64%, diathermy 53% and the catherisation 50%. The main reasons for these failures are technical and human error, and to a lesser extent overuse. The frequency of preventative maintenance is insufficient, often only occurring annually and outsourced to an external company. As mentioned above, there are time delays and additional costs associated with this method. Further, the

relationship between CME that fail regularly and the availability of critical spare parts is interesting.

5.8 The Frequency of Availability of Spare Parts

Q20. How often are the critical spare parts readily available?

In this survey, 102 of the 103 respondents fully completed Question 20, and results are plotted in Table 5-18 below.

Table 5-18: shows the percentage of readily available for critical spare parts

Q20: How often are the critical spare parts readily available?						
Equipment	Very often	Often	Occasionally	Seldom	Never	Response %
Kidney dialysis machines	75%	6%	13%	6%	0%	100%
Catheterisation	38%	50%	13%	0%	0%	100%
Anaesthesia	30%	63%	5%	0%	3%	100%
Defibrillator	25%	68%	4%	1%	1%	100%
Diathermy	20%	47%	27%	0%	7%	100%
BIPAP, CPAP etc.	0%	100%	0%	0%	0%	100%
Ventilator	25%	73%	0%	3%	0%	100%
Infusion pump	17%	83%	0%	0%	0%	100%
ECG Machine	20%	79%	2%	0%	0%	100%
Electrosurgical	26%	74%	0%	0%	0%	100%
Defibrillator Manual	0%	95%	5%	0%	0%	100%
Nebuliser	0%	100%	0%	0%	0%	100%
Oxygen concentrator	29%	71%	0%	0%	0%	100%

Overwhelmingly, critical spare parts were readily available for the majority of CME. Only slight concerns were raised about the anaesthesia machine, defibrillator and some other CME. Despite these results appearing optimistic, this is attributed to the perception that critical spare parts are easier to access through outsourced maintenance companies that deal directly with the purchase of these devices. The actual availability of parts for CME that are not outsourced is far more

difficult because many critical spare parts are manufactured overseas. The following question explores why this is so.

Q21. Please explain why there might be difficulty in obtaining parts (e.g., parts not available in Australia) in the box below.

In this survey, 57 of the 103 respondents fully completed Question 21. Although there was a low response rate, the majority stated that it was difficult to obtain critical parts for the following reasons: (1) lack of available critical spare parts in Australia, (2) contract conditions with outsourced maintenance companies, (3) storage problems and (4) accessing difficulties related to the age of CME.

5.8.1 Lack of Available Critical Spare Parts in Australia

In total, 40 out of the 57 respondents indicated that major issues are associated with obtaining CME critical spare parts, the following explanations are representative of the overall responses.

- "Parts are not available in Australia".
- "Waiting for part/item to arrive from overseas."

These responses raise a very serious concern as CME availability is reduced together maintenance time is increased which has a ripple effect upon patient services.

5.8.2 Contract Conditions with the Outsourced Maintenance Companies

Eleven respondents indicated that there were other major issues to explain why it is difficult for hospitals to obtain spare parts. For example some companies have a monopoly and control these parts making access more difficult due to contract conditions.

> "Parts may be difficult to obtain if you deal with companies who do not offer excellent after sales support."

This was also encountered by others who wrote similar explanations. After the sales contract is won, sometimes very poor after-sales support was experienced. The companies were not as enthusiastic about providing support to the client if the CME fails and spare parts are needed.

5.8.3 Storage Problems

Many respondents complained that storage is a reoccurring problem.

- *"Critical spare parts are not kept locally."*
- *"Parts are often not on site and require ordering from other sites around Australia."*

This was attributed to two key factors, storage location and ordering problems. The first being that CME spare parts are often not stored locally on site, as Local Health Districts (LHD) only have one Biomedical Engineering Department that stores these parts. There is also a lack of storage facilities in hospitals, as a very large space is required. So when critical parts are needed, hospitals must wait for the processing and delivery time of these CME parts from the LHD. Further, many hospitals are some distance from the biomedical department and this adds further delays, especially for rural and semi-rural hospitals. Secondly, maintenance policies governing the administration of CME spare parts, also slows down the process of receiving the parts in a timely manner. This generates many problems, as it was reported that when biomedical engineers order mass quantities of CME spare parts, sometimes over ordering occurs. This becomes an issue for several reasons eg the quality of the parts cannot be determined so more parts are ordered than necessary in case of failure. Thus additional storage problems must be faced, e.g. how to house unnecessary or over-ordered quantities of parts. Also, the quality is difficult to check prior to purchasing, particularly if the part is manufactured overseas.

5.8.4 Accessing Difficulties Related to the Age of CME

As the technology of CME is constantly advancing, hospitals that have older machines find it increasingly difficult to access spare parts if the device and its parts are no longer being manufactured.

> *"*As the machinery ages it become obsolete and thus it is increasingly difficult to locate replacement parts*."*

Therefore, the balance between functional CME and the quantity of spare parts required is difficult to assess upon initial purchase. Further, it is hard to predict when this equipment will become outdated or even obsolete. Additionally, if manufacturers of CME are different from the manufacturers of the newer spare parts, they may misalign when fitted onto an older machine, produced by a different company with different standards. Or if these parts are simply no longer being produced the CME is worthless and must be replaced. Hence, a long term management strategy that takes these factors into consideration is vital to avoid unnecessary costs in purchasing and maintaining CME with appropriate spare parts.

Q22. Are the critical spare parts kept in stock by you or your maintenance supplier or do they have to be ordered prior to or after a breakdown?

In this survey, 102 of the 103 respondents fully completed Question 22. The questionnaire asked respondents to identify the location and procedures used to supply hospitals with critical spare parts and what maintenance activities were employed to either repair and/or replace CME. The location and procedures of providing the critical spare parts are classified as; (1) critical spare parts are kept in stock, (2) critical spare parts are ordered prior to breakdowns and (3) critical spare parts are ordered after a breakdown. The results are shown in Table 5-19 below.

Table 5-19: Procedures used to access critical spare parts

Q22: Are the critical spare parts kept in stock by you or your maintenance supplier or do they have to be ordered prior to or after a breakdown?				
Equipment	In stock	Ordered prior to break down	Ordered after breakdown	Response %
Kidney dialysis	54%	8%	46%	108%
Catheterisation	43%	14%	43%	100%
Anaesthesia	82%	5%	13%	100%
Defibrillator	65%	18%	17%	100%
Diathermy	31%	19%	50%	100%
BIPAP, CPAP etc.	36%	9%	55%	100%
Ventilator	88%	5%	8%	100%
Infusion pump	57%	18%	25%	100%
ECG Machine	80%	13%	7%	100%
Electrosurgical	97%	3%	0%	100%
Defibrillator Manual	78%	22%	0%	100%
Nebuliser	93%	7%	0%	100%
Oxygen concentrator	77%	17%	6%	100%
Average	68%	12%	21%	101%

As can be seen in Table 5-19, most critical spare parts are kept in stock. The preventive maintenance strategy of ordering critical spare parts was used for most CME, the only exceptions being the electrosurgical, defibrillator manual and nebuliser. This strategy is used by up to19% for all CME. The least desirable option (to order the CME spare parts after it had broken down) was mostly used for respironics 55%, diathermy 50%, kidney dialysis 46% and catheterisation 43%. If CME spare parts are ordered after a breakdown, further problems arise that are often much more costly. Also the quality and compatibility of these parts cannot be guaranteed and there is often a time delay associated with sourcing, ordering and

waiting for deliveries. If these parts are of poor quality, which is often difficult to assess in advance, it can also lead to an increase in the frequency of sudden breakdown as these parts are inferior or less compatible with the original CME device. This compounds the problem often leading to further complications including additional maintenance and critical spare parts costs. As mentioned before in other sections, any time delays in maintenance may negatively affect patient services and outcomes.

5.8.5 Record Keeping of Maintenance Costs

The survey questionnaire in this study asked the respondents to identify if the hospital department/s in which they worked kept records of maintenance costs. The extent to which these records are used in the decision making process for maintenance strategies were also determined. The following data is from Questions 27, 28 and 29 below.

Q27. How often do you keep records of maintenance costs?

In this survey, 101 of the 103 respondents fully completed Question 27. The breadown of record keeping is presented in Figure 5-13 below. This figure shows, the majority of hospitals kept records of CME maintenance costs, yet surprisingly 10% revealed that it was never undertaken or seldom completed. In the current era of compliance and accountability, this result was very surprising as auditing requirements usually demand records of all expenditure, particularly in government organisations and institutions.

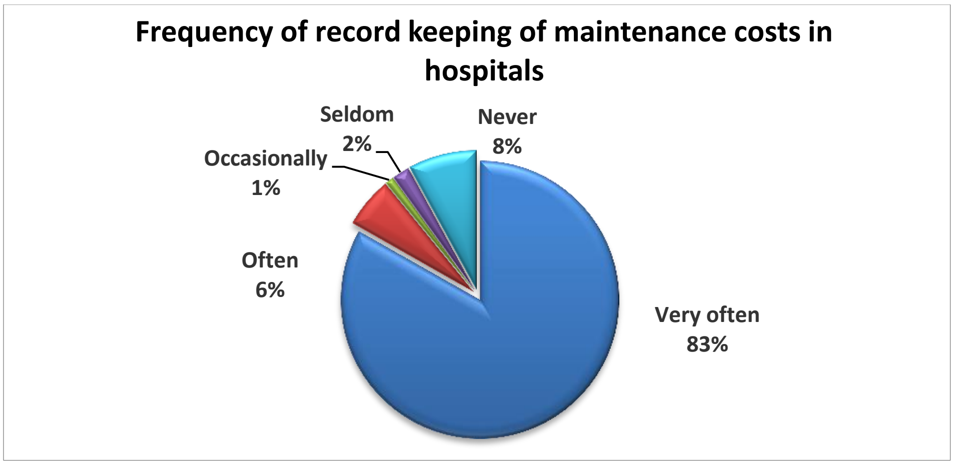


Figure 5-13: Frequency of record keeping of maintenance costs in hospitals

Q28: How detailed are your records?

In this survey, 85 of the 103 respondents fully completed Question 28. The details of respondents' record keeping practices are grouped as follows; (1) type of data stored, (2) database systems, and (3) outsourced by maintenance companies.

The majority of respondents reported they kept in-house records detailing CME maintenance activities and costs.

> *"*Accurate account of work carried out as per manufacturer's specifications and associated costs.*"*

It is reassuring that record maintenance was accurately and diligently occurring. They also identified who was responsible for this;

> *"*We have equipment nurses and biomedical specialists who keep records.*"*

In most cases a biomedical engineer or specialist was responsible for record keeping and there were other references that equipment nurses also assumed this role. The level of responsibility that is required is best suited to an experienced and trained staff member because a sound knowledge of how to accurately keep records is needed. Valuable data is generated from these records. Those selected for this study are the cost and types of management maintenance strategies.

5.9 Types of Data Stored

Respondents reported on the specific type of data they recorded.

- "Cost and sometimes a description of repairs [to an item]."
- "Full details kept."
- "All episodes of repairs and maintenance are kept by the hospital.*"*

The costing and extent of detail recorded, ranged from "sometimes" to "full details" of the repair. These responses suggest there are discrepancies between what data should be recorded and what is actually written, as there are no regulations about the extent to which repairs should be described. This shows that standardised record keeping should be encouraged through training and a stricter adherence to procedures to ensure that consistency between hospitals and maintenance record keeping occurs.

5.10 Database Systems

A number of respondents reported that hospitals used database systems to keep records and details of maintenance activities and costs.

"Rely on database kept at area level."

While database systems were frequently referred to being used, it was difficult to ascertain the extent to which these records were being accurately entered and whether or not staff had been trained in this area. Reliance on databases has its advantages as the information can be more easily stored and shared amongst hospitals and LHD. However, there is a risk that the databases can be destroyed if they are not properly maintained and backup files are not generated.

5.10.1 Outsourcing to Maintenance Companies

Other respondents reported that all repairs and maintenance activities were recorded and kept by the maintenance company to which the work was outsourced.

- "All episodes of repairs and maintenance are kept by the maintenance company."
- "Kept by Dialysis Company".

As a large proportion of respondents confirmed that record keeping is outsourced to contracted maintenance companies, this is a matter of concern as strategies to protect the devices from failure are not being shared with the hospitals who also play a significant role in CME maintenance. For example, kidney dialysis machines are in high demand and the need for functional machines has been emphasised in this study. There were concerns about repeated failure, which may be linked to the maintenance companies not working collaboratively with hospitals because records are kept by the contracted companies. As the maintenance records are not accessible, vital information about factors that potentially reduce failure rates and breakdowns is not being shared. A further complication related to the data collection in this study was that the researcher was unable to access these outsourced records and hence it was not possible to verify some of the hypotheses, without more comprehensive records.

5.10.2 Impact of Maintenance Records on Maintenance Management Strategies

The extent to which maintenance record keeping is evaluated and used to inform future decisions related to CME maintenance management strategies is examined below. The aim is to identify whether hospital administrations use maintenance records to ensure best practice. These results have been generated from data in Question 29.

Q29. How often is the data used for maintenance decisions?

This question asked respondents to report on the frequency that maintenance records are used in CME maintenance decision making. In total, 100 of the 103 respondents fully completed Question 29. The results are presented in Figure 5-14 below.

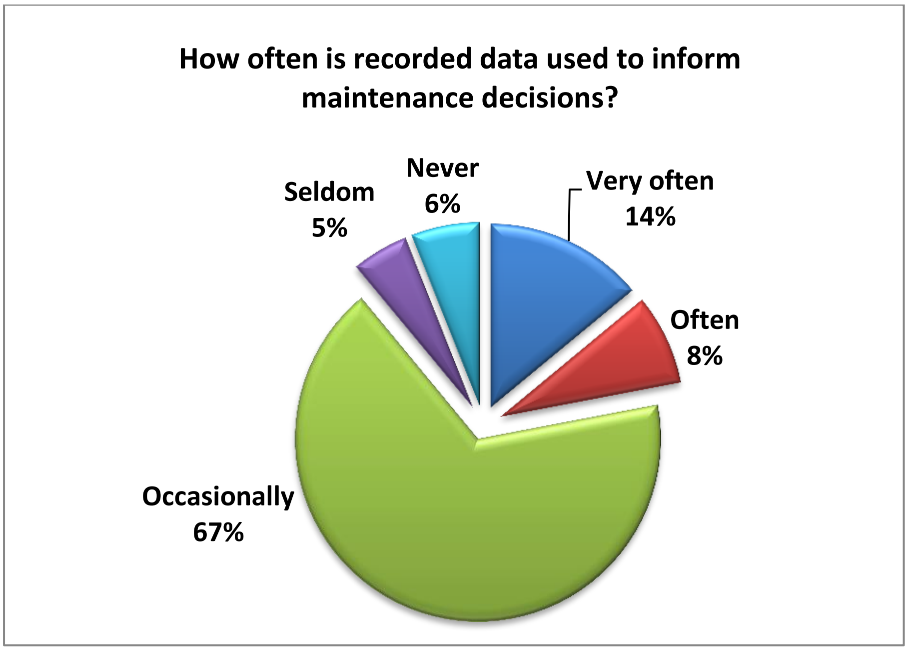


Figure 5-14: How often are data used for maintenance decisions

Surprisingly, the results for the records being frequently used was only 22% (Very Often and Often). This highlights a key problem, as the purpose of record keeping is not only to describe but to show trends and features that will feed back into the system as how to best maintain CME. What is concerning is that 11% of hospital staff Never or Seldom use this data for maintenance decision-making. The greater proportion, 67% of respondents, admitted that these records were only Occasionally

referred to. Unless these records are actively evaluated and used, crucial information will not be factored into future decision making.

5.10.3 Recording of Maintenance and Subsequent Equipment Reliability

This question aimed to discover how often maintenance records were kept about subsequent equipment reliability. These results have been generated out of data from Question 43.

> *Q43. How often do you keep records of maintenance and subsequent equipment reliability?*

In this study, 100 of the103 respondents fully completed Question 43. The results are presented in Table 5-20 below. Table 5-20: Frequency of keeping maintenance records and subsequent equipment reliability

Q43: How often do you keep records of maintenance and subsequent equipment reliability?						
Equipment	Very often	Often	Occasionally	Seldom	Never	Response %
Kidney dialysis	62%	8%	8%	0%	23%	100%
Catheterization	38%	0%	13%	13%	38%	100%
Anaesthesia	82%	5%	5%	3%	5%	100%
Defibrillator	88%	4%	3%	1%	4%	100%
Diathermy	40%	13%	20%	13%	13%	100%
BIPAP, CPAP etc.	82%	9%	0%	0%	9%	100%
Ventilator	97%	3%	0%	0%	0%	100%
Infusion pump	96%	1%	0%	0%	3%	100%
ECG Machine	94%	0%	0%	2%	5%	100%
Electrosurgical	100%	0%	0%	0%	0%	100%
Defibrillator Manual	96%	0%	0%	4%	0%	100%
Nebuliser	93%	0%	0%	0%	7%	100%
Oxygen concentrator	100%	0%	0%	0%	0%	100%
Average	82%	3%	4%	3%	8%	100%

The vast majority kept records of maintenance and equipment reliability, as there were a very high percentage of 'Very Often' responses. The only concerns were with the kidney dialysis at 61.5%. More disturbing was the low level of record keeping for diathermy 40% and catherisation 38%. The reason attributed to this low level of record keeping was because the maintenance of these machines was outsourced.

5.10.4 Different Methods of Record Keeping

This question aimed to identify whether different record keeping was used. The results are produced below from Questions 44.

Q44. How are your records kept?

99 of the 103 respondents fully completed Question 44. The results are presented in Figure 5-15 below.

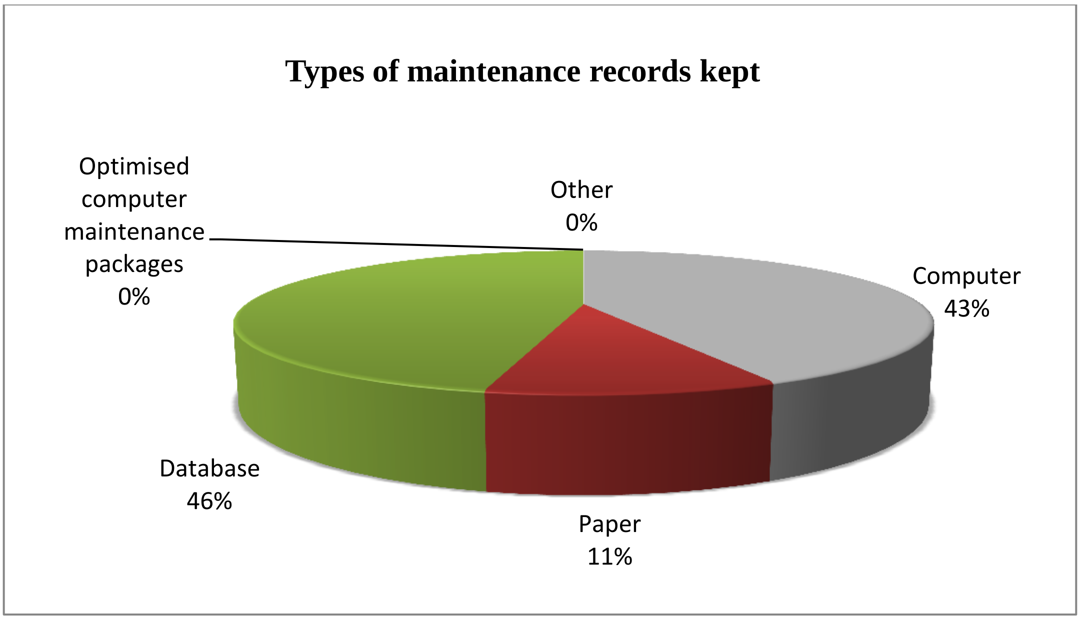


Figure 5-15: Types of maintenance records kept

As confirmed by previous results in this study, database systems were used to keep maintenance records by 46% of the respondents but these were all from only 1 of the 17 LHD which covered more than 80 hospitals. This was closely followed by other computerised methods at 43%. One surprising result was that only 1 LHD reported that they used databases. The vast majority employed electronic methods so it was unforeseen that there would be no consistency in the methods of keeping records. What was also surprising was that no hospital used optimised computer maintenance packages given that these are considered to be a superior method of record keeping. Considering preference was for electronic storage, it would not be difficult to transfer databases and computerised records to optimised programs specialising in maintenance record keeping. Appropriate staff training has been offered but 11% of hospital staff still kept manual paper records of CME maintenance activity, unanticipated in this age of technology.

5.10.5 Use of Maintenance Management Software Programs

This aimed to identify whether hospitals use any maintenance management software programs in order to predict the occurrence of sudden failure of CME and which program is used. These results have been generated out of data from Questions 50 and 51 in the survey questionnaire.

Q50. Do you use any maintenance management software programs in order to predict the occurrence of sudden failure of these [CME] devices?

In this survey, 101 of the 103 respondents fully completed Question 50. The questionnaire asked respondents to identify whether maintenance management software programs are used to predict sudden failure in CME.

Because a large percentage of the respondents were senior managers in hospitals, including biomedical engineers, these results may be inflated and not representative of the actual percentage of staff that use maintenance management software programs to evaluate and anticipate future performance and failure. From the survey 14% of respondents indicated they were using maintenance management software programs to predict sudden failure. This highlights that statistical data from maintenance management records are not being used effectively to reduce sudden failure rates.

Q51. What program is used [for electronic record keeping]?

In this survey, 15 of the 103 respondents fully completed Question 51. The response rate was low for this question and 13 respondents all gave the same answer. It should be noted that they all came from one Local Health District that covers 13 hospitals.

> *"*Utilise equipment Management System (EMS) for all these hospitals.*"*

Another respondent [H14] who was a biomedical manager from another much larger LHD indicated;

> *"*We have our own database.*"*

This result shows that only 2 LHD's from 17 responded. This is a very poor finding in comparison with the number and size of hospitals located in NSW. As the majority, from 1 LHD, revealed they used Equipment Management System EMS

software to manage their record keeping, this suggests that other participants did not respond because they were either not directly involved in data entry or were unaware of the software their department was using.

5.10.6 Improvements in Current Maintenance Management Strategies

This section aimed to identify whether hospitals have any suggestions for improving current maintenance management strategies for CME. These results have been generated from data received from Question 52 in the survey questionnaire.

Q52. Do you have any general suggestions on how to improve current maintenance management strategies in the hospital?

In this survey, 98 of the 103 respondents fully completed Question 52. Of the 98 participants 1 LHD indicated its aim was to improve current maintenance management strategies and that hospitals needed to re-engineer their biomedical engineering departments to maximise involvement in CME maintenance management. One biomedical engineer from a large LHD stated:

> "Increase FTE [Full Time Equivalent] for the Biomedical Engineering Department."

Full Time Equivalent (FTE) is the ratio of paid hours during a period of contract working hours either part or full time, *(www.businessdictionary.com/definition/full).* The respondent [H14] implied that biomedical engineering departments are not being fully funded.

Other responses [H1] indicated the following points;

> "Regular check-ups, [and] maintenance quick fixes of defects".

One respondent noted that PM including regular check-ups resulted in a lower Mean Time between Failures (MTBF). Strategies need to be sought in order to reduce unavailability. This suggestion was from expert maintenance personnel, who had first-hand experience of strategies that actually worked as gauged from their field experience with CME.

Respondent [H73] suggested better management would be achieved by more efficient use of alternative devices during breakdowns/failures, reduce MTBF for

both in-house and outsourced maintenance, and increasing facilities for in-house maintenance.

"Increased availability of borrowed machines when items go for repair or maintenance. More timely service is needed with internal and external suppliers. A space available for on-site maintenance to be provided rather than items sent to major centres away from our hospital".

These recommendations are practical solutions to maximise maintenance outcomes. Increasing the number of borrowed machines or the availability of alternate devices is a good idea. However, cost and storage needs must be evaluated against allocating resources using more effective maintenance management strategies that could possible reduce the number of borrowed machines required. A a significant factor in improving CME maintenance was the reduction of MTBF (Santos *et al.,* 2010). Yet it was noticed by one respondent that is was also necessary to embrace both in-house and outsourced maintenance strategies. While the advantages of in-house CME maintenance management are known, other factors need to also be considered, e.g. space. It is usually very difficult to find surplus space in hospitals. The benefits however of in-house maintenance and its correlation with better MTBF is noteworthy and needs to also be considered when evaluating CME maintenance management strategies.

Staff training was also deemed a factor to assist in improving CME maintenance.

[H2] *"More hospital staff and training to better support the equipment."*

Higher overall demands made on the health service sectors and greater accountability together with increasing the number of trained hospital staff for use of CME equipment are a logical proposal.

As implied from the previous response increasing preventive maintenance is a factor.

[H3-R1] *"Preventative maintenance, prompt fixing, and enough spare parts."*

This is understandable. Competent preventative maintenance factored into procedures and policies is a most effective method of repairing and replacing parts and ensuring the availability of spare parts.

The relationship between external maintenance by outsourced companies and the transparency of their maintenance records of services is proposed.

> **[H10-R2]** *"Service logs of regular maintenance from outsourced service providers."*

Hospitals working on maintenance records collaboratively with external companies leads to a greater awareness of the factors contributing to CME breakdown and failure. However, the questionnaire revealed that many respondents had experienced reluctance from outside companies to share these records. This was confirmed when the researcher's request for access to this information was declined.

Decisions about repairing or replacing out-dated or obsolete CME devices need to be brought forward.

> **[H13-R3]** *"Update CME so that we are not using obsolete equipment."*

As most hospitals have strict budgets, they often face the predicament of choosing between the cost of replacing obsolete equipment and the risk of the equipment failing. There is the uncertainty that this device could be repaired or serviced, particularly if the spare parts are no longer in production. Further, the time delay of sourcing and receiving delivery of an updated device, in the case of obsolete CME replacement, is critical to patient health care outcomes. Hence, budgets need to factor in provision for updating CME.

5.11 Summary

Evaluating the effectiveness of CME maintenance management practices is complex. The relationship between skilled staff and departments, the range and combination of methods used to manage CME failure and increase availability, staff involvement in maintenance decision making, strategies for storing and accessing critical spare parts, record keeping practices, evaluating records for future maintenance decisions, assessing different methods of record keeping, using maintenance management software programs and recommendations from hospital staff for improving current CME maintenance management strategies, all impinge on the process of determining best practice. The correlation between these factors and the quantitative findings from chapter 4 will be synthesised in the subsequent discussion in chapter 6.This section forms much of the backbone of the work in the thesis. To summarise the

findings, it is clear that in the opinion of medical professionals, equipment users and maintainers, there is lack of awareness of state of the art maintenance strategies as used, for example in manufacturing and aerospace industries. It also appears apparent that there is a lack of education in the ways in which CME could potentially be made more available and operated more efficiently using state of the art strategies. It is clear that data capturing on equipment performance is in its infancy and that there is little use and appreciation of the potential of condition based monitoring. In general, data capturing of measured CME performance (E.g. Condition Based Monitoring) is essential to (say) optimised equipment availability an efficient spare parts inventory strategy. This work appears to show that whilst some practitioners are well aware of the issues that result from inefficient maintenance practices, some even reporting loss of human life and serious injury, there is currently little impetus for a major strategic push from senior to improve this situation. The basic premise that equipment performance must be measured before it can be controlled is not well understood. As such, improvements cannot be made and will likely no happen until processes are first measured and controlled.

5.12 Descriptive Analysis

Descriptive statistics are used in this study to identify the mean and frequency of the key variables, such as the dependent variable the maintenance management strategy used for selected critical medical equipment (CME), and the independent variables: failure rate, maintenance practice, reliability, maintenance costs and patient outcomes.

This section aims to investigate:

I. Medical equipment performance
II. Availability of substitutes (back-up) equipment
III. Critical spare parts inventory, supplier and the effects on reliability of CME
IV. Medical equipment reliability
V. The efficiencies of current maintenance strategies and their reliability
VI. Maintenance records
VII. The effect of CME on patient outcomes
VIII. Maintenance Costs

The hypotheses in relation to the aims are:

> *H1: That the current maintenance management strategies for critical medical equipment have an influence on reliability and patient outcomes.*
>
> *H1a: That failure rate of critical medical equipment is influenced by the type of maintenance management strategies.*
>
> *H1b: That the downtime of failed critical medical equipment is influenced by the type of maintenance management strategies used.*

The mean and standard deviations for each survey question relating to practitioners' opinions of the reliability and subsequent outcomes of the failure of CME are presented and considered. To compute the average of each variable (construct), firstly, the total values for all items (CME) for a given construct were calculated. Subsequently, the average of the mean was computed by dividing the total value by the number of items, where N is the number of respondents that answered the questions in relation to each CME type. Maximum and minimum mean the maximum and minimum scores given by a participant in response to the questions on a particular construct. In general, the responses represent the professional opinions of practitioners who use and manage CME. Inferences are then presented in relation to the trends of practitioner thinking and opinion for each question by considering the medians and means of the responses. Standard deviations are considered to be measures of the consistency of opinion in responses for each CME type. It appears that some general trends in practitioner thinking are evident, but variations in standard deviations are also evident for some particular types of CME indicating diversity of opinion in those cases and some major skews in the data.

5.12.1 Medical Equipment Performance

The following questions outline the effective performance of CME selected in this study. This explains the extent of the operational capacity of these devices as follows:

1. Total number of machines available and in use - Question 4,
2. Operation of life of machine - Question 5,
3. Total number of patients per month - Question 6,

4. Average usage time for machines per patient - Question 7
5. Average Treatment Time per Patient per year (ATTPP),
6. Annual Operation Time (OT)

Results shown in the following Table 5- 21 describe the comparison between the results of each of the survey Questions 4, 5, 6 and 7. In this table the range seems very high for a number of CME, which implies that the data is highly skewed. Some hospitals have a very high number of machines and some have very few. Comparison of the results indicates that there is a significant number of patients (Question 6) for the number of machines (Question 4 anaesthesia, ECG and kidney dialysis machines) which appear to be close to the end of their useful life and approaching obsolescence (Question 5). While it seems that the number of machines is acceptable for the number of patients compared to other CME, the mean of usage time per patient is higher for the infusion pump (47 hrs), kidney dialysis (5 hrs) and ventilator machine (4 hrs).

Table 5-21 : Results of Questions 4, 5, 6 and 7

Q4 The total number of units of this device currently in use.						
Equipment	**NH**	**Mean NE per hospital**	**Median**	**Range**	**Min**	**Max**
Infusion pump	**57**	**48.12**	**8.0**	**1092**	**1**	**1093**
Defibrillator	**48**	**04.69**	**1.0**	**122**	**1**	**123**
Ventilator	**25**	**09.04**	**2.0**	**100**	**1**	**101**
ECG machine	**45**	**04.44**	**2.0**	**58**	**1**	**59**
Anaesthesia	**25**	**06.32**	**4.0**	**29**	**1**	**30**
Kidney dialysis	**14**	**13.07**	**14.5**	**24**	**1**	**25**
Q5: Years of service of these devices.						
Equipment	**NH**	**Mean**	**Median**	**Range**	**Min**	**Max**
Anaesthesia	**25**	**2.04**	**2**	**2**	**1**	**3**
Defibrillator	**48**	**2.23**	**2**	**2**	**1**	**3**
ECG machine	**45**	**2.38**	**2**	**1**	**2**	**3**
Infusion pump	**57**	**2.39**	**2**	**2**	**1**	**3**
Ventilator	**25**	**2.20**	**2**	**1**	**2**	**3**
Kidney dialysis	**14**	**2.36**	**2**	**1**	**2**	**3**
		X=2.27				
Where N is Number of Hospitals						
Q6 Average number of patients who are serviced by this device per month.						
Equipment	**NH**	**Mean**	**Median**	**Range**	**Min**	**Max**
ECG machine	**45**	**566.31**	**200**	**11750**	**50**	**11800**
Ventilator	**25**	**328.76**	**150**	**2018**	**2**	**2020**
Anaesthesia	**25**	**403.56**	**300**	**1500**	**100**	**1600**
Infusion pump	**57**	**307.49**	**140**	**1240**	**10**	**1250**
Kidney dialysis	**14**	**462.50**	**443**	**1185**	**15**	**1200**
Defibrillator	**48**	**08.48**	**8**	**49**	**1**	**50**
Q7 Average usage time per patient (hours)						
Equipment	**NH**	**Mean**	**Median**	**Range**	**Min**	**Max**
Infusion pump	**57**	**42.97**	**48**	**47.00**	**1**	**48**
Kidney dialysis	**14**	**5.00**	**5**	**0.00**	**5**	**5**
Ventilator	**25**	**4.00**	**4**	**0.00**	**4**	**4**
Anaesthesia	**25**	**1.80**	**2**	**1.00**	**1**	**2**
ECG machine	**45**	**11.33**	**10**	**5.00**	**10**	**15**
Defibrillator	**48**	**1.29**	**1**	**7.00**	**1**	**8**
Where N is Number of Hospitals						

The following Tables 5-22 and 5-23 show the average treatment time per patient and appear to suggest that the majority of the hospitals have a high average treatment time per patient. Comparison of availability of the number of these machines and the annual operating time indicates a greater diversity of opinion about the types of devices which are being used daily in the treatment of patients.

Table 5-22: Average Treatment Time per Patient

Average Treatment Time per Patient						
Equipment	NH	Mean	Median	Range	Min	Max
Infusion pump	57	11691.43	5760	68588	532.26	69120
Ventilator	25	3577.82	2880	9552	48.00	9600
Anaesthesia	25	2205.52	2880	4704	96.00	4800
Kidney dialysis	14	1724.50	2057	3873	60.00	3933
ECG machine	45	15856.21	14400	40800	2400.00	43200
Defibrillator	48	88.78	60	718	1.95	720

Table 5-23: Annual Operation Time per machine per year

Annual Operating Time per machine (total life in hours)						
Equipment	N	Total hours of use of all machines?	Median	Range	Min	Max
Infusion pump	57	171952.84	69120	717600	2400	720000
Kidney dialysis	14	27750.00	26580	71100	900	900
Anaesthesia	25	9042.24	5760	37200	1200	38400
ECG machine	45	1193.60		23500	100	23600
Ventilator	25	3577.82	2880	9552	48	9600
Defibrillator	48	88.78	60	718.05	1.75	720

5.12.2 Availability of Back-Up Equipment

The following question outlines the availability of spare complete items of CME that can be substituted in the event of unforeseen breakdown. In general 58% of responses to Question 8 indicated that alternatives are not available. The following Table 5-24 describes the frequency of substitutes used. The mean of the means is high (x=3.46) which appears to suggest that in many cases hospitals do have spare CME available. However, in the case of kidney dialysis and ventilator, the standard deviation is higher (above 1) indicating a greater diversity of opinion on the availability and use of those types of back-up CME.

Table 5-24: Results for Question 10

Q10: How often is alternative CME available and used?							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Anaesthesia	**25**	**4.04**	**4**	**0.806**	**3**	**2**	**5**
Ventilator	**25**	**3.92**	**4**	**1.038**	**4**	**1**	**5**
ECG machine	**45**	**3.89**	**4**	**0.689**	**2**	**3**	**5**
Infusion pump	**56**	**3.80**	**4**	**0.644**	**3**	**2**	**5**
Kidney dialysis	**14**	**3.29**	**3**	**1.254**	**4**	**1**	**5**
Defibrillator	**45**	**1.80**	**2**	**0.661**	**2**	**1**	**3**
		X=3.46					
Where N equals the number of valid respondents. The respondents are a measurement of the Likert scale from 5 to 1 where 5 is Very often, 4 is Often, 3 is Occasionally, 2 is Seldom, and 1 is Never.							

5.12.3 Critical Spare Parts Inventory, Suppliers and the Effects on Reliability

In this study, the measurement elements are strategies for storage and supply of critical spare parts. The relevant data has been collected from Questions 19 and 33. The following Table 5-25 describes suitable strategies for the provision and storage of critical spare parts.

Table 5-25: Results for Question 19

Q19: Are there specific parts to this device that are critical and/or fail regularly?							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Infusion pump	**57**	**2.16**	**2**	**0.751**	**5**	**0**	**5**
Kidney dialysis	**14**	**4.13**	**5**	**1.458**	**4**	**1**	**4**
Defibrillator	**48**	**2.85**	**2**	**1.111**	**3**	**2**	**5**
ECG machine	**44**	**2.18**	**2**	**0.620**	**3**	**2**	**5**
Ventilator	**25**	**3.16**	**3**	**0.554**	**3**	**2**	**5**
Anaesthesia	**25**	**3.24**	**3**	**0.663**	**2**	**3**	**5**
Where number values relate a Likert scale from 1 to 5, where 5 is all parts are critical and/or fail regularly, 4 is most parts are critical and/or fail regularly, 3 is some parts are critical and/or fail regularly, 2 is parts are not critical and have redundancy (machine will still function after a failure), and 1 is not critical and/or fails regularly.							

As can be seen in Table 5-25, it appears that kidney dialysis machines have parts that are critical (Median=5 all parts are critical and/or fail regularly). The low SD seems to support that this is a common opinion. At the other extreme, almost the opposite is true of the ECG and the ventilator machines.

Responses to Question 22 identified the replacement parts policy used in the event of failure of CME.

- Generally, duplicate machines are kept for substitution in the event of ECG failure.
- Respondents suggested that there are some machines, e.g. kidney dialysis where failure of parts is critical.
- Although availability of spare parts is supposedly guaranteed, even for the most critical machines, it is more likely that parts are unavailable.

As can be seen in the following Table 5-26, hospitals need to use duplicate equipment from 4 (hospitals need to use substitute delicate equipment 75% of the time (e.g. the kidney dialysis machine) to zero ie never use substitute equipment (eg defibrillator, ECG and ventilator machines).

Table 5-26: Results for Question 33

Q33: How often do you need to substitute duplicate equipment?							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Kidney dialysis	**14**	**1.64**	**1**	**1.206**	**4**	**1**	**5**
Anaesthesia	**25**	**1.32**	**1**	**0.690**	**3**	**1**	**4**
Infusion pump	**57**	**1.14**	**1**	**0.515**	**3**	**0**	**3**
Defibrillator	**46**	**1.11**	**1**	**0.315**	**1**	**1**	**2**
ECG machine	**45**	**1.11**	**1**	**0.318**	**1**	**1**	**2**
Ventilator	**24**	**1.17**	**1**	**0.381**	**1**	**1**	**2**
		X=1.25					
Number values relate to a Likert scale from 1 to 5, where 1 is zero% of the time, 2 is 25% of the time, 3 is 50% of the time, 4 is 75% of the time, and 5 is more than 75% of the time							

5.12.4 Medical Equipment Reliability

This section aims to investigate the reliability of CME in terms of the number of equipment failures per year (Question 23, FR, and MTBF), whether this device fails while in service (Question 25), number of the failures over the last 5 years (Question 26) and reasons for failure (Question 24).

- The hypotheses in relation to this aim are: -

H1: That the current maintenance management strategies for critical medical equipment have an influence on reliability and patient outcomes.

H1a: That failure rate of critical medical equipment is influenced by the type of maintenance management strategies.

H1b: That downtime of failed critical medical equipment is influenced by type of maintenance management strategies.

