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RESEARCH NOTE

Data protection, information governance and the potential erosion of ethnographic methods in health care?

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Abstract

With the most recent developments to the European General Data Protection Regulations (GDPR) introduced in May 2018, the resulting legislation meant a new set of considerations for study approvers and health-care researchers. Compared with previous legislation in the UK (The Data Protection Act, 1998), it introduced more extensive and directive principles, requiring anybody 'processing' personal data to specifically define how this data will be obtained, stored, used and destroyed. Importantly, it also emphasised the principle of accountability, which meant that data controllers and processors could no longer just state that they planned to adhere to lawful data protection principles, they also had to demonstrate compliance. New questions and concerns around accountability now appear to have increased levels of scrutiny in all areas of information governance (IG), especially with regards to processing confidential patient information. This article explores our experiences of gaining required ethical and regulatory approvals for an ethnographic study in a UK health-care setting, the implications that the common law duty of confidentiality had for this research, and the ways in which IG challenges were overcome. The

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purpose of this article was to equip researchers embarking on similar projects to be able to navigate the potentially problematic and complex journey to approval.

KEYWORDS

data protection, ethnography, health services research, research governance

RESEARCH (GOVERNANCE) QUESTIONS

We know from our prior work that children and young people living with long-term inflammatory arthritis and their parents/guardians do not always get the opportunities to discuss the pain that they are experiencing in rheumatology clinics (Lee et al., 2020). Hence, we developed a study to support the creation of an intervention to help improve Communication by Healthcare Professionals Assessing and Managing paediatric musculoskeletal Pain; The CHAMP study (www.champ-study.co.uk). The work proposed was a multi-phase, mixed-methods programme across three tertiary paediatric rheumatology departments in the UK. We were interested in the language that professionals used to describe and discuss chronic pain, the ways in which professionals interacted and responded to one another about reports of pain and the assumptions that professionals had about pain in patients. In order to focus on pain conversations between professionals outside of consultations directly with children/young people and their parents, we planned to observe multi-disciplinary team meetings as part of an ethnography within the study.

In the UK, approval needs to be sought from the Health Research Authority (HRA) for health and social care research involving specific groups such as patients and service users of the NHS or adult social care, as well as relatives, carers and professional staff who work with these groups (Health Research Authority, 2020). The HRA is the main organisation that oversees that GDPR and information governance (IG) practices are appropriately implemented throughout research. IG practices even prior to the new version of GDPR could at times act as an obstacle to health-care research, particularly where methods included some form of observation, recording or intervention in naturally occurring settings in the UK (Goodyear-Smith et al., 2015; Parry et al., 2016). Research ethics committees (REC) and the Confidentiality Advisory Group (CAG) who the HRA seeks advice from also have an interest in ensuring these key principles are upheld. RECs provide an independent ethical opinion on the studies and methods proposed and the CAG advise the HRA (upon request) about the acceptability of processing patient-identifiable information without consent. GDPR and IG issues are not only UK specific, and so challenges with the interpretation of the same legislation may be experienced in similar or different ways in equivalent European research approval processes.

We have had extensive experience of research within NHS contexts, including the use of ethnographic methods (Farre et al., 2016; Rapley et al., 2019). We built upon this expertise to develop our application for HRA approval. Utilising ethnographic methods was central to answering our research questions. The very nature of these meetings means that sharing information about patients was intrinsically part of the discussion. However, in our application, we stressed that we were interested in observing how health-care professionals talked

about pain, and we would not record any personal identifiable information about the patients that professionals were discussing. We applied for HRA approval for our study in July 2020 and received full ethics approval five months later in November 2020. Even though this process took place during the COVID-19 pandemic, the period between submission and review was consistent with our experiences of such ethics approval processes prior to the pandemic. However, the final approval of the study was significantly delayed due to diverse ways of interpreting legislation around the common law duty of confidentiality, GDPR and IG practices in ethnographic research (Figure 1).

INTERPRETING LEGISLATION

A key issue which acted as a barrier to approval for our study was the HRA's implementation of the common law duty of confidentiality, specifically their assertion that our research would result in the disclosure of confidential personal information (CPI) without consent. Centrally, the ambiguity around the meaning and the degree to which CPI is 'disclosed' is challenging, as a project may not involve any active or direct disclosure, but may still include some level of indirect or incidental disclosure (e.g., a patient's name). Overhearing information but never recording, analysing or 'doing' anything with information which is outside the focus of the research is a common feature of much ethnographic research.

