Developing an instrument to measure informed consent comprehension in non-cognitively impaired adults

Laura D. Buccini
University of Wollongong

UNIVERSITY OF WOLLONGONG

COPYRIGHT WARNING

You may print or download ONE copy of this document for the purpose of your own research or study. The University does not authorise you to copy, communicate or otherwise make available electronically to any other person any copyright material contained on this site. You are reminded of the following:

This work is copyright. Apart from any use permitted under the Copyright Act 1968, no part of this work may be reproduced by any process, nor may any other exclusive right be exercised, without the permission of the author.

Copyright owners are entitled to take legal action against persons who infringe their copyright. A reproduction of material that is protected by copyright may be a copyright infringement. A court may impose penalties and award damages in relation to offences and infringements relating to copyright material. Higher penalties may apply, and higher damages may be awarded, for offences and infringements involving the conversion of material into digital or electronic form.

Recommended Citation
Buccini, Laura D., Developing an instrument to measure informed consent comprehension in non-cognitively impaired adults, Doctor of Public Health thesis, School of Health Sciences, Faculty of Health and Behavioural Sciences, University of Wollongong, 2009.
http://ro.uow.edu.au/theses/3064

Research Online is the open access institutional repository for the University of Wollongong. For further information contact the UOW Library:
research-pubs@uow.edu.au
Developing an instrument to measure informed consent comprehension in non-cognitively impaired adults

Laura D. Buccini
University of Wollongong
NOTE

This online version of the thesis may have different page formatting and pagination from the paper copy held in the University of Wollongong Library.

UNIVERSITY OF WOLLONGONG

COPYRIGHT WARNING

You may print or download ONE copy of this document for the purpose of your own research or study. The University does not authorise you to copy, communicate or otherwise make available electronically to any other person any copyright material contained on this site. You are reminded of the following:

Copyright owners are entitled to take legal action against persons who infringe their copyright. A reproduction of material that is protected by copyright may be a copyright infringement. A court may impose penalties and award damages in relation to offences and infringements relating to copyright material. Higher penalties may apply, and higher damages may be awarded, for offences and infringements involving the conversion of material into digital or electronic form.
Developing an Instrument to Measure Informed Consent Comprehension in Non-Cognitively Impaired Adults

Laura D. Buccini

Thesis submitted for the degree of Doctor of Public Health,
School of Health Sciences, University of Wollongong

15 May 2009
Declaration

I, Laura D. Buccini, declare that this thesis, submitted in fulfilment of the requirements for the award of Doctor of Public Health, in the School of Health Sciences, University of Wollongong, is wholly my own work unless otherwise referenced or acknowledged. The document has not been submitted for qualifications at any other academic institution.

Laura D. Buccini
14 May, 2009
Dedication

This work is dedicated to my family, specifically my father Chuck Buccini, my mother Kathy Buccini who although hasn’t been with us for a while, I’m sure she’s been watching over me, my little sister Nichole Buccini, my precious dogs Montana and Dakota and especially to my wonderful husband Keith Boicey. Thanks to all of you for your support, encouragement and guidance. None of this would have been possible without you. Keith your patience, love, support and technical skills over the last three years has been more then impressive. I’m glad we have shared this journey together, as difficult as it may have been at times.

To my wonderful Aussie friends Liz Deane and Anne Maree Parish: you two are the best friends a girl could ask for. I’m indebted to you both for your eternal encouragement and support. Having met you both was worth all the hardship. It will be difficult to leave you but I know our friendship withstand the distance.
Acknowledgements

I’m grateful to my team of supervisors.

- My primary supervisor, Professor Don Iverson provided assistance with the study design throughout the project as well as constructive and helpful comments on the draft of journal articles and the final thesis. Thank you Don for granting me the opportunity to undertake my doctoral studies with you, for the conception of the project and for your guidance during the project.