The following Table 5-27 describes the number of failures, failure rates and MTBF of CME. It appears that FR and MTBF were highest in the case of the kidney dialysis and ventilator machines. The number of machine failures while in services is considered in Figure 5-7[46]. This shows that most of these machines failed at the same time during the 5 years 2007-2011. Furthermore this section aimed to identify common reasons for failure of CME. The data in Figure 5-16 appear to suggest that a large number of this CME commonly fail due to human error rather than technical error or over-use.

Table 5-27: Results for Question 23: Failure rate and MTBF

Q23: If this equipment ever fails; please indicate how many times per year in your experience?

Equipment	N	Mean	Median	SD	Range	Min	Max
Kidney dialysis	**14**	**19.64**	**12**	**26.401**	**95**	**1**	**96**
Defibrillator	**48**	**1.88**	**1**	**4.532**	**30**	**0**	**30**
Anaesthesia	**25**	**2.96**	**2**	**2.389**	**11**	**1**	**12**
Infusion pump	**57**	**4.90**	**4**	**3.282**	**11**	**1**	**12**
Ventilator	**25**	**1.60**	**1**	**1.225**	**6**	**0**	**6**
ECG machine	**45**	**2.42**	**2**	**1.357**	**5**	**1**	**6**

[46] Figure 5-7: Average number of machine failures while providing health care to patients, p.199.

Table 5-27: Results for Question 23: failure rate and MTBF(cont)

Equipment	N	Mean	Median	SD	Range	Min	Max
Failure Rate							
Ventilator	**25**	**2806.49**	**121.53**	**12207.15**	**62500**	**0.00**	**62500**
Kidney dialysis	**14**	**1890.91**	**725.05**	**3307.928**	**12486**	**14.00**	**12500**
Anaesthesia	**25**	**0.653**	**0.347**	**0.828**	**3.255**	**0.078**	**3.333**
Infusion pump	**57**	**0.00097**	**0.00069**	**0.00111**	**0.0056**	**0.00003**	**0.00564**
Defibrillator	**48**	**14612.79**	**10416.67**	**22311**	**125000**	**0.00**	**125000**
ECG machine	**45**	**5805.25**		**4429.748**	**19958**	**42.37**	**20000**
MTBF							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Kidney dialysis	**14**	**9118.04**	**1925**	**19252.03**	**71920**	**80.00**	**71920**
Ventilator	**24**	**10631.33**	**8400**	**10909.35**	**47984**	**16.00**	**48000**
Infusion pump	**57**	**3184.79**	**1440**	**4734.088**	**28623**	**177.42**	**28800**
Anaesthesia	**25**	**3801.44**	**2880**	**3076.108**	**12500**	**300.00**	**12800**
ECG machine	**45**	**855.54**		**3508.078**	**23550**	**50.00**	**23600**
Defibrillator	**38**	**105.08**	**96**	**110.497**	**592**	**8.00**	**600**

Where time measured for all machines is per hour with the exception of the defibrillator and ECG measured per second.

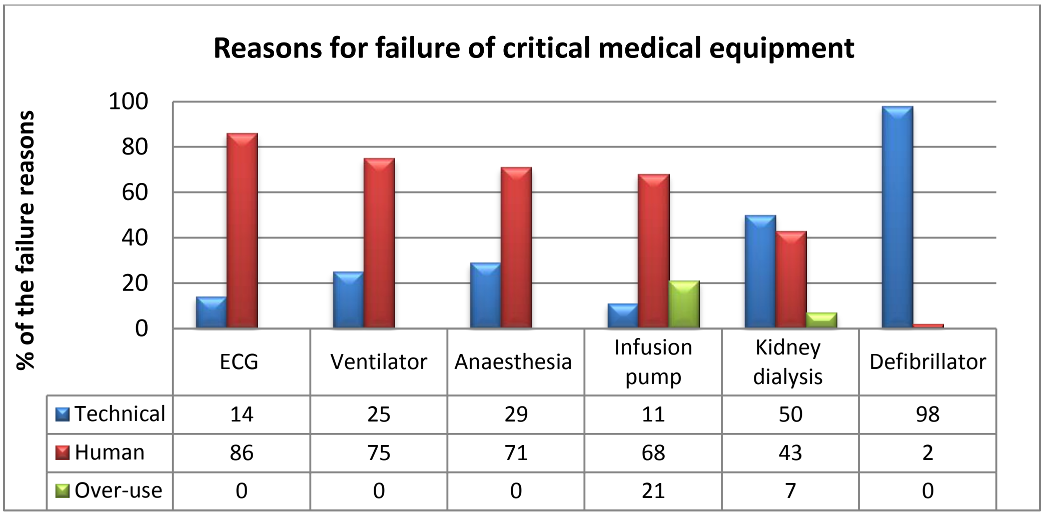


Figure 5-16: Reasons for the failure of the critical medical equipment

5.12.5 Efficiency and Reliability using Current Maintenance Strategies

The aim in the following section was to further investigate current maintenance strategies in relation to critical medical equipment reliability. Data was collected from Questions 37, 38, 41, 42, 43, 46, 47, 48 and 49. The following Table 5-28 shows whether current maintenance strategies help increase the availability of CME to provide timely health care. It appears that the mean of means is high (102.42, 15, 93, respectively; Q37, Q38), indicating a strong belief by respondents that CME becomes unavailable to treat a patient when a hospital is carrying out in-house maintenance. The high standard deviation of all CME indicates consistent views of practitioners in most types of CME

Table 5-28: Results for Questions 37 and 38

Q37: If maintenance is carried out in- house, how long is the device unavailable on average (per day/month)?							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Infusion pump	**57**	**329.39**	**360.00**	**101.194**	**384**	**0**	**384**
Defibrillator	**45**	**90.87**	**96.00**	**52.035**	**360**	**0**	**360**
ECG machine	**45**	**51.36**	**48.00**	**48.543**	**360**	**0**	**360**
Kidney dialysis	**13**	**73.85**	**72.00**	**57.518**	**216**	**24**	**240**
Ventilator	**24**	**36.08**	**24.00**	**37.368**	**166**	**2**	**168**
Anaesthesia	**24**	**33.00**	**24.00**	**21.009**	**72**	**24**	**96**
Q38: How often does the medical device become unavailable for treating patients who require its service? (times per month)							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Infusion pump	**57**	**34.05**	**24**	**44.964**	**168**	**0**	**168**
Defibrillator	**46**	**9.13**	**0**	**16.158**	**72**	**0**	**72**
Kidney dialysis	**13**	**33.31**	**24**	**33.200**	**72**	**0**	**72**
ECG machine	**45**	**5.93**	**2**	**10.015**	**48**	**0**	**48**
Anaesthesia	**25**	**6.76**	**4**	**9.225**	**24**	**0**	**24**
Ventilator	**23**	**6.39**	**2**	**9.590**	**24**	**0**	**24**

The following Table 5-29 shows the measurement of CME reliability used to evaluate the maintenance strategy. The mean of means seems high (1.95, 1.94, 1.99 and 1.99 for unavailability, FR, MTTR and MTBF respectively) and the SD is low for all reliability measurement elements (less than 1). However in this study the majority of hospital practitioners indicated that they do not measure CME reliability to evaluate their maintenance management strategy.

Table 5-29

Q46: Do you use measures of critical medical device reliability to evaluate your maintenance policy?

Q46.1 Unavailability Measurement		
Equipment	**N**	**Yes**
Anaesthesia	**25**	**2**
Defibrillator	**46**	**1**
ECG machine	**45**	**0**
Infusion pump	**57**	**3**
Ventilator	**24**	**0**
Kidney dialysis	**13**	**2**
Q46.2 FR Measurement		
Equipment	**N**	**Yes**
Anaesthesia	**25**	**1**
Defibrillator	**46**	**2**
ECG machine	**44**	**1**
Infusion pump	**57**	**5**
Ventilator	**24**	**1**
Kidney dialysis	**13**	**2**
Q46.3 MTTR measurement		
Equipment	**N**	**Yes**
Anaesthesia	**25**	**0**
Defibrillator	**46**	**0**
ECG machine	**45**	**0**
Infusion pump	**57**	**2**
Ventilator	**24**	**0**
Kidney dialysis	**12**	**0**
Q46.4 MTTB measurement		
Equipment	**N**	**Yes**
Anaesthesia	**25**	**0**
Defibrillator	**46**	**0**
ECG machine	**45**	**0**
Infusion pump	**57**	**2**
Ventilator	**24**	**0**
Kidney dialysis	**12**	**0**

5.12.6 Maintenance Records

The aim of this study was to investigate whether hospitals kept adequate maintenance records. In Table 5-30 Question 27 outlines how hospitals keep records of maintenance costs. Question 27 also investigates the hospital administration's use of maintenance records in their maintenance decision-making. Practitioners indicated that hospital departments are keeping accurate maintenance records; the mean of the mean is higher (4.29). However, there were high SDs for the defibrillator, ventilator and kidney dialysis machines. This demonstrates that hospitals kept records of maintenance costs for their equipment and in addition investigated how the frequency of maintenance data affects maintenance decisions (Question 29). As shown in Table 5-30 the mean of means are high (3.013), indicating the frequency of use of maintenance data in maintenance decision making. However, the SD was low for all CME. This highlighted inefficient data recording for maintenance decision-making.

Table 5-30: Results for Questions 27 & 29

Q27: How often do you keep records of maintenance costs?

Equipment	N	Mean	Median	SD	Range	Min	Max
Anaesthesia	**25**	**2.64**	**3**	**0.700**	**2**	**1**	**3**
Defibrillator	**48**	**4.63**	**5**	**1.024**	**4**	**1**	**5**
ECG machine	**45**	**04.7**	**5**	**0.895**	**4**	**1**	**5**
Infusion pump	**57**	**4.72**	**5**	**0.996**	**5**	**0**	**5**
Ventilator	**23**	**4.52**	**5**	**1.159**	**4**	**1**	**5**
Kidney dialysis	**13**	**4.54**	**5**	**1.127**	**4**	**1**	**5**

N is the number of valid responses displayed as a measurement of the Liker scale from 5 to 1, where 5 is Very often, 4 is Often, 3 is Occasionally, 2 is Seldom, and 1 is Never.

Q29: To How often maintenance data are used in make maintenance decisions

Equipment	N	Mean	Median	SD	Range	Min	Max
Anaesthesia	**25**	**3.04**	**3**	**0.539**	**3**	**2**	**5**
Defibrillator	**48**	**3.04**	**3**	**0.658**	**4**	**1**	**5**
ECG machine	**45**	**2.93**	**3**	**0.402**	**3**	**1**	**4**
Infusion pump	**57**	**2.96**	**3**	**0.706**	**5**	**0**	**5**
Ventilator	**23**	**2.92**	**3**	**0.504**	**3**	**1**	**4**
Kidney dialysis	**13**	**3.15**	**3**	**0.801**	**3**	**2**	**5**

N is the number of valid responses displayed as a measurement of the Liker scale from 5 to 1, where 5 is Very often, 4 is Often, 3 is Occasionally, 2 is Seldom, and 1 is Never.

5.12.7 The Effect of CME Maintenance Practices on Patient Outcomes

The aim of this section is to investigate (1) how patient outcomes are affected by maintenance issues (2) how patients are affected by breakdowns in equipment (eg death, injury or misdiagnosis) (3) the level of risk to patients posed by the failure of CME while in use.

The research question and hypothesis to achieve this aim are:

> Q3: *What kind of maintenance management strategies could be used to increase equipment availability and decrease the cost of ownership while achieving the desired level of patient outcomes?*
>
> *H1d: That patient outcomes serviced by the critical medical equipment is influenced by the type of maintenance management strategies*

5.12.7.1 Patient Outcomes Affected by Maintenance Issues

In this study investigation was conducted to establish whether there were any particular issues/problems in keeping CME properly maintained and if these issues affected patient outcomes through a breakdown when CME was in use. The following Table 5-31 outlines the final result.

Table 5-31: Patient outcomes affected by maintenance issues

Q16: If there are issues, does this affect patient outcomes?							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Anaesthesia	**24**	**2.13**	**2**	**0.537**	**2**	**1**	**3**
Defibrillator	**47**	**1.62**	**2**	**0.610**	**2**	**1**	**3**
ECG machine	**45**	**2.04**	**2**	**0.737**	**3**	**0**	**3**
Infusion pump	**57**	**2.16**	**2**	**0.560**	**3**	**0**	**3**
Ventilator	**24**	**1.79**	**2**	**0.509**	**2**	**1**	**3**
Kidney dialysis	**14**	**1.00**	**1**	**0.000**	**0**	**1**	**1**
N relates to ordinal values from 3 to 1, where 3 is often affected, 2 is sometimes affected, and 1 is never affected							

Table 5-31 shows the mean of means is high (1.79), indicating that there are maintenance issues affecting patient outcomes, although the standard deviation is low (less than 1). This highlights a risk to patients if this equipment breaks down while in use.

5.12.7.2 Death, Injury And Misdiagnosis caused by Breakdown of Equipment

This investigative study looked at (1) whether patient outcomes were affected in the case of non-availability of a medical device (2) the experiences of breakdowns of CME, which may have been the cause of accidents and compromised patient-outcomes causing death, injury or misdiagnosis.

The following Table 5-32 outlines the results. The effects range from death through breakdowns in infusion pumps while in use, injury from anaesthesia, defibrillator and ventilator machines and misdiagnosis by ECG machines. The additional aim of this study was to identify the level of risk to patients posed by the failure of CME as shown in Table 5-33. The range indicated a high level of risk of death to patients posed by breakdown of the infusion pump and ventilator machines while in service. Kidney dialysis was rated as a high level risk of injury and it has the highest level of misdiagnosis of this CME.

Table 5-32**:** Patient outcomes affected by maintenance practices

Q34: In your experience, do you know of cases in hospitals, where patient outcomes have been affected by the breakdown of critical medical equipment?							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Infusion pump	**57**	**1.05**	**1**	**0.838**	**4**	**0**	**4**
Anaesthesia	**22**	**1.32**	**1**	**0.690**	**3**	**1**	**4**
Defibrillator	**44**	**1.20**	**1**	**0.668**	**3**	**1**	**4**
Ventilator	**24**	**1.23**	**1**	**0.752**	**3**	**1**	**4**
ECG machine	**42**	**1.10**	**1**	**0.431**	**2**	**1**	**3**
Kidney dialysis	**14**	**1.00**	**1**	**0.000**	**0**	**1**	**1**
N values displayed relate to "nominal data" from 1 to 4, where 1 is not at all, 2 is misdiagnosis, 3 is injury, and 4 is death.							

Table 5-33 Level of risk to patients posed by failure of equipment while in use

Q35: In your experience, do you know of cases in hospitals, where patient outcomes have been affected by the breakdown of critical medical equipment?								
	Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Death	**Ventilator**	**24**	**3.33**	**4**	**1.523**	**4**	**0**	**4**
	Kidney dialysis	**13**	**1.69**	**1**	**1.494**	**4**	**0**	**4**
	ECG machine	**45**	**0.91**	**1**	**0.793**	**4**	**0**	**4**
	Infusion pump	**56**	**3.16**	**3**	**0.496**	**3**	**1**	**4**
	Anaesthesia	**25**	**1.00**	**1**	**0.288**	**2**	**0**	**2**
	Defibrillator	**46**	**3.94**	**4**	**0.323**	**2**	**2**	**4**
	Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Injury	**Kidney dialysis**	**13**	**1.62**	**1**	**1.758**	**4**	**0**	**4**
	Defibrillator	**47**	**3.00**	**4**	**1.549**	**3**	**1**	**4**
	Ventilator	**24**	**0.13**	**0**	**0.612**	**3**	**0**	**3**
	Infusion pump	**57**	**0.12**	**0**	**0.537**	**3**	**0**	**3**
	Anaesthesia	**25**	**0.20**	**0**	**0.500**	**2**	**0**	**2**
	ECG machine	**45**	**0.02**	**1**	**0.149**	**1**	**0**	**1**
	Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Misdiagnosis	**ECG machine**	**45**	**2.39**	**4**	**2.526**	**4**	**0**	**4**
	Anaesthesia	**25**	**0.16**	**0**	**0.800**	**4**	**0**	**4**
	Kidney dialysis	**13**	**0.69**	**0**	**1.182**	**4**	**0**	**4**
	Ventilator	**24**	**0.32**	**0**	**0.945**	**4**	**0**	**4**
	Defibrillator	**47**	**1.75**	**1**	**1.500**	**3**	**1**	**4**
	Infusion pump	**57**	**0.09**	**0**	**0.434**	**3**	**0**	**3**
N values displayed relate to "nominal data" from 4 to 1, where 4 is High, 3 is Middle, 2 is Low, and 1 very low.								

5.12.8 Maintenance Costs

Another aim of this study was to compare costs for in-house or outsourced maintenance. The hypothesis relating to this is:

H1c: That cost of ownership of critical medical equipment is influenced by the type of maintenance management strategies

The following Tables 5-34, and 5-35 outline the final results. The mean of the mean is higher ($181.68, $97.23, $21.607.64 for Q30, Q31, Q53 respectively). In the case of the anaesthesia, infusion pump, kidney dialysis and ECG machines the SD was difficult to compare between their final results because of a lack of maintenance cost data resulting in very small sample sizes shown (Question 30 and 53).

Table 5-34: In-house and outsourced maintenance costs per month

Q30 Please estimate the total maintenance costs per month (in terms of either or both $ or downtime) when it is carried out in-house for the following equipment.							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Anaesthesia	**1**	**$226.45**	**$226.45**	**---------**	**$0.00**	**$226.45**	**$226.45**
Defibrillator	**3**	**$289.35**	**$285.52**	**$51.477**	**$102.74**	**$239.89**	**$342.63**
ECG machine	**3**	**$109.91**	**158.9**	**$92.694**	**$164.83**	**$3.00**	**167.83**
Infusion pump	**1**	**$83.27**	**$83.27**	**$158.9**	**0.00**	**$83.27**	**$83.27**
Ventilator	**3**	**$60.12**	**$33.10**	**$46.991**	**$81.50**	**$32.88**	**$114.38**
Kidney dialysis	**2**	**$267.50**	**$267.50**	**$287.792**	**$407.00**	**$64.00**	**$471.00**
		X=$181.68					
Q31: Please estimate the total maintenance costs (in terms of either or both $ or downtime) when it is outsourced for the following equipment (per month).							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Anaesthesia	**21**	**$97.94**	**$60.00**	**$137.891**	**$657.80**	**$15.52**	**$673.32**
Defibrillator	**38**	**$65.64**	**$38.13**	**$127.126**	**$795.29**	**$13.00**	**$808.29**
ECG machine	**41**	**$50.41**	**$23.22**	**$86.985**	**$520.34**	**$9.10**	**$529.44**
Infusion pump	**50**	**$15.39**	**$10.03**	**$15.582**	**$95**	**$5**	**$100**
Ventilator	**21**	**$81.98**	**$32.00**	**$135.038**	**$535.39**	**$1.00**	**$536.39**
Kidney dialysis	**3**	**$272.01**	**$121.04**	**$284.343**	**$505.00**	**$95.00**	**$600.00**
		X=$97.23					

Table 5-35: Annual maintenance cost

Q53: Please estimate the maintenance costs per year of the medical devices listed.							
Equipment	**N**	**Mean**	**Median**	**SD**	**Range**	**Min**	**Max**
Anaesthesia	**25**	**$27,914.75**		**$62,664.965**	**$232,761.35**	**$45.65**	**$232,807.00**
Defibrillator	**41**	**$609.87**	**$439.91**	**$567.718**	**$3,270.25**	**$156**	**$3,426.25**
ECG machine	**45**	**-----**	**------**	**------**	**------**	**------**	**-------**
Infusion pump	**57**	**$200.04**	**$121.32**	**$185.604**	**$939.82**	**$59.40**	**$999.22**
Ventilator	**20**	**$57,705.91**	**$827.00**	**147166.382**	**$643,522.36**	**$146.64**	**$643,669.00**
Kidney dialysis	**04**	**$3,636.50**	**$3,103.00**	**$2,883.59087**	**$6,060.00**	**$1,140.00**	**$7,200.00**
		X= $ 18,013.41					

Note: There is an apparent discrepancy in total maintenance costs between Questions 30, 31 and 53. Question 53 was asked in the context of Reliability Centred Maintenance, which is longer term and therefore a much more inclusive view of maintenance strategy. As expected in Q30/Q31 respondents reflected a short term view of immediate needs and in Q53 ignored a wider range of ownership costs beyond direct monthly maintenance costs for immediate breakdown or prevention. It

is likely that major long term scheduled maintenance costs are not included in Q30 and 31 and respondents have responded only to immediate scheduled maintenance needs. This is often a focus for cost cutting and it seems likely that immediate outsourced costs and in-house costs are significantly lower than total costs because they do not include long term preventive maintenance. However assuming that Q30/31 compares similar short term maintenance tasks, it is notable that respondents found in-house maintenance significantly more expensive that outsourced.

5.12.9 Summary

Through a comprehensive survey of results it was found that the majority of hospitals prefer to maintain their CME (selected in this study) by outsourcing maintenance rather than using in-house maintenance. The most significant correlation were PM and Mixed Maintenance strategies, whether the hospitals carried out their maintenance in-house or it was outsourced. The experiences of CMMS for most participants was (1) it does not help to increase the availability of anaesthesia and defibrillator machines (2) whether their strategy helped to increase availability of the ventilator machine was unclear (3) this strategy however is one reason for unavailability of this CME with the exception of the infusion pump machine (4) this helps to reduce the failure rate of the CME (5) this significant strategy does not reduce the sudden failure of the anaesthesia, ventilator, and kidney dialysis machines. The majority of the hospitals surveyed rarely use reliability measurement in terms of unavailability, FR, MTTR, and MTBF. Unavailability measurement was used in 15% of kidney dialysis, 5% of anaesthesia, 4% of defibrillator and 2% of ECG machines; FR measurement was used in 25 % of anaesthesia, 21% of defibrillator, 21% ventilator, 17% infusion pump, 18% ECG and 15% of kidney dialysis machines. *MTTR* was used only 1.4% in maintaining the defibrillator.

(1) Of 14 hospitals statistically analysed, the responses indicated there are only 4 hospitals with an alternate kidney dialysis machine, with a highly significant correlation variation between the variables. Ten of these 14 hospitals had encountered a direct impact on patient health services. From a total, of 183 dialysis machines, it was found the median operating time was 2658 times per year, with a median FR of 725 per one thousand hours, median MTBF of 1925 hours. This means that more than half the patients that are affected by

equipment failure cannot access alternative equipment. The responses showed that this machine failed 20 times in the 5 years 2007-2011. This study also indicated the level of risk to patients on this machine. There is a high level (18%) risk of **death,** a high level risk of **injury (**44%) and a high level of risk of **misdiagnosis (**33%) if the kidney dialysis machine failed while in use.

(2) Responses from the 25 hospitals statistically analysed indicated that there are only 8 hospitals with an alternate anaesthesia machine, with a highly significant correlation between the variables. Five hospitals surveyed experienced a direct impact on patient health services. From a total of 158 anaesthesia machines the median operational time was 5760 hours per year, a median FR of 0.35 per one thousand hours and a median MTBF of 2880 hours. This means that 71% of patients may be affected by anaesthesia machine failure cannot access alternate equipment as this machine has failed 60 times in the 5 years 2007-11 while in use. This study also indicates that there are significant findings for the level of risk in relation to the patients:, a high level 65% of death risk, a high level 50% of injury risk and a very low level 67% of misdiagnosis risk if the anaesthesia machine failed while in service.

(3) Of 57 hospitals there are only 26 hospitals with an alternative infusion pump machine, with a highly significant correlation between the variables. In 13 of the 57 hospitals surveyed this had a direct impact on patient health services. From a total of 2743 infusion pump machines in use, the median operating time was 69120 hours per year, the median FR of 58.87 per one thousand hours and the median MTBF of 17280 hours. This means that 46% of the patients that

may be affected by the failure of this machine cannot access alternative equipment as this machine has failed 12 times over the 5 years 2007-11 while in use. This study also indicates there is a significant finding for level of risk: there is a high level of risk 17% deaths, 25% injuries and 60% medial level of misdiagnosis if this machine failed while in use. The responses reported that there were cases of death in the hospitals while this device was in service.

CHAPTER 6: QUANTITATIVE RESULTS

6.0 Introduction

This chapter provides the results obtained from the statistical analysis of the survey data. The chapter includes the data analysis methods, and the analysis of results according to the research questions and hypotheses. The results are examined; then the significant findings and relationships between Failure Rate (FR) and MTBF with the five variables set out in the conceptual framework of the maintenance management strategy are discussed[47]. These variables are:

- Maintenance strategy,
- Maintenance practices,
- Maintenance performance,
- Maintenance costs, and
- Patient outcomes.

Three types of maintenance strategies for CME were identified in 84 Public Hospitals located in 17 different Local Health Districts. It was found that 72.2% used outsourced maintenance strategies, 15.9% used in-house maintenance strategies and 11.9% used a mixed maintenance strategy.

6.1 Correlation Analysis and Causality

The well-known Pearson correlation coefficient is used to determine the statistical relationships between Failure Rate (FR) and other variables. Where the other variable is a dichotomous variable (for example, a Yes/No variable) that special case of the Pearson correlation coefficient is known as a point-biserial correlation coefficient. For small sample sizes the 5% critical values used for significance testing differ slightly from those where two metric variables are involved. These critical values have been tabulated and are widely available. If the sample size is greater than 41 the two critical values are identical to two decimal places. The magnitude of the correlation coefficient indicates the strength of the statistical relationship between two variables. Classification of strength of relationship into “weak”, “strong”, etc. is somewhat subjective. .In this chapter the ranking proposed by Dancey and Reidy (2004) is used with correlation coefficients rounded to 1 decimal place, namely:

---

[47] Chapter 3, Section 3.3; Theoretical and Conceptual Framework, Figure 3-1, p. 135, Figures 3-2, p136 and Figure 3-6, p.144.

- A correlation of magnitude 1 indicates a **perfect** relationship, that is, an exact linear relationship.
- A correlation of magnitude 0.7 to 0.9 indicates a **strong** relationship.
- A correlation of magnitude 0.4 to 0.6 indicated a **moderate** relationship.
- A correlation of magnitude 0.1 to 0.3 indicates a **weak** relationship, and we can be confident that the population value of that correlation coefficieny is small and thus does not indicate an important causal relationship.
- A correlation of magnitude 0 indicates **no relationship**.

As well as strength and direction of a relationship between two variables the statistical significance of the calculated r-value needs to be considered. This is measured by the p-value which is the probability that a calculated r-value at least as large as that obtained from the sample could have arisen through random sampling variability from a population in which the true r-value is zero. Correlation coefficients with a p-value of 0.05 or less are generally considered to be statistically significant. However, statistical significance does not equate with causal importance. If the sample size is large, even weak correlations can be statistically significant but in that case the 95% confidence limits for the population value of that correlation coefficient are close to the calculated sample value. So we can be confident that the population correlation coefficient is also small and thus does not indicate an important causal link between the two variables.

Finally, even a strong correlation between two variables does not necessarily indicate a causal relationship. Additional data from the system under study or additional information from theoretical models is needed to identify causal relationships. This problem has been thoroughly discussed by Pearl (2015). However, where as in this study, there are no strong cross correlations among variates that are potentially causal factors for Failure Rate, the square of a correlation coefficients provides a reliable estimate of Size Effect, being the proportion of Failure Rate variance that can be explained by a particular variate.

Thus, although the available sample sizes in this study do not allow the use of complex statistical techniques, including factor analysis and structural equation modelling it has been possible to suggest tentative causal models from the correlations between FR and MTBF and other independent variables measured by the questionnaire administered to participants in the responding hospitals. These are shown in Figures 6-1 to 6-3, below.

Figure 6-1 for the number of machines in a facility. The suggested causal flow models are not examples of Causal Path Models as described by Wright (1921) and further developed in Blalock (1985) which include measurable and immeasurable exogenous variables, and also require larger sample sizes than are available in the present research.

They simply show empirically based proposed causal links between system variables and machine failure rates and serve as a basis for further research where larger data sets are available.

Using the tentative causal models, the research questions and the hypotheses of this study were reviewed in the conceptual frameworks proposed from the five variables and associated factors that affect patient outcomes[48].

6.2 Variable Measurements

The survey questionnaire was designed to provide data to investigate whether there are correlations between the machine FRs, MTBFs and other variables. Table 6-1 shows the variables and their related questions in the survey questionnaire [49]

Table 6-1: Variables and their related questions in the survey questionnaire

Variables	**Questions number/s listed in the survey questionnaire**
1. Machine properties and usage	Q4, Q5, Q6, Q7 and Q19.
2. Maintenance management strategies	Q11, Q12, and Q13
3. Maintenance practices	Q18, Q20, Q22, Q27, Q29, Q36, Q42, Q43, Q44, and Q5
4. Maintenance performance	Q10, Q23, Q24, Q25, Q26, Q33, Q37, Q38, Q40, Q41, Q46, Q 47, Q48, Q49,
5. Maintenance costs/ Cost of ownership	Q30, Q31, and Q53
6. Patient outcomes	Q16,Q32,Q33,Q34,Q35,and Q39

[48] Chapter 3, Fig. 3-1, p.135.
[49] Appendix A, pp. A1-A30.

6.3 Pearson Correlations of Maintenance Management System Variables with CME Reliability and Patient Outcomes

I. The "Research Questions" and "Hypotheses" related to the correlations between variables describing the CMMS and reliability of CME are as follows:

> Q1. What are the opinions of users and maintainers in relation to the influence of current maintenance management strategies have on the reliability of CME in hospitals?
>
> *Q1.1: Is there an apparent correlation between the type of maintenance strategy used and the availability of CME?*
>
> *Q1.2 Is there an apparent correlation between the type of maintenance strategy used and the failure rates of CME?*
>
> *Q1.3 What are user opinions of the magnitude of downtime of failed CME and how do current maintenance management strategies affect this?*
>
> H1: That the current maintenance management strategies for critical medical equipment have an influence on reliability and patient outcomes.
>
> *H1a: That failure rate of critical medical equipment is influenced by the type of maintenance management strategies.*
>
> *H1b: That downtime of failed critical medical equipment is influenced by type of maintenance management strategies*.

II. The research questions and their hypotheses [H1a, H1b, and H1c], related to correlation between maintenance management strategies and maintenance costs are as follows:

> *H1c: That cost of ownership of critical medical equipment is influenced by the type of maintenance management strategies.*

Q3- What kind of maintenance management strategies could potentially be used to increase equipment availability and decrease costs while achieving the desired level of patient outcomes?

III. The Research Question-3 and the hypotheses [H3a, H3b, and H3c] related to correlations between **maintenance management strategies and computerized maintenance systems** as follows:

H3.1: Computerized maintenance systems based on condition-based maintenance have the potential to improve reliability and patient outcomes in the maintenance of critical medical equipment.

H3a: Computerized maintenance systems based on condition-based maintenance have the potential to improve failure rates.

H3b: Computerized maintenance systems based on condition-based maintenance have the potential to improve availability.

IV. The research questions and hypotheses for the variable **maintenance practices** are as follows:

Q2: *What are the likely major factors that influence the selection of maintenance strategies for CME in hospitals?*

H2: That the selection of current maintenance management strategies for critical medical equipment is the result of a lack of knowledge of 'state of the art' maintenance management strategies and practices used in other industries.

V. The research questions and hypotheses for finding correlations on whether patient outcomes are affected by current maintenance management strategies and the breakdown of CME are: Research Question 1 and Research Question 3 [Hypothesis: H3.1]

In general, Failure Rate (FR) is a better measure than MTBF of the relationship between equipment reliability and other significant variables FR and MTBF have a strict mathematical relationship, each being the reciprocal of the other. Pearson's correlation coefficients (r) were used to explore the relationship of FR

and MTBF with each of the other significant variables in a series of pair comparisons. In most cases the relationship between FR and other significant variables is closer to a straight line than the relationship of MTBF with those same variables. In the other cases noted below, the reverse is the case. Several distinct patterns emerged. The data used in the analysis was gathered from Questions 2, 4, 5, 6, 7, 8, 10, 18, 19, 20, 22, 23, 24, 25, 26, 27, 29, 31, 33, 38, 40, 41, 44, 47, 48, 49, 50 and 53.

6.4 Data Analysis for Anaesthesia Machine

In this study, 39 of 103 Public Hospitals in NSW provided responses to the questions pertaining to the surgical anaesthesia machine. Of these, 25 hospitals (64%) provided sufficiently comprehensive data to allow statistical analysis. The results are shown in Table 6-2. The main patterns that emerge from correlation analysis are as follows:

6.4.1 Reliability Measurement of Anaesthesia Machine

The results of correlations show that, in most cases, Failure Rate (FR) is a better measure than MTBF for determining the relationships between equipment reliability and other system variables.

1. As observed with other machines, responses to Question 5 indicate that anaesthesia machines aged between 1 and 5 years have a significantly lower failure rate than newer or older machines correlation of ($r=- 0.437$, $P < 0.029$).
2. It is the busiest hospitals with large numbers of patients and the most heavily used machines that have the lowest observed values of FR. Question 6 of the questionnaire asks how many patients are treated per year. The correlation of Q6 results with MTBF is ($r=0.805$, $p < 0.001$), which indicates that hospitals that treat more patients have higher MTBFs for the anaesthetic machines. The responses to Question 7 record the average operating time the anaesthetic machine spends treating each patient. The responses to Q6 and Q7 thus allow the calculation of the "Average operating time per year for the facility" that is, in this case, the total annual operating time for all anaesthetic machines in the hospital. The correlation of "Average operating time per year for the facility" with FR is ($r=-0.418$, $p = 0.088$) and with MTBF the correlation is (r

= 0.829, P < 0.001). This indicates that hospitals in which the anaesthetic machines have a higher total patient treatment time per year have significantly lower FRs and longer MTBFs for the anaesthesia machines. This is an example where the relationship between the independent variable and MTBF is closer to a straight line than the relationship of the independent variable with FR (which is closer to a hyperbola).

Dividing "Average operating time per year for the facility" by the total number of anaesthetic machines in the facility (Q4), it is possible to calculate average usage time per year per machine, that is the average time per year that each anaesthetic machine in the facility spends treating patients and that variable has a significant correlation with FR of (r = -0.639, P = 0.001). This indicates that anaesthesia machines that are running for a higher proportion of the time have a significantly lower FR.

A possible explanation of the above results is that the correlations, as a whole, show that it is the more heavily loaded facilities and machines that have lower failure rates. This is what would be expected from modern maintenance theory. It is not the case that lower failure rates lead to more patients being treated. If that were the case, then the machines and facilities with higher failure rates would have queues of patients unable to get immediate treatment. However, responses to Question 39 show that of the 25 responding hospitals that have anaesthetic machines, all but one reported that patients are treated on demand and the remaining hospital reported that patients are treated according to a priority list. Not one hospital reported that patients are placed on a waiting list.

3. Question 8 asks if duplicate machines are available in the event of anaesthetic machines breaking down. Here, a "Yes" answer is coded as 1 and a "No" answer is coded as 2. Thus a negative correlation between the response to Q8 and MTBF means that facilities that have a longer MTBF also have backup machines. This is the situation with the data for anaesthetic machines where the correlation between MTBF and the response to Q8 is (r = -0.573, P = 0.003). Thus having backup of duplicate machines is one factor in reducing failure rate. Given the possibility of patient injury from failure of an anaesthetic machine during surgery (as acknowledged in responses to Q34) it is surprising that not all hospitals have duplicate anaesthetic machines, yet of

the 25 hospitals reporting that they had anaesthetic machines, only 8 reported having duplicate machines. This is an area for future research.

4. In the case of anaesthetic machines, 20 of the 25 responding hospitals used outsourced maintenance services and no significant difference could be detected between the failure rate for in-house service and that for outsourced service. There were no significant correlations between FR or MTBF and the various in-house strategies. In the case of outsourced maintenance strategies, the data gathered from **Question 13** indicates that an outsourced Preventive Maintenance strategy results in a higher FR than other outsourced strategies with a correlation of ($r=0.843$ $P < 0.001$) though none of the other outsourced maintenance strategies have significant correlations with FR or MTBF. .
5. Responses to Question 19 (on the proportion of machine parts that are critical or fail regularly) indicate that anaesthetic machines that have a higher proportion of critical parts fail more frequently ($r=0.841$, $p < 0.001$), with a shorter MTBF ($r=-0.413$, $p = 0.040$). Responses to Question 20 (on availability of critical spare parts) indicate that a higher availability of critical spare parts leads to a lower FR ($r=-0.595$, $P = 0.002$). Responses to Question 22 (on inventory policy for spare parts) indicate that a hospital ordering critical spare parts only after breakdown leads to higher failure rate ($r=0.757$, $p < 0.001$) while keeping critical spare parts in stock reduces failure rate ($r=-0.771$, $p < 0.001$).
6. Responses to Question 24 (on cause of failure) indicate that in hospitals with relatively high anaesthesia machine FR, the failures are mostly due to technical problems rather than human error and no failures are caused by overuse. Responses to Question 25 indicate that most failures of anaesthesia machines occur during surgery (as one might expect). Also, responses to Question 26 indicate that anaesthetic failures over the 5 years 2007-2011 are consistent with the 2012 failure rates recorded in the responses to Q23.
7. The results of Question 46 indicated that hospitals that use unavailability as a measure of device reliability (Yes=1, No=2) have higher FRs ($r=-0.429$, $P= 0.032$),
8. Question 47 asks whether respondents agree that their current maintenance strategy optimises (minimizes) machine failure rate. The correlation of the

responses with FR (r=-0.823, P < 0.001) indicates that those respondents who agree that CMMS optimises FRs are those with lower FRs. In this case the coding of the responses is: Strongly Agree = 5, Agree = 4, Indifferent = 3, Disagree = 2, Strongly Disagree = 1. The same coding is used for Q48 and Q49. Question 48 asks respondents if they think their CMMS is one reason for unavailability of anaesthetic machines. The correlation of the results of Q48 with FR (r=0.440, P = 0.031) indicating that those respondents who agree that their CMMS is a reason for unavailability of anaesthetic machines are in hospitals have higher FRs. Question 49 asks residents if they agree that their CMMS helps reduce sudden failures of equipment. The correlation of the results of Q49 with FR (r=-0.593, P = 0.002) indicates that those who agree that their CMMS helps reduce sudden failures are those with lower FRs. The responses to Q47, Q48 and Q49 indicate that respondents have knowledge of how their FRs compare to those in other facilities and base their opinion of their CMMS on the comparative FRs.

All significant correlations of FR and MTBF for anaesthetic machines and the implications to be drawn from those correlations are summarised in Table 6-2, below.

As discussed in Section 3.1 above a suggested causal flow model has been developed showing the relationships between FR and other system variables for anaesthetic machines. This model is shown in Figure 6-2, below. In this model an arrow represents a suggested causal relationship where the factor at the tail of the arrow is a cause of the factor at the head of the arrow, the thickness of the arrow indicates the strength of the causal relationship. The construction of the causal flow model is based on the interpretation of the correlations already discussed together with other knowledge gained during the field study and logical factors including that a cause must precede its effect in time.

Where MTBF (which equals 1/FR) is more strongly correlated than is FR with a potentially causal variable this indicates a curvilinear relationship of the potentially causal variable with FR and that relationship has been used in constructing the tentative causal models in Figures 6-1, 6-2 and 6-3, below.

