Designing a Solution to Manage Electronic Consent for Children

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Abstract. Electronic systems for managing consent do exist but are generally only able to record consent from the research subject directly. Consent for research is also challenging to integrate into many electronic patient record systems. The Born In Bradford study is a large, from birth cohort study in the North of England which requires consent to be recorded by the pregnant mother of a child who will be included in the study from birth. This creates a complex challenge for consent management that has previously been achieved through paper-based processes. As the study begins a new phase with the objective of inviting all new parents within the Bradford region to participate in the study the solution also needs to work with existing maternity systems. This paper considers the specific challenges of converting the often grey rules around consent of children into an electronic system that is transparent and supports the trust of both the family and the clinical and care teams recruiting research subjects into a large cohort study, and describes the user centred design and technical approach taken to resolve it.

Keywords. Digital consent, User centred design, UCD, Electronic Patient Records

1. Introduction

The first Born In Bradford study began in 2010[1]. Following its success, a second birth cohort study, Born In Bradford 2019[2] (BiB) began recruitment. BiB will give every mother in Bradford the opportunity to participate in a second cohort which will collect and link patient records from across NHS organisations for both mother and child, and also link to education and other data sources. The BiB team identified that continuing to use paper-based processes for collection and management of maternal consent would be impractical, but had not found a digital solution able to meet their requirements, such as easy integration with their electronic medical record (EMR) system and their existing research dataset. Most systems record consent either directly within the EMR (usually only for medical treatment) or within the study dataset, making it inflexible, hard to maintain and potentially lacking transparency. Consent by mothers for children, especially when planned over the lifetime of the child, is a relationship that must adapt to changes in the child's life. Connected Health Cities[3] (CHC) was established to test learning health systems at scale across the North of England, and has worked with BIB 19 to develop a solution to address the complex consent management requirements of a birth cohort study.

2. Methodology

We adopted a user-centred approach to the design and development of the consent system. User centred design (UCD) is a collection of methods emphasising end users of a system and their goals, over the technology, and provide mechanisms for the users to be deeply involved in the design, development and testing of a system. A number of key principles inform this approach[4]:

Early focus on users and tasks: it was important for us to work with users to understand their existing and to-be working practices, environment, tasks and goals.

Empirical measurement: the testing and measurement of current performance, and throughput, e.g. numbers of births, recruitment rates, as well as testing of prototypes.

Iterative design - following cycles of investigation - design - build - measure. This approach fits well with Agile software development practices.

Our starting point was a project charter jointly developed by the teams from BIB and CHC, which set out key functional and nonfunctional requirements, including legislative and regulatory constraints. The project charter was used to derive a programme of UCD work: interviews and workshops with users to explore and document existing working practices, and develop a shared understanding of the requirements implied by the project's Standard Operating Procedures (SOPs.) We co-developed a series of artefacts:

- user stories to understand stakeholders' motivations, goals and context
- process maps to document current and future workflows
- system architecture diagrams, showing where different types of data would be stored
- low fidelity prototypes of user interfaces

These artefacts were used to support discussions with users, and iteratively updated to reflect our emerging joint understanding.

3. Consent Requirements and Implementation

Consent is a key component for people to be able to participate in research, as defined in the Declaration of Helsinki.[5] BiB is a birth cohort study that does not involve a direct clinical intervention in the consented subject but consent for data access is still required. The guidance for consent of children from the MRC is that a legal guardian can provide consent for themselves and their children.[6]

The process for recruiting subjects into the BIB 2019 study has been to train midwives to discuss the project with all women during pregnancy and, if they consent, to record this within the maternity EMR. Only the mother or a guardian is required to provide this initial consent, which allows for both the mother and child's current and future medical records to be collected, de-identified and used in future research.

Understanding how to codify and implement complex consent requirements is challenging: developers do not have the detailed domain knowledge necessary, whilst the study team are used to working with paper or simple spreadsheets. An iterative UCD approach allowed us to jointly explore and resolve these challenges. Through the design process with stakeholders different requirements were mapped, including:

The data must be kept up to date and accurate. As far as possible the identity details, for example a person's address, are checked against hospital systems connected to the

NHS spine at regular intervals and also when the consent for a specific individual is requested.

The key for identity within the NHS is the NHS number. However, children are not given an NHS Number until they are born and so their consent and identity record needs to be directly linked to their mother and updated in the EMR, and then our consent store at the time of birth, once an NHS number is allocated. This is also linked to a birth order in the case of multiple births.

Children could be born out of area. This means updating of the child's identity record will not possible through the local hospital IT systems and must be manually investigated if the maternity record shows a pregnancy longer than 10 months (implying birth may have taken place out of area.)

Consent is given by mother for both herself and the child. Alternatively, a young or vulnerable mother may have a guardian who can give consent for the mother and her child. This means that both consents need to be managed, and the relationship between the consent owner and the child recorded. When withdrawing consent a later requirement was added to ensure that the person requesting the change and their relationship to the data subject is also recorded.

Mechanisms to request and integrate data from external agencies (e.g. education) must minimise the information shared externally.