- My co-supervisors Associate Professor Peter Caputi and Associate Professor Caroline Jones provided assistance with the study design and invaluable feedback on drafts of journal articles and the final thesis. Thank you Peter for your statistical wisdom and guidance through the psychometric analysis. Not to be forgotten are your motivational speeches which were always entertaining!

I would also like to thank the following persons:

- All my family, especially my husband Keith Boicey who always, despite reluctance, proofread my thesis and provided substantial technological assistance.

- All of my friends for their interest in my research and their support.

- Dr. Hazer and Dr Kremer, the best mentors anyone could ask for. The life lessons I’ve learned from each of you are irreplaceable. I only hope I can be the mentor to others like you both have been to me. Thank you for always believing in me!

- My research participants who generously volunteered their time and energy.
Abstract

Informed consent in human research involves a process of communicating information about a research study so as to promote informed decision-making. Current research suggests, however, that a high proportion of participants do not fully understand what it is they are consenting to when enrolling onto a research study. In other words, for many participants consent to participate in research is not truly informed. Evaluating participants' comprehension of informed consent information through the use of comprehension tests is one possible method for increasing the likelihood that consent to take part in research is truly informed. This thesis, therefore, comprises a series of both qualitative and quantitative studies that build upon one another culminating in the development of a new instrument that measures potential research participants' comprehension of informed consent information.

Assessments of readability provide a preliminary indication of document complexity in terms of writing style (word choice, sentence length). Therefore, a small-scale descriptive study, as described in Chapter 2, was conducted: i) to measure the readability of Australian-based clinical trial informed consent documents; and ii) to determine whether national or local ethics committees within Australia have formally established informed consent readability standards. The results of the study revealed that the majority of informed consent documents were written at a reading level appropriate for individuals with some university education thus beyond the reading ability of a majority of Australian adults. Official readability recommendations and/or standards could not be located at the national or local level.

One method of gathering evidence of informed consent comprehension is through the use of comprehension tests. Chapter 3 consists of a systematic review, which identifies and critically evaluates instruments that have been developed to measure clinical trial informed consent comprehension in non-cognitively impaired adults. A total of three instruments were identified. Strengths and limitations of each instrument were evaluated against the following criteria: i) method of item generation; ii) type and
format of test items; iii) administration and interpretation of test results; and iv) psychometric properties.

None of the instruments identified in Chapter 3 were developed based on a construct definition. This may be due to the absence of an accepted construct definition of informed consent comprehension. A construct definition provides a framework for determining how an instrument should be constructed, implemented, interpreted and applied. Furthermore, the validity of what is being measured will rest largely on that definition. Chapter 4 describes and reports on the results of a qualitative study, involving an international expert panel, which was conducted to develop consensus for a construct definition of informed consent comprehension.

The construct definition proposed in Chapter 4 was utilized as the conceptual framework for the development a new of informed consent comprehension instrument, called the Modular Informed Consent Comprehension Assessment (MICCA) instrument. Chapter 5 describes the methodologies used to develop the instrument and presents the results of preliminary readability and content validity testing. Chapter 6 is an extension of Chapter 5 in that it presents the results of a psychometric study conducted to assess the reliability, generalizability and validity of the MICCA. Results of the psychometric study provide preliminary evidence that the MICCA can be utilized in various clinical trial settings and can produce reliable and valid test scores. Evidence of comprehension through the use of comprehension instruments, such as the MICCA, can help ensure that consent to participate in a research study is truly informed.
Publications and Presentations

The following publications and presentation have been produces as a result of the research conducted for this thesis.

