Managing quality, safety and promoting visibility in research using electronic health records

Lisa Hyatt, Karen Ward, Sophie Johnson, Anna Thornhill, Meg McConnell - Solent NHS Trust
Correspondence to: lisa.hyatt@solent.nhs.uk Team Twitter: @ClinResSolent

Introduction

Solent NHS Trust is a community and mental health trust with services across Portsmouth, Southampton and parts of Hampshire. Qualitative responses in a trust wide staff survey carried out in 2015 identified that we needed to improve awareness of clinical research activity. The trust hosts research across all service lines, so this highlighted that there was a potential risk to the quality and safety of research conducted across geographically distinct clinical services. The **primary aim** of this project was to work collaboratively with clinicians to ensure that individual patients and service users who are participating in research were easily identified when attending their usual appointments with clinicians across the trust. We worked collaboratively with our Older Persons' Mental Health (OPMH) Inpatient Unit and Musculoskeletal Physiotherapy staff (clinical areas that currently undertake interventional research), information governance and patient systems teams and a patient and public representative to identify how best to achieve the aim.

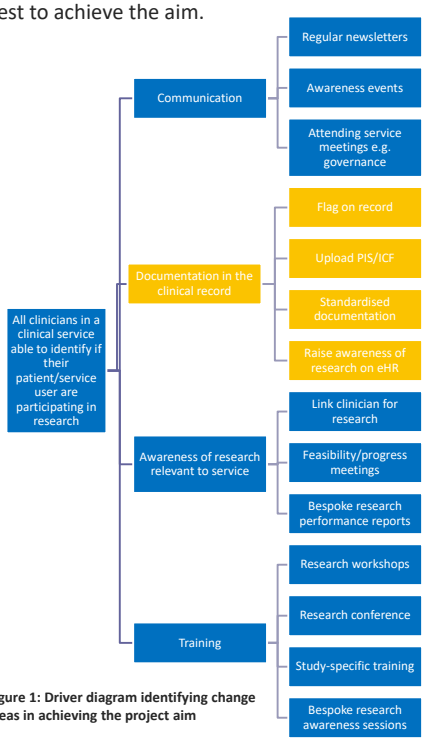


Figure 1: Driver diagram identifying change ideas in achieving the project aim

Key benefits of the eHR for research teams:

Our experience is that the eHR provides many opportunities to improve the quality and safety of research, particularly in the community setting:

- **Improved lone working practices**, where home visits for research are the norm – clinicians have a visit diary with a link to the patient record
- **Improved feasibility** through anonymised reports of patient cohorts – particularly in primary care sites
- Facilitates **remote monitoring, audit and peer review** of quality – clinical notes/source data are accessible regardless of location
- Record sharing between clinical services to allow thorough **screening for eligibility**

1. Factors involved in identifying patients participating in research

Discussion with clinicians revealed several drivers in knowing that their patient/service user is participating in research (Figure 1). However, it was identified that the focus of change for this project should be on the **electronic health record** (eHR).

A single eHR (SystmOne™) has been adopted across the majority of clinical services in the trust. The research team developed and adopted a SystmOne™ unit in April 2016 in order to document research activity. This unit is used by both the core CRN-funded research team and clinicians undertaking research in their clinical areas. Discussion with clinicians identified that the consistency of documentation is key to communicating with clinicians in disparate services.

2. Using eHR to communicate with clinical teams

Three auditable standards of documentation were agreed :

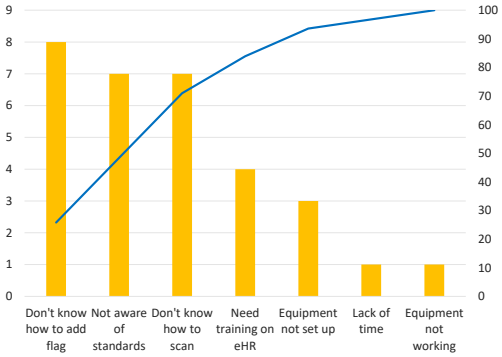
- **Flag on the patient record for interventional studies** – free text high priority reminder (HPR) function which flashes red when activated. The reminder text is visible on the 'front page' of the record. Key information about the study is placed here and alerts clinicians about the need to report adverse events to the research team
- The **participant information sheet and consent form** should be scanned into the record – compliance with GCP and to provide clinicians with information on the study.
- Documentation should be clear and standardised using the **research template** – allows clinicians to search/filter for research entries in the eHR.

In addition to standardising documentation, members of the core research team attended existing eHR user groups to raise awareness of research activity and demonstrate identifying whether patients attending their service are taking part in research.

Figure 2: Audit of the quality of documentation by research team

Standard	Expected	Actual (%)	Expected	Actual (%)
	Pre-training		Post-training	
All patients referred into S1 unit have documentation in the research template	472	286 (60.6)	545	339 (62.2)
All patients recruited into an interventional study have a HPR on their S1 record	131	18 (13.7)	131	18 (13.7)
All patients recruited into all types of study have a PIS and ICF scanned into their S1 record	282	27 (9.5)	314	282 (89.8)

Figure 3: Priorities for improving compliance with documentation standards



3. Quality of documentation in research

Given the importance placed on the documentation of patient participation in research by the clinicians, an audit of the quality of documentation in the eHR by the research team was undertaken to identify current performance against the standards (figure 2). It was identified that the team were not consistently working to these standards. Figure 3 shows the key reasons expressed by the research team for this. To address these concerns, a bespoke refresher training session incorporating the key standards for documentation was provided and all equipment issues discussed were resolved. A second audit 6 weeks after the training session showed that quality of documentation improved, but that ongoing support is likely to be needed.

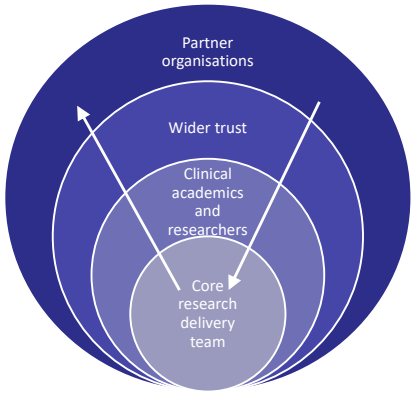


Figure 4: eHR research unit in Solent NHS Trust

4. Next steps

In order to examine whether the improved documentation practice of the research team enables clinicians to more readily identify patients taking in part in research, a second trust wide staff survey will be undertaken. In addition, we would like to identify the effect this has in the reporting of adverse events. We will also review our practices regularly to ensure that the information shared about research participation across the trust is appropriate and meaningful to clinicians outside of the core delivery team. In time, we hope to continue to develop the research SystmOne™ unit to allow more integration with other local services and allow better communication between trusts and social care, and, most importantly, patients.

The collaborative approach adopted in this project has enabled us to create an eHR instance and **standardised documentation practices** to proactively communicate with clinicians about research participation across a disparate community trust.

Solent NHS Trust:
Great care at the heart of our community