Two types of withdrawal of consent that are defined. Firstly, a subject can ask to stop future data collection, but agree that existing data will remain within the cohort dataset. Secondly consent can be completely withdrawn meaning the collection of data is halted and the records associated with that consent are deleted.

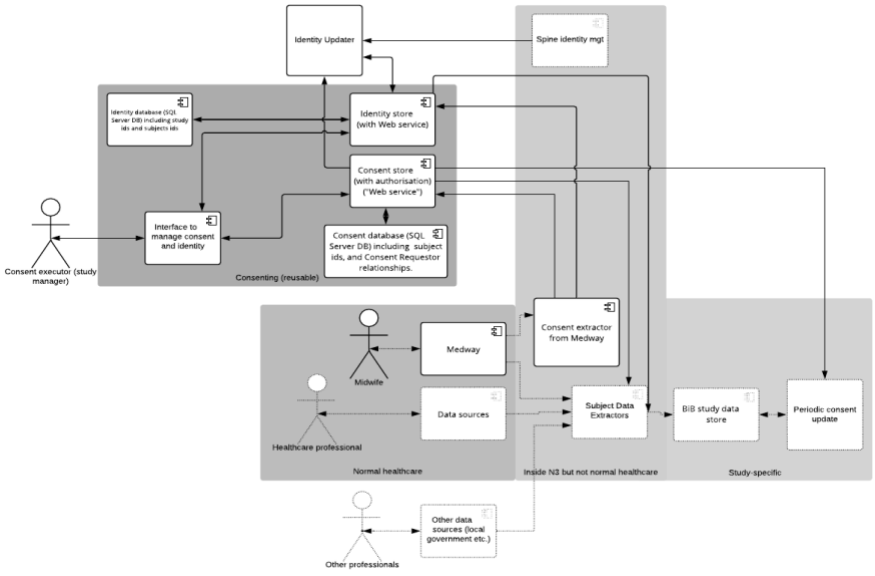

Figure 1. Consent Process Technical Scope including existing NHS systems, BIB 19 consent management and pseudonymised research datastores.

Other considerations include the death of a participating mother or child, and monitoring other changes in the child subject's status, such as being taken into care. In this latter case the parents of the child may no longer have the right to give or withdraw consent. This responsibility is now that of the new guardian of the child. There is a

further question as to when the child becomes responsible for consent and can be considered competent to manage consent for themselves. The age at which the child becomes solely responsible for their consent is defined as 16 although they do not need to be re-consented, in-line with other approaches and the Gillick test in the UK.[7,8] Where a guardian previously gave consent for the mother and her unborn child, when the mother reaches the age of 16 she must be re-consented.

The technical implementation of the consent model was based on two main data stores: Identity and consent in order to reflect the need to manage the relationships and consent through distinct mechanisms, as well as make it easier to logically separate identifiable data from the consent. Figure 1 describes how these data stores are managed and updated through a local administration web application, by the study team, and how it interfaces with numerous NHS systems to manage identity and provide core services for the pseudonymised research data set.

Once consent has been collected this gives permission for data to be collected about both the mother and the child. The processes for this data collection are currently in place within Bradford Teaching Hospitals NHS Foundation Trust and cover a variety of sources, including hospital and primary care medical records. This data is stored separately, in a de-identified format using a key linking to the original consent. The record of consent is regularly checked via an API that was developed to match a subjects' study id, and check any date constraints for consent. Standard Operating Procedures (SOPs) for managing consent have been developed and technical changes to the forms within the maternity EMR were agreed. The key requirement for the consent store is to enable the data management team to regularly check for changes in consent amongst the study cohort data in order to be able to update the research dataset.

Finally, there is a web-based administration application which enables the study administrators to manage subjects' details and consent preferences directly.

4. Conclusions and Challenges

The basic principles of consent are clear, but the numerous edge cases and changes to consent that can occur through a child's life present challenges in the design of a computerised consent solution for birth cohort studies. Furthermore, the translation of soft, paper-based processes to computer-based algorithms requires upfront discussion. Interpretation of rules and regulations that are not well codified is challenging, especially for consent for children, which can also vary between different jurisdictions.[9] There are related challenges to guardianship, divorce, and changes in legal status. Using a UCD approach allowed the project teams to negotiate a joint understanding of these complex requirements, and provided users and developers with a clearer understanding of the implications of the legal requirements and study procedures on the architecture and software implementation.

Benefits include the ability to audit a complex area of consent more closely and simplified management of a large cohort. The solution integrates with the midwives' existing workflow and EMR systems, simplifying subject recruitment. The solution has been designed to be flexible and meet a wide range of edge cases, including integration with different EPRs and research data systems using APIs, making it flexible for the

future. The code is made available under open source licence[10] and continues to be improved based on users' feedback.

Working closely with the software team using UCD ensured that the platform met the requirements of the study team while also consulting other stakeholders, such as information governance, to provide a new type of consent management tool necessary for the scale, self-management and linkage of family and consent given for multiple individuals. In order for this, or similar consent stores, to be able to deliver even greater value for research there is a need to define consent processes more precisely, especially consent for children, within ethical guidelines and law in order to be able to better codify and audit consent against best practice. This will be increasingly important with regards to international co-operation and standards for use of EHR data in research.

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