In most ethnographic contexts, prospective informed consent from a patient is not possible, particularly in study designs that involve fast-moving hospital settings where it may be logistically challenging to identify patients who are going to be in attendance or discussed (Mapedzahama & Dune, 2017; Savage, 2000). For example in our study, the patient cases to be reviewed at the multi-disciplinary team meetings would be decided upon the same morning, hence prior identification and recruitment of patients/guardians were not feasible. There are several scenarios in which the disclosure of CPI without consent can be justified, one of which is if the activity will be in the public interest or in the interests of improving patient care (Everri et al., 2020; General Medical Council, 2019; The National Health Service, 2006). Clearly, much health and social care research has the potential to lead to such changes, although the acceptability and justifications of these scenarios are widely open to interpretation (Parry et al., 2016).

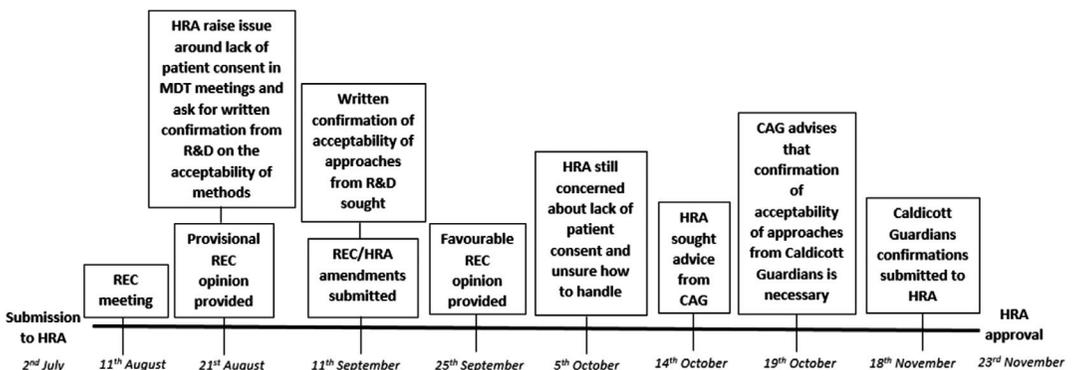


FIGURE 1 Timeline for CHAMP HRA study approval from July to November 2020

Questions of consent have routinely centred around how patient or service user information must not normally be disclosed to anyone outside of the direct care team without prior consent of the patient/service user. There have been several accepted methods for satisfying this duty of patient confidentiality in multi-disciplinary team meetings, without having their consent in place prior. Anonymised field notes have been an accepted data collection approach rather than audio or video recording any conversations that may capture patient-identifiable data as an element of larger discussions (Librett & Perrone, 2010; Parry et al., 2016). Further assurances include institutional access approvals such as honorary research contracts, letters of access and confidentiality agreements which vouch for trust in the researcher's credibility to conduct research safely and with integrity. As academics and practitioners, the research team was also bound by the standards and codes of conduct and ethics by their different professional organisations (such as the British Psychological Society and the Health and Care Professions Council). However, despite all these assurances being in place and the fact that methods such as anonymised field notes do not involve the collection of any identifiable data, these traditional methods are potentially considered no longer acceptable.

SUGGESTING ALTERNATIVES

In our study approval process, the HRA suggested several alternative study design options to bypass the need for patient consent. However, all of these options would have disrupted the everyday work of the rheumatology team and meant that legislation rather than the scholarship drove research design.

One proposal was that health-care professionals chose codes to reflect specific patient's names prior to their meetings so that the researcher only heard pseudo-anonymised patient data. This was reasoned to be too burdensome for professionals and was also likely to change the way professionals communicated about pain which was our central focus. This would have changed the data in fundamental ways. Most importantly, it could prove to be hazardous if the coding system confused professionals, impacting upon the management of patients whose codes became muddled. This was not a practical, safe nor ethically sound alternative.

The second recommendation was that the health-care professionals who would attend the multi-disciplinary team meeting could make field notes on behalf of the researcher, rather than the researcher attending the meeting. This creates a set of methodological challenges around adequate training and experience in analytical focus and reflexivity for the professional making field notes. There would also be pragmatic issues around the capacity to take on this role within busy organisational schedules. Having a health-care professional act as a researcher would change their routines, which would in turn alter the social dynamics of the whole team.

