2015

Streaming physiological data: General public perceptions of secondary use and application to research in neonatal intensive care

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**Publication Details**  
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Keywords
neonatal, intensive, application, secondary, perceptions, research, public, care, general, data, physiological, streaming

Disciplines
Arts and Humanities | Social and Behavioral Sciences

Publication Details

This journal article is available at Research Online: http://ro.uow.edu.au/asdpapers/525
Streaming Physiological Data: General Public Perceptions of Secondary Use and Application to Research in Neonatal Intensive Care

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Abstract

High speed physiological data represents one of the most untapped resources in healthcare today and is a form of Big Data. Physiological data is captured and displayed on a wide range of devices in healthcare environments. Frequently this data is transitory and lost once it is initially displayed. Researchers wish to store and analyze these datasets; however, there is little evidence of any engagement with citizens regarding their perceptions of physiological data capture for secondary use. This paper presents the findings of a self-administered household survey (n=165, response rate = 34%) that investigated Australian and Canadian citizens’ perceptions of such physiological data capture and re-use. Results indicate general public support for the secondary use of physiological streaming data. Discussion considers the potential application of such data in neonatal intensive care contexts in relation to our Artemis research. Consideration of the perceptions of secondary use of the streaming data as early as possible will assist in building appropriate use models, with a focus on parents in the neonatal context.

Keywords

Patient data privacy; Data collection; Medical device

Introduction

In recent research, there has been an increased interest in the analysis of physiological data, particularly in real-time. Many critical care and neurological monitoring applications capture physiological data. Examples include electrocardiogram (ECG), electroencephalogram (EEG) and pulse oximetry data [1].

High speed physiological data represents one of the most untapped resources in healthcare today and is a form of Big Data. In neonatal intensive care for example, a premature newborn infant’s heart beats approximately 7000 times an hour and yet traditional charting on paper, or within an electronic health record (EHR), includes one number per hour of an indicative heart rate for that hour. The heuristics employed to determine the number to write are as much qualitative as quantitative and part of the function is to express overall stability or instability hour to hour. The potential for the use of high speed physiological data for earlier and potentially more reliable pathophysiological indicators have been presented for late onset neonatal sepsis [2], pneumothorax [3], intraventricular haemorrhage [4, 5] and periventricular leukomalacia [6]. Opportunities abound for the exploration of new pathophysiological indicators for many other conditions, but these are yet to be explored due to the absence of a collection of physiological data for patients developing such conditions. Analytics on high frequency physiological data, from both the perspective of retrospective knowledge discovery and real-time monitoring has the potential to be equally disruptive for healthcare as genomics research.

Within the Neonatal Intensive Care Unit (NICU), a variety of medical devices monitor the infant’s vital organs while other equipment assist with breathing, maintains appropriate body temperature and provides necessary drugs and nutrients. Many of these devices continuously create physiological data second-by-second. Although many health care settings are in the process of transitioning from the use of paper to electronic for charting purposes, this does not include new approaches for new analytics derived from this sensor data. This leads health care professionals to rely on sharing clinical information in a qualitative manner [7]. Comparable to the concept of business intelligence and analytics, which stems from the prompt interpretation of large volumes of data for actionable information, there is a growing urgency for the health care sector to similarly adopt a notion of “health care intelligence” in (near) real-time [1]. There are limitations regarding the use of analytics in health care due to the time it takes to deliver predictions to healthcare providers and enable action [8].

The value of Big Data comes from the ability to make “connections between pieces of data, about an individual, about individuals in relation to others, about groups of people, or simply about the structure of information itself” [9]. An example of a Big Data platform that includes the use of physiological streaming data is Artemis. Artemis supports online health analytics that allows for concurrent multi-patient, multi-diagnosis and multi-stream temporal analysis of complex, high-frequency physiological data streams in real-time for purposes of clinical management and research. By comparing the analytical results that are gathered in the platform with current treatment practices, new patterns in real-time physiological data can be discovered, thus enabling earlier detection and possible prevention of various health conditions before clinical symptoms are visible. Artemis captures ECG data and ECG derived signals including the heart rate, respiration rate and chest impedance for purposes of breath detection. Other signals captured include blood oxygen saturation in addition to diastolic, systolic and mean blood pressure when such data is available [7].