Table 6-2: Factors Related to FR and MTBF for anaesthesia machines

NQ.	Details	Pearson Correlation			Comment
		r	FR	MTBF	
Q5	Age of machines between 1 and 5 years	r	-0.437	Not Sig.	Machines aged between 1 and 5 years have a significantly **lower FR** than newer or older machines
		p	0.029		
		N	25		
Q6	Number of patients per month	r	Not Significant	0.805	Hospitals that treat higher numbers of patients per month have **lower machine FRs**
		p		0.000	
		N		25	
	Average patient treatment time per machine per year	r	-0.639	Not Sig.	Machines that spend more time per year treating patients have **lower FRs**
		p	0.001		
		N	25		
	Average operating time per year for facility	r	-0.418	0.829	Facilities that have a higher number of patient treatment hours per year have **lower failure rates**
		p	0.038	0.000	
		N	25	25	
Q8	Alternatives available	r	Not Significant	-0.573	Hospitals that have duplicate machines available have **longer MTBF**s.
		p		0.003	
		N		24	
Q13.2	Outsourced Preventive Maintenance Strategies	r	0.843	Not Sig.	Hospitals using Preventive MS* with outsourced maintenance providers have **higher FRs**
		p	<0.001		
		N	20		
Q13.4	CBM carried out using outsourcing	r	Not Significant	0.403	Hospitals using outsourced CBM to maintain their machines experience **longer MTBF**
		p		0.046	
		N		25	
Q16.2	Maintenance issues sometimes affect patient outcomes	r	Not Significant	0.445	Respondents who think maintenance issues sometimes affect patient outcomes are those with **longer MTBFs of machines**
		p		0.029	
		N		24	
Q18	Staff involved in maintenance decision making	r	0.823	Not Sig.	Hospitals, where respondents are involved in maintenance decisions have **lower FRs**
		p	<0.001		
		N	25		
Q19	Proportion of machine parts that are critical	r	0.841	-0.413	Machines that have a higher proportion of critical parts have **higher FRs**
		p	<0.001	0.040	
		N	25	25	
Q20	Availability of critical spare parts	r	-0.595	Not Sig.	Hospitals with a higher availability of critical spare parts experienced **lower machine FRs**
		p	0.002		
		N	25		
Q22.1	Critical spare parts are held in stock	r	-0.771	0.545	Keeping critical spare parts in stock **reduces machine FRs**
		p	0.001	0.006	
		N	24	24.	
Q22.3	Ordering spare parts after breakdowns	r	0.757	-0.428	Ordering critical spare parts after breakdown leads to **higher FRs**
		p	0.001	0.037	
		N	24	24	
Q24.1	Machine failures due to technical reason	r	0.621	-0.418	FRs in anaesthetic machines were found to be mainly due to technical reasons
		p	0.001	0.038	
		N	25	25	
Q24.2	Machine failures due to human error	r	-0.621	0.418	
		p	0.001	0.038	
		N	25	25	

MS = Maintenance Strategy

Table 6-2: Factors Related to FR and MTBF for anaesthesia machines (cont)

No	Details		FR	MTB	Comment
Q25	Has this device failed while in service? Y=1, N=2	r	-0.927	0.512	Most anaesthetic machine failures occur during surgery (as one might expect)
		p	<0.001	0.012	
		N	23	23	
Q26	If Q25=Yes, number of failures in the last 5 years	r	0.553	Not Sig.	FRs reported over the 5 years 2007-2011 were consistent with the reported annual FRs in 2012
		p	0.004		
		N	2		
Q33	How often are duplicate machines used when unavailability would cause adverse patient outcomes?	r	0.654	-0.424	Hospitals that experience high machine FRs need to use duplicate equipment more often, as would be expected
		p	<0.001	0.035	
		N	25	24	
Q34	Known cases of patients affected by machine breakdowns	r	0.599	-0.436	Hospitals with higher machine FRs are more likely to experience adverse patient outcomes
		p	0.003	0.042	
		N	22	22	
Q34.3	Machine breakdowns cause patient injury	r	0.550	Not Sig.	Hospitals with higher FRs reported that anaesthetic machine breakdown had caused patient injury
		p	0.003		
		N	22		
Q36.4	Manage failures through the borrowing of machines from other hospitals.	r	0,823	Not Sig.	Hospitals that have a higher FR tend to more frequently use borrowed equipment
		p	<0.001		
		N	25		
Q42	How often optimize hospital's maintenance strategies to avoid over servicing machinery	r	0.532	Not Sig.	Hospitals that report they try to avoid over- maintenance servicing tend to experience **higher machine FRs**
		p	0.006		
		N	25		
Q43	Keeping records of maintenance and subsequent equipment reliability	r	-0.432	Not Sig.	Hospitals that keep machine maintenance and reliability records have lower machine FRs
		p	0.031		
		N	25		
Q44.2	The use of system databases for the keeping of maintenance records	r	0.731	Not Sig.	Hospitals that use a paper records to store maintenance and FR data are those with **higher FRs** .
		p	<0.001		
		N	24		
Q46.1	Hospitals use **unavailability** as a measure of reliability	r	-0.429	Not Sig.	Hospitals that use **unavailability** as a measure of device reliability have **higher FRs**.
		p	0.032		
		N	25		
Q47	Respondents think that their CMMS optimizes machine FRs	r	-0.823	0.442	Respondents who agree that CMMS* optimizes FRs are those with **lower FRs**
		p	<0.001	0.035	
		N	23	23	
Q48	Respondents think that their CMMS is one reason for the unavailability of machine	r	0.440	Not Sig.	Respondents who agree that their CMMS is a reason for the unavailability of anaesthetic machines are those **with higher FRs**
		p	0.031		
		N	24		
Q49	Respondents think that their CMMS helps reduce sudden failures	r	-0.593	0.431	Those who agree that CMMS helps reduce sudden failures are those **with lower FRs**
		p	0.002	0.032	
		N	25	25	

*CMMS; Current Maintenance Management Strategies

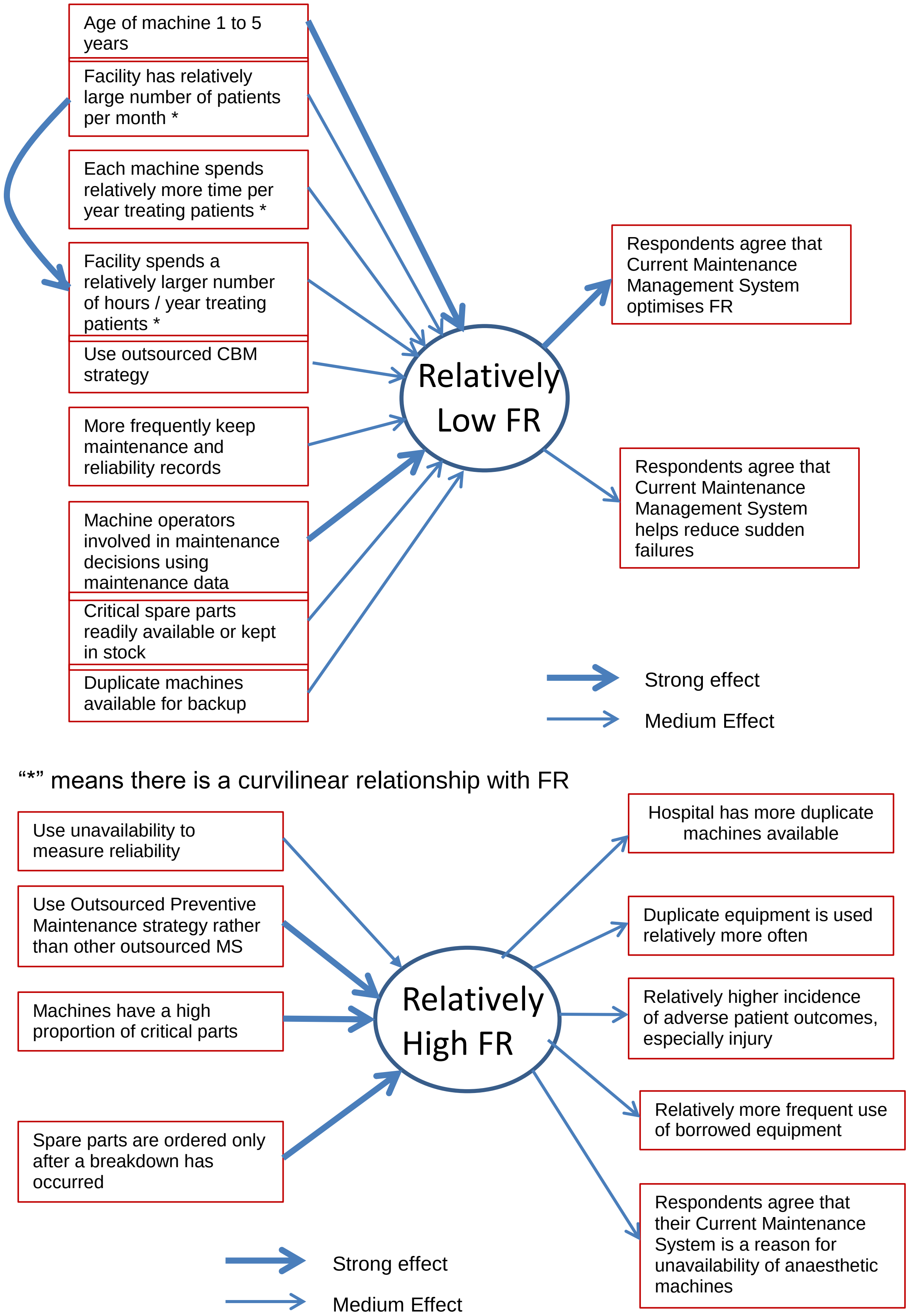


Figure 6-1: Suggested causal flow model for Anaesthetic Machine failure rate

6.5 Data Analysis for the Defibrillator Machine

In this study, 73 of 103 Public Hospitals in NSW responded to survey questions on the defibrillator machine. Of these, only 48 hospitals (47%) provided responses that were sufficiently complete to use in correlation analysis. The results of the correlation analysis and the interpretations of correlation coefficients are shown below in Table 6-3. A suggested causal flow model for defibrillator failure is shown in Figure 6-2.

6.5.1 Reliability Measurement of Defibrillator Machine

The results obtained show that, for defibrillator machines, MTBF is a better measure of reliability than Failure Rate (FR) for calculating the relationship between equipment reliability and other significant variables. This means that when plotted against other significant system variables, the graphs of MTBF are mostly closer to straight lines than those for FR.

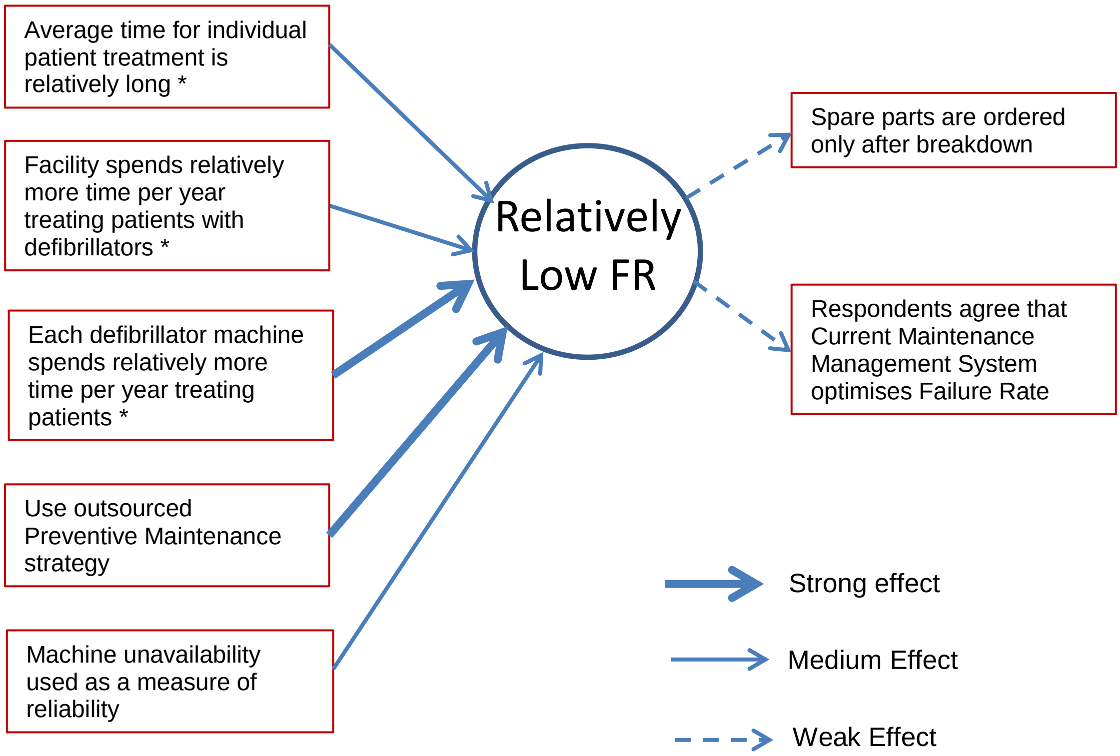
Table 6-3: Results of comparisons between failure rates and MTBF for the defibrillator machine

N	Details	Pearson Correlation			Comment
		Value	FR	MTBF	
Q4	Number of machines	R	0.729**	Not Sig.	Hospitals with more machines have a significantly higher FRs
		P	<0.001		
		N	48		
Q6	Number of patients per year	R	Not Sig.	0.675**	Hospitals that treat high patient numbers per year experience significantly increased MTBF
		P		<0.001	
		N		38	
Q7	Average usage time per patient (minutes)	R	Not Sig.	0.554**	Increasing average usage time per patient results in significantly higher machine MTBF
		P		<0.001	
		N		38	
	Average Annual Operational Time for all machines	R	Not Sig.	0.743**	Hospitals with heavy machine usage have a significantly higher machine MTBF
		P		<0.001	
		N		38	
	Average Annual Operation time per machine	R	Not Sig.	0.404*	Those facilities with higher operating time/year have higher MTBFs
		P		0.012	
		N		38	
Q11.1	In-house Maintenance strategy	R	0.332*	Not Sig.	In-house maintenance strategy is associated with higher FR
		P	0.021		
		N	48		
Q11.2	Outsourced Maintenance strategy	R	-0.332	Not Sig.	An outsourced maintenance strategy is associated with lower FR
		P	0.021		
		N	48		
Q13.3	Outsourced PM strategies	R	-0.375*	Not Sig.	Hospitals with increased outsourced PM for their defibrillator machines have a lower FR
		P	0.022		
		N	37		
** Significant at 1% level					

Table 6-3: Results of comparisons between failure rates and MTBF for the defibrillator machine (cont)

N	Details	Value	FR	MTBF	Comment
Q13.4	Mixed outsourced maintenance strategies	R	0.375*	Not Sig.	Hospitals implementing outsourced mixed MS experience higher FRs
		P	0.022		
		N	37		
Q19	Proportion of parts that are critical	R	0.325*	Not Sig.	Machines containing a high proportion of critical parts fail more frequently
		P	0.024		
		N	48		
Q22.3	Spare parts ordered after breakdown	R	Not Sig.	0.385*	In hospitals where defibrillators have a long MTBF spare parts tend to be ordered only after machine failure.
		P		0.007	
		N		45	
Q25	Has this device failed while in service? Y=1 N=2	R	-0.459**	-0.431**	Where defibrillator machines have higher FR more failures occurred in service
		P	0.001	0.008	
		N	46	37	
Q26	If response to Q25 is Yes how many failures have occurred in the last 5 years?	R	0.709**	Not Sig.	These are consistent with overall FRs recorded of the defibrillator
		P	<0.001		
		N	46		
Q33	If lack of duplicate equipment causes harm to patients, how often is duplicate machine used.	R	0.543**	Not Sig.	High FRs leads to more frequent replacement by duplicate machines after in service failure
		P	<0.001		
		N	46		
Q34.4	Has machine breakdown caused patient death?	R	0.731**	Not Sig.	Hospitals with higher machine FRs reported that machine breakdowns have caused the death of patients
		P	<0.001		
		N	44		
Q43	Keeping records of maintenance and subsequent equipment reliability	R	Not Sig.	-0.611	Higher rate record keeping of maintenance activities is associated with shorter MTBF
		P		0.000	
		N		38	
Q46.1	Machine reliability measured by its unavailability	R	-0.731**	Not Sig.	Using unavailability as measure of reliability is associated with **higher FRs**
		P	0.001		
		N	46		
Q47	Respondents think CMMS optimizes machine FRs	R	Not Sig.	0.347*	Respondents who agree that CMMS optimizes FRs are those with longer MTBF
		P		0.048	
		N		33	
Q48	Respondents think CMMS helps cause machine unavailability	R	0.285**	Not Sig.	Respondents who agree that CMMS is a cause of machine unavailability are those with **lower FR.**
		P	0.050		
		N	48		

******. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).



"*" means there is a curvilinear relationship with FR

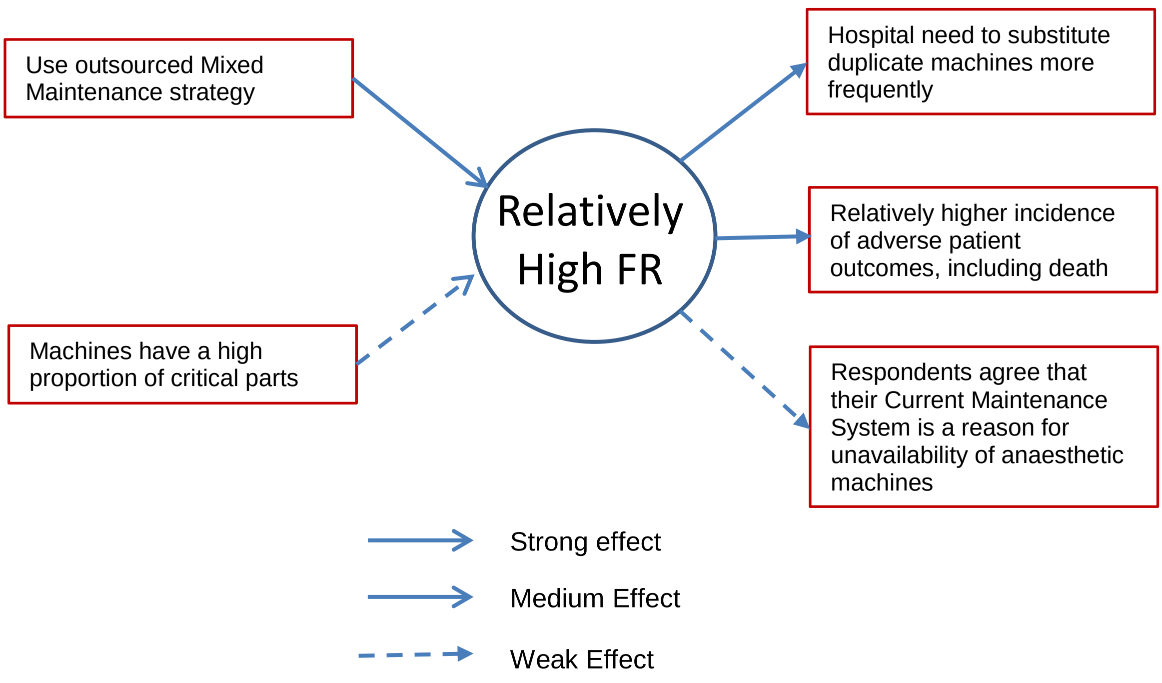


Figure 6-2: Suggested causal flow model for Defibrillator failure rate

6.6 Data Analysis for ECG Machines

In this study, 64 of 103 Public Hospitals in NSW were represented in answering the survey questions concerning their ECG machines. Of these, 59 hospitals (57%) provided responses that were sufficiently complete for correlation analysis. The results of the correlation analysis and the interpretations of the correlation coefficients are shown in Table 6-4 below. The suggested causal flow model based on those correlations the correlations between FR and other significant system variables are larger than is shown in Figure

Reliability Measurement of ECG Machine

The results of the correlation analysis show that FR is a better measure than MTBF for determining the relationship between equipment reliability and other significant variable. In most cases, the correlations between FR and other significant system variables are stronger that the correlations between MTBF and those same system variables.

6.6.1 Data Analysis of Infusion Pump Machines

In this study, 75 of 103 possible Public Hospitals in NSW, 63 hospitals and clinics responded to survey questions concerning infusion pump machines. Of these, 45 responses (60%) were sufficiently complete to use for correlation analyses. The results of the correlation analysis and the interpretations of the correlation coefficients are shown in Table 6-5 for FR and in Table 6-6 for MTBF. A suggested causal flow model for Infusion Pump failures is shown in Figure 5-3.

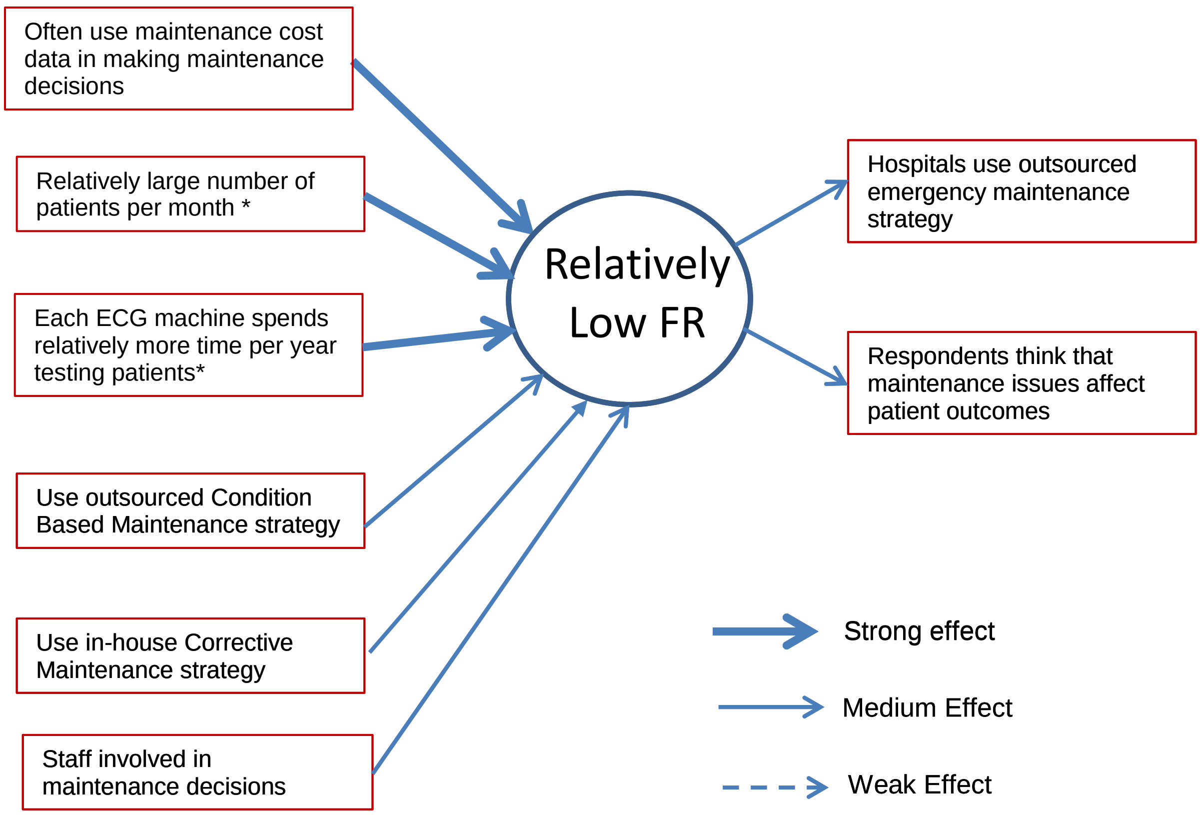
The results of the correlation analysis show that Failure Rate (FR) is a better measure than MTBF for determining the relationship between equipment reliability and other significant variable because the GR correlations are stronger in most cases.

Table 6-4: Results of comparisons between failure rates and MTBF for ECG machines

N	Details	Pearson Correlation			Comment
			FR	MTBF	
Q4	Number of machines	r	-0.300*	0.923**	Hospitals with a higher number of ECG machines are those with lower FR, and a longer MTBF
		p	0.046	0.000	
		N	45	45	
Q6	Number of patients per month	r	-0.287	0.989**	Hospitals treating a higher numbers of patients per month have higher MTBF
		p	0.056	0.000	
		N	45	45	
	Annual Operating Time per machine	r	-0.571**	0.631**	Longer average operating time per year per machines is associated with lower machine FRs and longer MTBF.
		p	<0.001	<0.001	
		N	45	45	
Q11.1	Using in-house maintenance strategies	r	Not Sig.	0.476**	Hospitals using in-house service to maintain machines have longer MTBF
		p		0.001	
		N		45	
Q11.2	Using outsourced maintenance strategies	r	Not Sig.	-0.476**	Hospitals using outsourced maintenance strategies have reduced MTBF
		p		0.001	
		N		45	
Q12.1	Corrective maintenance carried out using in-house MS	r	Not Sig.	1.000**	Hospitals implementing CM in-house services have a higher MTBF for their machines
		p		0.007	
		N		3	
Q12.3	Emergency maintenance carried out using in-house MS	r	Not Sig.	1.000**	Hospitals that implement EM in-house have a higher MTBF with their machines
		p		0.007	
		N		3	
Q13.3	Outsourced emergency MS used	r	-0.418**	Not Sig.	Outsourced emergency MS is used in hospitals with a lower machine FR
		p	0.007		
		N	40		
Q13.4	Outsourced Condition Based Maintenance (CBM)	r	-0.361*	Not Sig.	Hospitals using outsourced CBM maintenance strategies have lower FR among OS maintenance.
		p	0.022		
		N	40		
Q16	Maintenance issues affect patient outcomes	r	Not Sig.	0.383*	Respondents who think patient outcomes are often affected by maintenance issues are in hospitals with longer MTBF.
		p		0.009	
		N		45	
Q18	Staff involved in maintenance decisions	r	0.453**	Not Sig.	Respondents who are involved in making maintenance decisions in hospitals are associated with lower machine FR
		p	0.002		
		N	45		
Q24.2	Machine failures due to human errors	r	-0.372*	Not Sig.	ECG failures are mostly not due to human error, they are technical failures
		p	0.012		
		N	45		
Q25	Has this device failed while in service? Y=1 N=2	r	0.489*	Not Sig.	Most ECG failures do not occur during servicing of patients
		p	0.001		
		N	45		

Table 6-4: Results of comparisons between failure rates and MTBF for ECG machines (cont)

N	Details	Pearson Correlation			Comment
		r	FR	MTBF	
Q27	How often do hospitals keep records of maintenance costs?	r	Not Sig.	-0.615**	Hospitals that keep records of maintenance costs have a shorter machine MTBF
		p		<0.001	
		N		45	
Q29	Maintenance cost data used in decision-making	r	Not Sig.	-0.743**	The more often maintenance cost data is used in maintenance decisions the longer the machine MTBF
		p		<0.001	
		N		43	
Q38	Times per month machine unavailable to treat patients	r	Not Sig.	0.315*	The longer the MTBF, the more frequent ECG is available to treat patients. This needs further investigation.
		p		0.035	
		N		45	
Q42.2	Optimizing hospital maintenance strategies to avoid over servicing machinery	r	0.532	Not Sig.	Hospitals that often attempt to optimize maintenance to prevent overservicing have a higher FR for ECG machines
		p	0.006		
		N	25		
Q43	Keeping maintenance records of maintenance and subsequent equipment reliability	r	-0.483**	Not Sig.	Keeping records of maintenance and equipment reliability more often is associated with lower FRs for ECG machines
		p	0.001		
		N	45		
Q44.2	Using computer to keep data records	r	0.545**	Not Sig.	Using computer to keep data records is associated with higher FRs
		p	<0.001		
		N	45		
Q48	Is CMMS a reason for the unavailability of machine?	r	-0.380**	Not Sig.	Respondents who agree that CMMS is a reason for unavailability of ECG machine have lower FRs
		p	0.010		
		N	45		



"*" means there is a curvilinear relationship with FR

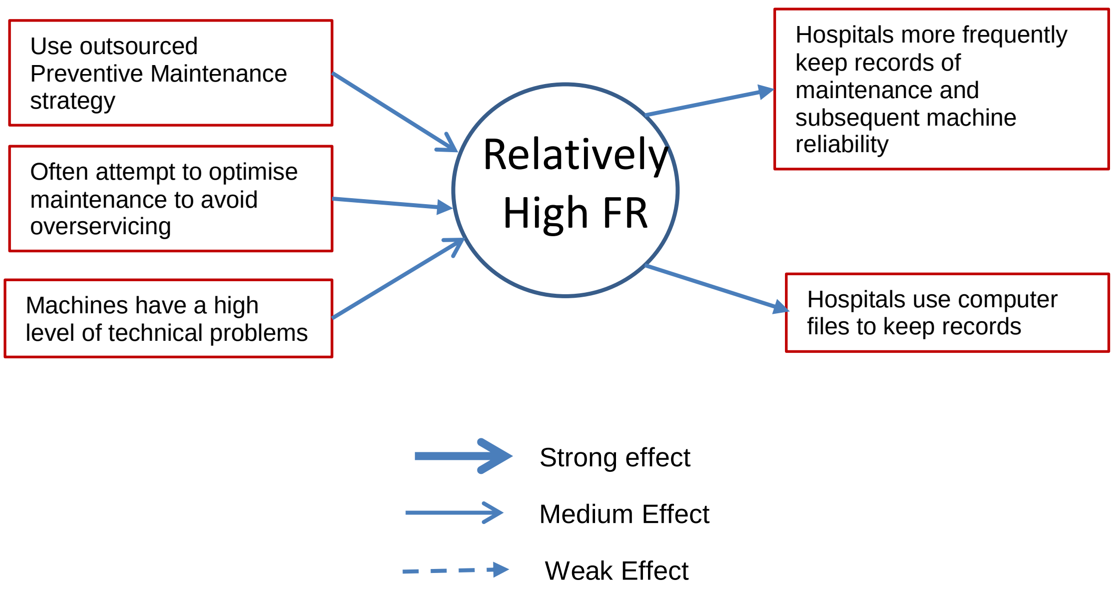


Figure 6-3: Suggested causal flow model for ECG Failure Rate

Table 6-5: Results of comparisons between failure rates for infusion pump machine

N	Details	Value	FR	Comment
Q7	Average usage time (patient hrs)	r	-0.702	Hospital with higher average usage time per patient are those with lower machine FRs
		p	0.001	
		N	57	
	Average Annual Operational Time for all machines	r	-0.265	Hospitals undertaking heavier machine use, have significantly lower machine FRs
		p	0.047	
		N	57	
	Operational time per year	r	-0.453	Hospitals with longer operating time per year for the group of infusion pumps are those with lower machine FRs
		p	0.001	
		N	57	
Q8	Alternatives available	r	0.373	Hospitals without alternative machines available have higher machine FRs
		p	0.004	
		N	57	
Q10	Frequency of alternative machine usage	r	-0.352	Hospitals with higher machine FRs for infusion pump machines use alternative machine more often.
		p	0.006	
		N	57	
Q11.1	Using in-house maintenance strategies	r	-0.374	Hospitals that use in-house MS for their infusion pump machines are those with lower FRs for infusion pump machines
		p	0.004	
		N	57	
Q11.2	Using outsourced strategy	r	0.374	Those hospitals that using an outsourced MS for their infusion pump machines are those with higher machine FRs
		p	0.004	
		N	57	
Q22.1	Holding spare parts in stock	r	-0.371	Those hospitals that keep critical spare parts in-stock are those with lower FR for their infusion pump machines
		p	0.005	
		N	57	
Q22.3	Ordering spare parts after breakdowns	r	0.308	Those hospitals that order critical spare parts after breakdown are those with higher FRs for infusion pumps
		p	0.021	
		N	57	
Q36.3	Managing failures with in-house MS	r	-0.301	Managing failures with in-house MS lowers the overall FR
		p	0.023	
		N	57	
Q39	How is patient health care provided?	r	-0.557	A lower FR is associated with a higher percentage of patients being treated on demand rather than being placed in a queue or on a priority list
		p	0.001	
		N	57	
Q40	The reason for the unavailability of the infusion pump to treat patients	r	-0.612	When FRs are higher, the primary reason for not being able to treat patients immediately is an under supply of machines
		p	0.001	
		N	57	
Q41	Does CMMS help to increase equipment availability?	r	-0.289	Where FRs are higher, respondents do not think CMMS help increase machine availability
		p	0.033	
		N	57	
Q42	Optimizing hospitals' maintenance strategies to avoid the over servicing of machinery	r	- 0.502	More frequent optimizing to prevent over-servicing is associated with higher FR.
		p	0.001	
		N	57	
Q43	Keeping equipment maintenance records for subsequent reliability	r	- 0.522	Keeping records on maintenance and subsequent reliability more frequently is associated with higher FRs
		p	0.001	
		N	57	

Table 6-4: Results of comparisons between failure rates for infusion pump machine (cont)

N	Details	Value	FR	Comment
Q46.1	Maintenance measurements used to evaluate the reliability of critical maintenance devices, according to their unavailability	r	- 0.480	Using unavailability for FR, MTTF or MTBF measurements of the infusion pump device are all associated with higher FRs compared to other reliability measures.
		p	0.002	
		N	57	
Q46.2	Machine reliability measured by FRs	r	-0.437	
		p	0.002	
		N	57	
Q46.3	Machine reliability measured by MTTF	r	-0556	
		p	0.002	
		N	57	
Q46.4	Machine reliability measured by MTBF	r	-0.557	
		p	0.002	
		N	57	
Q47	Does CMMS optimize machine FRs?	r	- 0.408	Those respondents that agree that CMMS optimizes FR are those with lower FRs
		p	0.002	
		N	57	
Q48	Dose CMMS a reason for the unavailability of machines?	r	- 0.371	Those respondents that agree that CMMS is one of the reasons for the unavailability of infusion pumps are those with lower FRs
		p	0.005	
		N	57	
Q49	Does CMMS help to reduce sudden failures?	r	-0.400	Those respondents that agree that CMMS helps to reduce sudden equipment failures are those with lower FRs
		p	0.002	
		N	57	

Table 6-5: Pearson Correlation of MTBF of the infusion pump machine

N	Details	Value	MTBF	Comment
Q6	Number of patient treatments per year	r	0.729	Hospitals treating higher numbers of patients per year have a significantly higher machine MTBF
		p	0.001	
		N	57	
Q29	Data maintenance used in decision making	r	-0.286	Hospitals that used maintenance cost records more often for maintenance decisions making are those with shorter MTBF
		p	0.031	
		N	57	
Q53	Total annual maintenance costs for infusion pumps	r	-0.553	Hospitals with higher total annual maintenance cost for infusion pump machines are those with shorter MTBF for their machinery
		p	0.001	
		N		

6.7 Data Analysis of the Ventilator Machines

In this study, 40 of the 103 Public Hospitals in NSW responded to survey questions concerning ventilator machines. Of these, 37 (92.5%) were sufficiently complete to allow correlation analysis. The results of the correlation analysis and the interpretations of the correlation coefficients are shown in Table 5-7 for MTBF and Table 6-8 for FR.

The results of the correlation analysis show that Failure Rate (FR) is a better measure than MTBF of the relationship between equipment reliability and other significant system variables because in most cases, the correlations of FR with significant system variables are stronger than the correlations of MTBF with those same variables.

Table 6-6: Results of comparisons between MTBF and maintenance variables for ventilator machines

N	Details	Value	MTBF	Comment
Q4	Number of machines	r	0.742	Hospitals with more ventilator machines have longer MTBFs for these machines
		p	0.001	
		N	24	
Q6	Number of patients per month	r	0.786	Hospitals treating a higher number of patients per month on ventilator machines have longer MTBF for ventilator machine
		p	0.001	
		N	24	
	Average Operational Time per year per machine	r	0.786	Hospitals with heavily used ventilator machines have longer machine MTBF
		p	0.001	
		N	24	
Q8	Alternatives available	r	0.425	Hospitals that have alternatives machines available have longer MTBFs for ventilator machines
		p	0.043	
		N	23	
Q29	Data maintenance used in decision making	r	-0.442	Hospitals that have more often used maintenance cost data for maintenance decision-making have shorter MTBFs for ventilator machines
		p	0.035	
		N	23	
Q33	If Q32=Y, how often are duplicate machines used	r	0.550	More frequently substitution of duplicate equipment is associated with longer MTBFs for ventilator machine
		p	0.007	
		N	23	
Q44.3	Using a database for keeping maintenance records	r	0.425	Hospitals that utilize a system database for maintenance records are those with longer MTBFs, because it is possible to access the history of FRs for this machinery
		p	0.039	
		N	24	
Q48	CMMS is a one reason for the unavailability of machinery?	r	0.570	Hospitals that agree that CMMS is a reason for unavailability of ventilator machines are those with longer MTBFs for this machine
		p	0.004	
		N	24	

Table 6-7: Results of comparisons between failure rates and maintenance variables for ventilator machines

N	Details	Value	FR	Comment
Q5.2	Age of machine between 1 to 5 years	r p N	-0.428 0.033 25	Ventilator machines aged 1 to 5 years old have a lower FR compared to those machines that are new or obsolete
Q5.3	Age of machines over 5 years	r p N	0.428 0.033 25	
Q18	Staff involved in maintenance decisions	r p N	0.414 0.027 25	Respondents participating in maintenance decisions in hospitals noted that the machinery had a lower FR
Q24.1	Technical failures common	r p N	0.389 0.05 25	Most failures due to technical reasons rather than human error
Q24.2	Failure commonly due to human error	r p N	-0.389 0.05 25	
Q33	If the answer to Q32=Yes*, how often are duplicate machines used	r p N	0.460 0.024 24	More frequent use of duplicate machines is associated with lower machine FRs
Q34.1	Known cases of patients affected by machine breakdowns	r p N	-0.549 0.024 24	Hospitals with no known cases of patients being affected by machine breakdowns are those with lower machine FRs
35.4	Risk of death of patient if ventilator fails	r p N	0.449 0.014 25	Hospitals with higher FR for ventilators indicated more frequently that there is a possibility of patient death if ventilator fails in service
35.2	High risk level of misdiagnosis	r p N	0.390 0.054 25	Hospitals with higher FR for ventilators stated that ventilator failure in service may lead to misdiagnosis
Q41	Has CMMS helped increase machine availability?	r p N	-0.524 0.047 25	Those hospitals that agree that CMMS helps increase machine availability are those with lower FRs for ventilators
Q42	Optimizing hospitals' maintenance strategies to avoid over servicing machinery	r p N	-0.677 0.001 24	Those hospitals that report they frequently optimize maintenance strategy to avoid over servicing are those with lower FRs for ventilator machines
Q43	Keeping maintenance records for subsequent equipment reliability	r p N	-0.432 0.031 25	Those hospitals that frequently keep records of maintenance and subsequent equipment reliability are those with lower FRs for ventilator machines
Q48	Is CMMS a reason for the unavailability of machines?	r p N	0.410 0.042 25	Those hospitals that agree that CMMS is a reason for the unavailability of the ventilator are those with higher FRs for ventilator machines

* Adverse patient outcomes would result if machine failed while servicing patient

6.8 Data Analysis of the Kidney Dialysis Machines

Of the 103 questionnaires collected, 14 of 25 NSW Public Hospitals, which had kidney dialysis units responded. All of these responses were suitable for correlation analysis. The results of the correlation analysis and the interpretations of the correlation coefficients are shown in Table 6-9, below.