The last alternative option provided was to abandon this part of the planned study. However, this meant that important understandings would not have been gained, and alternatives like interviewing practitioners about discussions of pain in multi-disciplinary team meetings or between professionals would probably lose much of the (seen-but-unnoticed) detail of the phenomena. Hence, this was also not a methodologically efficient approach. Our study aims and methods were heavily influenced by and co-designed alongside health-care professionals, children/young people and families, and these alternative study design suggestions were unacceptable.

NEGOTIATING ALTERNATIVES

We liaised with the HRA and were provided with two alternative scenarios which could potentially satisfy the common law duty of confidentiality in the absence of patient informed consent. It was suggested that we could either submit written confirmation of the acceptability of our data collection methods and the ‘incidental’ processing of patient-identifiable information from the Caldicott Guardians at each of the hospital trusts we were working with or we could seek CAG approval.

Caldicott Guardians are a network of organisational guardians at NHS trusts who are responsible for developing data security and confidentiality policies and for reviewing protocols on the acceptability of the use of patient-identifiable information across NHS organisations (The Caldicott Committee, 1997). The alternative to written confirmation from Caldicott Guardians was to seek CAG approval. This was suggested towards the end of the HRA approval process. At this point, a separate CAG application was unfeasible within the timelines and budget of the study. There are eleven CAG precedent set categories that can lead to a more timely review process for applications that share similar issues with previous applications, and if pursued, this may have helped to streamline the process (Ranieri et al., 2020). We discovered only later on that one particular precedent set category was applicable to our project: ‘Incidental disclosures of identifiable information made to an applicant who is observing practices and procedures within a health setting’.

GOING FORWARD

These experiences and reflections will be valuable for researchers beginning similar research studies in the future and our recommendations for preparing for potential IG challenges will ensure that researchers using ethnographic methods are not discouraged. We faced a range of bureaucratic, organisational, methodological and practical difficulties in this particular HRA review process. These difficulties could potentially limit the ability to undertake independent research examining important contextual factors affecting complex health-care delivery issues in naturally occurring settings. Researchers should be mindful that overcautious approaches to and misunderstandings around the nature of ethnographic research and the implications of legislation may hinder research. Having a (more) detailed understanding of the common law, GDPR and IG legislation will allow researchers to strategically navigate these challenges. For future work, in the UK context at least, it would also be valuable to be aware of the HRA, REC and CAG approval processes in this context and develop an understanding about which organisation is responsible for ensuring which legislation are acted upon. For example, discussions about CPI with the absence of patient informed consent may sit with CAG or HRA, so researchers should be equipped for working with a single organisation or several to resolve these issues. In addition to this, researchers need to liaise between the local Research and Development departments within hospitals (Bosk & De Vries, 2004; Murphy & Dingwall, 2007) and work with gatekeepers to navigate internal assurances. These contacts may be able to liaise with Caldicott Guardians on behalf of the research team.

In the UK context, HRA approaches are not aligned to ethnographic practices and it is valuable for researchers to be able to explain key elements and rationales of ethnographic working to all organisations involved in the approval process, if concerns are raised. In our experience, the HRA tried their utmost to help us gain full regulatory approval as efficiently as possible and

they were considerate about their suggestions for alternatives. However, they are less aware of the nuances of this type of research compared with other types of study designs and this is where we have a duty to help facilitate understanding.

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AUTHOR CONTRIBUTIONS

Rebecca Rachael Lee: Conceptualization (lead); Funding acquisition (lead); Methodology (lead); Project administration (lead); Resources (lead); Writing-original draft (lead); Writing-review & editing (lead). **Lis Cordingley:** Conceptualization (equal); Funding acquisition (equal); Methodology (equal); Project administration (equal); Supervision (equal); Writing-original draft (equal); Writing-review & editing (equal). **Janet McDonagh:** Conceptualization (equal); Funding acquisition (equal); Methodology (equal); Project administration (equal); Supervision (equal); Writing-original draft (equal); Writing-review & editing (equal). **Sarah Peters:** Conceptualization (equal); Funding acquisition (equal); Methodology (equal); Project administration (equal); Supervision (equal); Writing-original draft (equal); Writing-review & editing (equal). **Albert Farre:** Methodology (equal); Supervision (equal); Writing-original draft (equal); Writing-review & editing (equal). **Tim Rapley:** Conceptualization (equal); Methodology (equal); Project administration (equal); Resources (equal); Supervision (equal); Writing-original draft (equal); Writing-review & editing (equal).

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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