Secondary usage of health data is defined as the use of personal health information collected for purposes unrelated to the initial purpose of providing direct delivery of health care to the patient/data subject. This includes activities such as research, analysis, quality and safety measurement, payment, provider accreditation and commercial activities [10].
secondary usage of personal health data plays an essential role in expanding current knowledge and understanding of health care and its delivery. Utilitarian motivations are strong in this research area, however, less utilitarian and more commercial focused and personally confronting issues are also significant. Privacy issues in this area are well documented and challenging [11-13]. Physiological data (e.g. ECG data) has the potential to reveal more information about an individual than what may be realized on first consideration. Nonetheless, it appears that many people are still willing to contribute the use of physiological data generated by themselves or even by their neonate(s) as a resource for the advancement of health research. Suitable privacy and governance frameworks are required in this fast moving domain. The potential for secondary use of physiological streaming data is clear and it is important for us to begin to understand what the public opinion is regarding the secondary use of their health data, specifically physiological data for health research purposes.

The remainder of this paper is structured as follows: The survey of Australian and Canadian citizens will be introduced and results pertaining to secondary use of data captured through physiological devices will be reported. This section is followed by a discussion about related work regarding neonatal contexts and associated issues surrounding the use of Big Data in health care. Prior research regarding parental attitudes towards research in the neonatal population and privacy concerns will be considered. Conclusions and future research are then presented.

Materials and Methods

The opinion of patients regarding the possibility of analytics on physiological data was explored, as part of a larger study, through a pilot survey deployed in Australia and Canada in 2009. The pilot survey included thirty attitudinal statements using a seven point Likert scale for responses and two open-ended questions. Focus groups reviewed the survey design before deployment. These groups included teenagers, aged pensioners, early school leavers, postgraduates and citizens with English as a second language. Between August and November, 482 self-administered surveys were distributed to residential blocks in regional New South Wales (NSW) and Darwin. During October and November, 250 surveys were distributed to sample populations in Ontario. The survey sampling strategy included high, medium and low socio-economic populations in regional and urban areas. Cronbach’s Alpha results for reliability were in the acceptable range. Ethics approval was provided by the Research Ethics Board at the University of Ontario Institute of Technology and the Human Research Ethics Committee of the University of Wollongong.

The broader study that these questions are drawn from explored general public expectations and concerns regarding secondary use of their medical data, particularly pertaining to privacy matters [14, 15]. Constructs in the survey investigated the concepts underpinning the contemporary privacy theories of Restricted Access and Limited Control (RALC) [16] and a proposed framework for contextual integrity [17].

Results

The Australian and Canadian pilot surveys achieved response rates of 34.8% and 21.5% respectively. Question 26 in the survey explored the reuse of data captured through physiological devices: If I was in hospital and a medical device was used to care for me – like a heart monitor or oxygen saturation monitor – I would agree for the information displayed on the screen to be saved in an anonymous way and used for medical research purposes.

The stimulus statement used to capture feedback on physiological devices makes it clear that the data will be anonymized and used only for medical research purposes. Results for both Australians and Canadians indicate agreement with this type of secondary use of streaming data.

Discussion

The discussion here considers the secondary use of physiological streaming data within the neonatal intensive care context. It has been demonstrated that many parents are very willing to enroll their neonate in research studies [18, 19] even if it is known that there are significant gaps in knowledge about the study [18]. Many parents would also be willing to enroll their neonate again, if presented with the opportunity [18]. This is further supported by a study conducted by Morley et al. [20]. Parental opinions regarding the enrollment of their premature neonate(s) into several research studies in the days following birth were examined via the use of a questionnaire. Parents of preterm infants in the NICU who were invited to participate in two or more research studies were approached with this survey. Amongst the invited participants, 10% declined to allow their infants to join any studies. The majority of parents were willing to have their infant(s) be enrolled in multiple studies. In fact, 58% of the parents were willing to give their permission to enroll their infant(s) in three or more studies and 20% were willing to have their infant(s) participate in more than ten studies [20].
Many parents choose to consent for their neonate’s participation in research studies because they are hopeful that it would somehow benefit their infant [18]. Many parents also want to contribute to the advancement of health research. According to findings by Morley et al. [20], 94% of the parents thought that if their baby joined a research study, the care of infants in the future would either be “better” or “very much better”. Parental altruism was further demonstrated when parents were asked “Who will benefit from these studies?” in which 91% responded that “future babies”, 67% said “researchers”, 25% mentioned “my baby” and 2% said “no one”. The insight provided by the Australian and Canadian survey results suggest that perhaps parents making decisions for neonates would also agree with the anonymised use of physiological streaming data for research purposes. This is an open research area where results could inform the governance and strategy surrounding deployment of data analytics platforms, utilizing physiological streaming data in neonatal contexts.