The results of correlation analysis show that MTBF is a better measure than FR of the relationship between equipment reliability and other significant variables because the correlations are stronger, indicating a closer approximation to a straight line than would be obtained using MTBF.

Table 6-8: Results of comparison between failure rate and MTBF of the kidney dialysis machine

N	Details	*P*	FR per Million OT (Hrs.)	MTBF (Hrs.)	Comment
Q6	Number of patients per month	r	Not Sig.	**0.713****	Hospitals treating more patients per month have a significantly longer machine MTBF.
		p		**0.004**	
		N		**14**	
	Total Operational Time per year	r	Not Sig.	**0.713****	Hospitals that spend more time per year treating patients have longer MTBF.
		p		**0.004**	
		N		**14**	
	Average OT per year per machine	r	**-0.518**	Not Sig.	Hospitals with more heavily used machines have significantly lower machine FRs
		p	**0.05**		
		N	**14**		
Q13.2	PM carried out by outsourced MS	r	Not Sig.	**0.998 ****	Hospitals using PM carried out by outsourced services have higher MTBF.
		p		**0.001**	
		N		**14**	
Q13.6	Mixed maintenance carried out by outsourced MS	r	Not Sig.	**- 0.998 ****	Hospitals using mixed maintenance carried out by outsourced services have a lower MTBF.
		p		**0.001**	
		N		**14**	
Q36.2	Failure managed by calling supplier	r	Not Sig.	**0.635***	Hospitals who call a supplier to resolve failure are those with higher MTBF.
		p		**0.015**	
		N		**14**	
Q48	CMMS is one reason for unavailability	r	Not Sig.	**0.653***	Respondents who think CMMS leads to unavailability are those with a higher MTBF.
		p		**0.011**	
		N		**14**	

**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

6.9 Summary

From the interpretations of the correlation analyses described above, the following key points were established:

- The more heavily loaded facilities and the more heavily loaded machines within facilities experience lower failure rates. This is in accordance with the Waddinton effect because routine maintenance tends to be carried out at fixed time intervals, so the most heavily loaded machines get less maintenance per operating hour.
- In general, failure rate is a better measure of machine reliability for studying the relationships of reliability with other system variables. This is because the relationships between system variables and failure rate tend to approximate straight lines more closely than the relationship between system variables and MTBF, However, there are cases where MTBF has more linear relationships with other system variables, so both FR and MTBF should be used in developing causal models of machine reliability.
- In the case of anaesthetic machines, machines aged 1 to 5 years have a significantly lower failure rate than younger or older machines. This might be expected as younger machines have problems stemming from manufacturing errors that need to be eliminated through routine maintenance and older machines are nearing the end of their lives. However this effect was not observed in the other five machine types studied possibly because most of those machines are replaced under contract on a regular basis and few are younger than one year or older than 5 years.
- Discussions with hospital staff in large hospitals indicated that they think in-house maintenance is better than outsourced maintenance because they have better access to technicians to solve minor problems before machines reach the stage of failure. Others said that in most regional health areas in-house technical services are based at the main regional centre and other hospitals in the region experience difficulties in gaining timely access to technical staff. The correlation analyses did not provide a definitive answer to this problem. For anaesthetic, ventilator and dialysis machines there was no significant difference in failure rate between in-house and outsourced maintenance. The small sample size (14) for dialysis machines may have masked any difference.

However, in-house maintenance services are associated with significantly lower failure rates for ECG machines and infusion pumps but with significantly higher failure rates for defibrillators. It may be that for some machines the specialist skills of the manufacturer's staff are required for optimum service.

- Few hospitals reported using CBM or predictive maintenance alone. But some respondents noted on the survey form that Mixed Maintenance included CBM or predictive maintenance. Overall, there is some evidence from the correlations that the few hospitals using CBM or predictive maintenance, even in a Mixed Maintenance environment, do have lower failure rates. Clearly there is an opportunity to educate hospital staff on he advantages of CBM and predictive maintenance.
- The results of correlation analysis show that hospital staff are aware of the reliability of their equipment relative to that of other hospitals and base their opinions of their CMMS on that data. Those with lower failure rates tend to agree that their CMMS minimizes failures and prevents sudden failures. However, for most machine types respondents who say their CMMS is one reason for unavailability of equipment have relatively low equipment failure rates. So there is some inconsistency here in the respondents' evaluation of their CMMS.
- In most cases, having spare parts readily available in stock leads to lower failure rate, presumably because preventive maintenance can be carried out. However, in the case of defibrillators where failures are relatively rare and major hospitals have large numbers of that device. Spare parts are not ordered until after a breakdown has occurred. This may be one reason why outsourced condition based maintenance provides lower failure rates for this device.
- Based on the correlation analyses and other data gathered during the field study as well as logical considerations of time precedence, suggested causal flow models have been developed for anaesthetic, defibrillator and ECG machines. Although there is not sufficient data available to construct more complex causal path models or models based on structural equation modelling, these suggested causal path models provide a succinct summary of probable causal relationships for the machines concerned and point to suggested approaches for further research.

CHAPTER 7: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

7.0 Introduction

After an extensive literature review and survey of a large number of hospitals, the author believes this is the first study of this type based in Australia. The results have certainly created new knowledge and pointed to some serious limitations and concerns relating to patient outcomes and opportunities for improvement in the management of critical medical equipment. The work has brought to light many hitherto unanswered questions that require further investigation.

Answers to the research questions and testing of their hypotheses are significantly supported by five variables encompassed within the theoretical and conceptual framework of the methodology and hypothesis[50]: *(1) Maintenance Management Strategies (2) Maintenance Practice (3) Medical Equipment Reliability (4) Maintenance Costs (5) Patient Outcomes*.

These variables allowed a reasonable investigation of critical medical equipment used in NSW public hospitals with regard to common maintenance practices. As referred to in the literature review (Pun *et al.* 2002; Mutia *et al.* 2012; Tsantis and Apostolakis 2014), these variables were used to evaluate effective maintenance strategies that can potentially increase the availability and reliability of medical equipment, providing safe medical health care, increased health care service productivity, reduced critical equipment failure rates and lower life cycle costs. The results of the study here have shown broad agreement with (Pun *et al.,* 2002; Mutia *et al.,* 2012) as evidenced by the correlations between the five variables indicated in the conceptual framework, the qualitative analysis results and validated hypotheses.

7.2 Avoiding adverse patient outcomes

In the health care environment, the Hippocratic principle of "First, do no harm" is of primary concern. Analysis of the survey results shows there were significant correlations between maintenance strategies and patient outcomes. Question 34 of the survey asks respondents whether they know of incidents of misdiagnosis, injury or death resulting from in-service breakdowns of critical medical equipment. For the

---

[50] Figure 3-3, Chapter 3, p.136.

principal equipment types studied, the adverse patient outcomes reported were as follows:

- For dialysis machines, no adverse outcomes were reported.
- For anaesthetic machines, no respondents reported misdiagnosis, 6% reported patient injuries and 3% reported patient deaths.
- For defibrillator machines, no respondents reported misdiagnosis, 7% reported patient injuries and 2% reported patient deaths.
- For ECG machines, no respondents reported misdiagnosis, 6% reported patient injuries and no respondents reported patient deaths.
- For infusion pump machines, no respondents reported misdiagnosis, 4% reported patient injuries and 2% reported patient deaths.
- For ventilator machines, no respondents reported misdiagnosis, 5% reported patient injuries and 3% reported patient deaths.

The above responses clearly show that respondents believe that there is a significant level of risk to patients as a result of machine failures while treating patients. This leads to the question of whether those risks could be reduced by adopting more advanced maintenance strategies like Condition Based Maintenance and Predictive Maintenance working in a Reliability Centred Maintenance management regime.

Correlation analysis clearly shows that for most machine types, overall failure rate has a strong positive relationship with adverse outcomes for patients, that is, high failure rates results in harmful outcomes. (See Causal Models Figure 6-2 and Table 6-3, for anaesthetic machines). For defibrillator machines, the correlation between high failure rate and adverse patient outcomes (Question 34) is $r = 0.375$. $P = 0.012$. For ventilator machines the correlation of high failure rate with adverse patient outcomes (Question 34) is $r = 0.649$, $P = 0.008$. For ECG machines, the correlation of short MTBF with frequency of patients being affected (Question 16) is $r = 0.338$, $P = 0.025$.

As mentioned in Chapter 6, and as an indication of a lack of implementation of state of the art asset and maintenance management practices used in other industries, not one respondent reported that they rely to any extent on Condition Based Maintenance or Predictive maintenance and the management emphasis tends to be on more traditional maintenance strategies. However, some respondents reported that their

Mixed Maintenance Strategy included Condition Based Maintenance or Preventive Maintenance. Using correlation analysis to compare the failure rates of equipment using mixed maintenance strategies with other traditional strategies alone shows that there is evidence that utilizing a Condition Based Maintenance strategy or a Predictive Maintenance strategy, even as part of a Mixed Maintenance strategy results in lower failure rates and can thus be expected to improve patient outcomes. However, for defibrillators, using mixed maintenance resulted in an increased failure rate, as shown in Table 6-3 and Figure 6-2 of Chapter 6,

In the case of anaesthetic machines and ECG, there was sufficient data to directly assess the outcome of utilizing Condition Based Maintenance and it was shown as reported in Table 6-2, Figure 6-1, Table 6-4 and Figure 6-3 of Chapter 6, that using Condition Based Maintenance results in lower failure rate or longer MTBF and can thus be expected to reduce asverse patient outcomes. Overall, it can be concluded that this study has established that moving to a Condition Based Maintenance system can help NSW hospitals reduce failure rates of critical medical equipment and thus reduced harmful outcomes for patients.

- Significant correlation coefficients were found between current maintenance strategies (CMS) used and medical equipment reliability. In general, respondents believe that current maintenance strategies do not minimise sudden breakdowns of most CME considered. Further, it could be inferred that current maintenance strategies are a reason for high unavailability of CME. This implication shows that maintenance systems in NSW hospitals could be improved and is consistent with a need to improve medical equipment maintenance as expressed by the World Health Organisation (2011, p.5)[51]. In that paper, it was argued three important issues of medical equipment in the healthcare organisations are: (1) maintenance policy (2) computerised maintenance management systems and (3) medical equipment inventory. The results reported here also agree with the study by Taghipour *et al.* (2011) that showed hospitals and clinical engineering departments around

[51] 227 - World Health Organization (2011), '*Medical equipment maintenance programme overview: World Health Organization medical device technical series*'World Health Organization, Switzerland.

the world, including Australia, United States and Canada are in the early stages of adoption of modern, effective and cost-efficient maintenance strategies rather than depending on manufacturers and outsourced maintenance providers.

- A Correlation Coefficient test could not be obtained between CMS and one of the most important factors of maintenance systems, i.e. Computerised Maintenance Management Software (CMMS) because the majority of hospitals do not use CMMS as: (1) they have a shortage of trained staff and limited organisational knowledge and expertise on state of the art maintenance strategies (2) the process of implementing CMMS may involve a dual system of reporting, where the initial inventory of some equipment is on computer but some of it is on paper, making timely record keeping difficult and (3) CMMS may not be possible or may not be necessary to implement in small hospitals and health centres with limited CME (WHO 2011).

These findings, integrated with the evaluation of standards used to assess the quality of performance in maintenance management strategies are argued in the literature review. The evaluation standards are shown in Figure 7-1.

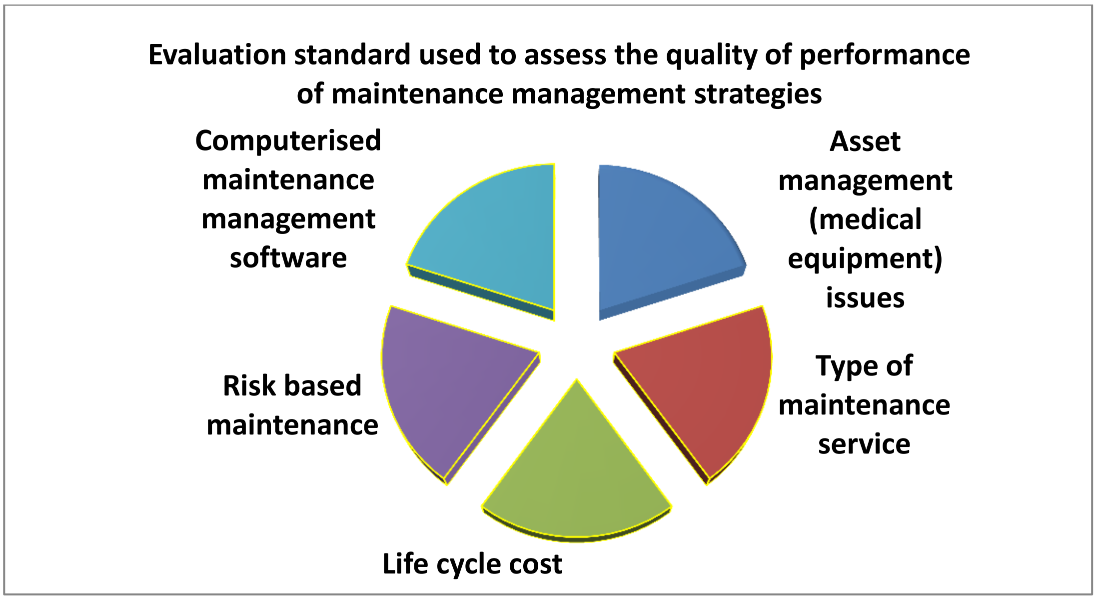


Figure 7-1: Evaluation standard used to assess the quality of performance of maintenance management strategies

7.1 Adequacy of the Sample Studied

In total, 116 (55%) of 212 hospitals invited to participate in this study responded. From these, 84 hospitals responded to the survey questionnaire. This is a good response rate of over 72.4% that most likely yielded representative results within the sample study. Qualitative researchers generally study fewer responses when collecting data that can be objectively, validly and reliably assessed (Alder and Alder, 2012, p. 9), and this is also generally true of research on the maintenance of CME. The study targeted 4 hospital departments: Biomedical Engineering, Surgical Operations, Cardiac Craterisation and Kidney Dialysis. To become a world class health organisation the NSW health sector needs to pursue improved maintenance strategies that are currently being carried out by Biomedical Engineering Departments located in hospitals within the local health district or are outsourced. The CME studied indicated a variation in clinical specialisations of health care services for patients, as shown in the Figure 7-2. Hence, a diversified approach to the research in this work across clinical specialities supports qualitative and quantitative analysis for the majority of current maintenance issues of critical medical devices.

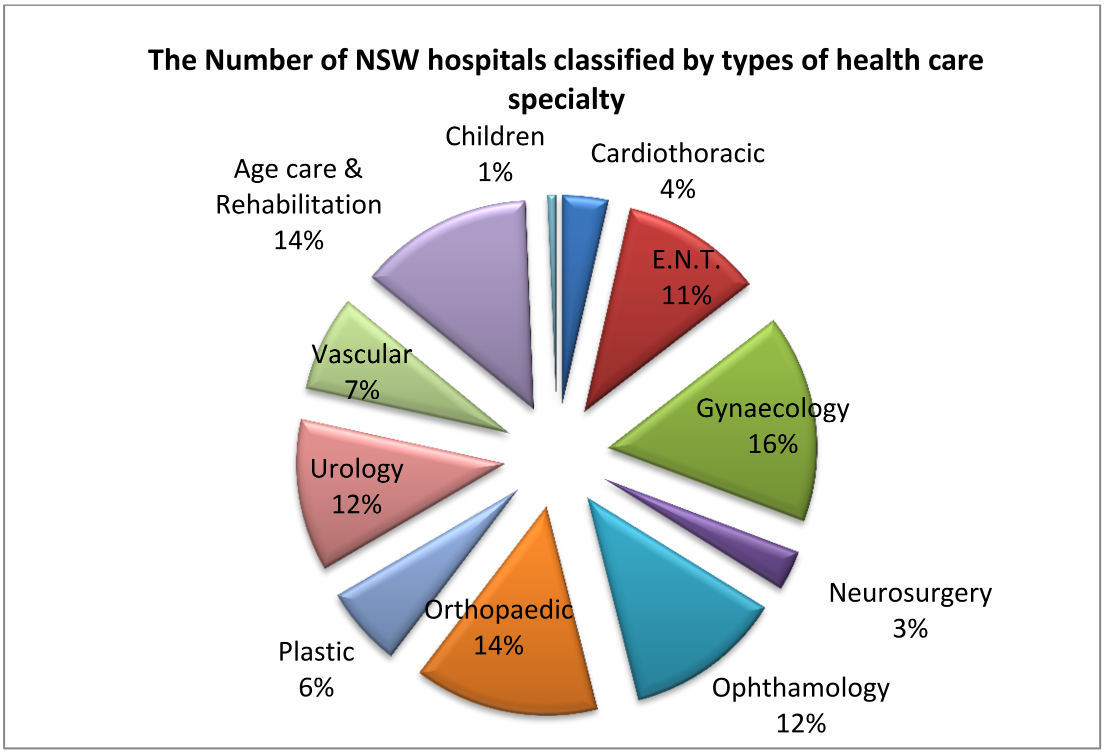


Figure 6 2: The number of NSW hospitals classified by the type of the health care services

7.2 Limitations of the Pilot Study

The pilot study supported continuous improvement of the survey questionnaire and assisted in the selection of types of CME that had a high risk of non-availability. The resulting equipment types studied were: Kidney Dialysis, Anaesthesia, Defibrillators, Diathermy and Cardiac Catheterisation machines. The investigation of CME in this work is consistent with the relevant literature that revealed there was a level of high risk from CME in four high profile hospitals in China referred by to by Wu and Liu (2010). The pilot study similarly showed that CME in NSW hospitals, as indicated by hospital staff is seen as critical with high risks to patients but there were some limitations:

1. The time factor in retrieving information.
2. Most staff wanted to retain their anonymity.
3. The hospitals were hesitant about being identified for fear of being openly criticised.
4. The time factor in having to interview and survey a large number of busy staff.
5. Staff unfamiliarity with hospital maintenance practices.
6. The pilot study was done with a diverse cross-section of hospital staff.
7. There was no central administration unit or consistent processes for CME covering all hospital departments.
8. Ethical approval policies limited the scope and available sample size of the approved pilot study, particularly where sensitive data relating to patient outcomes was requested.

7.3 Adequacy of Survey Questionnaire

The survey questionnaire significantly supports the aims of the theoretical and conceptual framework, the methodology aimed to resolve the research questions and hypotheses[52]. Large amounts of data were collected for different types of CME. Some of the limitations are as follows:-

1. It was noted during the pilot study that hospital staff workloads and priorities required a greater concentration of time and effort to ensure complete questionnaires and comprehensive interviews ensued. Hospital staff needed to pass survey questionnaire forms between hospital departments with the result that several people may have contributed to one form and hence there may have been some limitations in the consistency of responses due to slightly differing understandings of the survey questions.

[52] Figure 3-3, Chapter 3, p.136.

2. In total, 102 of the 157 questionnaires distributed were submitted to the researcher. (These came from 84 hospitals that responded to the survey referred to earlier in section 7.2.) This was a significant survey participation rate (56%). Thus, determining the time and cost of collecting data was a limitation in addition to estimating the population variability characteristics (Graziano and Raulin 2007). For this reason, there is difficulty in collecting data about CME listed in the survey questionnaire from small hospitals (45%), although they later showed interest in this study for consideration of their maintenance issues.

7.4 Appropriateness of Critical Medical Equipment

This study focused on CME where failure or non-availability posed a high level of risk to patients' lives. This was consistent with relevant literature revealing the need to avoid risks posed by medical equipment (Khan and Haddara 2003; Bevilacqua *et al.,* 2009), and to minimise those effects on patients, the quality of the operators' performance and the productivity of health care organisations (Tchokodjeu 2011; Kumar and Srinivas 2014).

The survey results in this thesis were extracted from the data gathered from respondents who were involved with a total of 5,769 devices. This is significantly effective data for statistical analysis. Although the hospitals selected in the study suggested other types of CME that could be considered, it was decided that the study would be better limited to 14 types of CME that were in common usage across all hospitals incorporated in the study. However, due to the difficulties in managing very large amounts of data, only 6 of the 14 CME that were considered to have the most significant statistical results were examined: kidney dialysis, anaesthesia, defibrillator, ECG, infusion pump and ventilator machines.

The following section discusses conclusions and implications from the study. This includes contributions to the literature, the limitations and the recommendations when undertaking further research. In this thesis, CME was classified as follows: -

1. Criticality: 14 devices were identified after being classified critical, important or necessary. These contributed significantly to the outcome of the pilot study.

This was consistent with the relevant literature adopting classifications for medical equipment (Khalaf *et al.,* 2010).

2. The results obtained from the survey questionnaire establish that most CME has a level of risk to patients' lives (death, injury or misdiagnosis). This is consistent with relevant literature classifying the level of risk for patients at three similar levels (a, b and c), (khalaf *et al.,* 2010; Wang *et al.,* 2006). The results from points a, b and c were supported by the evidence obtained from Question 34 of the survey questionnaire reported in this thesis, and determined the critical level risk of the devices causing death, injury or misdiagnosis. Also, these results were consistent with relevant literature revealing the risks when using a Likert Scale: a risk level of 5 was assigned to the ventilator and defibrillator and 3 to the infusion pump machine (khalaf *et al.,* 2010). Wu and Liu (2010) considered that anaesthesia, ventilator, ECG monitors and infusion pump machines increased the risk of failure from 10% to 40% when using an alternative measurement scale for the same devices. This seems to confirm a significant apparent risk level from CME to patient health but actual quantification of that risk is vague. Unfortunately, this thesis adds little to that quantification and so this is an area for further work so that actual risk levels can be more accurately quantified. Findings of this study are consistent with a report of the UK National Patient Safety Agency in reference to to Canadian Hospitals and patient influence. In the case of "cardiovascular device" where device failure (44.8%), inappropriate use (29.3%), lack of training (12.3%), and poor maintenance (1.3%) (Polisena, Jutai and Chreyh 2014) contributed to failures.

7.5 Current Maintenance Strategies used for CME

Across all NSW public hospitals, questionnaire results identified 3 major forms of maintenance policy being used widely for CME. These were in-house, outsourced and mixed. This was consistent with the relevant literature that found healthcare organisations and many non-health industries widely use these policies (De Vivo *et al.* 2004; World Health Organization 2011). The maintenance strategies used that were found to be the most common were: PM, CM or EM rather than CBM,

Predictive or Mixed Maintenance Strategies. This finding revealed a contrast in NSW hospitals in that that most CME targeted by this study is maintained through traditional maintenance strategies (PM, CM or EM), whereas literature suggests that PM is used to maintain infusion pump machines for example (Ridgway 2009) and CM to maintain haemodialysis machines because of the difficulty in scheduling PM (McCarthy, 2012). CBM is a mainstay of Reliability Centred Maintenance (Nowlan and Heap 1978; Moubray 1997). CBM is proposed for health asset management by Blechertas *et al.,* (2009) but there appears to be little knowledge and/or use of CBM in a philosophy of RCM in NSW hospitals. CBM is now common practice in many industries such as aviation and manufacturing but appears to be in its infancy in NSW hospitals. NSW hospitals may well have much to gain in terms of risk to patients and overall maintenance costs by considering wider use of CBM. It seems likely that equipment may well be currently over-maintained or run to unnecessary breakdown. There is real potential for CBM practices to embrace RCM type philosophies that aim to ensure that unnecessary breakdowns do not occur while not engaging in unnecessary preventative maintenance which, in itself, may well be increasing the probability of failure (The Waddington effect)

Additionally, the results in this study found that most maintenance activities consist of setting up machines, cleaning and sterilisation or the replacement of faulty parts. Maintenance procedures tend to occur after a machine fails, as PM is often only arbitrarily scheduled on an annual basis. Some surprising situations were noted e.g. the storing of equipment within corridors of hospitals for years, without being tagged for scheduled maintenance. Computerised maintenance systems and equipment inventory control would potentially avoid much of this. As discussed in the literature review (Endrenyi *et al.,* 2001), three types of maintenance strategies (CM, PM and EM) are incapable of avoiding sudden failures of equipment in use. It is argued in this thesis that to improve the efficiency and effectiveness of maintenance management, RCM type predictive maintenance strategy utilising CBM, facilitated by computer based data collection and monitoring offers potential for improved service and reduced risk to patients while also reducing overall maintenance costs by avoiding costly breakdowns and over maintenance of equipment.

7.6 Conclusions on Traditional Maintenance Strategies for In-House or Outsourced Maintenance Service:

- Age of Equipment: Of the 14 types of CME studied, findings showed that around 35% of the CME in NSW hospitals is effectively obsolete (over 5 years old) and 59% of CME is 1-5 years old. This means that around 94% of the CME may need to be planned for replacement[53]. Alternatively, hospitals may need to reconsider their current maintenance strategy in order to increase the life of equipment. The age of the equipment was consistent with relevant literature as the main factor when assessing the likelihood of failure of a particular device (Tagipour 2011). CME may fail at any time while in service because it suffers from decline with age combined with over use (Tsantis and Apostolakis, 2014). On average, 58% of CME had no backup to provide required health services for patients in the event of breakdown or unavailability. However, this work in some cases has shown that machines that are in regular use actually are less likely to fail than those used irregularly and hence require less maintenance overall. (The Waddington Effect). This is in line with principles of RCM and points to further evidence that NSW hospitals could improve their FRs by adopting an RCM culture and philosophy. Relevant literature (Ridgway *et al.,* 2009c) shows that resolved breakdowns and equipment repairs within 14 hospitals numbered 2,598 repair calls over three months during 2009 which, for the sample size concerned, is a very large number of failures that must offer opportunities for improvement if breakdowns can potentially be lessened by use of CBM engineering techniques and computerised data management within an RCM philosophy.

7.7 Hypothesis Testing and Inferences

a. The correlations among the five variables investigated in the conceptual framework of the maintenance management strategy (Fig 3.1) are considered. It was found that outsourced maintenance is frequently used for CME, but strategies used both in-house and by outsourced providers are corrective,

[53]The Waddington Effect: Reliability Centred Maintenance ideas, originally put forward by Nowlan and Heap (1978) as a means of more economic and safer aircraft maintenance showing that unnecessary and arbitrarily applied preventive maintenance is costly, increases probability of failure and can actually be harmful.

preventative and emergency maintenance and accordingly there was no significant difference in failure rates between outsourced and in-house maintenance. As discussed in the literature review (Endrenyi *et al.,* 2001), these three types of maintenance strategies are incapable of avoiding sudden failures of equipment. It is argued that to increase the efficiency and effectiveness of maintenance management strategies using greater proportions of predictive maintenance strategies involving CBM and RCM are desirable, both in-house and outsourced.

b. This research investigated whether patient outcomes were influenced by the current maintenance strategies being used for CME. Accordingly, it was found that there was a significant correlation with patient outcomes for most of the CME selected and Hypothesis 1 is therefore supported. In addition, there was a significant correlation between patient outcomes and the break-down of CME when in service, where the majority of hospitals reported incidents of patient deaths, injury and misdiagnosis and hence Hypothesis 1.d is supported. However, it is noted that quantification of the actual risk has not been possible and the political sensitivity of data relating to this risk will continue to make this a difficult area to investigate.

c. The present study has investigated whether the cost of ownership (lifecycle) of CME is influenced by the current maintenance strategies. Accordingly, it was found that current maintenance strategies significantly correlated with the total maintenance cost and in particular outsourced maintenance was considered by medical practitioners to be significantly more costly than in house alternatives. Hypothesis 1.c is supported.

d. The survey questionnaire revealed that the current maintenance management strategies for CME correlated significantly with different maintenance culture and practices, e.g. staff participation in maintenance decision-making, availability of substitute (back-up) equipment, availability of spare parts and maintenance record-keeping. Hence Hypothesis 2 is supported.

e. This study also investigated whether hospitals used Computer Maintenance Management Software (CMMS) based on CBM to improve the reliability of

CME for better patient outcomes. The results of this study found that most NSW Public Hospitals do not use CMMS due to a lack of data available from very few hospitals using CMMS. Therefore, there is no evidence to support Hypotheses 3, 3a, 3b or 3c due to a lack of relevant data available. However, this does not imply that there are not significant advantages for NSW hospitals to more vigorously pursue CMMS.

Efficient maintenance strategies for CME must be integrated into all departments within health organisations to provide a safe and timely quality health service to patients. The findings of this work are a significant contribution to the design of the research model proposed[54] by the author and significant correlations between medical equipment maintenance strategies and variables associated with factors that can affect patient outcomes.

The results of this section of work are in line with the findings of Kumar (2006) and Parida (2007) who offer further explanations for poor performance of CME that may explain some of the reasons for the above by using seven further relevant key criteria for the measurement of maintenance performance in health organisations which are: (1) Process-Related Maintenance (2) Maintenance Costing (3) Maintenance Activity (4) Customer Satisfaction (5) Quality Maintenance, Competitive Growth, Training and Innovation (6) Staff Satisfaction and (7) Health, Safety and Environmental Issues.

7.8 Qualitative Analysis and Inferences

Of the 84 hospitals surveyed, 37% had a combination of the 14 CME types that are the focus of this study. Butof these hospitals, only 25 had kidney dialysis and renal departments. This is because they are costly and require specialised skills for their operation. However, 14 (56%) of the 25 hospitals is a statistically significant sample for the research hypothesis of this study.

A surprise finding from this survey was that 3 biomedical engineering departments that participated in this study were responsible for approximately 56% of the NSW Public Hospitals across 17 LHD and Health Services. This shows that the biomedical

[54] Chapter 7, Figure 7-4, p. 297.

engineering departments are centralised in cities and their staff may be required to travel across their LHDs when undertaking maintenance (CM, EM and PM). The remaining 44% of public hospitals were close to other medical providers: such as private hospitals, medical centres, etc. Figure 7-3 shows the distribution of biomedical engineering departments in NSW.

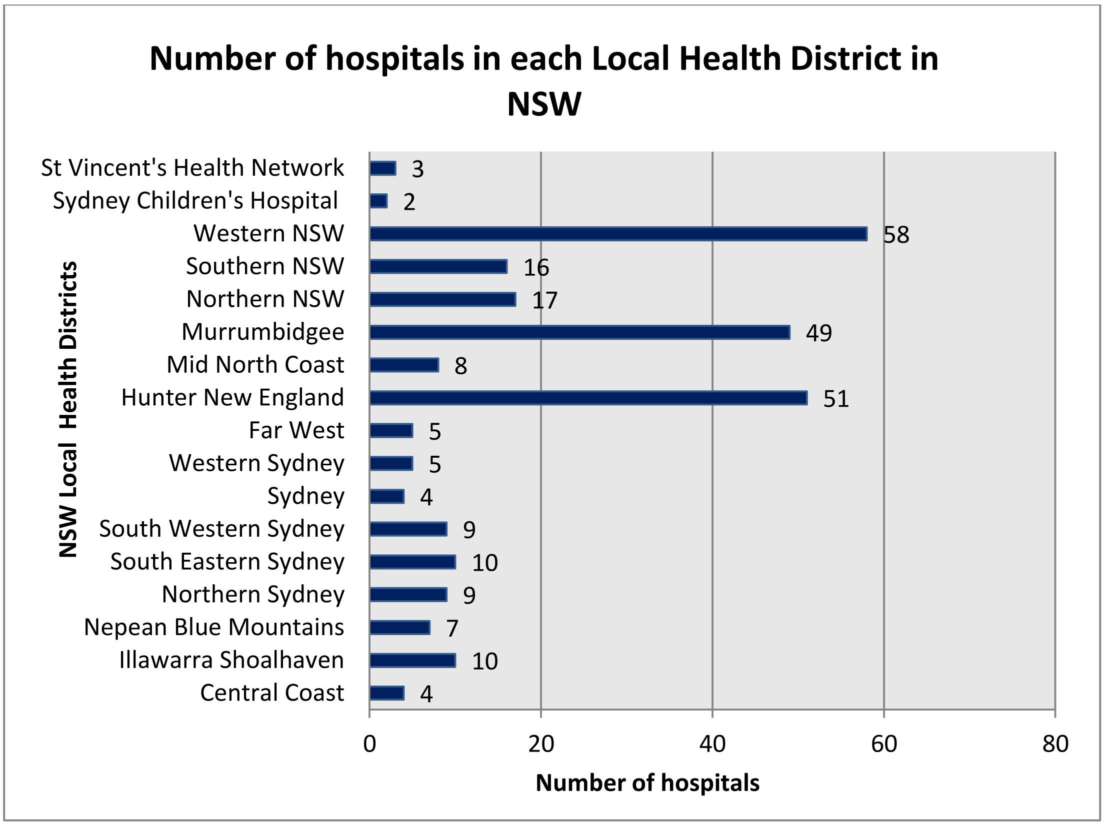


Figure 7-2: Number of hospitals distributed by the Local Health District

Centralisation may or may not be the most appropriate way to maintain CME. While it might be the most cost efficient way to manage maintenance functions, it is likely that some of the poor availability and MTTR of equipment and the need for duplicates reported in this study are caused by delays and lack of immediately available maintenance engineers. It seems that LHDs may need to reconsider centralisation to determine whether some of the reported risks to patients and poor equipment performance are caused by this type of centralised organisation. Some of the principles of RCM and TPM relate to training equipment users and practitioners to be responsible for maintenance functions. Local Health Areas should consider this

as a way to reduce risk to patients and improve CME performance and thus reduce MTTR.

The results obtained from the field study reported in Chapter 4 identify a lack of (or insufficient) in-house biomedical engineering staff. This is seen as a major maintenance issue when referring to particular hospitals denoted by R4, R6 and R25 in this work. Medical practitioners have to solve problems related to the failure of CME during the provision of health services to patients and need to manage failures in the presence of patients as referred by R2. The outcome of this work is consistent with the annual report to the NSW Ministry of Health 2014 that indicated, in 2010-2014, the number of maintenance and trades staff in NSW hospitals continued to decline (respectively 4%, 6%, 9%, and 10%), as shown in Figure 7-4.

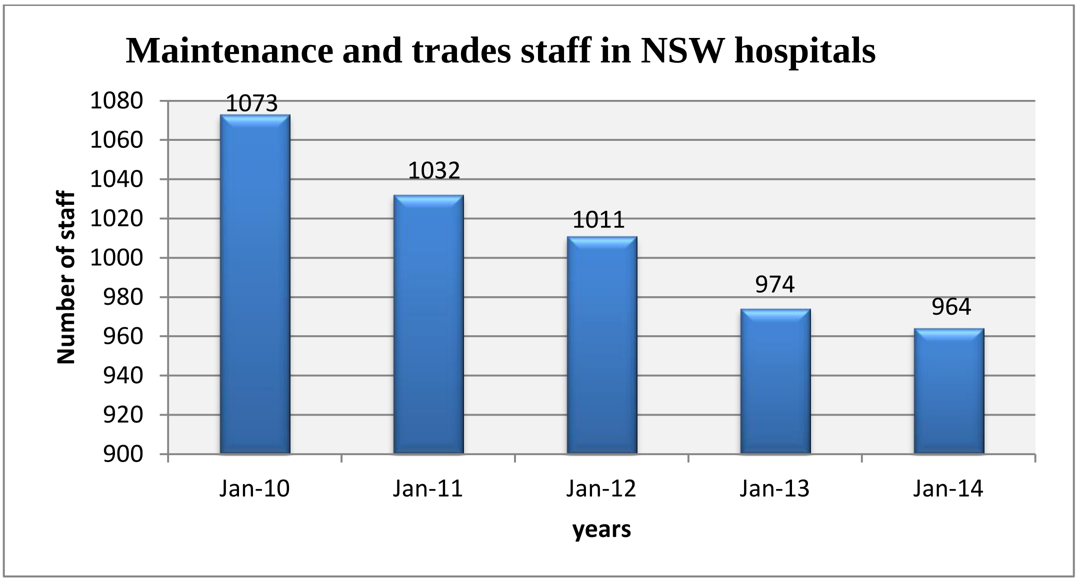


Figure 7-3: Maintenance and trades staff in NSW hospitals

Figure 7-4 above, illustrates a decline in the number of maintenance staff, which is likely to lead to the further decline in MTTR and availability of equipment and increase risk to patients. This trend lends further evidence of opportunities to consider TPM, CBM and RCM to lessen the stress on maintenance staff.

For future work, there is certainly a question of whether a centralised structure is optimal in terms of outcomes for patients and equipment availability and cost effectiveness or simply the cheapest.

Risk to a patient's life is a one of most significant factors resulting from the use of breakdown maintenance because breakdowns in service cannot be predicted or avoided (Taghipour *et al.,* 2011). Sullivan and Cooper (2013) argued that 9% of a sample of 2000 reported patient harm by the failure of anaesthesia machines. Also more recently, the American Society of Anaesthesiologists Closed Claims Project Adverse Outcomes reported a 3% risk of death from failure of anaesthesia machines and a 7% risk of injury from failure of ventilator machines e.g. brain damage (Sullivan and Cooper, 2013). In this survey, results show there are some cases where patients are exposed to harm through the breakdown of CME, e.g. H4, H5-R3, H5-R4, H7-R2, H10-R2, H10-R3, H12, H15-R2, H15-R3 and H73 showed failures in anaesthesia, defibrillator, ECG, infusion pumps, cardiac catheterisation and diathermy machines were believed to be some of the causes of death or injury.

This study is the first that has been able to identify the potential harm patients could suffer during their treatment due to breakdowns of CME, although data sensitivity excludes the actual number of patients exposed to harm. These results add a new scientific value to previous studies (Khlafa *et al.,* 2010; Wu and Liu 2010) that identified risk levels when using anaesthetic, ventilator, defibrillator and infusion pump machines. This researcher agrees with the proposals of Sullivan and Cooper (2013) that risk management of medical devices needs to be considered to provide a safe medical service for patients.

An evaluation of the efficiencies of maintenance strategies and medical equipment reliability is reflected in the important factors affecting the performance of CME, e.g. FR, reliability, availability and maintainability. In this survey, very small numbers of survey respondents indicated they used reliability and availability data when evaluating CME performance.

However, respondents estimated the average unavailability of CME ranged between 96 and 360 hours per month. The defibrillator and infusion pump machines had the highest instance of unavailability at 360 hours per month. This result led to the inability to verify research hypothesis H1.1. It is agreed by Pintelon and Parodi-Herz (2008) that present literature shows that RCM is theoretical rather than practical in most organisations, where its philosophy is known. RCM in NSW hospitals has an emphasis on risk that that most staff do not appear to be familiar with and hence they

may not see the potential for RCM in the management of CME. The findings of this work support previous work that shows that risk management must become a more prominent part of Medical Equipment Management Programs (Taghipour *et al.,* 2011).

