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Electronic Patient Reported Outcomes for Miscarriage Research in Tommy's Net

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Abstract. The Tommy's National Centre for Miscarriage Research aims to support the diagnosis and treatment for couples suffering from recurrent miscarriage. Tommy's Net is an electronic data gathering tool, collecting miscarriage data and links with hospital Clinical Information System databases. The gathering of patient reported data is an important aspect, especially as data relating to pregnancy and miscarriage events are often left unreported. **Methods:** Both traditional paper-based and electronic patient reported outcome (ePRO) solutions have been explored to improve response rates, minimize data redundancy and reduce burden on staff. Popular ePRO survey solutions have been compared, including REDCap, SurveyMonkey, Qualtrics and LimeSurvey. **Results:** LimeSurvey was selected as the most appropriate solution as it provided self-hosting capability, SMS integration and ease of use. **Conclusion:** We have implemented a LimeSurvey based ePRO system for collection of baseline and follow-up data for participants on the Tommy's study.

Keywords. Recurrent Miscarriage, ePRO, e-Consent

1. Introduction

Miscarriage is the most common complication of pregnancy, occurring in 15-25% of pregnancies[1]. The Tommy's National Centre for Miscarriage Research aims to collate information from multiple observational and interventional studies, miscarriage clinics, and maternity databases, across the UK (at 4 sites across the cities of Coventry, Birmingham and London), into one system called Tommy's Net[2], to improve on the limited data collected so far. Tommy's Net uses this data to enable actual miscarriage rates to be known, enable women to be stratified according to pregnancy outcome and

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risk of miscarriage, and help deliver appropriate treatment. Pregnancy and miscarriage outcomes reported by patients are key to ensuring correct classification, but the main difficulty stems from these events often occurring outside of visits to the miscarriage clinics, resulting in the information not being recorded or not being available from primary care or other care domains.

Figure 1 shows the Tommy's Net architecture. The system is hosted at the University Hospitals Coventry and Warwickshire (UHCW) NHS Trust. It is intended to connect to the sites' clinical Patient Information Systems and consolidate information, map data elements between sources, resolve differences in procedures and capture study-specific information for analysis at a national level. Tommy's Net is based on the CURE framework[3], a modular system for collecting research data in secondary care settings. The framework includes methods for the standardized, flexible capture and storage of data.

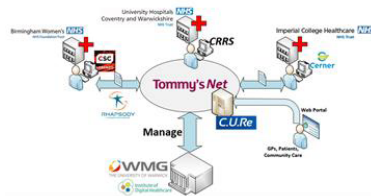


Figure 1. Tommy's Net architecture.

Within the miscarriage clinics, women are followed-up every 6 months for information about any unreported pregnancies or miscarriages. A system for collecting follow-up data was required due to the following challenges faced by the research team. Firstly, the lead time for outcome information collection is long. As the study is a national one, patients are based all across the UK and cannot regularly travel to the miscarriage clinics. This results in sporadic visits to the miscarriage clinic. Additionally, outcomes, such as a successful birth, can also only be collected after nine months of pregnancy plus the time taken to get pregnant. Secondly, the current state of data collection remains fragmented as the events (pregnancy/miscarriage) occur outside of the miscarriage clinics and the information related to those events are often not be collected, or correctly recorded in primacy care or other health services that the patients may have visited. Thirdly, the difficulty in contacting patients and obtaining information is a known challenge in research, where participant engagement, and communication approaches are active research topics. In the recurrent miscarriage study, phone calls were often left unanswered and follow-up forms sent in the post were not responded to. Hence, follow-up by the research team is time-consuming. Postal follow-ups were, additionally, quite costly. As such, an electronic system for collection of follow-up data was proposed, to reduce burden on research staff and increase data collected from participants who would have otherwise been lost to follow-up.

2. Methods

Due to the short timescales for follow-up needed to keep participants actively engaged, electronic patient reported outcome (ePRO) solutions were investigated. ePRO solutions are increasingly being used to collect information from patients as part of clinical studies. In Tommy's Net, these solutions were considered within the context of the information

governance and security policies, in place at the hospital where Tommy's Net is hosted. Due to restrictions in hosting public-facing systems at the hospital, the solution of a link-anonymised survey data collection tool with SMS invitations was explored.