The issue of well informed consent arises, particularly in emotion charged contexts such as neonatal environments and the next section considers these issues.

**Consent in the NICU context**

The practice of acquiring informed consent is a crucial component of the research process for the protection of a neonatal research subject [21]. For consent to be considered valid, the following elements must be satisfied: full comprehension, information, and voluntariness. The participant must be mentally competent to make a free and adequately informed decision and must give their consent voluntarily and freely. Sufficient information, including the risks about the decision to be made must also be provided to the participant [22, 23].

The informed consent process is straightforward when it comes to dealing with a competent adult [24, 25]. Obtaining informed consent presents ethical and legal difficulties in certain groups of people who are considered to be part of vulnerable populations, often as a result of limited capacity or inadequate access to social goods such as rights, opportunities and power [26]. This includes but is not limited to minors and individuals living with mental disabilities or diminishing mental power [26]. This includes but is not limited to minors and individuals living with mental disabilities or diminishing mental power [26]. This includes but is not limited to minors and individuals living with mental disabilities or diminishing mental power [26].

Proxy consent is therefore required for such groups of people and/or in such situations. Proxy consent is the process which occurs when individuals with the legal right to consent give advance permission to an authorized third party who is legally and competent to consent on their behalf when the individual is unable to consent for themselves. This adult may be designated through the power of attorney to consent or via a living will [22, 26, 27]. In the case of a newborn, the proxy consent at best represents parental discretion, preferences and family values [22, 25] as the neonate is incapable of communicating his/her own opinion about research and their willingness to participate [22].

It is well understood that the information provided regarding the details of a study should be sufficient enough for the reasonable parent to make an informed decision. Yet striking an ideal balance is easier said than done, since by providing too little information can render consent invalid, whereas providing too much information may consequently cause unnecessary distress. In addition to the emotional stress associated with the birth of a premature and/or critically ill infant, the mother may also have to deal with the physical stress related to the recovery period following the birth [22, 28]. The parents of such infants then face a multitude of complicated and urgent decisions while rapidly digesting new and changing information [29] in an unfamiliar environment. They are then obliged to take on the responsibility of being surrogate decision-makers on behalf of their infant. With no previous experience on which to turn, this can be a frightening experience as these parents are concerned with trying to make the right decision to benefit their infant or if they are unable to, at the very least, they want to make a decision that will benefit future infants [30].

However, it is difficult to test if parents truly understand what they are consenting their infant to when it comes to research studies [25]. Stenson et al. [31] conducted a survey that examined if parents of infants who entered into a randomized controlled trial of pulmonary function testing had any recollections about being asked to give consent for enrolling their infant in a research study and how they felt the research had affected their experience as parents of a sick infant. Although the parents were given a detailed verbal description and printed information sheet regarding the trial, of the 99 respondents, 12% could not remember being approached for consent and did not think that their infant had participated in a research study and 6% remembered being approached for consent but were unsure of whether or not their infant actually participated in a study. 99% parents who remembered being approached for consent felt that a full explanation of the studies they were enrolling their infant in had been provided to them; however only 27% and 42% of those parents felt that they understood the explanation completely and reasonably well respectively. The rest of the parents either understood a little of the explanation or not at all.

Ballard et al. [18] also examined the validity of informed consent obtained in the perinatal period in relation to their NEOPAIN study. To determine the level of parental understanding of the study, participating parents were asked open-ended questions that addressed the timing of consent, understanding of the study’s purpose, benefits and risks, the voluntary nature of the project, and their willingness to enroll in future studies if applicable. Of the 64 parents who were interviewed, 5 parents (7.8%) did not remember the study or signing of consent. Of the remaining 59 parents who remembered the study, only 67.8% understood the study’s purpose. It was observed that maternal understanding regarding the purpose of the study was greater than that of paternal understanding (73.3% vs 57.1%) which was particularly interesting as this study also evaluated the mother’s medication effect on their memory. The medication given most frequently to the mothers in this study population was magnesium sulfate, a drug that can cause adverse effects on memory and mentation although in reality, the risks are minimal. At the time they signed their consent to enroll their infant in the NEOPAIN study, 37 of the 43 mothers were being treated with magnesium sulfate but it was noted that the administration of the drug in this case appeared to have minimal effect on the mother’s ability to recall the study. It was proposed that despite exposure to labor and medication, mothers are better able to handle stress or process information more effectively. Invoking the father in the consent process did not improve the overall understanding of the study or its benefits and risks.