The survey respondents gave an estimate over a five year period (2007-2011) of failures of CME in their care. However, in 2012, they indicated an increase in the number of failures per year. These figures are inconclusive, because they are not statistically reliable as the survey requested opinions. Accurate quantitative statistics were not available within the scope of this research but it seems likely that there may be an increasing number of failures of CME in recent years, perhaps as a result of the reduction in the number of qualified maintenance personnel (Fig 7.4) and the tendency to centralise maintenance functions in LHDs (Fig 7.3). The FN was analysed for each individual piece of equipment to find the FR in 2012 for CME (Mkalaf and Gibson 2012). Usually respondents indicated that the majority of hospitals did not utilise an optimum maintenance strategy which in turn led to increases in failure rate and finally to rapid obsolescence of CME supporting the findings of Tsantis and Apostolakis (2014).

7.9 Descriptive Analysis and Inferences

The results obtained from the descriptive analysis were investigated using the following elements:

- Medical Equipment Performance
- Availability of substitutes (back-up) equipment
- Critical spare-parts inventory
- Supplier and the effects on reliability of CME
- Medical equipment reliability
- The efficiencies of the current maintenance strategies and their reliability
- Maintenance records
- The effect of CME on patient outcomes
- Maintenance costs.

The results show that some of the hospitals had few anaesthesia, ECG and kidney dialysis machines compared to the number of patients they were required to service. Additionally, respondents indicated that the machines mentioned were facing obsolescence, which is a serious situation when considering high operational times

per patient for most CME (See Table 5-21, p.209). This is the time the patient remained connected to the equipment during treatment. The defibrillator and ECG were deemed critical and exposed the patient to potentially high risks of death, injury or misdiagnosis, although their operational time was measured in seconds (Khalaf *et al.,* 2010). The results show here a significantly higher Average Treatment Time Per Patient (ATTPP) compared with the capacity of all these machines. On an annual basis it appears that most CME is operational for significant lengths of time each day.

Significant investigation into past patient-outcomes found that hospitals reported some patient deaths through breakdowns of infusion pumps. Injury because of maintenance issues with anaesthesia, defibrillator and ventilator machines and misdiagnosis with the operation of ECG machines was reported but no formal statistics were forthcoming (See Table 5-32). In addition, the results indicated a higher level of risk (death, injury or misdiagnosis) to patients' lives than by failure of CME while in service that has been mentioned above (See Table 5-33). A critical factor identified in this work is the need to evaluate the level of risk to patients in relation to failed CME, which supports the reports of Taghipoure *et al.*, 2011).

Further investigation of current hospital maintenance strategies in relation to CME reliability indicated results through significance testing that showed a strong belief from survey respondents that CME maintained in-house was a significant reason for the unavailability of CME resulting in poor quality of patient medical services. The results obtained from a descriptive analysis of all CME indicated a consistent view from respondents about most CME types. Results indicated that the majority of large hospitals do not use reliability statistical measurements in terms of unavailability, FR, MTTR and MTBF to evaluate their CME maintenance.

The reliability of CME was investigated in terms of FR and MTBF. It seemed that FR is higher in the case of kidney dialysis and ventilator machines and test results indicated that most of the CME machines tested failed while in service during the last 5 years. With the exception of kidney dialysis and defibrillator machines, survey results appear to suggest that the most common failures with CME are due to technical problems rather than human error or over-use. However, it is likely that at least some reported technical failures are the result of human error. Equipment failures indicated in the relevant literature were commonly user related or human

interference related (Ridgway *et al.*, 2009c). Further, anaesthesia machine failures are commonly due to human error as argued by Sullivan and Cooper (2013). These results show that patients' lives are at risk as most of the respondents reported alternative machines were not always available. This agrees with the Taghipoure *et al.* (2011) who indicated that alternative machines are not available at all times. In addition, CME was generally described by respondents as critical and/or failed regularly, e.g. kidney dialysis machine. At the other extreme, ECG machines fitted into management of replacement parts policy favourably. Duplicate ECG machines were kept for substitution in the event of failure.

There was a significant investigation into the costs of in-house vs outsourced maintenance strategy (Hypothesis-1c). The results showed that beyond the direct monthly costs of immediate breakdowns and preventative maintenance, longer term scheduled maintenance costs were not included. Outsourcing is often a focus for cost-cutting of machine maintenance and it seems likely that immediate outsourced costs are significantly lower. However, there is likely to be a discrepancy when compared with total in-house costs, because outsourced costings do not always include necessary longer term preventive maintenance strategies in contracts.

7.10 Correlation Analysis and Inferences

The main results showed that there is a significant correlation between maintenance strategy and reliability of CME which had an effect on patient outcomes.[55]. The results showed:

Current Maintenance Management Strategy (CMMSt) has a relatively significant correlation with higher FRs in anaesthesia machines. For example, Emergency Outsourced Maintenance Strategy does not appear to be effective in reducing FR of anaesthesia machines and hence this appears to suggest that LHDs should reconsider using this type of maintenance strategy. This issue is exacerbated by spare parts inventory policy, where parts not ordered until after breakdown has occurred, leading to long downtimes. Use of mixed, outsourced maintenance for defibrillator machines exhibited a medium significant correlation with higher FRs. Hospitals need to substitute duplicate machines more frequently as a result. For ECG machines,

[55] Figure 3-3, Chapter 3, p.115.

respondents indicated that using emergency maintenance and condition based maintenance carried out by outsourcing and corrective maintenance carried out in-house could have some effect on reducing FRs. Using outsourced preventive maintenance on ECG machines has a medium correlation with higher FRs, which can lead to misdiagnosis and hence risk to patients. However, the results appear to show that respondents feel in general that Condition-Based Maintenance that is outsourced appears to lead to lower FRs.

The above is in broad agreement with Khalaf, Djouani, Hamam and Alayli (2010) who argue that in a hospital context, advancing medical technologies showed traditional maintenance types (e.g. preventive, corrective and emergency) are no longer effective for ensuring that medical equipment operates at optimum performance. Clinical engineering professionals need to continually review and improve their management strategies in order to keep up with the development of maintenance technology for medical equipment to meet the rising demands of healthcare organisations. This requires the development of risk-focused maintenance management plans (Wang *et. al.,* 2006). There is further potential here for risk reduction by use of RCM (Nowlan and Heap, 1978 and Moubray, 1997). Failure Mode and Effects Analysis (FMEA) has further potential to reduce medical errors and to increase improvements in the quality of the healthcare sector (Gilchrist, 1993; Sharma, Kumar and Kumar 2005; Kutlu and Ekmekçioğlu 2012). CBM, as part of a predictive maintenance strategy, reduces incidences of sudden random failures by working towards a “zero-failure” strategy, condition monitoring helps to predict potential failures and the mechanisms of failures (Temple-Bird, Mhiti and Bloom 1995). This thinking promotes cost-effective maintenance because it can be performed without stopping equipment or processes (Slack *et al.,* 2005). LHDs should consider the potential for using these strategies much more widely.

Higher failure rates significantly affect patient outcomes**.** For example, results show significant correlation between high FR of anaesthesia and defibrillator machines and risk of death or injury to patients. Most hospitals with high machine failures recognised possible serious outcomes, which were consistent with the literature that revealed a strong consensus that current maintenance strategies are not efficient when focus is on the risk to patients due to equipment failure. Emphasis must be on the

timely and accurate diagnoses of patients so immediate therapeutic and surgical decisions or interventions can be implemented (Wang *et al.*, 2006) as most of the devices can suffer errors, temporary malfunction or permanent damage (Armstrong 2013).

The work in this thesis lends further evidence to these findings by illustrating strong relationships between sudden failure of CME and negative outcomes for patients. The results of this study are consistent with (Adachi and Lodolce 2005) who argued that medical errors detrimentally affect patient well-being through the sudden failure of medical equipment (as reported by the Institute of Medicine on the safety of the health care system), and have the potential to be catastrophic. Particular areas of health care have high-risk zones for patient safety as reported in Harvard Medical Practice (HMP) Study II (ref), Quality of Australian Health Care Study (QAHCS) and Kalra (2011) where it has been reported that more than half the adverse events were associated with surgical operations. Their analysis identifies operating rooms (anaesthetic/surgical), in-patient rooms, emergency rooms and intensive-care units. Landrigan *et al.*, (2010) indicated in their study that there were 10 hospitals in North Carolina that had reported patient harm from 2002 to 2007. This means there is no medical device that is one hundred percent safe and resources are never unlimited (Khalaf, *et al*., 2010). This study agrees with Wang, *et al.*, (2013) that there is no data specific to “equipment management” that can be obtained from the approximation of sentinel events caused by maintenance omissions (known as physical environment) and covering a wide range of failures and inefficiencies. The work reported in this thesis is also consistent with the previous studies that report difficulty in collecting data to demonstrate that high percentages of patient harm are the result of medical equipment failure.

Using unavailability as a measurement of machine reliability has a significant medium correlation with maintenance practices.

The results seem to show that lower FRs correlate significantly with maintenance practices e.g. respondents in hospitals with lower failure rates of anaesthetic machines agree that CMMS helps to reduce sudden failures. It appears that hospitals that have duplicate machines available have a lower failure rate. There is no mention of borrowed machines in Figure 6-1. One thing it does show is that keeping critical

spare parts in stock leads to lower failure rates. Similarly, for defibrillator machines the results show that hospitals need to substitute duplicate defibrillator machines more frequently than should be necessary. The respondents agreed that CMMS is a reason for the unavailability of anaesthesia and defibrillator machines. While for the ECG machines, it appears that hospitals more frequently keep records of maintenance and subsequent machine reliability on computer.

Respondents who think that the Current Maintenance Management Strategy (CMMS) is optimising (reducing) FRs are those respondents who operate machines with lower FRs anyway. The results seem to show anaesthesia machines between 1 and 5 years old have significantly lower failure rates, although machine operators are involved in maintenance decisions in those cases. Whereas Current Maintenance Management Strategy (CMMS) has a relatively significant correlation with lower FRs, this does not reduce sudden failure of machines because (1) facilities have a relatively large number of patients to treat per month while also spending longer annual operational time in treating patients (2) hospitals that more frequently keep maintenance records offer better subsequent equipment reliability (3) critical spare parts are readily available or kept in stock and (4) machines are used as a measure of reliability. This study agreed with Vanier (2010) who argues that while Computerised Maintenance Management Software CMMS is excellent for storing and analysing data, it was not widely used in the hospitals surveyed in this study.

This is consistent with proposals by Wang *et al.* (2006a) that health care organisations must analyse their equipment and their spare-parts inventories in order to operate effective, safe and reliable machines. This study provides evidence that healthcare organisations need to implement different maintenance strategies for CME, e.g. Reliability Centred Maintenance (RCM) because it is an effective measurement to evaluate the availability and reliability of medical equipment in healthcare organisations, increase health care provision and reduce FR and life cycle costs (Pun, Chin, Chow and Lau 2002).

This study agreed with the recommendations of the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) that hospitals need to improve their current maintenance strategies of CME and that CME be used differently for different equipment, e.g. alternative strategies may be employed for defibrillators

used in emergency departments and intensive care units, as opposed to equipment operating in general patient care areas or clinics (Wang and Levenson 2000; Wang *et al.* 2006). PM often does not increase reliability and actually may introduce failure, a notion well documented in industrial maintenance (Wang *et al.* 2006) as medical equipment becomes more complex and PM activities become less relevant. Whereas predictive maintenance actively utilises diagnostic methods such as CBM in order to avoid the risk of breakdown of medical equipment (Endrenyi *et al.*,(2001), it is important to be flexible in the planning and scheduling of maintenance activities because it is often difficult to perform planned maintenance activities at a suitable time due to the equipment being used on patients as well as outside factors beyond the operator's control. Also, there is a need to use a grace period (or slippage) for determining when an item of medical equipment must be considered overdue for planned inspection or maintenance (Wang et al., 2006).

7.11 Summary

This chapter brings together different types of critical medical equipment with varying characteristics (e.g. advantages, functions, machine manufacturers) leading to different sample sizes for each machine according to its availability and the type of health care service the equipment provides to patients. In statistical analysis within a study such as this, the results do not depend on sample size. Research questions and their hypotheses were generally supported through statistical analysis tests. Interesting findings for the majority of NSW public hospitals were:

1. LHDs do not implement and are largely unaware of Reliability-Centred Maintenance to evaluate and optimise the performance of their CME.
2. There were cases of patient outcomes affected by the sudden breakdown of the following machines: anaesthesia, defibrillator, infusion pumps, diathermy and cardiac catheterisation but as these cases are politically sensitive quantitative data was difficult to procure.
3. Few LHDs implement computerised maintenance management software, and hence data that could be used to better understand failure patterns and maintenance needs in relation to service, risks and cost is not widely available.
4. There is a lack of maintenance cost records for external contractual

maintenance and so while respondents felt that current practices are not cost effective, there is a lack of data available to confirm this.

5. Centralisation of medical facilities, reductions in dedicated maintenance staff, inventory policies and outsourcing may lead to inefficiencies in terms of cost and mean times to repair.

In conclusion, this study adds scientific value to maintenance management strategies by examining five integrated variables mentioned above[56], which play an important role in the safety, economics and life cycle of CME.

7.12 Conclusion and Contributions

A proposed model shown in Figure 7.5 for improving maintenance management strategies for CME is designed based on the results, discussions and recommendations in this thesis to improve patient outcomes. Model design steps are:

1. Identify the problem
2. Identify the current maintenance strategies used and the types of maintenance management strategies that could be used to increase CME availability and decrease the cost of ownership while achieving the desired level of patient outcomes including:
    a. Condition-Based Maintenance CBM
    b. Total Productive Maintenance TPM and
    c. Predictive maintenance
3. Introduce computerized maintenance management software (CMMS) which aims to provide data for analysis leading to the evaluation of availability of CME according to different strategic maintenance choices.
4. Integrate continuous improvement philosophies and cultures such as TPM and RCM into maintenance management strategies.

[56] Chapter 7, Section 7.0 Introduction, p. 274.

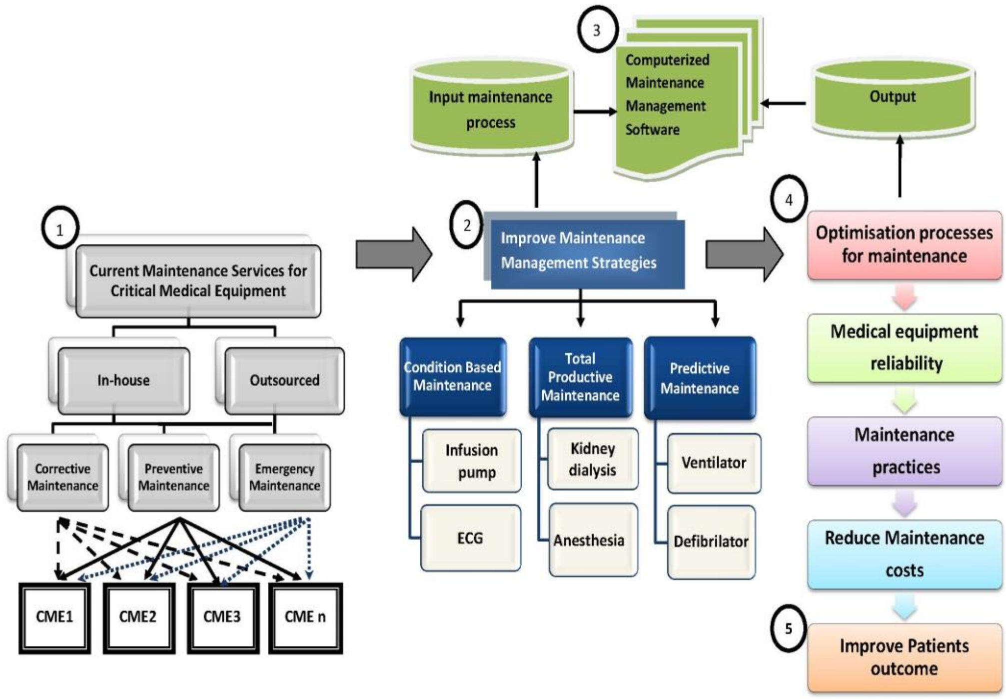


Figure 7-4: Model for improving maintenance management strategies used for critical medical equipment[57]

The formulation of the model proposed in this study could be of value for improving equipment maintenance strategies in hospitals and increasing the reliability of CME resulting in safer health care and improved patient outcomes

In conclusion, this study has highlighted that hospital management does not always rely on data gathering and predictive maintenance for CME. It also recognises the limitations of biomedical engineering departments and the consequently heavy reliance on outsourced contracts with maintenance companies. The evaluation of performance of CME was carried out by using qualitative and quantitative measures in order to examine failure rates and effects. Major factors considered by measurements were availability of CME and failure rates. As the final conclusion of this study it is proposed that maintenance management strategies could increase CME

[57] Figure designed by the researcher Mkalaf (2013)

availability and decrease the life-cycle costs while achieving the desired level of patient outcomes.

This study proposes the use of:

i. Computerised Maintenance Management Software CMMS
ii. Condition-Based Maintenance CBM
iii. Total Productive Maintenance (TPM) which has the potential to improve the quality of CME performance.

7.13 Limitations of this Study

The limitations of this study relate to the difficulties in accessing relevant and reliable data. This is because:

1. Many hospitals do not have a biomedical engineering department and a central database of maintenance activities because they tend to outsource these activities. Of the 230 hospitals only 13 hospitals (6%) had a biomedical engineering department. These hospitals tended to be large urban hospitals,
2. Each hospital uses different methods for keeping records of maintenance activities. For example one local health district uses a database (46%), another uses computers (43%) and others paper (11%). Of 101 survey respondents, only 6% said records of maintenance costs were often kept, 1% occasionally kept and 2% seldom kept. The lack of accessible data means that some hypotheses and research questions could not be answered,
3. The majority of hospital departments surveyed do not have available data records from biomedical departments when they carry out in-house maintenance services or data are not available for outsourced maintenance to assist these departments and/or management to make maintenance decisions.
4. The majority of hospitals do not have an efficient maintenance system which has adopted RCM, TPM, and CBM. Moreover, they generally do not have sufficient information on whether the device manufacturers use these types of maintenance strategies.
5. The hospitals' ethical approval policies were relaxed to facilitate the undertaking of the survey. But it was managed so that outcomes could be

achieved without concerns about possible repercussions. Ethics approval was obtained from the responsible authorities for each hospital.

7.14 Future Research

As stated at the beginning of this chapter, the author strongly believes this is the first substantial investigation into the area of asset and maintenance management of critical medical equipment. In the course of this investigation some serious concerns in relation to risks to patients and opportunities for more efficient and economic operation of equipment have been highlighted. The major restriction in making objective conclusions from this work has been limited quantitative data on machine performance, risk, failure patterns, life cycle maintenance costs and service to patients. While the opinions of operators, practitioners and maintenance professionals are extremely valuable and indicative of the likely overall situation, they are somewhat anecdotal and do not provide extensive statistical data of actual machine performance but there are some valid quantitative data of failure rates. The work has yielded significant further questions that should be the focus of future work. Programs designed to provide data that can be used for objective operational decision making on future maintenance policies should be the immediate goal. Central to the major theme and purpose of this research, the first question that should be answered is the rather delicate issue of death or injury to patients. This work has shown unequivocally that death or injury has occurred as a result of unpredicted equipment failure but in common with previous work, has not quantified the actual extent. The author suggests that a focussed ethics approval be sought to allow anonymous responses from practitioners on their recollections of death or injury resulting from failed medical equipment. It is then proposed that for each equipment type, and each hospital in which it is operated, a probability of death or injury resulting from each item of CME is calculated. This should then be correlated accurately with the asset management and maintenance policies used in particular locations to determine accurately which practices strongly correlate with death and/or injury. The aim would be to develop a benchmark from which improvement could be planned and managed in individual locations.

It is clear that maintenance policies used for critical medical equipment lag behind those developed in aviation and manufacturing industries in recent decades and there

are opportunities for hospitals to make cost and service improvements if they adopt some of these ideas. Therefore, it seems sensible that future work should more deeply investigate the potential for adoption of state of the art maintenance policies and practices. A prerequisite for this is a representative focussed computer management and data processing system. Therefore, the next logical step in this work is to implement a project to create a standard computerised maintenance data gathering and management system that could be adopted by all hospitals and applied to any item of CME. When correlated with maintenance policy and practice, this would provide essential data that could be used in a Reliability Centred Maintenance (RCM) environment to optimise management decisions on, for example, the need for preventive maintenance for each machine.

Leading on from the above, Condition Based Maintenance (CBM) clearly offers the potential for optimising cost-effective maintenance strategies and reducing unpredicted failures. However, implementing CBM is not straightforward and requires an intimate engineering knowledge of critical mechanical and electrical mechanisms and measurable wear factors that point to deteriorating machine performance. Therefore, it is likely that for CBM to be applicable a much enhanced engineering knowledge of the machines will be required. It is recommended that there should be an engineering pilot study using Failure Mode and Effects Analysis (FMEA) to determine and create knowledge bases of the critical wear factors and failure mechanisms in a few chosen pieces of CME. Then there will be need for engineering design work to develop measuring systems for critical wear factors and additions to machines to gather data to predict future maintenance needs. There is further potential to develop expert systems and intelligent programs to automatically predict when maintenance is becoming necessary and perhaps even make automatic adjustments to machines. CBM has enormous potential to improve the performance of CME while minimising arbitrary requirements for potentially harmful preventive maintenance (Waddington effect) thus making progress towards true Reliability Centred Maintenance (RCM).

A further study of human factors and culture of machine operators, medical practitioners and maintenance professionals is recommended to study the influence of human intervention on machine performance. Total Productive Maintenance (TPM)

requires machine users to be more intimately involved with their machines and capable of making minor maintenance decisions and carrying out interventions as required. This thesis suggests that machine operators in the NSW hospital system may not see maintenance as part of their job and may be actively discouraged by management from becoming involved because of a centralised organisation structure also a strict demarcation of job roles. The author strongly believes that for the proposed state of the art maintenance practices and decision making to be implemented successfully a degree of informed operator involvement is essential. However, there seems to be evidence that in NSW hospitals the opposite is common practice. Therefore, a study of maintenance management culture at all levels of the organisation to evaluate the need for culture change seems essential for the adoption of state of the art maintenance practices.

As with all effective research, this thesis has opened up many questions and it is unlikely that organisation wide research will be practical. It is therefore recommended that a pilot study be performed as a case study on the critical medical equipment available in one department of a hospital. (e.g. Surgical and Operation Theatre units), facilitated by biomedical or clinical engineering and medical management departments for obtaining a quantitative data sample. Biomedical engineering is one of the important factors that impacts on providing medical services in most health care organisations (Amissah *et al.* 2013) and so this function cannot be ignored. This would provide a statistical analysis test bed. It was difficult in this work to undertake a study such as this for different departments distributed across 17 LHD and Health Services. It was noted that it was impossible to pass survey forms between hospital staff when utilising the Monkey Survey website leading to incomplete online survey questionnaires from some hospitals, which were excluded from the statistical sample analysis.

There does not appear to be a significant variation in machine performance results when comparing in-house and outsourced maintenance strategies, although there is a general belief that outsourced maintenance costs are higher because outsourced maintenance contracts are not directly comparable with in-house requirements. Finally, it is recommended, that access to maintenance activity data for outsourced

maintenance is undertaken through biomedical departments and machine manufacturers to objectively investigate this question.

REFERENCES

1. Acevedo-Garcia, D., E. V. Sanchez-Vaznaugh, E. A. Viruell-Fuentes and J. Almeida (2012),"Integrating social epidemiology into immigrant health research: A cross-national framework", *Social science & medicine*, Vol 75, No 12, pp 2060-2068.

2. Acevedo, F. J., J. E. Fuentes and J. Enderie (2005), Design of computerised maintenance management system for the Chilean Naval Hospital Biomedical Engineering Department, *In 27th Annual International Conference of the Engineering in Medicine and Biology Society, September 1-4, 2005*, Shanghal, China, IEEE, pp 174-177.

3. Acevedo, F. J., J. E. Fuentes and J. Enderie (2006), *Design of computerised maintenance management system for the Chilean Naval Hospital Biomedical Engineering Department*, University of Connecticut.

4. Adachi, W. and A. E. Lodolce (2005),"Use of failure mode and effects analysis in Improving the safety of iv drug administration", *American Journal of Health-System Pharmacy*, Vol 62, No 9, pp 917-920.

5. Adler, P. A. and P. Adler (2011), *The tender cut: Inside the hidden world of self-injury*, New York University Press, New York.

6. Agrawal, V. and O. Gandhi (1997), Reliability-Centered Maintenance, *Proceedings of SERC School on RAM*, IIT Delhi, India, pp 145–152.

7. Ahuja, I. P. S. and J. S. Kamba (2008),"Total productive maintenance: Literature review and directions", *International Journal of Quality & Reliability Management*, Vol 25, No 7, pp 709-756.

8. Alexander, K. E. (1996), *Facilities Management: Theory and Practice*, Taylor & Francis, New York.

9. Alsyouf, I. (2006),"Measuring maintenance performance using a balanced scorecard approach", *Journal of Quality in Maintenance Engineering*, Vol 12, No 2, pp 133 -149.

10. Amissah, R. Q., A. K. Atchurey, L. L. Appiah, E. K. Fiakumah, E. E. Gyapong-Korsah, J. J. Boadu, E. E. Tetteh, E. E. Offei and E. Effah Kaufmann (2013),"Biomedical Engineering in Ghana", *European Scientific Journal*, Vol 9, No 9, pp 171-182.

11. Amuasi, J. and J. Crawley (2002), Twinning over the internet: Medical equipment repair, *Appropriate Medical Technology for Developing Countries, (Ref. No 2002/057), IEE Seminar on*, The Institution of Electrical Engineers, IET, pp 12/11-12/12.

12. Anderson, R. T. and L. Neri (1990), *Reliability-Centered Maintenance: management and engineering methods*, Elsevier Applied Science, LTD, London.

13. Apkon, M., J. Leonard, L. Probst, L. DeLizio and R. Vitale (2004),"Design of a safer approach to intravenous drug infusions: Failure mode effects analysis", *Quality and Safety in Health Care*, Vol 13, No 4, pp 265-271.

14. Armstrong, K. (2013), Cost-effective risk management of EMC without special EMC design expertise or testing, *Electromagnetic Compatibility (EMC), 2013 IEEE International Symposium*, IEEE, pp 386-391.

15. Avendaño, G., P. Fuentes, V. Castillo, C. Garcia and N. Dominguez (2010), Reliability and safety of medical equipment by use of calibration and certification instruments, *In Test Workshop (LATW), In the 11th Latin American*, 28-31 March 2010 Pule del Este, IEEE, pp 1-4.

16. Ayadi, D., L. Azzabi, A. Kobi, K. Bachar and C. Robledo (2013), A multicriteria failure mode and effects analysis approach for optimizing human safety, *Reliability and Maintainability Symposium (RAMS), 2013 Proceedings-Annual*, Orlando, FL IEEE, pp 1-9.

17. Baker, S. E. and R. Edwards (2012), How many qualitative interviews is enough?: Expert voices and early career reflections on sampling and cases in qualitative research, *National Center for Research Methods Review Paper*, pp 1-43, http://www.ncrm.ac.uk/TandE/video/podcas.

18. Barrett, C. B. and T. Reardon 2000, *'Asset, activity, and income diversification among African agriculturalists: Some practical issues'*, Ithaca, New York 14853-7801 USA: Department of Applied Economics and management, Cornell University.

19. Barrett, P. (1995), *Facilities Management: Towards Best Practice*, Blackwell Science, Oxford.

20. Barrett, P. (2000),"Achieving strategic facilities management through strong relationships", *Facilities*, Vol 18, No 10-12, pp 421-426, DOI: http://dx.doi.org/10.1108/02632770010349655.

21. Barrett, P. and D. Baldry (2009), *Facilities management: Towards best practice*, John Wiley & Sons.

22. Belak, S. (2004), Terotechnology, *Ocean '04 - MTS/IEEE Techno-Ocean '04*, pp 201-204.

23. Belak, S. and D. Cicin-Sain (2005),"Evolution of the terotechnology concept", *Scientific Journal of Maritime Research*, Vol 19, No 1, pp 79-87.

24. Bevilacqua, M., F. E. Ciarapica and G. Giacchetta (2009),"Critical chain and risk analysis applied to high-risk industry maintenance: A case study", *International Journal of Project Management*, Vol 27, No 4, pp 419-432.

25. Blalock, H. M. (1985), *Causal models in the social sciences*, Aldine Transaction Publishers, New Brunswick, U.S.A. and U.K.

26. Blechertas, V., A. Bayoumi, N. Goodman, R. Shah and Y. J. Shin (2009), CBM Fundamental Research at the University of South Carolina: A Systematic Approach to US Army Rotorcraft CBM and the Resulting Tangible Benefits, *The American Helicopter Society technical Specialists' Meeting on Condition Based Maintenance*, 10-11 Fecb. 2009, Huntsville, AL, American Helicopter Society International, Inc., pp 1-20.

27. Bloom, N. B. (2006), *Reliability- Centered Maintenance: Implementation made simple*, McGraw-Hill, New York,US.

28. Bluemke, D. H. (1995),"Long-term service contracts may not be advantageous", *Healthcare Financial Management*, Vol 49, No 4, pp 72-76.

29. Brady, M. (2013),"Prevent sudden deaths: Make sure your workers can quickly handle a cardiac crisis", *ISHN*, Vol 47, No 12, pp 24-24.

30. Braun, O., R. McCallion and J. Fazackerley (1990),"Characteristics of midsized urban EMS systems", *Annals of emergency medicine*, Vol 19, No 5, pp 536-546.

31. Briggs, A., Sculpher, M., Claxton, K. (2006), Decision modelling for health economic evaluation, OUP Oxford, pp 1-256.

32. Brook, R. (1998),"Total predictive maintenance cuts plant costs", *Plant Engineering*, Vol 52, No 4, pp 93-98.

33. Brown, I., A. Smale, M. Wong and C. Yeo (2001), The management of medical technology, *IEEE*, IEEE, pp 367-372.

34. Bryman, A. (2012), *Social research methods*, Oxford University Press Inc., New York.

35. Bureau of Health Information December 2010, *'Healthcare in Focus: How NSW Compares Internationally'*, Annual performance report, NSW Health Government, Sydney, NSW, Australia.

36. Bureau of Heath Information 2011, *'Technical Supplement'*, NSW Health Government, Sydney, NSW, Australia.

37. Bureau of Heath Information 2012/2013, *'Health In Focus: Financial and Corporate Report;Timely, accurate and comparable information about the performance of the NSW public health system'*, Annual performance report, NSW Ministry of Health Corporate Governance and Accountability Compendium, Sydney, NSW, Australis.

38. Cannesson, M., G. Pestel, C. Ricks, A. Hoeft and A. Perel (2011),"Hemodynamic monitoring and management in patients undergoing high risk surgery: a survey among North American and European anesthesiologists", *Crit Care*, Vol 15, No 4, pp 197.

39. Cassady, C. R. and J. A. Nachlas (1998), Preventive maintenance: the next frontier in industrial productivity growth, *Industrial Engineering' 98 Solutions Conference Proceedings*, pp 254-260.

40. Checkland, P. B. (1979),"Systems approach to terotechnology: Defining the concept", *Terotechnica*, Vol 1, No 2, pp 83-88.

41. Chelbi, A., N. Rezg and M. Radhoui (2008),"Simultaneous determination of production lot size and preventive maintenance schedule for unreliable production system", *Journal of Quality in Maintenance Engineering*, Vol 14, No 2, pp 161-176.

42. Cheng, M. (1995),"An international strategy in medical equipment maintenance", *Journal of Clinical Engineering*, Vol (20), No (1), pp 66-76.

43. Cheng, Z.-H., L.-Q. Rong and Z.-Y. Liu (2013), A RCM analytical method considering proactive maintenance, *International Conference on: Quality, Reliability, Risk, Maintenance, and Safety Engineering (QR2MSE)*, IEEE, pp 1473-1476.

44. Chien, C. H., Y. Y. Huang and F. C. Chong (2010), A framework of medical equipment management system for in-house clinical engineering department, IEEE, pp 6054-6057.

45. Chin, K.-S., A. Chan and J.-B. Yang (2008),"Development of a fuzzy FMEA based product design system", *The International Journal of Advanced Manufacturing Technology*, Vol 36, No 7-8, pp 633-649.

46.Chin, K.-S., Y.-M. Wang, G. K. K. Poon and J.-B. Yang (2009),"Failure mode and effects analysis by data envelopment analysis", *Decision Support Systems*, Vol (48), No (1), pp 246-256.

47. Cholasuke, C., R. Bhardwa and J. Antony (2004),"The status of maintenance management in UK manufacturing organisations: results from a pilot survey", *Journal of Quality in Maintenance Engineering*, Vol 10, No 1, pp 5-15.

48. Chompu-inwai, R., S. Tipgunta and A. Sunawan (2008a), Implementation of total productive maintenance in healthcare: A pilot study, *International Conference on Service Systems and Service Management*, Melbourne, VIC, IEEE, pp 1-6.

49. Chompu-inwai, R., S. Tipgunta and A. Sunawan (2008b), Implementation of total productive maintenance in healthcare: A pilot study, *Service Systems and Service Management, 2008 International Conference on*, June 30 2008-July 2 2008, Melbourne, VIC, IEEE, pp 1-6.

50. Coetzee, J. L. (2004), *Maintenance*, Trafford Publishing, Victoria, Canada.

51. Cohen, T. (2003), Computerized Maintenance Management Systems for Clinical Engineering, C. 2th Edition, AAMI MIR pp 7-10.

52. Cooper, M. and M. A. Makary (2012),"A comprehensive unit-based safety program (CUSP) in surgery: improving quality through transparency", *Surgical Clinics of North America*, Vol 92, No 1, pp 51-63.

53. Da Rocha, L., E. B. Sloane and J. W. M. Bassani (2005), Optimal medical equipment maintenance service proposal decision support system combining Activity Based Costing (ABC) and the Analytic Hierarchy Process (AHP), *IEEE*, Engineering in Medicine and Biology 27th Annual Conference, IEEE, pp 7103-7106.

54. Da Silva, C. M. I., C. M. P. Cabrita and J. C. de Oliveira Matias (2008),"Proactive reliability maintenance: a case study concerning maintenance service costs", *Journal of Quality in Maintenance Engineering*, Vol 14, No 4, pp 343-355.

55. Dancey, C. P. and J. Reidy (2004), *Statistics without maths for psychology students using SPSS for Windows*, Pearson Education, London, Premtice Hall.

56. Danielson, B. (1987), A study of maintenance problems in Swedish mines, *Status Report (3rd ed.) Idhammar Konsultant AB*, Stockholm (Swedish), Sweden.

57. Danylo, N. H. and A. Lemer (1998), Asset management for the public works manager: Challenges and strategies findings of the APWA task force on asset management, July, 25, p. 2007, Washington, DC.

58. De Souza, R. V. B. and L. C. R. Carpinetti (2014),"A FMEA based approach to prioritize waste reduction in lean implementation", *International Journal of Quality & Reliability Management*, Vol 31, No 4, pp 346-366.

59. De Vivo, L., P. Derrico, D. Tomaiuolo, C. Capussotto and A. Reali (2004), Evaluating alternative service contracts for medical equipment, *Engineering in Medicine and Biology Society, IEMBS '04. 26th Annual International Conference of the IEEE*, 1-5 Sept. 2004, IEEE, pp 3485-3488.

60. Dekker, R. (1996),"Applications of maintenance optimization models: a review and analysis", *Reliability engineering & system safety*, Vol (51), No (3), pp 229-240.

61. Dekker, R., M. J. Kleijn and P. De Rooij (1998),"A spare parts stocking policy based on equipment criticality", *International Journal of production economics*, Vol 56, No 20, pp 69-77.

62. Derfel, A. (2012a),"Jewish General discloses more accident details; Hospital won't reveal exactly how medical errors killed some patients, harmed others", *The Gazette, CanWest Digital Media*, 16 Mar 2012.

63. Derfel, A. (2012b),"Montreal's McGill and Jewish hospitals blame accidents for 10 deaths in 2011", *Postmedia News, CanWest Digital Media*, 15 Mar 2012.

64. Dhillon, B. S. (2002), *Engineering maintenance: a modern approach*, CRC Press, Boca Raton, FL.

65. Dhillon, B. S. and Y. Liu (2006),"Human error in maintenance: a review", *Journal of Quality in Maintenance Engineering*, Vol 12, No 1, pp 21-36.

66. Dieffaga, T., M. Sanogo and S. Maiga (2013),"P360: Materiovigilance and improvement of the maintenance of the biomedical equipment by the implementation

of strategies for the use of equipment: case study of the hospital Gabriel Touré of Mali", *Antimicrobial Resistance and Infection Control*, Vol (2), No (Suppl 1), pp 360.

67. Dos Santos, R. and R. M. V.R. Almeida (2010),"Hospital medical equipment maintenance schedules using the mean time between failures", *Rio de Janeiro (RJ), Brazil*, Vol 18, No 2, pp 309-314.

68. Drăguţoiu, D. (2009),"Optimizing maintenance based on the principles of terotechnology", *Petroleum-Gas University of Ploiesti Bulletin, Technical Series*, Vol 61, No 1, pp 79-81.

69. Ehrenwerth, J., J. B. Eisenkraft and J. M. Berry (2013), *Anesthesia Equipment, Principles and Applications (Expert Consult: Online and Print), 2: Anesthesia Equipment*, Elsevier Health Sciences.

70. Ellner, S. J. and P. W. Joyner (2012),"Information technologies and patient safety", *Surgical Clinics of North America*, Vol 92, No 1, pp 79-87, DOI: http://dx.doi.org/10.1016/j.suc.2011.11.002.

71. Emmanuel, E. T. J. (2010), *Maintenance performance measurement perception in the oil and gas industry*, A Thesis Submitted for the Master of Engineering, National University of Singapore.

72. Endrenyi, J., S. Aboresheid, R. Allan, G. Anders, S. Asgarpoor, R. Billinton, N. Chowdhury, E. Dialynas, M. Fipper and R. Fletcher (2001),"The present status of maintenance strategies and the impact of maintenance on reliability", *Power Systems, IEEE Transactions on*, Vol 16, No 4, pp 638-646.

73. Eti, M. C., S. Ogaji and S. Probert (2006),"Strategic maintenance-management in Nigerian industries", *Applied energy*, Vol 83, No 3, pp 211-227.

74. Frisch, P. H., C. C. Ling and W. Lui (2003), Optimization of biomedical engineering within a comprehensive cancer center, *Engineering in Medicine and Biology Society, 2003. Proceedings of the 25th Annual International Conference of the IEEE*, 17-21 Sept. 2003, pp 3586-3589.

75. Garg, A. and S. Deshmukh (2006),"Maintenance management: Literature review and directions", *Journal of Quality in Maintenance Engineering*, Vol 12, No 3, pp 205-238.

76. Ghasemi, A., S. Yacout and M. S. Ouali (2008),"Optimal strategies for non-costly and costly observations in Condition Based Maintenance", *IAENG International Journal of Applied Mathematics*, Vol 38, No 2, pp 99-107.

77. Glaser, B. G. and A. L. Strauss (2009), *The discovery of grounded theory: Strategies for qualitative research*, Transaction Publishers.

78. Graziano, A. M. and M. L. Raulin (2007), *Research methods: A process of inquiry*, HarperCollins College Publishers, US, Americ.