A few survey system options were compared, assessing their feature set against cost and data management considerations. These systems included REDCap, SurveyMonkey, Qualtrics and LimeSurvey. Table 1 summarises the comparison between survey system options considered. REDCap[4] is a web application for building and managing online surveys, built for data capture in research. For the Tommy's Net project, although REDCap has a full set of features, the steps for joining the consortium and complexity of the tool were the downsides to this solution. SurveyMonkey[5] is a popular survey software, which can be used with free basic account available for surveys with few questions. However, for the project, the fact that the data collected is currently hosted in the USA and is not compatible with the EU GDPR requirements, prevented the system from being selected. Qualtrics[6] is an online survey and data collection tool, normally used for market research. Although it had all the required features, the high SMS integration cost made it unsuitable for the project. LimeSurvey[7] is an open-source survey software solution that had all the features required by the project, including mobile-friendliness, a web-based form and SMS integration. Additionally, a self-hosted option, which allowed the research team to remain in control of the data, was viewed as an advantage for information governance purposes.

Table 1. Comparison of survey system options.

Survey system	Usage context	Feature set	Cost	Data management
REDCap	Health research, clinical trials management	Mobile-friendly, web-based, can send SMS through separate service	Free to use (need to join Consortium),	Local installation possible
SurveyMonkey	Market research	Mobile-friendly, web-based	Free option and paid plans available	Data held in USA
Qualtrics	Approved for clinical trials	Mobile-friendly, web-based, SMS integration	High SMS integration cost	University license
LimeSurvey	Universities, for clinical research	Mobile-friendly, web-based, SMS plug-in	Free, open source	Self-hosted option

3. Results and Future Work

The mobile-friendly, LimeSurvey solution was selected as it could be hosted locally with the appropriate storage requirements and could be integrated with external SMS solutions. Within the project, patients are sent a link to the survey in an SMS (Figure 2a) or email with a unique one-time use token. The survey can be easily completed on a mobile device (Figure 2b). Once completed, the study staff receive a notification that new information is available on the survey system. The data collection is managed by the University of Warwick, and the survey data is uploaded into Tommy's Net after verification by authorized study staff.

The system is now in use at all 4 miscarriage centers for collection of follow up data monthly. Further work will focus on exporting data from the LimeSurvey system to the Tommy's Net system, at all 3 sites, for both consent and baseline data collection, which

aims to reduce the manual entry of patient data within Tommy's Net. As part of this work, we have started implementing an e-consent survey, where participants are consented electronically before recruitment, filling out a baseline registration form for historical data, which is then reviewed at their first clinic appointment.

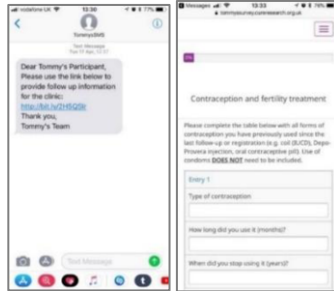


Figure 2. (a) Unique token sent in SMS invitations; (b) Screenshot of the survey on a mobile device

4. Conclusions

In conclusion, in this paper, we present an e-PRO solution that is expected to improve the response rates of patients and minimize effort by the study staff, eliminating redundant data entry. This considers the security, data protection and privacy needs related to health data, as well as current IT capabilities for the deployment of the solution. We have discussed the considerations made for Tommy's Net, where patients from across the UK are seen by the four miscarriage centers across Coventry, Birmingham and London. Further work in this area will focus on automated extraction and import or the responses to the consent and baseline surveys from the LimeSurvey system to Tommy's Net system, allowing seamless integration between the patient and clinician facing portals.

Ethics approval: The study associated to the work described in the paper was approved by West Midlands-South Birmingham Regional Ethics Committee IRAS No: 213740, 2225751 REC Ref: 17/WM/0050: 17/WM/208.

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