Publications in Refereed Journals


Conferences and Presentations


### List of Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
<tr>
<td>AU</td>
<td>Australia</td>
</tr>
<tr>
<td>BICEP</td>
<td>Brief Informed Consent Evaluation Protocol</td>
</tr>
<tr>
<td>BIQ</td>
<td>Brief Investigator Questionnaire</td>
</tr>
<tr>
<td>CA</td>
<td>Canada</td>
</tr>
<tr>
<td>DICCT</td>
<td>Deaconess Informed Consent Comprehension Test</td>
</tr>
<tr>
<td>Fog</td>
<td>Gunning Fog Index</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HREC</td>
<td>human research ethics committees</td>
</tr>
<tr>
<td>ICC</td>
<td>Intraclass correlation</td>
</tr>
<tr>
<td>MICCA</td>
<td>Modular Informed Consent Comprehension Assessment</td>
</tr>
<tr>
<td>MIMS</td>
<td>Monthly Index of Medical Specialties</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>QuIC</td>
<td>Quality of Informed Consent questionnaire</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SMOG</td>
<td>Simple Measure of Gobbledygook</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>WAIS-R</td>
<td>Wechsler Adult Intelligence Scale-Revised</td>
</tr>
<tr>
<td>WRAT-R</td>
<td>Wide Range Achievement Test-Revised</td>
</tr>
</tbody>
</table>
Table of Contents

Chapter 1: Introduction
1.1 Informed Consent Comprehension-A Brief Background...........................................1
1.2 Thesis Outline........................................................................................................3
1.3 Significance of Thesis.............................................................................................4
1.4 References...........................................................................................................5

Chapter 2: An Australian Based study on the Readability of HIV/AIDS and Type 2 Diabetes Clinical Trial Informed Consent Documents
2.1 Introduction...........................................................................................................8
  2.1.1 Informed Consent............................................................................................8
  2.1.2 Readability......................................................................................................8
2.2 Methods................................................................................................................10
  2.2.1 Readability Assessments..............................................................................10
  2.2.2 Readability Standards..................................................................................11
2.3 Results..................................................................................................................12
  2.3.1 Readability Assessments..............................................................................12
  2.3.2 Readability Standards..................................................................................14
2.4 Discussion.............................................................................................................14
2.5 References...........................................................................................................17

Chapter 3: Assessing Clinical Trial Informed Consent Comprehension in Non-Cognitively Impaired Adults: A Systematic Review of Instruments
3.1 Introduction...........................................................................................................20
3.2 Methods................................................................................................................21
3.3 Results..................................................................................................................23
  3.3.1 Item Generation and Format.................................................................24
  3.3.2 Test Administration....................................................................................25
  3.3.3 Interpretation of Test Results.................................................................25
3.3.4 Psychometrics.................................................................26
3.4 Discussion............................................................................27
3.5 References...........................................................................30

Chapter 4: Toward a Construct Definition of Informed Consent Comprehension

4.1 Introduction...........................................................................32
4.2 Methods................................................................................33
  4.2.1 Participants.................................................................33
  4.2.2 Phase 1: Preliminary Construct Definition......................33
  4.2.3 Phases 2-5: Revisions Based on Experts' Responses..........33
4.3 Results..................................................................................35
  4.3.1 Phase 1: Initial Construct Definition...............................35
  4.3.2 Phase 2: First Revision..................................................35
  4.3.3 Phase 3: Second Revision..............................................38
  4.3.4 Phase 4: Third Revision................................................38
  4.3.5 Phase 5: Call for Consensus..........................................39
4.4 Discussion.............................................................................39
4.5 References............................................................................41

Chapter 5: A New Measure of Informed Consent Comprehension:
Part I-Instrument Development

5.1 Introduction...........................................................................44
5.2 Methods................................................................................46
  5.2.1 Phase 1: MICCA Conceptual Framework.........................46
  5.2.2 Phase 2: MICCA Test Construction.................................47
  5.2.3 Phase 3: BIQ Construction.............................................47
  5.2.4 Phase 4: Revisions.......................................................49
  5.2.5 Phase 5: Preliminary Testing..........................................49
Chapter 6: A New Measure of Informed Consent Comprehension:
Part II-Preliminary Psychometric Evaluation