79. Gresenz, C. R. and D. M. Studdert (2004),"Disputes over coverage of emergency department services: A study of two health maintenance organizations", *Annals of emergency medicine*, Vol 43, No 2, pp 155-162.

80. Guion, L. A. (2002), *Triangulation: Establishing the validity of qualitative studies,* Department of Family, Youth and Community Scienices University University of Florida, USA.

81. Hartmann, E. H. and H. L. Charles (2001), Total productive maintenance, *Maynard's Industrial Engineering Handbook*, K. B. Zandin, McGraw-Hill, New York, pp 16.57-16.77.

82. Hay, J., S. Forrest and M. Goetghebeur (2001), Executive summary: Hospital costs in the US, *Blue Cross Blue Shield Association*.

83. HCPRO (2014),"CMS approves new risk-based preventive maintenance strategy on hospital equipment", *Healthcare Life Safety Compliance*, Vol 16, No 3, pp 1-5.

84. He, D. and E. Bechhoefer (2008), Development and validation of bearing diagnostic and prognostic tools using HUMS condition indicators, *Aerospace Conference*, Big Sky, MT, IEEE, pp 1-8.

85. Hekmatpanah, M., A. Shahin and N. Ravichandran (2011),"The application of FMEA in the oil industry in Iran: The case of four litre oil canning process of Sepahan Oil Company", *African Journal of Business Management*, Vol 5, No 8, pp 3019-3027.

86. Ishida, K., M. Hirose, K. Fujiwara, H. Tsuruta and N. Ikeda (2014),"Analysis of Medical Equipment Management in Relation to the Mandatory Medical Equipment Safety Manager (MESM) in Japan", *Journal of Healthcare Engineering*, Vol 5, No 3, pp 329-346.

87. Jardine, A. and A. Tsang (2006), *Maintenance, Replacement, and Reliability Theory and Applications*, Taylor and Francis Group LLC, London and New York.

88. Jaw, L. C. (2005), Recent advancements in aircraft engine health management (EHM) technologies and recommendations for the next step, *ASME Turbo Expo 2005: Power for Land, Sea, and Air*, Reno, Nevada, USA, American Society of Mechanical Engineers, pp 683-695.

89. JCAHO (2006),"Infusion Pump Maintenance Strategy", *Biomedical Instrumentation & Technology*, Dec. 2006.

90. Jick, T. D. (1979),"Mixing qualitative and quantitative methods: Triangulation in action", *Administrative Science Quarterly*, Vol 24, No 4, pp 602-611.

91. Judd, T., J. Dyro and J. Wear (2004), Advanced health technology management workshop, *Clinical Engineering Handbook*, Elsevier.

92. Kachieng'a, M. (2001), Development of a health technology policy framework for sustainable health care services in South Africa, *IEEE*, IEEE, pp 298-304.

93. Kalra, J. (2011), '*Medical errors and patient safety: Strategies to reduce and disclose medical errors and improve patient safety'* Walter de Gruyter, New York.

94. Keil, O. R. (1997),"Is preventive maintenance still a core element of clinical engineering?", *Biomedical Instrumentation & Technology*, Vol 31, No 4, pp 408-409.

95. Khalaf, A., K. Djouani, Y. Hamam and Y. Alayli (2010), Evidence-based mathematical maintenance model for medical equipment, *International Conference on Electronic Devices, Systems and Applications (ICEDSA)*, 11-14 April 2010, Kuala Lumpur, IEEE, pp 222-226.

96. Khalaf, A. B., Y. Hamam, Y. Alayli and K. Djouani (2013),"The effect of maintenance on the survival of medical equipment", *Journal of Engineering, Design and Technology*, Vol 11, No 2, pp 142-157.

97. Khalid, R. A.-M., D. A.-T. Mohammad and T. J. Enas (2006), Performance measures for improvement of maintenance effectiveness: A Case study in King Abdullah University Hospital (KAUH), *International Conference on Service Systems and Service Management*, Oct. 2006, Troyes, IEEE, pp 632-637.

98. Khan, F. I. and M. M. Haddara (2003),"Risk-based maintenance (RBM): a quantitative approach for maintenance/inspection scheduling and planning", *Journal of Loss Prevention in the Process Industries*, Vol 16, No 6, pp 561-573.

99. Khan, M. R. R. and I. A. Darrab (2010),"Development of analytical relation between maintenance, quality and productivity", *Journal of Quality in Maintenance Engineering*, Vol 16, No 4, pp 341-353.

100. Khandpur, R. S. (1989), Strategy for biomedical equipment maintenance in developing countries, *Engineering in Medicine and Biology Society, 1989. Images of the Twenty-First Century. Proceedings of the Annual International Conference of the IEEE in Engineering*, 9-12 Nov 1989, Seattle, WA, IEEE, pp 1593-1594

101. Khoury, M., L. Burnett and M. A. Mackay (1996),"Error rates in Australian chemical pathology laboratories", *The Medical Journal of Australia*, Vol 165, No 3, pp 128-130.

102. Kleijn, M. J. and R. Dekker (1999), *An overview of inventory systems with several demand classes*, Springer, Verlag Berlin Heidelberg.

103. Kostic, T. (2003), Asset management in electrical utilities: how many facets it actually has, *Power Engineering Society General Meeting, 2003, IEEE*, Beden, Switzerland, IEEE, pp 275-281.

104. Kumar, N. P. and N. J. Srinivas (2014),"Insights into equipment planning of a 250-Bed hospital project", *International Journal of Health Sciences and Research* Vol 4, No 10, pp 311-321.

105. Kumar, U. (2006), Development and implementation of maintenance performance measurement system: Issues and challenges, *In Engineering Asset Management, WCEAM Paper*, Springer London.

106. Kusinitz, A. (2004),"Understanding CAPA Requirements in a Software Context", *Biomedical Instrumentation & Technology*, Vol 38, No 3, pp 221-224.

107. Kutlu, A. C. and M. Ekmekçioğlu (2012),"Fuzzy failure modes and effects analysis by using fuzzy TOPSIS-based fuzzy AHP", *Expert Systems with Applications*, Vol 39, No 1, pp 61-67.

108. Landrigan, C. P., G. J. Parry, C. B. Bones, A. D. Hackbarth, D. A. Goldmann and P. J. Sharek (2010),"Temporal trends in rates of patient harm resulting from medical care", *New England Journal of Medicine*, Vol 363, No 22, pp 2124-2134.

109. Lemer, A. (1998), Progress toward integrated infrastructure-assets-management systems: GIS and beyond, Citeseer, pp 7-24.

110. Levery, M. (1998),"Maintenance strategies", *Manufacturing Engineer*, Vol 77, No 1, pp 29-33.

111. Licona, F. M., J. A. Leehan, M. C. Méndez, S. D. Yuriar, R. M. Salazar and A. T. Gilmore (2009),"Knowledge network for medical technology management in Mexico", *International journal of technology assessment in health care*, Vol 25, No 4, pp 564-569.

112. Lo, M. (2004a), Benchmarking biomedical equipment maintenance in hospital authority (HA), *Appropriate Medical Technology for Developing Countries, 3rd IEE Seminar on*, 4-4 Feb. 2004, pp 13/11-13/15.

113. Lo, M. (2004b), Formulating equipment maintenance strategy in Hospital Authority (HA), *3rd IEE Seminar on Appropriate Medical technology for Developing Countries, 4-4 Febrary 2004*, London, United kingdom, Institution of Engineering and Technology, pp 61-64.

114. Logan, M., C. Davis-Smith and A. Gresch (2011),"Maintenance and repair of anesthesia machines", *AORN, Inc*, Vol 93, No 2, pp 195, DOI: Http://dx.doi.org/10.1016/i.aorn.2010.12.008.

115. Luo, J., M. Namburu, K. Pattipati, L. Qiao, M. Kawamoto and S. Chigusa (2003), Model-based prognostic techniques - maintenance applications, *IEEE Systems Readiness Technology Conference, 22-25 Sept. 2003*, IEEE, pp 330- 340.

116. Lynch, P. K. (2013),"Medical equipment maintenance abroad", *Biomedical Instrumentation & Technology*, Vol 47, No 5, pp 436-438.

117. MacGregor, R. C., P. N. Hyland, C. Harvie and B.-C. Lee (2007),"Benefits derived from ICT adoption in regional medical practices: perceptual differences between male and female general practitioners", *International Journal of Healthcare Information Systems and Informatics (IJHISI)*, Vol 2, No 1, pp 1-13.

118. Mages, M. E. (2006),"Clinical asset aanagement; How targeted planning saves time and money", *Healthcare Executive SEPT/OCr*, Vol 21, No 5, pp 56-57.

119. Malkin, R. and A. Keane (2010),"Evidence-based approach to the maintenance of laboratory and medical equipment in resource-poor settings", *Medical and Biological Engineering and Computing*, Vol 48, No 7, pp 721-726.

120. Manning, M. and D. Munro (2007), *The survey researcher's SPSS cookbook*, Pearson Education-Australia.

121. March, P. A. (2003),"Quantifying the maintenance costs associated with variable operating conditions", *HYDRO REVIEW*, Vol 22, No 4, pp 98-107.

122. Masmoudi, M., Z. Ben Houria and F. Masmoudi (2014), Multicriteria decision making for medical equipment maintenance: Insourcing, outsourcing and service contract, *International Conference on Control, Decision and Information Technologies (CoDIT)*, Metz, IEEE, pp 269-275.

123. Meckler, G., J. Leonard and J. Hoyle Jr (2014),"Pediatric patient safety in emergency medical services", *Clinical Pediatric Emergency Medicine*, Vol 15, No 1, pp 18-27.

124. Medhat, N., S. Samy, M. A. Wahed and A. Mohamed (2008), Medical equipment quality assurance by making continuous improvement to the system, *Cairo International Biomedical Engineering Conference, 18-20 Dec. 2008*, Cairo, IEEE, pp 1-4.

125. Medical Buyer (2014a),"ECG Equipment: More than Just Technology", *Medical Buyer*, Mar 2014.

126. Medical Buyer (2014b),"Hospital equipment management", *Medical Buyer*, Feb 2014.

127. Mitchell, J. S. (2007),"From Vibration Measurements to Condition-Based Maintenance", *Sound and Vibration*, Vol 41, No 1, pp 62.

128. Mkalaf, K., A. , P. Gibson and J. Flanagan (2013), A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes, *International Journal of Management Science and Engineering*, France, Paris, World Academy of Science, Engineering and Technology, pp 77-84.

129. Moayed, F. A. and R. L. Shell (2009),"Comparison and evaluation of maintenance operations in lean versus non-lean production systems", *Journal of Quality in Maintenance Engineering*, Vol 15, No 3, pp 285-296.

130. Mock, F., H. Schrenker and H. Stark (2005),"A clinical longitudinal study assessing the survival of double crown-retained prostheses", *Deutsche Zahnärztliche Zeitschrift*, Vol 60, pp 148-153.

131. Mosesso Jr, V. N., E. A. Davis, T. E. Auble, P. M. Paris and D. M. Yealy (1998),"Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest", *Annals of emergency medicine*, Vol 32, No 2, pp 200-207.

132. Moubray, J. (1997), *Reliability-Centered Maintenance*, Industrial Press, New York.

133. Muchiri, P., L. Pintelon, L. Gelders and H. Martin (2011),"Development of maintenance function performance measurement framework and indicators", *International Journal of Production Economics*, Vol 131, No 1, pp 295-302.

134. Mullally, S. and M. Frize (2008), Survey of clinical engineering effectiveness in developing world hospitals: Equipment resources, procurement and donations, *Engineering in Medicine and Biology Society, EMBS 20-25 Aug. 2008, 30th Annual International Conference of the IEEE*, Vancouver, BC, IEEE, pp 4499-4502.

135. Murthy, D., A. Atrens and J. Eccleston (2002),"Strategic maintenance management", *Journal of Quality in Maintenance Engineering*, Vol 8, No 4, pp 287-305.

136. Mutia, D., J. Kihiu and S. Maranga (2012),"Maintenance management of medical equipment in hospitals", *Industrial Engineering Letters*, Vol 2, No 3, pp 9-19.

137. Myeda, N. E., S. N. Kamaruzzaman and M. Pitt (2011),"Measuring the performance of office buildings maintenance management in Malaysia", *Journal of Facilities Management*, Vol 9, No 3, pp 181-199.

138. Nebeker, F. (2002),"Golden accomplishments in biomedical engineering", *Engineering in Medicine and Biology Magazine, IEEE*, Vol 21, No 3, pp 17-47.

139. Nelson, M. L. and K. Alexander (2002), The emergence of supply chain management as a strategic facilities management tool, in Alexander, K. (ed.), *Proceedings of the Euro FM Research Symposium in Facilities Management*, 9-10 April, 2002, Salford, UK, The University of Salford, pp

140. Nicholas, J. M. (1998), *Competitive manufacturing management*, Irwin/McGraw-Hill, New York, NY.

141. Nowlan, F. S. and H. F. Heap (1978), *Reliability-centered maintenance*, United Air Lines Inc., San Francsco CA.

142. NSW Health Statistics 2014, *'Population Growth by Local Health District'*, NSW Ministry of Health Corporate Governance and Accountability Compendium, Sydeny, NSW, Australia.

143. NSW Ministry of Health Decmber 2011, *'NSW Health Annual Report 2010 /2011'*, Sydney, Australia.

144. Olaiya, S. T. 1999, *'Selection of Equipment Service Option, Estimation of equipment maintenance costs, and comparative costs analysis, Brooke Army Medical Center'*, Fort Sam Houston, Texas: DTIC Document.

145. Pantelias, A. (2005), *Asset management data collection for supporting decision processes*, Master of Science In Civil and Environmental Engineering, Virginia Polytechnic Institute and State University.

146. Parida, A. (2007),"Study and analysis of maintenance performance indicators (MPIs) for LKAB-a case study", *Journal of Quality in Maintenance Engineering*, Vol 13, No 4, pp 325-337.

147. Parida, A. and U. Kumar (2006),"Maintenance performance measurement (MPM): issues and challenges", *Journal of Quality in Maintenance Engineering*, Vol 12, No 3, pp 239-251.

148. Patterson, D., A. Brown, P. Broadwell, G. Candea, M. Chen, J. Cutler, P. Enriquez, A. Fox, E. Kiciman and M. Merzbacher 2002, *'Recovery-oriented computing (ROC): Motivation, definition, techniques, and case studies'*, Citeseer, Berkeley, Calif.: Technical Report UCB//CSD-02-1175, UC Berkeley Computer Science, Univ. of Calif.

149. Pearl, J. (2015), '*An Introduction to Causal Inference'*.

150. Peters, R. W. (2007), Maintenance management and control, *Handbook of Industrial Engineering: Technology and Operation Management*, E. G. Salvendy, John Wiley & Sons Inc., New York, pp 1585-1623.

151. Pillay, A. and J. Wang (2003),"Modified failure mode and effects analysis using approximate reasoning", *Reliability engineering & system safety*, Vol 79, No 1, pp 69-85.

152. Pintelon, L. and A. Parodi-Herz (2008), Maintenance: an evolutionary perspective, *Complex System Maintenance Handbook*, Springer-Verlag London Limited, London, pp 21-48.

153. Pintelon, L., S. K. Pinjala and A. Vereecke (2006),"Evaluating the effectiveness of maintenance strategies", *Journal of Quality in Maintenance Engineering*, Vol 12, No 1, pp 7-20.

154. Pintelon, L. M. and L. Gelders (1992),"Maintenance management decision making", *European Journal of Operational Research*, Vol 58, No 3, pp 301-317.

155. Polisena, J., J. Jutai and R. Chreyh (2014), A proposed framework to improve the safety of medical devices in a Canadian hospital context, *Medical Devices : Evidence and Research*, Auckland, NZ, pp 139-147.

156. Pun, K. F., K. S. Chin, M. F. Chow and H. C. W. Lau (2002),"An effectiveness-centred approach to maintenance management: A case study", *Journal of Quality in Maintenance Engineering*, Vol 8, No 4, pp 346-368.

157. Rajagopalan, R. and C. R. Cassady (2006),"An improved selective maintenance solution approach", *Journal of Quality in Maintenance Engineering*, Vol 12, No 2, pp 172-185.

158. Ratnayake, R. C. and T. Markeset (2010a),"Technical integrity management: measuring HSE awareness using AHP in selecting a maintenance strategy", *Journal of Quality in Maintenance Engineering*, Vol 16, No 1, pp 44-63.

159. Ratnayake, R. M. C. and T. Markeset (2010b),"Technical integrity management: measuring HSE awareness using AHP in selecting a maintenance strategy", *Journal of Quality in Maintenance Engineering*, Vol 16, No 1, pp 44-63.

160. Reason, J. (2000), Cognitive Engineering in Aviation Domain, *Lawrence Erlbaum Associates*, Mahwah, NJ.

161. Ridgway, M. (2008), Decoding the PM puzzle, *In presented at 20th Biomedical Symposium Massachusetts*.

162. Ridgway, M. (2009),"Optimizing our PM programs", *Biomedical Instrumentation & Technology*, Vol 43, No 3, pp 244-254.

163. Ridgway, M., L. R. Atles and A. Subhan (2009),"Reducing equipment downtime: A new line of attack", *Journal of Clinical Engineering*, Vol 34, No 4, pp 200-204.

164. Rocha, L. S. and J. W. M. Bassani (2004), Cost management of medical equipment maintenance, *Engineering in Medicine and Biology Society, 2004. IEMBS '04. 26th Annual International Conference of the IEEE*, 1-5 Sept. 2004, pp 3508-3511.

165. Sadeghian, S., M. R. M. Dezfouli, G. A. Kojouri, T. T. Bazargani and A. Tavasoli (2011),"Pasteurella multocida pneumonic infection in goat: Hematological, biochemical, clinical and pathological studies", *Small Ruminant Research*, Vol 100, No 2, pp 189-194.

166. Saetang, S. and A. Haider (2014), IT Governance, Risk management and value delivery in construction organizations: Literature review analysis, *Proceedings of the 17th International Symposium on Advancement of Construction Management and Real Estate*, Springer Berlin Heidelberg, pp 935-942.

167. Sahney, V. K. and S. K. Kachhal (2001), Health service, *Maynard's Industrial Engineering Handbook*, K. B. Zandin, McGraw-Hill, New York, pp 15.43-15.64.

168. Salonen, A. (2011a), *Strategic maintenance development in manufacturing industry* Doctor Thesis, Mälardalen University Press Dissertations.

169. Salonen, A. (2011b), Strategic maintenance improvement: driving forces and obstacles, *Engineering Asset Management and infrastructure sustainability*, Springer-Verlag London Limited, London, pp 789-800.

170. Samat, H. A., S. Kamaruddin and I. A. Azid (2011),"Maintenance performance measurement: A review", *Pertanika J. Sci. & Technol*, Vol 19, No 2, pp 199-211.

171. Schrenker, R. (2010),'The case for a systems focus in healthcare', *in Biomedical Instrumentation &Technology, IT Horizons*, pp 13-17.

172. Schrenker, R. A. (2005),'Systems and software engineering contribute not only to advancing and improving the delivery of healthcare but also to doing it more safely than has been the case in the past', in *Biomedical Instrumentation and Technology*, pp 194-199.

173. Segal, B., D. Davis, C. Trueman and T. Pavlasek (2001), Risk of patient injury due to electromagnetic-interference malfunctions: Estimation and minimization, *IEEE International Symposium on Electromagnetic Compatibility*, 13 -17 Aug. 2001, Montreal, Que., IEEE, Vol 2, pp 1308-1312

174. Sethiya, S. (2010), Condition Based Maintenance (CBM), *Secy. to CME/WCR/JBP*, Citeseer.

175. Shahanaghi, K. and S. A. Yazdian (2009),"Analyzing the effects of implementation of Total Productive Maintenance (TPM) in the manufacturing companies: a system dynamics approach", *World Journal of Modelling and Simulation*, Vol 5, No 2, pp 120-129.

176. Sharma, R. K., D. Kumar and P. Kumar (2005),"Systematic failure mode effect analysis (FMEA) using fuzzy linguistic modelling", *International Journal of Quality & Reliability Management*, Vol 22, No 9, pp 986-1004.

177. Shohet, I. M. and S. Lavy (2004),"Development of an integrated healthcare facilities management model", *Facilities*, Vol 22, No 5/6, pp 129-140.

178. Sinha, P. R., L. E. Whitman and D. Malzahn (2004),"Methodology to mitigate supplier risk in an aerospace supply chain", *Supply Chain Management: an international journal*, Vol 9, No 2, pp 154-168.

179. Slack, N., S. Chambers, C. Harland, A. Harrison and R. Johnston (2005), *Operation Management*, Pitman Publishing, London.

180. Smith, A. M. (2004),'RCM-Gateway Toward Class Maintenance', in *Butterworth-Heineman*, Oxford, pp 10-15.

181. Smith, P. J. (2010), *An investigation of the strategies used by organizations participating in the welfare-to-work network programs and correlation of the strategies with the retention data to determine best practices for job retention among former welfare recipients*, Doctor of Eduction FIU Electronic Theses and Dissertations, Paper 326, Florida International University.

182. Stadnicka, D. and K. Antosz (2013),"TPM in Large Enterprises: Study Results", *World Academy of Science, Engineering and Technology, International Journal of Mechanical, Industrial Science and Engineering* Vol 7, No 82, pp 759-766.

183. Stadnicka, D. and K. Antosz (2014),"The results of the study concerning the identification of the activities realized in the management of the technical infrastructure in large enterprises", *Eksploatacja i Niezawodność*, Vol 16, No 1, pp 112-119.

184. Stadnicka, D., K. Antosz and R. M. Chandima Ratnayake (2014),"Development of an empirical formula for machine classification: Prioritization of maintenance tasks", *Safety Science*, Vol 63, No 0, pp 34-41.

185. Stenström, C. 2013, *'Link and effect model for maintenance of railway infrastructure; Research report'*, Luleå University of Technology, Sweden.

186. Sullivan, J. T. and J. B. Cooper (2013), Risk management and medicolegal aspects of anesthesia equipment, *Anesthesia equipment, principles and applications (Expert Consult: Online and Print), 2: Anesthesia Equipment*, Elsevier Health Sciences, pp 682-692.

187. Swanson, L. (2001),"Linking maintenance strategies to performance", *International Journal of Production Economics*, Vol 70, No 3, pp 237-244.

188. Taghipour, S. (2011), *Reliability and Maintenance of Medical Devices*, University of Toronto.

189. Taghipour, S. and D. Banjevic (2012),"Optimal inspection of a complex system subject to periodic and opportunistic inspections and preventive replacements", *European Journal of Operational Research*, Vol 220, No 3, pp 649-660.

190. Taghipour, S., D. Banjevic and A. K. Jardine (2011a),"Prioritization of medical equipment for maintenance decisions", *Journal of the Operational Research Society*, Vol 62, No 9, pp 1666-1687.

191. Taghipour, S., D. Banjevic and A. K. S. Jardine (2011b),"Prioritization of medical equipment for maintenance decisions", *The Journal of the Operational Research Society*, Vol 62, No 9, pp 1666-1687.

192. Tarawneh, W. and S. El-Sharo (2009), Assessment of medical equipment In respect to their down time, *IFMBE*, Munich, Germany, Springer Berlin Heidelberg, pp 267-270.

193. Tchokodjeu, E. K. (2011), *Setting up of a clinical engineering service in a high tech hospital in a remote area. The case of Shisong cardiac centre in Cameroon*, Master of Sciences Degree, Biomedical Engineering Master of Sciences Degree, Biomedical Engineering, Emmanuel Kouemo Tchokodjeu.

194. Temple-Bird, C., R. Mhiti and G. Bloom 1995, *'Medical equipment in Botswana: A framework for management development'*, WHO/SHS/NHP, Geneva/Switzerland: World Health Organization.

195. Teng, S.-H. and S.-Y. Ho (1996),"Failure mode and effects analysis an integrated approach for product design and process control", *The International Journal of Quality & Reliability Management*, Vol 13, No 5, pp 8-26.

196. Teng, S. G., S. M. Ho, D. Shumar and P. C. Liu (2006),"Implementing FMEA in a collaborative supply chain environment", *International Journal of Quality & Reliability Management*, Vol 23, No 2, pp 179-196.

197. Thun, J.-H. (2004), Modelling modern maintenance: A system dynamics model analyzing the dynamic implications of implementing total productive maintenance, *In Proceedings of the 22nd International Conference of The System Dynamics Society*, UK, Oxford, pp 1-12.

198. Thurston, M. and M. Lebold 2001, *'Standards developments for condition-based maintenance systems: Improving productivity through applications of condition monitoring'*, Citeseer, Virginia Beach, Virginia: DTIC Document.

199. Too, E. G. (2010), A framework for strategic infrastructure asset management, *Definitions, concepts and scope of engineering asset management*, Springer, pp 31-62.

200. Troyer, D. (2006), *Strategic plant reliability management course book*, Noria Publishing, Tulsa, Oklahoma.

201. Tsakatikas, D., S. Diplaris and M. Sfantsikopoulos (2008),"Spare parts criticality for unplanned maintenance of industrial systems", *European Journal of Industrial Engineering*, Vol 2, No 1, pp 94-107.

202. Tsang, A. H. C. (2002),"Strategic dimensions of maintenance management", *Journal of Quality in Maintenance Engineering*, Vol 8, No 1, pp 7-39.

203. Tsantis, S. M. P. and I. P. Apostolakis (2014),"Medical imaging devices assessment at Public Health Sector of Greece, Risk-Based Maintenance: A decision support model", *International Journal of Caring Sciences*, Vol 7, No 1, pp 24-31.

204. Tucker, A. L. (2004),"The impact of operational failures on hospital nurses and their patients", *Journal of Operations Management*, Vol 22, No (, pp 151-169.

205. Turchetti, G. and E. Geisler (2010), Economic and organizational factors in the future of telemedicine and home care, *Pervasive and Smart Technologies for Healthcare: Ubiquitous Methodologies and Tools: Ubiquitous Methodologies and Tools*, A. Coronato, IGI Global, p. 322.

206. Turchetti, G., E. Spadoni and E. E. Geisler (2010),"Health technology assessment: Evaluation of biomedical innovative technologies", *Engineering in Medical and Biology Magazine, IEEE*, Vol 29, No 3, pp 70-76.

207. Vanier, D. (2001),"Why industry needs asset management tools", *Journal of Computing in Civil Engineering*, Vol 15, No 1, pp 35-43.

208. Vanier, D. (2010a), Advanced asset management: tools and techniques, pp 39-56.

209. Vanier, D. (2010b), Asset management 101: a primer, pp 1-14.

210. Vanier, D. and S. Rahman 2004, *'Municipal infrastructure investment planning (MIIP) report: a primer on municipal infrastructure asset management'*, Canada: National Research, pp 1-45.

211. Vanier, D. J. (2006), Towards sustainable municipal infrastructure asset management, *Handbook on Urbon Sustainaility, Chapter 7*, Springer, Dordrecht, The Netherlands, pp 283-314.

212. Vellani, K. H. and C. CPP (2006), Crime analysis for problem solving security professionals in 25 small steps, *John J. Fay's Encyclopedia of Security*.

213. Walker, D. L. (1999), *Operations Management: A Supply Chain Approach*, International Thomson Business Press, Boston, MA.

214. Wang, B., R. Eliason, S. Richards, L. Hertzler and R. Moorey (2006a), Clinical engineering benchmarking: A preliminary analysis of clinical engineering data in American General Acute-Care Hospitals, *In Proceedings of the 29th Canadian Medical and Biological Engineering Conference*, 2006, 2 June, Vancouver, Canadá., pp 1-4.

215. Wang, B., J. Fedele, B. Pridgen, A. Williams, T. Rui, L. Barnett, C. Granade, R. Helfrich, B. Stephenson and D. Lesueur (2010),"Evidence-Based Maintenance: Part I: Measuring maintenance effectiveness with failure codes", *Journal of Clinical Engineering*, Vol 35, No 3, pp 132.

216. Wang, B., E. Furst, T. Cohen, O. R. Keil, M. Ridgway and R. Stiefel (2006),"Medical equipment management strategies", *Biomedical Instrumentation & Technology*, Vol 40, No 3, pp 233-237.

217. Wang, B., E. Furst, T. Cohen, O. R. Keil, M. Ridgway and R. Stiefel (2006b),"Medical equipment management strategies", *Biomedical Instrumentation & Technology*, Vol 40, No 3, pp 233-237.

218. Wang, B. and A. Levenson (2000),"Equipment inclusion criteria: a new interpretation of JCAHO's medical equipment management standard", *J Clin Eng*, Vol (25), No (1), pp 26-35.

219. Wang, B., T. Rui and S. Balar (2013),"An estimate of patient incidents caused by medical equipment maintenance omissions", *Biomedical Instrumentation & Technology*, Vol 47, No 1, pp 84-91.

220. Wang, Y.-M., K.-S. Chin, G. K. K. Poon and J.-B. Yang (2009),"Risk evaluation in failure mode and effects analysis using fuzzy weighted geometric mean", *Expert Systems with Applications*, Vol 36, No 2, pp 1195-1207.

221. Williams, J. S. (2006),"Switch software improves reliability of physiological network, patient safety", *Biomedical instrumentation & technology/Association for the Advancement of Medical Instrumentation*, Vol 40, No 6, pp 469.

222. Wireman, T. (1998), *Developing Performance Indicators for Managing Maintenance*, Industrial Press New York, NY.

223. World Health Organization 2011, *'Medical equipment maintenance programme overview: World Health Organization medical device technical series'*, Department of Essential Health Technologies, World Health Organization, Switzerland, pp 1-87.

224. Wright, S. (1921),"Correlation and causation", *Journal of agricultural research*, Vol 20, No 7, pp 557-585.

225. Wu, H. and G. Liu (2010), Building the quality control system for medical equipments in hospital, *International Conference on Management and Service Science (MASS)*, 24-26 Aug. 2010, Wuhan, IEEE, pp 1-4.

226. Yang, J., H.-Z. Huang, L.-P. He, S.-P. Zhu and D. Wen (2011),"Risk evaluation in failure mode and effects analysis of aircraft turbine rotor blades using dempster–shafer evidence theory under uncertainty", *Engineering Failure Analysis*, Vol 18, No 8, pp 2084-2092.

UNIVERSITY OF WOLLONGONG

Appendix A

Survey Questionnaire Form

Khelood A Mkalaf

A study of current maintenance strategies and the reliability of medical

PARTICIPANT INFORMATION SHEET FOR BIOMEDICAL ENGINEERING STAFF AND NUMs

RESEARCH TITLE: A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes

PURPOSE OF THE RESEARCH
This is an invitation to participate in research conducted by researchers of the Faculty of Engineering at the University of Wollongong. The purpose of the research is to assist Australian hospitals to improve their medical equipment maintenance practices by examining the relationship between the reliability of selected critical medical equipment and the type of maintenance strategies used. Also, the research examines the risks in relation to patient outcomes.

INVESTIGATORS

1. PhD student: Khelood A. Mkalaf
Faculty of Engineering-School of Mechanical, Materials and Mechatronic Engineering-University of Wollongong-NSW 2522 Australia.Mobile: ,Email:Kam489@ uowmail.edu.au

2. A/Professor Peter Gibson
Faculty of Engineering-School of Mechanical, Materials and Mechatronic Engineering-University of Wollongong-NSW 2522, Australia-Ph:+61 2 42215968-Email:peterg@uow.edu.au

3. Dr Senevi Kiridena
Faculty of Engineering-School of Mechanical, Materials and Mechatronic Engineering-University of Wollongong-NSW 2522, Australia-Ph:+61 2 4221 5849-Fax:+61 2 4221 3101- Email:skiriden@uow.edu.au

4.A/Professor Naj Aziz,School of Civil, Mining & Environmental Engineering,University of Wollongong,NSW NSW 2522 Australia.Tel: +61 2 4221 3449, Fax: +61 2 4221 3238, Email: naj@uow.edu.au

METHOD AND DEMANDS ON PARTICIPANTS
Information will be collected from participants by completing a questionnaire. Data collected will be analysed using qualitative and quantitative methods, like Reliability Centred Maintenance (RCM) to measure the availability and failure rate of critical medical equipment.

The questionnaire can be filled either manually using Microsoft Word or electronically on this website: https://www.surveymonkey.com/s/65VK396. The questionnaire will take approximately 30 minutes to complete. The questionnaire will include a number of questions dealing with maintenance strategies, maintenance costs, risk and patient outcomes relating to a selection of critical high-risk biomedical equipment such as: kidney dialysis machine, anaesthesia machine, cardiac catheterisation machine, diathermy and defibrillator or any device used for critical conditions in your medical department. Example questions are provided below:

- Is the current maintenance strategy for critical medical equipment carried out largely in the hospital or department, or outsourced, or mixed?
- What is the average usage time for each medical device per patient?
- How many patients are serviced by this equipment/device per month?
- How many times does this device fail on average per month?
- What are the common reasons for the failure of this equipment/device?
- Is this device available in time when patients need the healthcare service?
- Do you keep records of maintenance costs?
- Do you think the current maintenance strategy is one of the reasons for unavailability of this critical medical device?

Before participating in the questionnaire, you are asked to complete and sign the attached participant consent form.

POSSIBLE RISKS, INCONVENIENCES AND DISCOMFORTS
Apart from the 30 minutes of your time for answering the questionnaire, we can foresee no risks for you. Your involvement in the study is voluntary. It will not be possible to withdraw your participation from the study once the data has been de-identified. Refusal to participate in the study will not affect your relationship with the University of Wollongong or your facility.

FUNDING AND BENEFITS OF THE RESEARCH

The benefits of this research are to measure effectiveness of current maintenance strategies used in hospitals, and analyse the factors that increase the availability of medical equipment and reduce sudden breakdown of critical medical equipment. The results may also have economic benefits to patients, hospital and country. The results will be used for publication in a PhD thesis, and will also be used in summary form for academic publications in refereed journals and conference presentations.

ETHICS REVIEW AND COMPLAINTS

This study has been reviewed by the Human Research Ethics Committee (Health and Medical) of the University of Wollongong. If you have any concerns or complaints regarding the way this research has been conducted, you can contact the UoW Ethics Officer on (02) 42214457.

Thank you for your interest in this study.

Khelood A. Mkalaf

CONSENT FORM FOR FACILITY

RESEARCH TITLE: A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes

RESEARCHER'S NAME: Khelood A. Mkalaf/ Peter Gibson/ Senevi Kiridena/ Naj Aziz

I have been given information about " A study of current maintenance strategies and the reliability of critical medical equipment in hospitals in relation to patient outcomes " and discussed the research project with Khelood A. Mkalaf of the University of Wollongong, who is conducting this research as part of a PhD degree supervised by A/Professor Peter Gibson/ Dr. Senevi Kiridena/ A/Professor Naj Aziz from the Faculty of Engineering at the University of Wollongong.

I have been advised of the potential risks and burdens associated with this research, which includes staff time spent completing the questionnaire, and have had an opportunity to ask Khelood A. Mkalaf/ Peter Gibson/ Senevi Kiridena/ Naj Aziz any questions I may have about the research.

I understand that my participation in this research is voluntary. I am free to refuse to participate and I am able to withdraw my data up until the point that it has been de-identified, at which point it will not be possible. My refusal to participate or withdraw consent will not affect my relationship with the University of Wollongong.

If I have any enquiries about the research, I can contact Miss Khelood A. Mkalaf (phone , mobile: + , email: Kam489@uowmail.edu.au) and Peter Gibson (Phone 02 42215968, email peterg@uow.edu.au), Senevi Kiridena (phone 02 42215849, email: skiriden@uow.edu.au), Naj Aziz, (phone 242213449, email: naj@uow.edu.au) or if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on 4221 4457or email: rso - ethics@uow.edu.au.

By signing below I am indicating my consent for my facility to participate in the research, as outlined in the participant information sheet provided to me.

I understand that the data collected from my participation will be used for publication in a PhD thesis, and will also be used in summary form for academic publications in refereed journals and conference presentations, and I consent for it to be used in that manner.

Signed

Date ..../....../......

....
Name (please print)

Position: ....

CONSENT FORM FOR BIOMEDICAL ENGINEERING STAFF AND NUMs

Research Title: A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes

Researcher s Name: Khelood A. Mkalaf/ Peter Gibson/ Senevi Kiridena/ Naj Aziz

Dear Sir/Madam:

I have read the participation information sheet and have had the opportunity to ask the researcher any further questions I may have had.

I understand that my paparticipation in this research is voluntary and I may withdraw at any time from the research without affecting my work at hospital in any way.

I understand that the risks to me are minimal in this study and have read the information sheet and asked any questions I may have about the risks.

If I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on 4221 4457.

By signing below I am consenting to:

- I have read the Participant Information Sheet for this research project and I have had the opportunity to ask the researchers any questions.
- I consent to participate in the questionnaire based on specific questions which I have been shown in advance. I can specify any questions I do not wish to answer.
- I understand that my identity will be unknown (unless you request a copy of result) to the researchers. Information I provide will not be circulated to any other persons and the data will be confidential.
- I understand that information I provide will be used by the first researcher as Special Project PhD Thesis. I also understand that it may be used in the researchers' academic publications or conference presentations, but that no details which could identify me will be included in any of these research outcomes.
- I understand that taking part in the questionnaire is voluntary and I am able to withdraw my data until it has been de identified, at which point it will not longer be possible.
- I understand that the data collected from my participation will be used for publication in a PhD thesis, and will also be used in summary form for academic publications in refereed journals and conference presentations, and I consent for it to be used in that manner.
- I understand that I will not gain any benefit or suffer any loss as a result of participating or not participating in this research.

Full Name ____
Name (please print)

Signature ____

Date___________

-

SECTION A:GENERAL INFORMATION ABOUT THE MEDICAL EQUIPMENT

Please, read this information before answering this survey.

DEFINITION USED IN THIS SURVEY
==============================

- Critical medical equipment: used in the treatment of the patient when there no is no alternative available.
- High risk level: life support, key resuscitation, critical equipment and other devices whose failure or misuse is reasonably likelyoto seriously injure patients or staff.
- Middle risk level: Devices, including many diagnostic instruments, whose misuse, failure, or absence (e.g., out of service with no replacement available), would have a significant impact on patient care, but would not be likely to directly couse serious injury.
- Low risk level: Devices, whose failure or misuse is unlikely to result in serious consequences.

1. For data analysis, please give the name of the hospital.

Hospital [ ]

Department [ ]

State/Province: [ ]

2. Do you have any or all of the following critical medical equipment if Yes, tick Yes the critical medical equipment items. Otherwies tick "No" .