Yet even with a double consent process, in which parents experience the consent process twice with the first time taking place before the neonate’s birth and the second time occurring before the neonate’s enrollment in a study, it has been found that these parents are no more likely to have given valid consent in comparison to those parents who consented only once. The reasons for this phenomenon is not well understood.
Privacy in the NICU context

Philosopher Herman Tavani provides an insightful phrase which is a useful starting point for considering privacy matters: “Privacy is a concept that is neither clearly understood nor easily defined” [32, p.11] Within the scholarly literature, many have attempted and continue to attempt to provide the ideal definition of privacy. Some, such as Alpert (2000) see privacy as having the freedom to be whom and what one is as an individual while others such as Stephen (1873), Warren and Brandeis (1890), Westin (1967) and Gavison (1980) define it as “anything that offends decency”, “being let alone”, to “control over information” and “restricted access to persons and personal information” respectively, as cited by Allen [33]. There are also cultural dependencies with some cultures valuing privacy more than others [34].

Traditionally the privacy of medical patients’ personal information has been protected through application of the ‘limited access’ theory of privacy. With the change of medium used for capture and storage of personal medical information from paper to electronic, the ‘limited access’ approach to privacy is under pressure due to the ease with which electronic information can be exchanged. This is an issue of growing importance with the emergence of Big Data, and the physiological streaming data available in the NICU would benefit from consideration against more contemporary privacy theories [16, 17] that go beyond the ‘restricted access’ or ‘limited control’ paradigms.

The NICU context, with volumes of streaming physiological data, is well described by Nissenbaum’s definition of context: Contexts are structured social settings characterized by canonical activities, roles, relationships, power structures, norms (or rules) and internal values (goals, ends, purposes) [17, p. 132].

The survey question regarding reuse of streaming physiological data provides context related insights. The goal-ends-purposes of the data reuse were clearly described as being ‘for research purposes’. The role of the survey respondent as a patient was clarified. The power structures were considered with the patient given some power to make decisions regarding the re-use of their data. The wording of the survey question implied that the clinicians were seeking shared power over the streaming data.

The deployment of privacy frameworks within the NICU to explore: (1) the enhancement of consent and simultaneously (2) privacy as contextual integrity concepts is an open research area. The early survey results and NICU specific matters considered here are a useful launch-point for further work. The broader patient privacy study referenced here explored concepts of shared power involving clinicians and patients and results indicated there was an appetite for this type of arrangement from both Australians and Canadians surveyed. There is clearly a need for the development of an appropriate patient privacy/clinician engagement model.

Biometrics from the NICU

Biometric data is considered personal information when derived from an individual to determine or verify one’s identity [35]. The term “biometrics” may refer to quantifiable characteristics or the automated methods that utilize the aforementioned characteristics to identify or confirm one’s identity [36]. Any human behavioural and/or physiological characteristic has the potential to be utilized as a biometric identifier provided it satisfies the criteria of universality, distinctiveness, acceptability, collectability, performance, permanence and circumvention [37]. This may have implications for the secondary use of physiological streaming data – even when the data has been anonymized.

It is unclear how biometrics captured while an individual is a patient in a NICU environment could be exploited later in that individual’s life. However it is noted here that the issues surrounding biometrics will influence the future directions of secondary use of streaming physiological data.

Conclusion

This paper highlights the important contributions that physiological data, as captured by Big Data platforms, brings to health research. To date there has been little research relating to patient engagement in matters related to secondary use of such data. Contemporary privacy theories may aid navigating the emerging privacy and ethical issues, including biometrics, regarding streamlining physiological data. The survey results presented here formed part of a broader study into Australian and Canadian citizens opinions regarding application of contemporary privacy theory in medical domains. The focus here has been on the NICU context and potential for collaboration with parents of neonates on matters pertaining to consent, privacy and streamlining physiological data. The Artemis platform has been considered as one Big Data platform providing technological support. It is important to understand the perceptions of secondary use of data in this area as early as possible and build an appropriate use model. The initial patient perceptions presented here can inform the challenging privacy aspects of a future physiological data use model. Physiological data analysis could potentially be the path to the next major advances in healthcare thus serving as a motivation to our research on a parent engaged privacy model using Big Data.

Acknowledgments

This research has been funded by the Canada Research Chairs program and received support from the Centre for Canadian-Australian Studies, University of Wollongong.

References


[5] Tuzcu V, Nas S, Ulusar U. Altered heart rhythm dynamics in very low birth weight infants with impending...


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