6.1 Introduction ................................................. 57
6.2 Methods ................................................... 59
   6.2.1 Study Design ........................................... 59
   6.2.2 Participants ........................................... 60
   6.2.3 Informed Consent Documents and MICCAs .......... 61
   6.2.4 Scoring the MICCA ................................... 63
   6.2.5 Procedures ............................................ 63
   6.2.6 Statistical Analysis .................................... 64
      6.2.6.1 Reliability ....................................... 64
      6.2.6.2 Generalizability .................................. 64
      6.2.6.3 Validity .......................................... 65
6.3 Results .................................................... 65
   6.3.1 Descriptive Statistics ................................. 65
   6.3.2 Reliability ............................................ 66
   6.3.3 Generalizability ..................................... 67
   6.3.4 Validity ............................................... 67
   6.3.5 Secondary Analysis ................................... 68
6.4 Discussion .................................................. 69
6.5 References ............................................... 73
Chapter 7: Conclusions and Implications for Future Research

7.1 Summary ..................................................................................................................76
7.2 Limitations and Suggestions for Future Research ...............................................79
7.3 Conclusion ...............................................................................................................81
7.4 References .............................................................................................................83

Appendices

Appendix A Content Domain .......................................................................................84
Appendix B MICCA (full version) ................................................................................85
Appendix C BIQ .............................................................................................................89
Appendix D.1 Cancer Informed Consent Documents ...................................................93
Appendix D.2 Cancer Title Page ..................................................................................101
Appendix D.3 Cancer MICCA .....................................................................................102
Appendix E.1 Diabetes Informed Consent Documents ................................................109
Appendix E.2 Diabetes Title Page ...............................................................................118
Appendix E.3 Diabetes MICCA ...................................................................................119
Appendix F.1 Exercise Informed Consent Documents ................................................126
Appendix F.2 Exercise Title Page ...............................................................................133
Appendix F.3 Exercise MICCA ...................................................................................134
Appendix G.1 Hypertension Informed Consent Documents ........................................141
Appendix G.2 Hypertension Title Page ......................................................................149
Appendix G.3 Hypertension MICCA ..........................................................................150
Appendix H.1 Nutrition Informed Consent Documents ..............................................157
Appendix H.2 Nutrition Title Page ............................................................................163
Appendix H.3 Nutrition MICCA ...............................................................................164
List of Tables

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 2.1</td>
<td>Percent of Populations at or Below an 8th Grade Reading Level</td>
<td>9</td>
</tr>
<tr>
<td>Table 2.2</td>
<td>Readability Hand Calculation Methodology</td>
<td>11</td>
</tr>
<tr>
<td>Table 3.1</td>
<td>Summary of Informed Consent Comprehension Instruments</td>
<td>23</td>
</tr>
<tr>
<td>Table 3.2</td>
<td>United States Consent Requirements</td>
<td>24</td>
</tr>
<tr>
<td>Table 4.1</td>
<td>Answers to Commonly Debated Questions</td>
<td>35</td>
</tr>
<tr>
<td>Table 4.2</td>
<td>Expert Feedback</td>
<td>37</td>
</tr>
<tr>
<td>Table 5.1</td>
<td>Socio-demographic Variables</td>
<td>62</td>
</tr>
<tr>
<td>Table 6.1</td>
<td>Design Characteristics of Clinical Trial Informed Consent Documents</td>
<td>62</td>
</tr>
<tr>
<td>Table 6.2</td>
<td>Mean and Standard Deviations of Standardized Test Scores by Type of Clinical Trial</td>
<td>66</td>
</tr>
<tr>
<td>Table 6.3</td>
<td>Internal Consistency of MICCA by Clinical Trial and Information Conditions</td>
<td>67</td>
</tr>
<tr>
<td>Table 6.4</td>
<td>Correlations between Test Scores and Information Conditions</td>
<td>69</td>
</tr>
</tbody>
</table>
List of Figures

Figure 2.1  Mean Readability Scores of HIV/AIDS Informed Consent Documents.................................................................13
Figure 2.2  Mean Readability Scores of Type 2 Diabetes Informed Consent Documents..........................................................13
Figure 3.1  Systematic Review Search Strategy.........................................................22
Figure 4.1  Delphi Consensus Approach Methodology - Communication Flow Diagram............................................................34