	Yes=1	No=2
Kidney dialysis machine	○	○
Cardiac catheterization machine	○	○
Anaesthesia machine	○	○
Defibrillator	○	○
Diathermy	○	○
Respironics BIPAP,PUMP, AIR, CPAP	○	○
Ventilator	○	○
Infusion pump	○	○
ECG Machine	○	○
Electrosurgical +Unit+ Mechanical Vibration	○	○
Defibrillator, Manual	○	○
Respironics, Nebuliser	○	○
Oxygen concentrator	○	○

3. Do you have any other critical medical equipment that are not listed above, please give title of equipment.

4. The total number of units of this device currently in use.

Kidney dialysis machines	
Cardiac catheterization	
Anaesthesia machines	
Defibrillator	
Diathermy	
Respironics, BIPAP, PUMP, AIR, CPAP	
Ventilator	
Infusion pump	
ECG Machine	
Electrosurgical +Unit+ Mechanical Vibration	
Defibrillator, Manual	
RESPIRONICS, Nebuliser	
OXYGEN CONCENTRATOR	
Other critical equipment	

5. How long this device has been in service for?

	Up to one year=1	1-5 years=2	Over 5 years=3o
Kidney dialysis machines			
Cardiac catheterization			
Anaesthesia machines			
Defibrillator			
Diathermy			
Respironics, BIPAP, PUMP, AIR, CPAP			
Ventilator			
Infusion pump			
ECG Machine			
Electrosurgical +Unit+ Mechanical Vibration			
Defibrillator, Manual			
Respironics, Nebuliser			
Oxygen concentrator			
Other critical equipment			

6. Average number of patients who are serviced by this device per month.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics; BIPAP, PUMP, AIR, CPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Manual

Respironics, Nebuliser

Oxygen concentrator

Other critical equipment

7. Average usage time per patient.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics; BIPAP, PUMP, AIR, CPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Manual

Respironics, Nebuliser

Oxygen concentrator

Other critical equipment

8. IF these devices break down, are there any alternatives that can do the same work and provide the required health services to patients.

	Yes=1	No=2
Kidney dialysis machines		
Cardiac catheterization		
Anaesthesia machines		
Defibrillator		
Diathermy		
Respironics; BIPAP, PUMP, AIR, CPAP		
Ventilator		
Infusion pump		
ECG Machine		
Electrosurgical +Unit+ Mechanical Vibration		
Defibrillator, Manual		
Respironics, Nebuliser		
Oxygen concentrator		
Other critical equipment		

Other (please specify)

9. If there are alternative to these devices, please supply their name.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics; BIPAP, PUMP, AIR, CPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Manual

Respironics, Nebuliser

Oxygen concentrator

Other critical equipment

10. How often are these alternatives used?

	Very often=5	Often=4	Occasionally=3	Seldom=2	Never=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

SECTION B: QUESTIONS ABOUT THE MINTENANCE STRATEGIES

Please read these terms before answering Q7.

1. Corrective maintenance:Maintenance activities carried out after device breakdown,
2. Preventive maintenance: scheduled maintenance/replacement of parts carried out before device breakdown.
3. Condition based maintenance: maintenance activities and parts replacement carried out as needed based on continuous monitoring of equipment performance.
4. Predictive maintenance: activities and inspections are carried out when it is deemed necessary, based on periodic inspections, diagnostic tests or other means of condition monitoring before equipment break-down.
5. Emergency maintenance that must be carried out immediately, or with the shortest possible delay, after condition monitoring detects danger or imminent failure
6. Mixed maintenance: use more than one of the above maintenance strategy.

11. Is the maintenance for this equipment carried out [largely]

	Inhouse=1	Outsourced=2	Mixed=3
Kidney dialysis machines			
Cardiac catheterization			
Anaesthesia machines			
Defibrillator			
Diathermy			
Respironics; BIPAP, PUMP, AIR, CPAP			
Ventilator			
Infusion pump			
ECG Machine			
Electrosurgical +Unit+ Mechanical Vibration			
Defibrillator, Manual			
Respironics, Nebuliser			
Oxygen concentrator			
Other critical equipment			

Other (please specify)

12. If maintenance is carried out in house, what type of maintenance strategy is used for each of the critical medical equipment nominated?

	Corrective maintenance	Preventive maintenance	Emergency maintenance	Condition based maintenance	Predictive maintenance	Mixed
Kidney dialysis machines						
Cardiac catheterization						
Anaesthesia machines						
Defibrillator						
Diathermy						
Respironics; BIPAP, PUMP, AIR, CPAP						
Ventilator						
Infusion pump						
ECG Machine						
Electrosurgical +Unit+ Mechanical Vibration						
Defibrillator, Manual						
Respironics, Nebuliser						
Oxygen concentrator						
Other critical equipment						

13. If maintenance is outsourced (maintenance is done by contract or another hospital), what type of maintenance strategy is used for each of the critical medical equipment nominated?

	Corrective maintenance	Preventive maintenance	Emergency maintenance	Condition based maintenance	Predictive maintenance	Mixed
Kidney dialysis machines						
Cardiac catheterization						
Anaesthesia machines						
Defibrillator						
Diathermy						
Respironics; BIPAP, PUMP, AIR, CPAP						
Ventilator						
Infusion pump						
ECG Machine						
Electrosurgical +Unit+ Mechanical Vibration						
Defibrillator, Manual						
Respironics, Nebuliser						
Oxygen concentrator						
Other critical equipment						

14. from Q12 and Q13 above, Which of these do you suggest is the best maintenance strategy for critical medical equipment? Explain why.

15. Are there any particular issues/ problems in keeping this device properly maintained and available? If your answer is Yes describe in box below?

16. If there are issues, does this affect patient outcomes?

	Often affected=3	Affected sometimes=2	Never affected=1
Kidney dialysis machines			
Cardiac catheterization			
Anaesthesia machines			
Defibrillator			
Diathermy			
Respironics; BIPAP, PUMP, AIR, CPAP			
Ventilator			
Infusion pump			
ECG Machine			
Electrosurgical +Unit+ Mechanical Vibration			
Defibrillator, Manual			
Respironics, Nebuliser			
Oxygen concentrator			
Other critical equipment			

17. If so, please explain how patient's outcomes are affected in the box below.

18. Are you involved in decision making regarding maintenance policy for critical medical equipment?Tick the appropriate circle.

Yes=1

No=2

SECTION C: REPAIR AND REPLACEMENT POLICY

19. Are there specific parts to this device that are critical and/or fail regularly?

	All parts are critical and/or fail regulary =5	Most parts are critical and/or fail regularly=4 =4	Some parts are critical and/or fail regularly =3	Parts are not critical and have redundancy (machine will still function after failure) =2	Not critical and/or fail fail regularly =1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

20. How often are the critical spare parts readily available?

	Very often=5	Often=4	Occasionally=3	Seldom=2	Never=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

21. Please explain why there might be difficulty in obtaining parts (e.g. parts not available in Australia) in the box below.

22. Are the critical spare parts kept in stock by you or your maintenance supplier or do they have to be ordered prior to or after a breakdown?

	In stock=1	Prior to breakdown=2	Ordered after breakdown=3
Kidney dialysis machines			
Cardiac catheterization			
Anaesthesia machines			
Defibrillator			
Diathermy			
Respironics; BIPAP, PUMP, AIR, CPAP			
Ventilator			
Infusion pump			
ECG Machine			
Electrosurgical +Unit+ Mechanical Vibration			
Defibrillator, Manual			
Respironics, Nebuliser			
Oxygen concentrator			
Other critical equipment			

SECTION D: EQUIPMENT FAILURES

23. If this equipment ever fails, please indicate how many times per year in your experience?

Kidney dialysis machines	
Cardiac catheterization	
Anaesthesia machines	
Defibrillator	
Diathermy	
Respironics; BIPAP, PUMP, AIR, CPAP	
Ventilator	
infusion pump	
ECG Machine	
Electrosurgical +Unit+ Mechanical Vibration	
Defibrillator, Manual	
Respironics, Nebuliser	
Oxygen concentrator	
Other critical equipment	

24. What are the common reasons for the failure (Breakdown) of this device?

	Technical=1	Human=2	Over-use=3
Kidney dialysis machines			
Cardiac catheterization			
Anaesthesia machines			
Defibrillator			
Diathermy			
Respironics; BIPAP, PUMP, AIR, CPAP			
Ventilator			
Infusion pump			
ECG Machine			
Electrosurgical +Unit+ Mechanical Vibration			
Defibrillator, Manual			
Respironics, Nebuliser			
Oxygen concentrator			
Other critical equipment			

25. Has this device ever failed while providing health care services to patients?

	Yes=1	No=2
Kidney dialysis machines		
Cardiac catheterization		
Anaesthesia machines		
Defibrillator		
Diathermy		
Respironics; BIPAP, PUMP, AIR, CPAP		
Ventilator		
Infusion pump		
ECG Machine		
Electrosurgical +Unit+ Mechanical Vibration		
Defibrillator, Manual		
Respironics, Nebuliser		
Oxygen concentrator		
Other critical equipment		

26. If your answer is (Yes) to Q25, how many times has it broken down in the last 5 years?

Kidney dialysis machines	
Cardiac catheterization	
Anaesthesia machines	
Defibrillator	
Diathermy	
Respironics; BIPAP, PUMP, AIR, CPAP	
Ventilator	
Infusion pump	
ECG Machine	
Electrosurgical +Unit+ Mechanical Vibration	
Defibrillator, Manual	
Respironics, Nebuliser	
Oxygen concentrator	
Other critical equipment	

SECTION E: MAINTENANCE COST

27. How often do you keep records of maintenance costs?

Very often=5 | Often=4 | Occasionally=3 | Seldom=2 | Never=1

28. How detailed are your records?

29. How often is the data used for maintenance decisions?

Very often=5 | Often=4 | Occasionally=3 | Seldom=2 | Never=1

30. Please estimate the total maintenance cost per month (in terms either or both of $ or downtime) when it is-carried out in hospital, for the following equipment per month.

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics, BIPAP, PUMP, AIR, CPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Manual

Respironics, Nebuliser

Oxygen concentrator

Other critical equipment

31. Please estimate the total maintenance cost per month.(in terms either or both of $ or downtime)when it is carried out outsourced, for the following equipment.

Kidney dialysis machines	
Cardiac catheterization	
Anaesthesia machines	
Defibrillator	
Diathermy	
Respironics, BIPAP, PUMP, AIR, CPAP	
Ventilator	
Infusion pump	
ECG Machine	
Electrosurgical +Unit+ Mechanical Vibration	
Defibrillator, Manual	
Respironics, Nebuliser	
Oxygen concentrator	
Other critical equipment	

SECTION F: THE RISK

32. If duplicate equipment was unavailable, would there be adverse patient outcomes?

- Yes=1
- No=2

33. If so, how often do you need to substitute duplicate equipment?

	Zero% of time=1	25% of time=2	50% of time=3	75% of time	More than 75%=5
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

34. In your experience, do you know of cases in hospitals, where patient outcomes have been affected by the break down of critical medical equipment?

- Death=4
- Injury=3
- Misdiagnosis=2
- Not at all=1

35. Indicate the level of risk (High, Middle, Low, Very Low) in relation to a patient's life, if this medical device fails (breaks down) while it is in service.

	Death	Injury	Misdiagnosis
Kidney dialysis machines	6	6	6
Cardiac catheterization	6	6	6
Anaesthesia machines	6	6	6
Defibrillator	6	6	6
Diathermy	6	6	6
Respironics; BIPAP, PUMP, AIR, CPAP	6	6	6
Ventilator	6	6	6
Infusion pump	6	6	6
ECG Machine	6	6	6
Electrosurgical +Unit+ Mechanical Vibration	6	6	6
Defibrillator, Manual	6	6	6
Respironics, Nebuliser	6	6	6
Oxygen concentrator	6	6	6
Other critical equipment	6	6	6

Where:-

High=4, Middle=3, Low=2 and Very Low=1

36. When critical medical equipment does fail (break down), how is that failure usually managed?

	Duplicate equipment =5	Borrow equipment =4	In-house maintenance =3	Call supplier =2	Other =1
Kidney dialysis machine					
Cardiac catheterization machine					
Anaesthesia machine					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

Other (please specify)

SECTION G: AVAILAILITY OF DEVICE

37. If maintenance is carried out in- house, how long is the device unavailable on average (days/months)?

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics; BIPAP, PUMP, AIR, CPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Manual

Respironics, Nebuliser

Oxygen concentrator

Other critical equipment

38. How often does the medical device become unavailable to treat patients who require its its service?(Times per month)

Kidney dialysis machines

Cardiac catheterization

Anaesthesia machines

Defibrillator

Diathermy

Respironics; BIPAP, PUMP, AIR, CPAP

Ventilator

Infusion pump

ECG Machine

Electrosurgical +Unit+ Mechanical Vibration

Defibrillator, Manual

Respironics, Nebuliser

Oxygen concentrator

Other critical equipment

39. How is the health care service of this device provided to patients?

	On demand=1	Patient has to be placed on waiting list=2	Priority list=2
Kidney dialysis machines			
Cardiac catheterization			
Anaesthesia machines			
Defibrillator			
Diathermy			
Respironics; BIPAP, PUMP, AIR, CPAP			
Ventilator			
Infusion pump			
ECG Machine			
Electrosurgical +Unit+ Mechanical Vibration			
Defibrillator, Manual			
Respironics, Nebuliser			
Oxygen concentrator			
Other critical equipment			

40. What are the reasons for the unavailability of this device for providing healthcare to patients? Please give approximate %.

	Limited number of this device available=1	Device out of service/ breakdown=2
Kidney dialysis machines		
Cardiac catheterization		
Anaesthesia machines		
Defibrillator		
Diathermy		
Respironics; BIPAP, PUMP, AIR, CPAP		
Ventilator		
Infusion pump		
ECG Machine		
Electrosurgical +Unit+ Mechanical Vibration		
Defibrillator, Manual		
Respironics, Nebuliser		
Oxygen concentrator		
Other critical equipment		

41. Do you think the current maintenance strategy helps increase the availability of this medical device to provide health care to patients in time?

	Strongly agree=5	Agree=4	Indifferent=3	Disagree=2	Strongly Disagree=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, PUMP, AIR, CPAP					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

SECTION H: RELIABILITY-CENTRED MAINTENANCE

Reliability-cantred maintenance (RCM) works on a philosophy that equipment can be over maintained and thus become less reliable.

42. How often do you attempt to optimise the amount of maintenance to avoid over servicing?

	Very often=5	Often=4	Occasionally=3	Seldom=2	Never=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

43. How often do you keep records of maintenance and subsequent equipment reliability?

	Very often=5	Often=4	Occasionally=3	Seldom=2	Never=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

44. How are your the records kept?Please tick in the box below.

- Optimize Computer Maintenance Packages
- Database
- Computer
- Paper
- Other

Other (please specify)

45. If your answer is (Never) in Q43, how desirable would logging of maintenance data be in terms of unavailability per month ?

Kidney dialysis machines	
Cardiac catheterization	
Anaesthesia machines	
Defibrillator	
Diathermy	
Respironics; BIPAP, PUMP, AIR, CPAP	
Ventilator	
Infusion pump	
ECG Machine	
Electrosurgical +Unit+ Mechanical Vibration	
Defibrillator, Manual	
Respironics, Nebuliser	
Oxygen concentrator	
Other critical equipment	

46. Do you use measures of critical medical device reliability to evaluate your maintenance policy? Please answer Yes or No

	Unavailability	Failure rate	Mean time to failure	Mean time between failure
Kidney dialysis machines				
Cardiac catheterization				
Anaesthesia machines				
Defibrillator				
Diathermy				
Respironics; BIPAP, PUMP, AIR, CPAP				
Ventilator				
Infusion pump				
ECG Machine				
Electrosurgical +Unit+ Mechanical Vibration				
Defibrillator, Manual				
Respironics, Nebuliser				
Oxygen concentrator				
Other critical equipment				

47. Do you think the current maintenance strategy helps optimise the failure rates (breakdown) of this critical medical device?

	Strongly agree=5	Agree=4	Indifferent=3	Disagree=2	Strongly Disagree=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

48. Do you think the current maintenance strategy is one of the reasons for unavailability of this critical medical device?

	Strongly agree=5	Agree=4	Indifferent=3	Disagree=2	Strongly Disagree=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

49. Do you think the current maintenance strategy helps reduce the sudden breakdown of this critical device while providing medical service?

	Strongly agree=5	Agree=4	Indifferent=3	Disagree=2	Strongly Disagree=1
Kidney dialysis machines					
Cardiac catheterization					
Anaesthesia machines					
Defibrillator					
Diathermy					
Respironics; BIPAP, PUMP, AIR, CPAP					
Ventilator					
Infusion pump					
ECG Machine					
Electrosurgical +Unit+ Mechanical Vibration					
Defibrillator, Manual					
Respironics, Nebuliser					
Oxygen concentrator					
Other critical equipment					

50. Do you use any maintenance management software programs in order to predict the occurrence of sudden failure of these devices?

Yes=1 No=2

51. If your answer is Yes to Q50, What program is used?

52. Do you have any general suggestion to improve current maintenance management strategies in the hospital?

53. Please estimate the maintenance cost per year of the medical device listed below.

Kidney dialysis	
Cardiac catheterization	
Anaesthesia	
Defibrillator	
Diathermy	
Respironics; BIPAP, PUMP, AIR, CPAP	
Ventilator	
Infusion pump	
ECG machine	
Electrosurgical	
Defibrillator,Manual	
Nebuliser	
Oxygen concentrator	
Other critical equipment	

54. If you would like a copy of the results of this survey, please record your name/address below

Name:	
Hospital:	
Email address:	
Phone Number:	

UNIVERSITY OF WOLLONGONG

Appendix B

Pilot Study: Interviews and Survey Questionnaire Forms

Khelood A. Mkalaf

University of Wollongong

PARTICIPATION INFORMATION SHEET FOR BIOMEDICAL ENGINEERING STAFF AND NURES UNIT MANAGER RESPONSIBLE

RESEARCH TITLE: **A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes**

PURPOSE OF THE RESEARCH

This is an invitation to participate in research conducted by researchers of the Faculty of Engineering at the University of Wollongong. The purpose of the research is to assist Australian hospitals to improve their medical equipment maintenance practices by examining the relationship between the reliability of selected medical equipment and the type of maintenance strategy used. Also, the research examines the risks in relation to patient outcomes.

INVESTIGATORS

Khelood A. Mkalaf
Faculty of Engineering
School of Mechanical, Materials and Mechatronic Engineering
University of Wollongong
NSW 2522 Australia
Mobile;
Kam489@uowmail.edu.au

A/Professor Peter Gibson
Faculty of Engineering
School of Mechanical, Materials and Mechatronic Engineering
University of Wollongong
NSW 2522, Australia
Ph: +61 2 42215968
peterg@uow edu au

Dr Senevi Kiridena
Faculty of Engineering
School of Mechanical, Materials and Mechatronic Engineering
University of Wollongong
NSW 2522, Australia
Ph: +61 2 4221 5849
Fax: +61 2 4221 3101

A/Professor Naj Aziz School of Civil, Mining & Environmental Engineering
University of Wollongong
NSW 2522 Australia
Tel: +61 2 4221 3449
Fax: +61 2 4221 3238
naj@uow.edu.au

METHOD AND DEMANDS ON PARTICIPANTS

Information will be collected from participants using interviews and questionnaires. Each interview will take 15–20 minutes and there may be more than one interview throughout the research period. Interviews can be face to face, email, or by phone. With your consent the researcher will take notes by hand during the interview. Data collected will be analysed using qualitative and quantitative methods, like Reliability Centered Maintenance (RCM) to measure the availability and failure rate of the critical medical equipment. Interviews will include a number of questions dealing with maintenance strategies of selected critical high-risk biomedical equipment (such as kidney dialysis

machine, anaesthesia machine, cardiac catheterization machine, and defibrillator), maintenance costs, risk, and patient outcomes. The survey will include a number of questions that deal with current maintenance strategy used in hospitals. Example interview questions are provided below:

1. Is current maintenance strategies (Run to Breakdown, Preventive, schedule outsource, etc.) used in hospital or department is being carried out in house (hospital) or outsource (out hospital)?
2. The time it takes to provide the service to the patient (Run-time/patient).
3. Estimate the number of patients requiring the use of this equipment/device per month and year.
4. Is the maintenance policy is acted in house, what is the Mean Time To Repair (MTTR) or average time to repair to this equipment/device?
5. How many frequency of the failed (breakdown) this equipment/device?
6. What are reasons of the failure (Breakdown) to this equipment/device?
7. What policy is will for replacement of spare parts for this equipment/device?
8. Is this device available in time when patients need healthcare service?

Before participating in the interview, you are asked to complete and sign the attached participant consent form.

POSSIBLE RISKS, INCONVENIENCES AND DISCOMFORTS

Apart from the 15-20 minutes of your time for the interview and observing your maintenance actions of critical medical equipment for one hour, we can foresee no risks for you. Your involvement in the study is voluntary and you may withdraw your participation from the study at any time and withdraw any data that you have provided to that point. Refusal to participate in the study will not affect your relationship with the University of Wollongong or your facility.

FUNDING AND BENEFITS OF THE RESEARCH

The benefits of this research are to measure effectiveness of current maintenance strategy used in hospitals, and analysis the factors which leads to increasing availability of medical equipment and reducing sudden breakdown of medical equipment. The results may also have economic benefits to patients, hospital and country.

ETHICS REVIEW AND COMPLAINTS

This study has been reviewed by the Human Research Ethics Committee (Health and Medical) of the University of Wollongong. If you have any concerns or complaints regarding the way this research has been conducted, you can contact the UOW Ethics Officer on (02) 42214457.

Thank you for your interest in this study.

Khelood A. Mkalaf

CONSENT FORM FOR Facility

RESEARCH TITLE: **A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes**

RESEARCHER'S NAME: Khelood A. Mkalaf/ Peter Gibson/ Senevi Kiridena/ Naj Aziz

I have been given information about "A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes" and discussed the research project with Khelood A. Mkalaf of the University of Wollongong who is conducting this research as part of a PhD degree supervised by A/Professor Peter Gibson/ Dr. Senevi Kiridena/ A/Professor Naj Aziz Rolls from the Faculty of Engineering at the University of Wollongong.

I have been advised of the potential risks and burdens associated with this research, which include staff time spent on participating in the interview and questionnaire form, and have had an opportunity to ask Khelood A. Mkalaf/ Peter Gibson/ Senevi Kiridena/ Naj Aziz any questions I may have about the research.

I understand that my participation in this research is voluntary, I am free to refuse to participate and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect relationship with the University of Wollongong.

If I have any enquiries about the research, I can contact Miss Khelood A. Mkalaf **(**phone: , mobile: email: Kam489@uowmail.edu.au) **a**nd Peter Gibson (Phone: 02 42215968, email: peterg@uow.edu.au), Senevi Kiridena (phone: 02 42215849, email: skiriden@uow.edu.au), Naj Aziz, (phone: 242213449, email: naj@uow.edu.au) or if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on 4221 4457or email: rso-ethics@uow.edu.au.

By signing below I am indicating my consent for my facility to participate in the research, as outlined in the participant information sheet provided to me.

I understand that the data collected from my participation will be used for publication of the findings of the PhD thesis to get Doctor of Philosophy, and will also be used in summary form for academic publications in refereed journals and conference presentations, and I consent for it to be used in that manner.

Signed ***Date***

..../....../......

Name (please print)

....

Position: ....

University of Wollongong

Consent Form for Staff ON THE BIOMEDICAL ENGINEERING AND NUM RESPONSIBLE (PARTICIPANTS)

Research Title: A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes

Researcher's Name: Khelood A. Mkalaf/ Peter Gibson/ Senevi Kiridena/ Naj Aziz

Dear Sir/Madam:

I have read the participation information sheet and have had the opportunity to ask the researcher any further questions I may have had. I understand that my participation in this research is voluntary and I may withdraw at any time from the research without affecting on my work at hospital in any way.

I understand that the risks to me are minimal in this study and have read the information sheet and asked any questions I may have about the risks. I understand that I will be involved in three to six individual, 30 minute audio recorded interviews and that photographs will be taken of my work. My name will not be used to identify my comments or work in the study.

If I have any concerns or complaints regarding the way the research is or has been conducted I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on 4221 4457.

By signing below I am consenting to:

I have read the Participant Information Sheet for this research project and I have had the opportunity to ask the researchers any questions.

I consent to participate in the interview based on specific questions which I have been shown in advance. I can specify any questions I do not wish to answer.

I understand that my identity will be known to the four researchers, and that information I provide will not be circulated to any other persons.

I understand that information I provide will be used in the first researcher's Special Project PhD thesis. I also understand that it may be used in the researchers' academic publications or conference presentations, but that no details which could identify me will be included in any of these research outcomes.

I understand that even if my name is removed for publication purposes, because of the small number of people involved, the contextual information could lead to possible identification. Thus, although attempts will be made to maintain confidentiality, this cannot be guaranteed.

I understand that taking part in the interview is voluntary and I can withdraw my consent at any time. If I withdraw my consent later, any previous information I have provided will be destroyed and any of my data already used in the project will be withdrawn from it.

I understand that I will not gain any benefit or suffer any loss as a result of participating or not participating in this research.

Full Name ____Name (please print)

Signature ____ Date___________

General information about the hospital;

This information just for research, it will be kept confidential.

1	**Hospital Name:**	
2	**Address hospital:**	
3	**Phone number:**	
4	**Email:**	
5	**Fax:**	
5	**Number of beds:**	
7	**Department/unit:**	
8	**Full Name**	
9	**Position:**	
10	**Phone (Business):**	
11	**Email:**	
12	**Date:**	

Part 1: The interview form[1]

Please, answer the questions below for all critical medical equipment in your department or hospital. Examples of this device are:

- Kidney dialysis machine, Cardiac catheterization, Anaesthesia machine, and Defibrillator.

The key of terms

- *Critical medical equipment: A major medical device in the treatment of the patient and there no has no alternative it to provide healthcare services.*
- *Level of importance of medical device: is equipment that exposes patient to risks resulting in death, injury and misdiagnosis.*
- *High risk level: life support, key resuscitation, critical and other devices whose failure or misuse is reasonably likely to seriously injure patients or staff.*
- *Middle risk level: Devices, including many diagnostic instruments, whose misuse, failure, or absence (e.g., out of service with on replacement available) would have a significant impact on patient care, but would not likely to cause direct serious injury.*
- *Low risk level: Devices, whose failure or misuse is unlikely to result in serious consequences (Wang et al., 2000).*

[1] Interview form Version 1, dated September 1, 2011.

Q1.The date and information of this question are required to classify medical equipment as the first steps, and then selected the medical equipment which has *critical and high risk level in relation to patients.*

General information about the medical equipment;

	Medical equipment name	Function of Medical equipment	Level of important			Level of risk *(in relation to patient life)*			The number of this equipment
			Critical	Important	Necessary	High	Middle	Low	
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									

Q2. **The data and information in this question needs to analyse mathematical models in this study and measure reliability of critical medical equipment. Please, answer these questions for the medical equipment which are (critical and has high level risk relation with patient). Please,** ***give this data to at least four to five devices include this devices;*** **Kidney dialysis machine, Cardiac Catheterization, Anaesthesia machine and Defibrillator.**

Please Note: that for each device you have to fill separate form.

<table>
<tr><th>No</th><th>Question</th><th colspan="4">Answer</th></tr>
<tr><td>1</td><td>The scientific name of medical equipment.</td><td colspan="4"></td></tr>
<tr><td>2</td><td>Function of medical equipment.</td><td colspan="4"></td></tr>
<tr><td>3</td><td>Manufactured by (company).</td><td colspan="4"></td></tr>
<tr><td>4</td><td>Product of (country).</td><td colspan="4"></td></tr>
<tr><td>5</td><td>Production (years).</td><td colspan="4"></td></tr>
<tr><td>6</td><td>Equipment price.</td><td colspan="4"></td></tr>
<tr><td>7</td><td>The first day to run the medical devices(or Operating lifetime)</td><td colspan="4"></td></tr>
<tr><td rowspan="2">8</td><td rowspan="2">IF this devices breakdown, Are there any alternative of this devices can do the same work and provide the health services to patients.</td><td>Yes</td><td></td><td>No</td><td></td></tr>
<tr><td colspan="4">If your answer yes, Please give the name of this alternative devices.</td></tr>
<tr><td>9</td><td>The total number of these devices.</td><td colspan="4"></td></tr>
<tr><td>10</td><td>The time it takes to provide the service to the patient (Run-time/patient).</td><td colspan="4"></td></tr>
<tr><td rowspan="2">11</td><td rowspan="2">Please, estimate the number of patients who get this health care of this device per month and year.</td><td colspan="2"></td><td colspan="2">patient per month</td></tr>
<tr><td colspan="2"></td><td colspan="2">patient per year</td></tr>
</table>

<table>
<tr><th>No</th><th>Question</th><th colspan="3">Answer</th></tr>
<tr><td rowspan="4">12</td><td rowspan="4">Current maintenance strategies (types) used in hospital or department are done in</td><td rowspan="2">a. In-House (hospital)</td><td>Yes</td><td></td></tr>
<tr><td>No</td><td></td></tr>
<tr><td rowspan="2">b. Outsource (out hospital)</td><td>Yes</td><td></td></tr>
<tr><td>No</td><td></td></tr>
<tr><td>13</td><td>If you maintenance has done in house (hospital), what the types of maintenance strategies for critical medical equipment are used in the following beside;</td><td colspan="3">a. Corrective maintenance (Maintenance activities are done after device breakdown)
b. Preventive maintenance (Scheduled maintenance)
c. Condition Based maintenance (maintenance activities, replacement parts are done when the devices need it).
d. Predictive maintenance e. Emergency maintenance
f. Mixed maintenance (use more than one strategy) please, writes the name of these strategies.
g. Others? Please write the name of these strategies.</td></tr>
<tr><td>14</td><td>If your policy is to <u>outsource</u> <u>(maintenance is done by company product these equipment)</u>, what the type of maintenance strategies of critical medical equipment they used?</td><td colspan="3">a. Corrective maintenance (Maintenance activities are done after device breakdown)
b. Preventive maintenance (Scheduled maintenance)
c. Condition Based maintenance (Maintenance activities, replacement parts are done when the devices need it).
d. Predictive maintenance e.g. Emergency maintenance
f. Mixed maintenance (use more than one strategy). Please, write the name of these strategies.
g. Others? Please write the name of these strategies.</td></tr>
</table>

<table>
<tr><th>No</th><th>Question</th><th colspan="4">Answer</th></tr>
<tr><td>15</td><td>What do you suggest the best maintenance strategies of this device in Q13, 14. Why?</td><td colspan="4"></td></tr>
<tr><td rowspan="4">16</td><td rowspan="4">If your maintenance policy is act in house, what is the Mean Time To Repair (MTTR) or average time to repair to this medical equipment?</td><td colspan="2"></td><td colspan="2">Hours</td></tr>
<tr><td colspan="2">.</td><td colspan="2">Day</td></tr>
<tr><td colspan="2">..</td><td colspan="2">Week</td></tr>
<tr><td colspan="2">..</td><td colspan="2">Month</td></tr>
<tr><td rowspan="4">17</td><td rowspan="4">If your maintenance police is act out hospital, what is the Mean Time To Repair (MTTR) or average time to repair to this medical equipment?</td><td colspan="2"></td><td colspan="2">Hours</td></tr>
<tr><td colspan="2"></td><td colspan="2">Day</td></tr>
<tr><td colspan="2"></td><td colspan="2">Week</td></tr>
<tr><td colspan="2"></td><td colspan="2">Month</td></tr>
<tr><td>18</td><td>Is the parts of this device are critical?</td><td>Yes</td><td></td><td></td><td>No</td></tr>
<tr><td>19</td><td>List all names of the critical parts (spare parts) in this device.</td><td colspan="4"></td></tr>
<tr><td rowspan="2">20</td><td rowspan="2">The failure rate (breakdown) of this device is</td><td colspan="2">Often</td><td colspan="2">Not often</td></tr>
<tr><td colspan="2">Rare</td><td colspan="2">common</td></tr>
<tr><td rowspan="2">21</td><td rowspan="2">How many times failed (Breakdown) this device?</td><td colspan="2"></td><td colspan="2">Monthly</td></tr>
<tr><td colspan="2"></td><td colspan="2">Yearly</td></tr>
<tr><td rowspan="5">22</td><td rowspan="5">What are reasons of the failure (Breakdown) to this device?</td><td colspan="2">Mechanical</td><td colspan="2"></td></tr>
<tr><td colspan="2">Electron</td><td colspan="2"></td></tr>
<tr><td colspan="2">Electrical</td><td colspan="2"></td></tr>
<tr><td colspan="2">Human error</td><td colspan="2"></td></tr>
<tr><td colspan="2">Downloaded</td><td colspan="2"></td></tr>
<tr><td>23</td><td>Are the critical spare parts available?</td><td>Yes</td><td></td><td>No</td><td></td></tr>
</table>

No	Question	Answer			
24	What is the policy of replacement of spare parts to this medical device?	Before parts breakdowns (*with the inspection process*).			
		After parts breakdowns			
25	If your maintenance activities of the critical device are done *in house*, What the estimate total maintenance cost to this device per month/year?		per month		
			per year		
26	If your maintenance activities of the critical device are done *out hospital*, What the estimate total maintenance cost to this device per month/year?		per month		
			per year		
27	Are this medical device has failed while providing healthcare services to patients?	Yes		No	
		If yes, how many times are failed per			
		Month			
		Year			
28	What percentage of the risk degree in relation to the patient life, if this medical device has failed (breakdown) during provide healthcare service to the patient? Do you decide to select each of the following alternatives;	Less than 5%			
		Less than 10%			
		Less than 15%			
		Less than 20%			
		More than 20%			
29	What type of risk in relation to patient's life, if this medical device has been failed (breakdown) during providing healthcare service to patients? Do you decide to select each of the following alternatives;	Death? What the percentage?			
		Injury? What the percentage?			
		Misdiagnosis? What the percentage?			

No	Question	Answer	
30	How many physical risks in relation to patient's life of this medical device? Do you decide to select each of the following alternatives;	Patient death	
		Patient or operator injury	
		Inappropriate therapy or misdiagnosis	
		Not defined	
		No significant	
31	How often is the medical equipment unavailable to treat patients who require the medical equipment?	Times/ day	
		Times/ week	
		Times/ month	
		Times/ year	
32	How many patients suffer as a result of medical equipment not being available?		per day
			per week
			per month
			per year
33	How are their outcomes affected?	Not at all	
		Injury	
		Misdiagnosis	
		Death	
34	Is this device available in time when patients need healthcare service?	Often	
		Not often	
35	Is the number of medical devices enough to provide healthcare service to patients whenever required?	Yes	
		No	

No	Question	Answer	
36	When is the healthcare service of this device provided to patients?	In time	
		In waiting list	
		If your answer in waiting list, how long did they need to wait:	
		Day	
		Week	
		Month	
37	What is the reasons for unavailability this device to providing healthcare to patients?	Limited the number of this device out services (breakdown) Demand over to this health services.	
38	Do you have any suggestion to improve currently maintenance strategies in hospital?		

Q3. The data and information to this question will be used to find the Mean Time Between Failure (MTBF), Mean Time to Repair (MTTR), availability and failure rate to the medical equipment.

Please estimate the number of failure (breakdown) per month to the medical equipment which are ((critical and has high level risk relation with patient)).

1. Name of medical equipment: --

Month	Jan.	Feb.	Mar.	Apr.	May.	Jun.	July.	Aug.	Sept.	Oct.	Nov.	Dec.	Total number of failure
Number of Failure													

Part 2: The survey questionnaire[2]

In this survey questionnaire, all questions are in relation to current maintenance strategies foe critical equipment used in hospitals. How have these maintenance strategies impacted on the availability and reliability of medical equipment while providing medical care to patients?

Please, answer the questions below for all critical medical equipment in your department or hospital. Examples to these devices are:

- **Kidney dialysis machine, Cardiac catheterization, Anaesthesia machine and Defibrillator.**

N	Questions
1	**If you <u>schedule</u> some or all maintenance activities at fixed time intervals for critical medical equipment, how often are the following performed.** **a. Minor maintenance..................weeks/months/years** **b. Minor overhaul.........................weeks/months/years** **c. Major overhaul.........................weeks/months/years** **d. Other.......................................weeks/months/years**
2	**If you <u>schedule</u> some or all maintenance activities based on evaluating the condition of critical medical equipment while it is in service, which of the following do you use for the evaluation?** **a. Periodic inspection or testing at intervals of........................ weeks/months.** **b. Continuous monitoring** **c. Other technique (please describe)**

[2] survey questionnaire Version 1, dated September 1,2011.

N	**Questions**
3	**If you are using a <u>corrective maintenance</u> strategy for this critical medical equipment, how often are the following performed.** **a. Minor maintenance...............................weeks/months/years** **b. Minor overhaul....................................weeks/months/years** **c. Major overhaul....................................weeks/months/years** **d. Replacement damaged and corroded parts........................... weeks/months/years**
4	**If your policy is to <u>carry out maintenance as needed for this critical medical equipment</u>, what criteria do you use to perform the following levels of maintenance?** **a. No maintenance** **b. Minor maintenance** **c. Minor overhaul** **d. Major overhaul** **e. Emergency maintenance/overhaul**
5	**If your policy is <u>condition based maintenance for this critical medical equipment</u>, what criteria do you use to perform the following levels of maintenance?** **a. No maintenance** **b. Minor maintenance** **c. Minor overhaul** **d. Major overhaul** **e. Replacement of damaged and corroded parts**

N	Questions
6	**What percentage of the cases evaluated under your <u>condition based maintenance</u> strategy of this critical medical equipment do you decide to select each of the following alternatives?** **a. No maintenance....................................%** **b. Minor maintenance................................%** **c. Minor overhaul.......................................%** **d. Major overhaul.......................................%** e. **Replacement damaged and corroded parts……................%**
7	**If you use <u>condition based maintenance</u> for this critical medical equipment, how often are the following performed?** **a. Minor maintenance.............................weeks/months/years** **b. Minor overhaul..................................weeks/months/years** **c. Major overhaul..................................weeks/months/years** d. **Replacement damaged and corroded parts........................ weeks/months/years**
8	**If you use <u>Emergency maintenance</u> for this critical medical equipment, how often are the following performed?** **a. Minor maintenance....................days/weeks/months/years** **b. Minor overhaul...........................days/weeks/months/years** **c. Major overhaul...........................days/weeks/months/years** **d. Replacement damaged and corroded parts......................... days/weeks/months/years**
9	**In what percentage of the cases evaluated under your <u>emergency maintenance</u> strategy do you decide to select each of the following alternatives?** **a. No maintenance....................................%** **b. Minor maintenance................................%** **c. Minor overhaul.......................................%** **d. Major overhaul.......................................%** e. **Replacement damaged and corroded parts**

N	Questions
10	**Are you using a Reliability-Centered Maintenance (RCM) program for medical equipment?** **If yes, how long has it been in use?** **If not, are you considering adopting one?**
11	**What measures of critical medical equipment reliability do you use to evaluate your maintenance policy?** **a. Unavailability** **b. Failure frequency** **c. Mean time to failure** **d. Mean time between failure** **e. Other (explain)....................................**
12	**In what percentage of the cases evaluated under your predictive maintenance strategy of this critical medical equipment, do you decide to select each of the following alternatives?** **a. No maintenance....................................%** **b. Minor maintenance................................%** **c. Minor overhaul......................................%** **d. Major overhaul......................................%** e. **Emergency maintenance/overhaul..........%**

N	Questions
13	**Is replacement of critical parts of critical medical equipment a part of your maintenance policy?** **Yes No** **If your answer No, explain why?**
14	**If you have a <u>replacement of critical parts policy</u> for critical medical equipment, how often are the following performed?** **a. Minor replacement......................... weeks/months/years** **d. Major replacement .... weeks/months/years**
15	**Do you think the current maintenance strategy helped to increase the availability of critical medical device to provide healthcare to patients in time?** **Yes No**
16	**Do you think the current maintenance strategy is helped to reduce the failure rate (breakdown) of critical medical device?** **Yes No**
17	**Do you think the current maintenance strategy is the one of the reasons for unavailability of critical medical device?** **Yes No**
18	**Do you think the current maintenance strategy helped to reduce the sudden breakdown of critical medical device while provide medical service?** **Yes No**

UNIVERSITY OF WOLLONGONG

Appendix C

Published Conference Paper

Khelood A Mkalaf

APPENDIX C: PUBLISHED CONFERENCE PAPER

2013

A study of current maintenance strategies and the reliability of critical medical equipment in hospitals in relation to patient outcomes

Khelood Mkalaf
University of Wollongong, kam489@uowmail.edu.au

Peter Gibson
University of Wollongong, peterg@uow.edu.au

John Flanagan
University of Wollongong, grutwr@uow.edu.au

Publication Details

Mkalaf, K., Gibson, P. & Flanagan, J. (2013). A study of current maintenance strategies and the reliability of critical medical equipment in hospitals in relation to patient outcomes. International Journal of Social, Human Science and Engineering, 7 (10), 1-8.

