Research note title: Data protection, information governance and the potential erosion of ethnographic methods in healthcare?

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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 healthcare researchers. Compared to 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 healthcare setting, the implications that the common law duty of confidentiality had for this research, and the ways in which IG challenges were overcome. The purpose of this article is to equip researchers embarking on similar projects to be able to navigate the potentially problematic and complex journey to approval.

Main text

Research (Governance) Questions

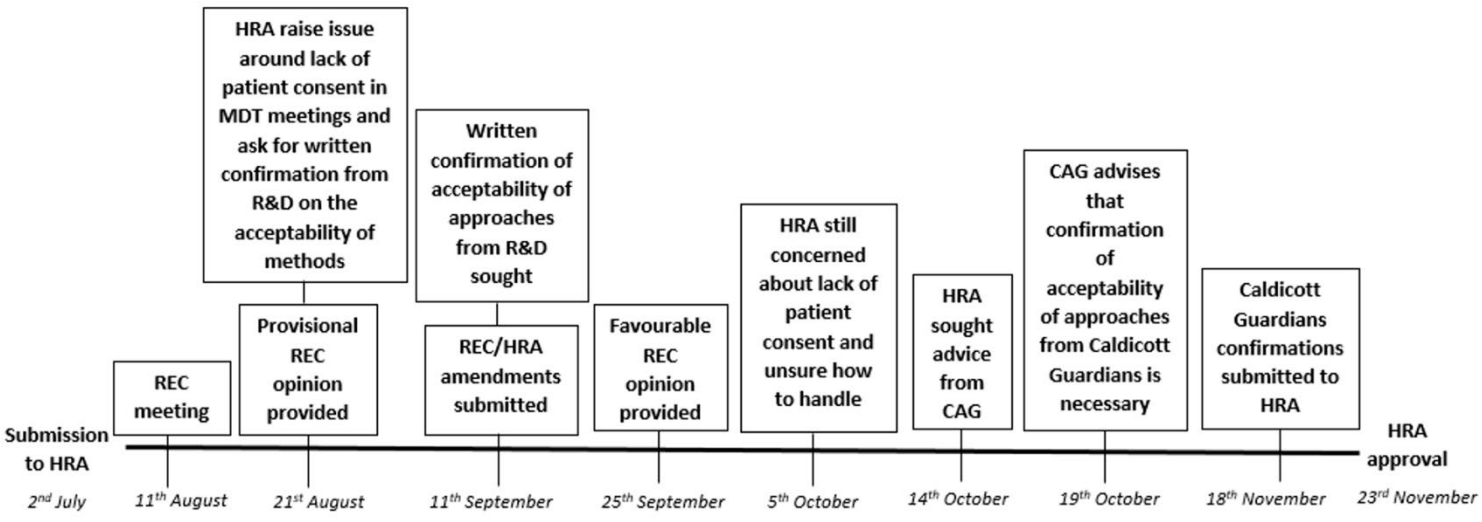
We know from our prior work that children and young people living with long-term inflammatory arthritis and their parents/guardians do not always get the opportunities to discuss the pain that they are experiencing in rheumatology clinics (Lee et al. 2020). Hence, we developed a study to support the 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 are the main organisation who oversee 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 healthcare 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 seek advice from also have an interest in ensuring these key principles are upheld. REC's 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 healthcare 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 ethical 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 ethical 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: The timeline for CHAMP HRA study approval from July to November 2020



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 are '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 (for example, 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 and 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 was 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 is widely open to interpretation (Parry, Pino, Faull, & Feathers 2016).

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 and Perrone 2010;Parry, Pino, Faull, & Feathers 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 are 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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 is central. 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 and De Vries 2004;Murphy and 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 upmost 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 to other types of study designs and this is where we have a duty to help facilitate understanding.

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References

Bosk, C.L. & De Vries, R.G. 2004. Bureaucracies of mass deception: Institutional review boards and the ethics of ethnographic research. *The Annals of the American Academy*, 595, 249-263

Everri, M., Heitmayer, M., Yamin-Slotkus, P., & Lahlou, S. 2020, "Ethical challenges of using video for qualitative research and ethnography," *In Challenges and solutions in ethnographic research: Ethnography with a twist*, 1 ed. T. Lähdesmäki et al., eds., London: Routledge, pp. 68-83.

Farre, A., Wood, V., McDonagh, J.E., Parr, J.R., Reape, D., Rapley, T., & on behalf of the Transition Collaborative Group 2016. Health professionals' and managers' definitions of developmentally appropriate healthcare for young people : Conceptual dimensions and embedded controversies. *Archives of Disease in Childhood*, 101, (7) 628-633

General Medical Council 2019, *Disclosing patients' personal information: A framework*.

Goodyear-Smith, F., Jackson, C., & Greenhalgh, T. 2015. Co-design and implementation research: Challenges and solutions for ethics committees. *BMC Medical Ethics*, 16, (78) 1-5

Health Research Authority. Do I need NHS REC review? 2020. 30-11-2020.
Ref Type: Online Source

Lee, R.R., Rashid, A., Thomson, W., & Cordingley, L. 2020. 'Reluctant to assess pain': A qualitative study of healthcare professionals' beliefs about the role of pain in Juvenile Idiopathic Arthritis. *Arthritis Care & Research*, 72, (1) 69-77

Librett, M. & Perrone, D. 2010. Apples and oranges: Ethnography and the IRB. *Qualitative Research*, 10, (6) 729-747

Mapedzahama, V. & Dune, T. 2017. A clash of paradigms? Ethnography and ethics approval. *SAGE Open* (1) 8

Murphy, E. & Dingwall, R. 2007. Informed consent, anticipatory regulation and ethnographic practice. *Social Science & Medicine*, 65, 2223-2234

Parry, R., Pino, M., Faull, C., & Feathers, L. 2016. Acceptability and design of video-based research on healthcare communication: Evidence and recommendations. *Patient Education and Counseling*, 99, 1271-1284

Ranieri, V., Stynes, H., & Kennedy, E. 2020. To CAG or not to CAG? Difficulties in determining submission to the Confidentiality Advisory Group: A commentary. *Research Ethics* 1-5

Rapley, T., Farre, A., Parr, J.R., Wood, V.J., Reape, D., Dovey-Pearce, G., & McDonagh, J. 2019. Can we normalise developmentally appropriate health care for young people in UK hospital settings? An ethnographic study. *BMJ Open*, 9, (9) e029107

Savage, J. 2000. Ethnography and health care. *BMJ*, 321, (7273) 1400-1402

The Caldicott Committee 1997, *Report on the review of patient identifiable information*.
The National Health Service. The National Health Service Act. 2006. 21-4-2021.
Ref Type: Online Source