A study of current maintenance strategies and the reliability of critical medical equipment in hospitals in relation to patient outcomes

Abstract

This study investigates the relationship between the reliability of critical medical equipment (CME) and the effectiveness of CME maintenance management strategies in relation to patient outcomes in 84 public hospitals of a top 20 OECD country. The work has examined the effectiveness of CME maintenance management strategies used by the public hospital system of a large state run health organization. The conceptual framework was designed to examine the significance of the relationship between six variables: (1) types of maintenance management strategies, (2) maintenance services, (3) maintenance practice, (4) medical equipment reliability, (5) maintenance costs and (6) patient outcomes. The results provide interesting insights into the effectiveness of the maintenance strategies used. For example, there appears to be about a 1 in 10 000 probability of failure of anesthesia equipment, but these seem to be confined to specific maintenance situations. There are also some findings in relation to outsourcing of maintenance. For each of the variables listed, results are reported in relation to the various types of maintenance strategies and services. Decision-makers may use these results to evaluate more effective maintenance strategies for their CME and generate more effective patient outcomes.

Keywords

study, relation, hospitals, equipment, medical, outcomes, critical, patient, reliability, strategies, maintenance, current

Disciplines

Engineering | Science and Technology Studies

Publication Details

Mkalaf, K., Gibson, P. & Flanagan, J. (2013), A study of current maintenance strategies and the reliability of critical medical equipment in hospitals in relation to patient outcomes, International Journal of Social, Human Science and Engineering, 7 (10), 1-8.

A Study of Current Maintenance Strategies and the Reliability of Critical Medical Equipment in Hospitals in Relation to Patient Outcomes

Khelood A. Mkalaf, Peter Gibson, John Flanagan

***Abstract*—This study investigates the relationship between the reliability of critical medical equipment (CME) and the effectiveness of CME maintenance management strategies in relation to patient outcomes in 84 public hospitals of a top 20 OECD country. The work has examined the effectiveness of CME maintenance management strategies used by the public hospital system of a large state run health organization. The conceptual framework was designed to examine the significance of the relationship between six variables: (1) types of maintenance management strategies, (2) maintenance services, (3) maintenance practice, (4) medical equipment reliability, (5) maintenance costs and (6) patient outcomes. The results provide interesting insights into the effectiveness of the maintenance strategies used. For example, there appears to be about a 1 in 10 000 probability of failure of anesthesia equipment, but these seem to be confined to specific maintenance situations. There are also some findings in relation to outsourcing of maintenance. For each of the variables listed, results are reported in relation to the various types of maintenance strategies and services. Decision-makers may use these results to evaluate more effective maintenance strategies for their CME and generate more effective patient outcomes.

***Keywords*—Critical medical equipment, maintenance strategy, patient outcomes, reliability.

I. Introduction

ENSURING the reliability and maintenance of critical medical equipment (CME) in hospitals is vital to patient outcomes and service availability. For these reasons, maintenance engineering is an important part of hospital management. Its aim is to develop an **optimal maintenance strategy that maximizes equipment availability and minimizes downtime**. This aim has become complicated by an increasingly complex array of technical medical equipment [1]. In hospitals, medical equipment can be classified according to mission criticality namely: critical, important or necessary, and the **risk equipment unavailability poses to patient outcomes as: high, medium or low** [1]-[3]. Further, the type of CME used in any hospital can be generally classified into: biomedical, laboratory, ward, service support, utilities and hospital furniture. **This study focuses on the maintenance strategies of six of the fourteen selected critical-high risk biomedical items of equipment specifically**: ***kidney dialysis, anesthesia, defibrillators, ventilators, infusion pumps and electrocardiograph (ECG) machines***. The contextual approach taken in this study, included *elements of Reliability Centered Maintenance (RCM)* [4], [5]. This is to analyze current maintenance strategies used on selected CMEs, and include both **quantitative and qualitative reliability analysis and reliability management** [6]. **Quantitative analysis** of reliability is established through evaluation of equipment availability, Mean Time Between Failure (MTBF), Mean Time To Repair (MTTR), and Failure Rate (FR) [7]. Various modes and causes of failure and unreliability are analyzed by **qualitative analysis** [6]. Improving maintenance performance leads to increasing productivity, quality, safety and environment in an organization [8]. Effectiveness and efficiency are significant elements to consider when evaluating the productivity of CME maintenance strategies [7]. Best practices developed for management of technical assets in other industries offers potential to improve services and patient outcomes and innovative proposals are discussed here.

Khelood A. Mkalaf is with the University of Wollongong, Faculty of Engineering and information science, PhD student, NSW 2522 Australia (Mobile: +61-4-0606-8383; e-mail: kam489@ uowmail.edu.au).

Peter Gibson, A/Professor, is a Post Graduate Coursework Director, is with University of Wollongong, Faculty of Engineering and information science, NSW 2522 Australia, (e-mail: peterg@uow.edu.au).

John Flanagan is with the Sydney Business School, University of Wollongong. He was Senior Lecturer/Director Logistics and Operations Management Program at University of Wollongong Assoc Manager Operations Research at BlueScope Steel, (e-mail: grutwr@uow.edu.au).

II. Research Objective

The study aims to: determine representative **failure rates** and **mean time to repair statistics**, in relation to the CME in order to make correlations between the representative probabilities of *harm to patients* in the event of sudden unpredicted failure, to determine if there is a statistically significant relationship between the *availability* of CME and the effective and *efficient treatment of patients*, and to explore whether alternative 'state of the art' maintenance management strategies from other relevant industries have the potential *to improve the availability of CME and reduce risk to patients.*

III. Methodology

This study examined the **maintenance management strategies of CME** in a group of public hospitals. Of the 220 hospitals considered, 200 were invited to participate and **84 responded**. Reasons for non participation included: small size or type of hospital, i.e. without specific equipment maintenance responsibilities, lack of a maintenance management department, and/or non-availability of the critical

medical devices selected for study. This study targets four different hospital departments: *biomedical engineering*, *surgical operations*, *cardiac catheterisation and dialysis*. The study also targets specific hospital staff, including the Directors of Bioengineering Departments, Directors and Managers of Nursing Units, and other users of CME including medicine and nursing staff.

A questionnaire survey was designed for this study, and each hospital was sent between 1 to 4 copies of this questionnaire depending on the number of relevant departments and the type of maintenance used. In total, 101 questionnaires were completed and submitted to the researcher. Ethics approval was necessarily obtained from the responsible authority for each hospital. This study focused on those CME whose failure or non-availability would pose a high level of risk to patients' lives. The criteria for judging the criticality of equipment included: the risk failure or breakdown poses to patients, the average usage time per patient, average number of patients who are serviced by these devices per month and year, the average operational life of CME and the availability of alternatives in case of failure of CME. This study is limited in its scope to the examination of 14 types of CME used in hospitals. A total of 5769 devices were examined using the questionnaire. However, for this paper only the six most significant CMEs are examined.

In a **pilot study** of *3 hospitals, five types of CMEs were examined, that had a non-availability high risk level*; kidney dialysis, anesthesia, defibrillators, diathermy and cardiac catheterization machines. In the process of collecting the data via the pilot questionnaire, the hospitals selected also suggested other types of CME that should be considered. These are shown in Table I below. However, only 14 CME were considered in this study. It is recommended that the comprehensive list is used in future research. This paper presents only the six most critical items.

The information from the pilot study was used to design the final questionnaire, which was divided into six key sections; (*1) maintenance management strategies (MMS) and maintenance service (MS), (2) reliability centered maintenance (RCM), and availability, (3) failures rate (FR), (4) patient risks, (5) maintenance cost and (6) maintenance practice*. These six sections were covered in 55 closed and open-ended questions. The questionnaire was designed according to research objectives and provides recommendations for best practice. The survey was available both online and as hard copy. Email, telephone, visits to hospitals, personal observations and meeting staff were also used in the data collection process and 11 hospitals were personally visited to enable the researcher to make observations of maintenance activities and gain further data.

TABLE I
OTHER CRITICAL MEDICAL EQUIPMENT TO BE CONSIDERED IN FUTURE RESEARCH

No	Equipment	No	Equipment
1	Surgical Laser	11	Bladder scanner
2	BIS Monitor	12	Reliance EPS
3	Insufflators	13	Olympus control unit
4	Respironics-light	14	Vision BIPAP
5	Trans illuminator	15	Respironics-Humidifier
6	PICCO machine	16	INR machine
7	Monitor	17	Respironics/Exsuffator
8	ABG Machine	18	Electronic Tourniquet
9	SCDS	19	Olympus Flushing
10	Autoclave	20	Respironics-Continuous positive Airway pressure units

IV. DATA ANALYSIS

The data analysis was carried out using the Monkey survey website, SPSS 19.0 for Windows and Microsoft Excel, which allowed the relationship and the degree of correlation between variables to be investigated [9], [10]. Each variable was given a standard unit measurement and the data was examined for validity and reliability. Three significant tests were performed; independent samples *t–test* of hypothesis for the Mean difference, compare means (One-Way ANOVA), and the chi-square test and descriptive statistics (means & frequencies) [11].

To investigate the research questions and hypotheses of this study, the conceptual frameworks proposing the five variables and associated factors that can affect patient outcome, are shown in Fig. 1. Where the data analysis was organized according to two variables: (1) independent: types of **maintenance management strategies (MMS)** and/ or **maintenance service (MS)**, and (2) dependent: these included **maintenance performance**, **maintenance practices**, **maintenance cost** and **patient outcomes**. The results enable the researcher to examine the relationship between the selected variables and the research hypotheses.

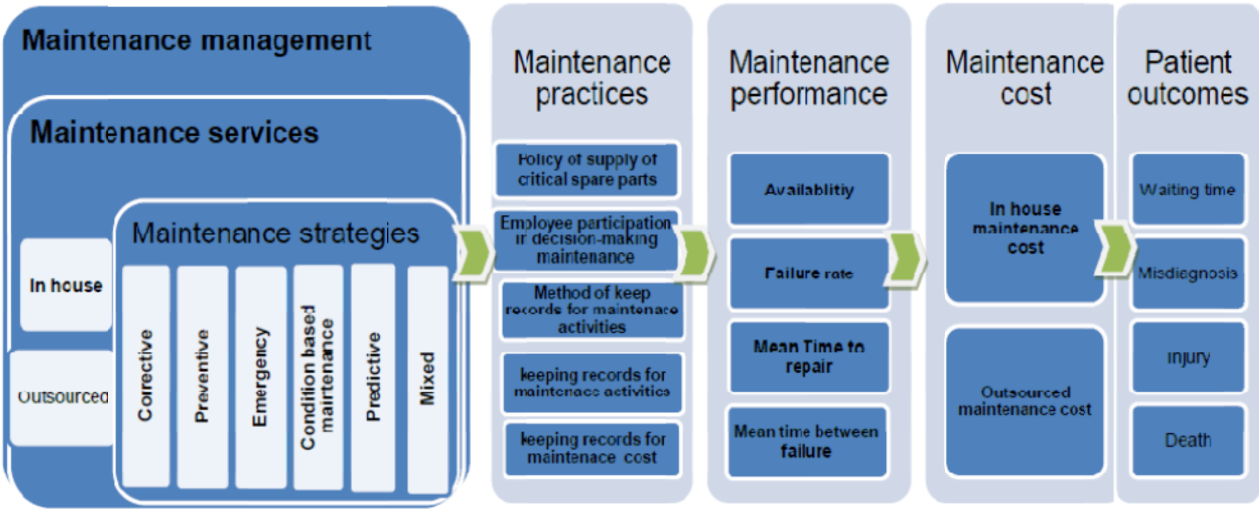


Fig. 1 Conceptual framework proposing of the variables that affect patient outcomes

V. Results

This study examined 14 types of CME; this was a total of **5769 devices**. From an average total number of CME; *8% were new, 57.6% had one to four years of use, and 39.6% had over five years of use*. In this study respondents indicated on average, *63% of particular items of CME had no alternatives or standby equipment* that could be substituted for the same work and provide the required health services to patients in the event of its **breakdown or unavailability**. The average frequency of usage per patient of CME was considered to be high per treatment. Operation times of CME investigated ranged from 1 to 48 hours. This meant that the patient remained in contact with the equipment during this period for healthcare service. The defibrillator and ECG equipment were deemed highly critical with potential high risks to patients, including *misdiagnosis, injury and death* [1].

In this study, an analysis of the results was used to examine the significance of the relationship between the six basic variables set out in the conceptual framework: *maintenance management strategy (MMS) and maintenance services (MS) of CME, maintenance practice (MP), maintenance costs (MC), medical equipment reliability and patient outcomes*. In this survey of 84 public hospitals located in 17 different local health districts, three types of maintenance services for CME were identified. *It was found that 72% used outsourced maintenance services, 16% used in-house and 12% used mixed maintenance services.*

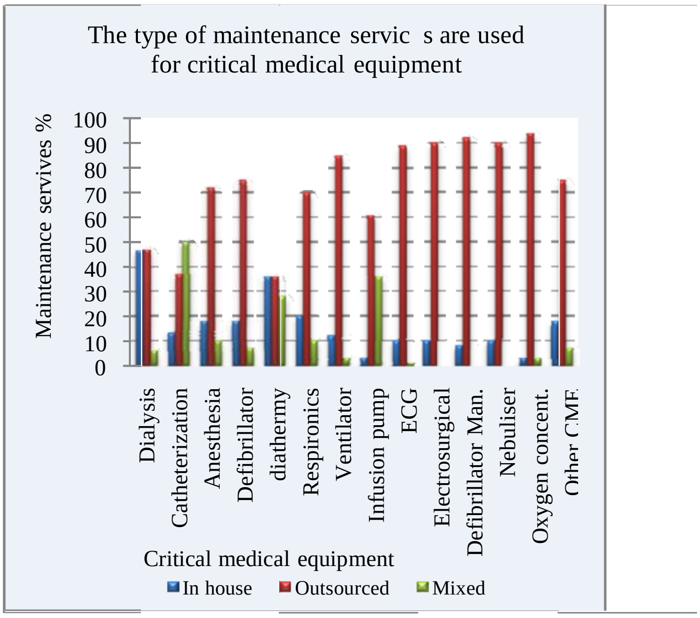


Fig. 2 The type of maintenance services used for critical medical equipment

The results sought to establish the relationship between **maintenance strategy**, **failure rate and availability** of **CME** and **improved of patient outcomes**. Using this analysis, it is proposed that alternative maintenance strategies for specific CME be used to increase their *availability and reliability*. The *total number* of CME usage was **107 171** and the reported *failure number FN* was 1534 per year, which as a generalized FN for the 84 hospitals appears to be low at **0.014% FR**.

TABLE II-A
RESULTS OF T-TEST EXAMINING THE RELATIONSHIP BETWEEN THE TYPES OF MAINTENANCE SERVICES USED FOR CME AND FN

Equipment	T- test					Results
	P-value	In-house		Outsourced		
		M	*SD*	*M*	*SD*	
Defibrillator	**0.001**	1.33	0.49	1.05	0.23	Sig.
Anesthesia	0.108	1.50	0.55	1.21	0.42	Not. Sig.
Ventilator	0.476	1.00	0.00	1.03	0.18	Not. Sig.
Infusion p.	**0.001**	2.00	0.00	1.39	0.49	Sig.
ECG	**0.052**	1.40	0.55	0.15	1.15	Sig.
dialysis	0.351	1.57	0.53	1.71	1.71	Not. Sig.

TABLE II-B
RESULTS OF T-TEST EXAMINING THE RELATIONSHIP BETWEEN THE TYPES OF MAINTENANCE SERVICES USED FOR CME AND FN

Equipment	T- t st				
	N	Unit	*F*	*DF*	*T*
Defibrillator	67	487	29.278	65	3.007
Anesthesia	34	91	2.739	32	1.441
Ventilator	36	268	0.520	34	-0.349
Infusion pump	46	3051	35.123	44	1.74
ECG machine	59	267	3.948	57	1.437
Kidney dialysis	14	151	0.941	12	-0.522

The reasons for the failure of this equipment were classified in the survey into three types from this survey: *technical causes 43.67%, human error 52.73% and over-use 3.6%*. Noteworthy, among the results were the highest percentages of FN attributed to the three classifications these were; *technical causes 90% FN with the defibrillator, human error 76% FN with the infusion pump, and over-use 12.5% FN with the cardiac catheterization machine*.

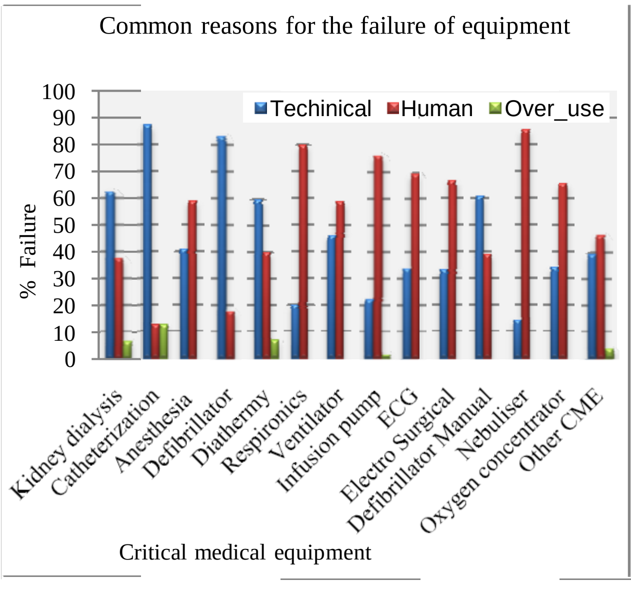


Fig. 3 The common reasons for the failure of the critical medical equipment

Participants claimed that in the last five years (2007-2011) only 660 failures occurred, yet this current study (2012) has generated a 20% increase in FN as 1534 failures while in service were reported in this study. These results however, are inconclusive, because they are not statistically reliable as the survey requested opinions, and accurate quantitative statistics were not available or access within the scope of this research. The failure number FN was analyzed for each individual piece of equipment, to find the failure rate FR in 2012, for CME.

Of the 101 respondents, a very few indicated that they used reliability and availability data to evaluate the performance of CME. Only 2.82% indicated they had no data to evaluate the performance of CME, such as the kidney dialysis, anesthesia and defibrillator machines. Similarly, only 12.83% indicated they used failure rate data to evaluate the performance of most of the equipment surveyed, and of this 1.4% indicated they used mean time to failure, and 3.7% indicated they used mean time between failures, for evaluation purposes.

TABLE III
FAILURE RATE OF CRITICAL MEDICAL EQUIPMENT

No	Equipment	RN	Usage time	FR%
1	Defibrillator	144	464	31
2	Defibrillator manual	16	104	15
3	Diathermy	136	1,340	10
4	Dialysis	366	4,937	7.4
5	Infusion pump	331	20,187	1.6
6	Oxygen concentrator	47	3,335	1.4
7	Anesthesia	132	13,549	0.1
8	Respironics	21	2,346	0.9
7	OCME	39	4,486	0.9
9	ECG	154	2,654	0.6
10	Ventilator	48	8,109	0.6
11	Electrosurgical	44	9,390	0.5
12	Nebuliser	39	0,810	0.4
13	Catheterisation	16	1,570	0.3

Respondents confirmed that the reasons for the **unavailability** of CME in this study for providing healthcare to patients was due to either, the CME being *limited in number* (according to 33.28% of respondents), or *the device was out of service* (according to the remaining 66.72% of respondents). The *unavailability of the surveyed equipment ranged between 96 to 360 hours per month*. The defibrillator and infusion pump had the highest instance of unavailability at 360 hours per month, followed by the diathermy and ECG machines at 336 hours per month, and the kidney dialysis machine at 240 hours per month. Overall, the average **availability** of these machines per year ranged between 96% for the anesthesia and ventilator, 94% for the ECG, 91%for the nebulizer 91%. The lowest availability rate of these machines per year was for the defibrillator at 89% and the infusion pump at 61%.

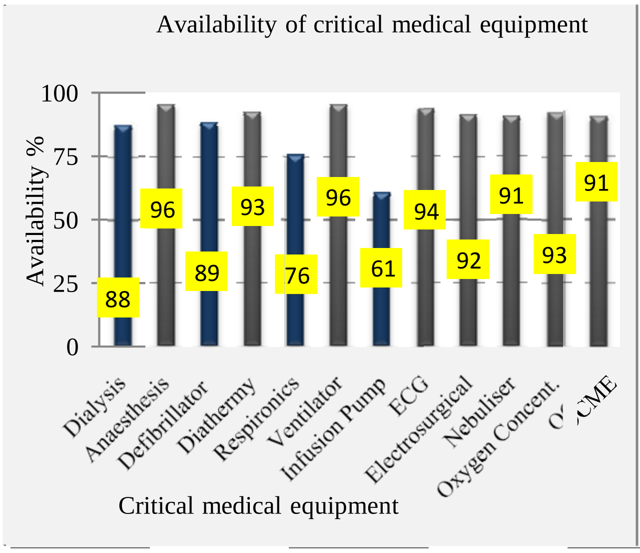


Fig. 4 Overall average of availability of critical medical equipment in 2011-2012

As can be seen in Fig. 4 above, the average availability of CME ranged from 61% to 96% in the year 2011-2012. It can be seen, however, that the availability of all the surveyed CME was well below this standard, particularly, in the case of the defibrillator, kidney dialysis, respironics and infusion pump machines. *This lack of availability may be due to the maintenance services used.*

In this study, 44% of respondents suggested there are problems in keeping each of the CME properly maintained and available. On average, 19.17% of respondents reported that this maintenance problem often affects patients outcomes, 56.64% reported that this happened sometimes and 24.26% reported it had never happened see Fig. 5. No significant difference was found between in-house and outsourced maintenance services in relation to effects on patient outcomes.

This study's examination of whether the breakdown of CME caused accidents where patient outcomes were affected, such as misdiagnosis, injury or death found that: 8% were aware of "patient death", 19% were aware of "patient injury" and 73% of answered "not at all". Additionally, respondents were asked to identify the level of risk to patients' lives posed by the failure of Review Stage CME during operation. In this survey, the level of risk was divided into four: high, middle, low and very low, for each of these cases of, death, injury and misdiagnosis. The most significant results of CME was 'a perceived higher level of risk of death' from: the defibrillator manual 100% of respondent, defibrillator 94.4%, oxygen concentrator 76.9%, the ventilator 67.5% and anesthesia 65.8% machines as shows in Table IV-A and Table IV-B.

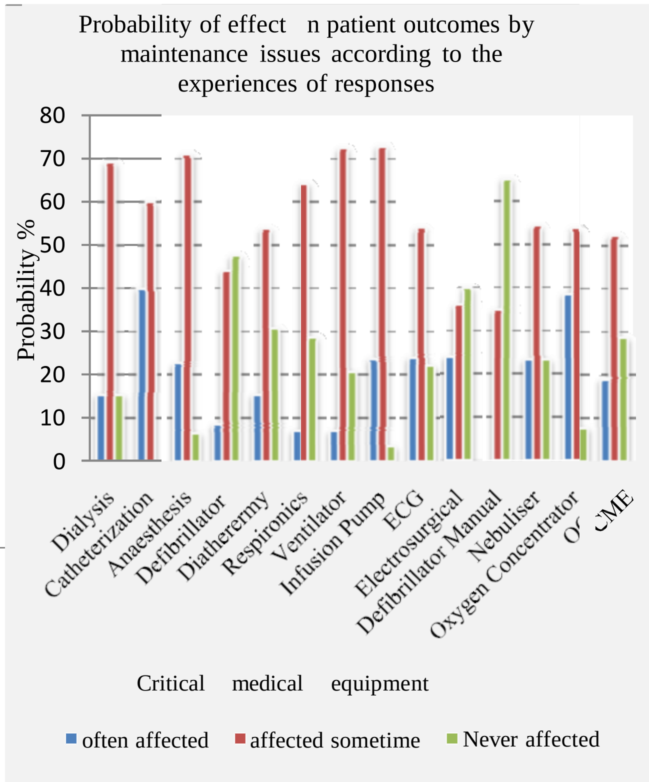


Fig. 5 Probability of effect on patient outcomes by maintenance issues according to the experiences of responses

TABLE IV-A
A HIGH RANGE OF LEVEL OF PERCEIVED RISK THAT EQUIPMENT FAILURE POSES TO PATIENTS ACCORDING TO DEATH, INJURY AND MISDIAGNOSIS

No	Equipment	% Death	% Injure	% Misdiagnosis
1	Defibrillator, Manual	100	0	0
2	Defibrillator	94	64	44
3	Oxygen concentrator	77	0	0
4	Ventilator	68	0	0
5	Anesthesia	66	50	0
6	Catheterization	50	75	100
7	Diathermy	44	50	25
8	Infusion pump	17	25	0
9	Electrosurgical	11	0	0
11	Nebuliser	31	0	0
12	Dialysis	18	44	33
13	Respironics	11	25	0
14	ECG	5	0	46
	OCME	9	17	61

VI. Discussion

Previous study has argued that in the context of hospitals, advancing medical technology means that traditional maintenance is no longer efficient to ensure that medical equipment is receiving the best possible maintenance [1]. Clinical engineering professionals need to continually review and improve their management strategies in order to keep up with equipment technology development, as well as with rising demands of health care organizations. This requires the

development of risk-focused maintenance management plans [12].

However, it is not efficient to focus on risks caused by individual pieces of equipment to individual patients. Emphasis should also be on the impact of equipment failure on patients, particularly, to provide timely and accurate diagnoses for immediate therapeutic decisions or surgical interventions [12]. For this reason, healthcare organizations are responsible for ensuring that their medical equipment is available and can be used safely and efficiently, while also complying with the related health and safety standards [4].

TABLE IV-B
A MID- RANGE OF LEVEL OF PERCEIVED RISK THAT EQUIPMENT FAILURE POSES TO PATIENTS ACCORDING TO DEATH, INJURY AND MISDIAGNOSIS

No	EQUIPMENT	% DEATH	% INJURE	% MISDIAGNOSIS
1	Defibrillator, Manual	0	0	0
2	Defibrillator	4	0	0
3	Oxygen concentrator	15	0	0
4	Ventilator	3	50	0
5	Anesthesia	5	30	0
6	Catheterization	50	25	0
7	Diathermy	0	25	0
8	Infusion pump	68	25	60
9	Electrosurgical	68	100	0
11	Nebuliser	50	0	0
12	Dialysis	0	33	0
13	Respironics	33	50	100
14	ECG	0	0	50
	OCME	18	17	17

In this study, it is suggested that the current maintenance strategies used need to be improved, CME in hospitals, have adopted the recommendation the Joint Commission on Accreditation of Healthcare Organisation (JCAHO) be used for different strategies for different parts as appropriate. For example, different strategies can be employed for defibrillators used in emergency departments and intensive care units than those used in general patient care areas or clinics [2], [12].

Preventive maintenance (PM) often does not increase reliability and actually may introduce failure, a notion well documented in industrial maintenance [12]. However, as medical equipment becomes more complex, it is argued that PM activities become less relevant. This is because PM is only concerned with inspection and scheduled maintenance activities, which do not take into consideration age-related failure [13]. In contrast to preventative and corrective maintenance strategies, predictive maintenance actively utilizes diagnostic methods in order to avoid the risk of breakdown Endrenyi et al. [14]. When applying predictive maintenance to medical equipment, it is important to be flexible in the planning and scheduling of maintenance activities. This is because it is often difficult to perform planned maintenance activities at a suitable time due to their use on patients and outside control factors. For this reason, Wang et al., [12] suggest the use of a grace period (or slippage) for determining when an item of medical equipment must be considered overdue for a planning inspection or maintenance occurrence.

It is argued that predictive maintenance (Pr.M) is more advanced than other maintenance strategies because it focuses on inspection, condition and risk-based techniques [13]. CBM as part of Pr.M strategy, reduces incidences of sudden random failures to achieve a “zero-failure” strategy, as the condition control helps to discover failure causes, potential failures and mechanisms of failure ahead of usage [15]. The main advantage of CBM is that it promotes cost-effective production because it can be performed without stopping equipment or processes [16]. Ghasemi et al., [17] found that CBM can assist in finding the optimal observation interval of an operation process based on the total long-run average cost as well as the corresponding replacement policy that optimizes the total long-run average cost of the replacement and observations. Reliability Centered Maintenance (RCM) however, does play an important role in measuring the availability and reliability of medical equipment in healthcare organizations [4]. An effective maintenance strategy can increase healthcare service productivity and reduce the failure rate and life cycle cost [18]. Despite the development of medical equipment, according to Khalaf et al., [1], no medical device is one hundred percent safe and resources are never unlimited. Vanier [19] argues that while the Computerized Maintenance Management Software CMMS is excellent for storing data it was not used in the hospitals surveyed in this study.

VII. LIMITATIONS OF THIS STUDY

The limitations of this study relate to the difficulties in accessing relevant and reliable data. This is because: (1) many hospitals do not have a biomedical engineering department and a central database of maintenance activity because they tend to outsource these activities. Of the 220 hospitals, only 13 hospitals or (5%) had a biomedical engineering department. These hospitals tended to be large urban hospitals. (2) Each hospital uses different methods of keeping records of maintenance activities; for example, one local health district uses a database (46%), computer (43%), and paper (11%). Of 101 survey respondents, 6% said they often kept records of maintenance cost, 1% occasionally kept records of maintenance cost and 2% seldom kept records of maintenance cost. The lack of accessible data means that some hypotheses and research questions could not be answered.

VIII. CONCLUSION AND RECOMMENDATIONS

A proposed model (Fig. 6) for improving MMS used for CME was designed based on the results, discussion and recommended in this paper to improve patient outcomes.

Model design steps are:

1. Identify the problem
2. Identify the current maintenance strategies

3. Proposed the kind of maintenance management strategies that could be used to increase CME availability and decrease the cost of ownership while achieving the desired level of patient outcomes including: (a) Condition-Based Maintenance CBM (b) Total Productive Maintenance TPM and (c) Predictive maintenance Pr. M.
4. Computerized maintenance management software (CMMS)
5. Continuous improvement process into maintenance management strategies.

In conclusion, this study has chosen hospitals that do not rely on predictive maintenance for CME. It also recognizes the lack of a biomedical engineering department and the consequently high reliability on contracts with maintenance companies. The evaluation of performance of CME was carried out by using qualitative and quantitative measures in order to examine the failure rate and it is affect the analysis. Major factors to perform measurements are the CME's availability and failure rate. As the final results of this study it is proposed that maintenance management strategies could increase CME of availability and decrease the cost of ownership while achieving the desired level of patient outcomes. This study provides several proposals; (1) Computerized Maintenance Management Software CMMS based on Condition-Based Maintenance CBM. (2) Using Total Productive Maintenance (TPM) which have potential to improve quality of perform CME.

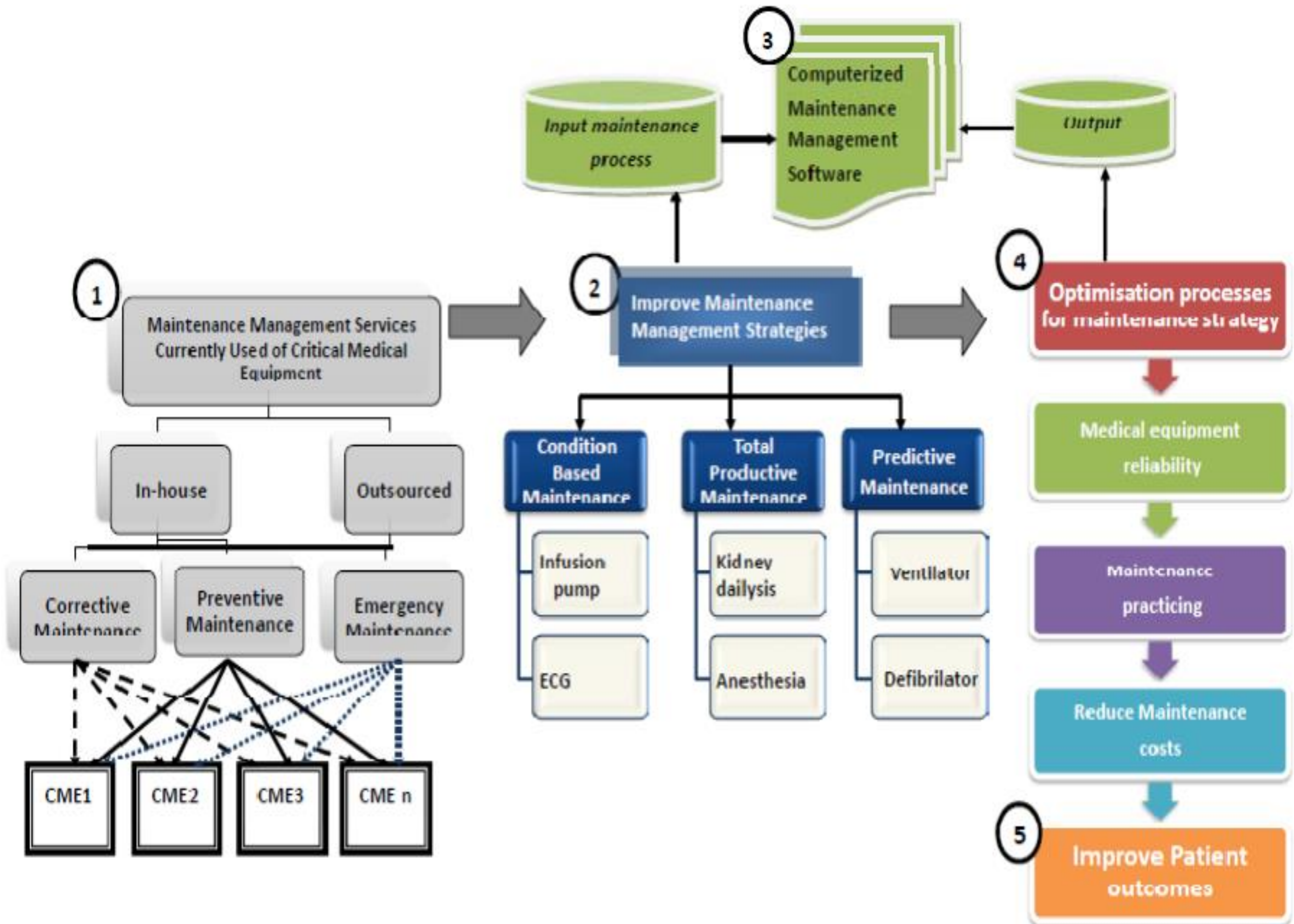


Fig. 6 Formulation of a model for improving maintenance management strategies used of critical medical equipment designed by the researcher Mkalaf (2013)

REFERENCES

[1] Khalaf, A., K. Djouani, Y. Hamam, and Y. Alayli. *Evidence-based mathematical maintenance model for medical equipment*. in *Electronic Devices, Systems and Applications (ICEDSA), 2010 Intl Conf on*. 2010.

[2] Wang, B. and A. Levenson, *Equipment inclusion criteria: a new interpretation of JCAHO's medical equipment management standard.* J Clin Eng, 2000. **25**(1): p. 26-35.

[3] Wang, B., *Evidence-Based Maintenance.* Soap Box, 2007.

[4] Tarawneh, W. and S. El-Sharo. *Assessment Of Medical Equipment In Respect To Their Down Time*. 2009: Springer.

[5] da Silva, C.M.I., C.M.P. Cabrita, and J.C. de Oliveira Matias, *Proactive reliability maintenance: a case study concerning maintenance service costs.* Journal of Quality in Maintenance Engineering, 2008. **14**(4): p. 343-355.

[6] Murthy, D., A. Atrens, and J. Eccleston, *Strategic maintenance management.* Journal of Quality in Maintenance Engineering, 2002. **8**(4): p. 287-305.

[7] Medhat, N., S. Samy, M.A. Wahed, and A. Mohamed. *Medical Equipment Quality Assurance by Making Continuous Improvement to the System*. 2008: IEEE.

[8] De Groote, P., *Maintenance performance analysis: a practical approach*. Journal of Quality in Maintenance Engineering, 1995. **1**(2): p. 4-24.

[9] Manning, M. and D. Munro, *The survey researcher's SPSS cookbook*. 2 nd edition ed. 2007: Pearson Education-Australia.

[10] Mkalaf, K., A. and P. Gibson. *A study of current maintenance strategies and the reliability of medical equipment in hospitals in relation to patient outcomes*. 2012, [cited 5 April 2012, https://www.surveymonkey.com/s/65VK396]; online survey available].

[11] Cannesson, M., G. Pestel, C. Ricks, A. Hoeft, and A. Perel, *Hemodynamic monitoring and management in patients undergoing high risk surgery: a survey among North American and European anesthesiologists.* Crit Care, 2011. **15**(4): p. R197.

[12] Wang, B., E. Furst, T. Cohen,O.R. Keil, M. Ridgway, and R. Stiefel,*Medical equipment management strategies.* Biomedical Instrumentation & Technology, 2006. **40**(3): p. 233-237.

[13] Pintelon , L. and A. Parodi-Herz *Maintenance: an evolutionary perspective.* Complex System Maintenance Handbook, 2008: p. 21-48.

[14] Endrenyi, J., S. Aboresheid, R. Allan, G. Anders, S. Asgarpoor, R. Billinton, et al., The present status of maintenance strategies and the impact of maintenance on reliability. Power Systems, IEEE Transactions on, 2001. 16(4): p. 638-646.

[15] Temple-Bird, C., R. Mhiti, and G. Bloom, *Medical equipment inBotswana: a framework for management development.* Geneva: World Health Organisation, 1995.

[16] Slack, N., S. Chambers, C. Harland, A. Harrison, and R. Johnston, *Operation Management* Second ed. ed. 1998, London: Pitman Publishing. p742.

[17] Ghasemi, A., S. Yacout, and M.S. Ouali, *Optimal Stategies for non- costly and costly observations in Condition Based Maintenance.* IAENG International Journal of Applied Mathematics, 2008. **38**(2).

[18] Pun, K.F., K.S. Chin, M.F. Chow, and H.C.W. Lau, *An effectiveness- centred approach to maintenance management: A case study.* Journal of Quality in Maintenance Engineering, 2002. **8**(4): p. 346-368.

[19] Vanier, D. *Asset management A to Z.* 2010.