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Victoria Foster and Alys Young

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**Victoria Foster and Alys Young on behalf of
the Medicines for Neonates Investigator Group**

University of Manchester, UK

Members of the Medicines for Neonates Investigator Group

Neena Modi, Professor of Neonatal Medicine, Imperial College London (Lead Investigator); Peter Brocklehurst, Professor of Perinatal Epidemiology, University of Oxford and Director, National Perinatal Epidemiology Unit; Jane Abbott, Head of Programmes, Bliss; Kate Costeloe, Professor of Paediatrics, Queen Mary University of London; David Field, Professor of Neonatal Medicine, University of Leicester; Azeem Majeed, Professor of Public Health, Imperial College London; Jackie Kemp, London Perinatal Director; Deborah Ashby, Professor of Medical Statistics and Clinical Trials, Imperial College London; Alys Young, Professor of Social Work, Education & Research, University of Manchester; Stavros Petrou, Professor of Health Economics, University of Warwick¹

Abstract

Over recent years in the UK there has been growing interest in the potential for routinely collected NHS (National Health Service) patient data to be used for secondary purposes, facilitated by the potential of increasingly sophisticated electronic databases. This article is based on a critically reflective literature review which analyses the key debates pertaining to this issue. The work arose in the context of a programme of research concerning routine patient data use in neonatal care. The article includes analysis of commentary (opinion and ethical inquiry) as well as empirically derived claims. It aims to deconstruct the knowledge assumptions on which relevant research studies have been based or are proposed and it also incorporates ontological position and moral argument. Results are presented according to three predominant debates:

Corresponding author:

Victoria Foster, School of Nursing, Midwifery and Social Work, University of Manchester, Manchester Academic Health Science Centre (MAHSC), Jean McFarlane Building, University Place, Oxford Road, Manchester, M13 9PL, UK.

Email: Victoria.Foster@manchester.ac.uk

the prevailing claim that all health research benefits civic society; the varieties of informed consent and choices open to patients regarding secondary uses of their data; and the 'rights and responsibilities' of patients when it comes to their data being used for research purposes. It examines the relevance of these themes specifically to the neonatal context and the implications for our own research, concluding that employing an alternative ethical model to the traditional professional one might be useful in order to provide a further perspective on the issue.

Keywords

data-sharing, electronic records, ethics of care, informed consent, patient attitudes

Introduction

This article concerns the use of routinely collected patient data for research purposes. It presents critical analysis of the key debates underpinning policy and knowledge assumptions driving research in this area of interest. The review grew out of a need to establish the parameters and central concerns of this topic in the preparatory phase of a research project regarding the acceptability to parents, who have babies in neonatal care, of their routinely collected clinical data being used for research purposes. Although there were no previous studies of this topic in the neonatal context, there was plenty of literature of different sorts available to consult. Patient data gathered for one purpose (clinical) being routinely used for another (research), whether to the benefit of the individual or unknown others, is a growing topic of interest in the UK. The existence of a National Health Service (NHS) providing care at the point of need, free of direct charge to the individual, ensures large population use of national medical services. The possibility of comprehensive data collection within diverse national populations with little additional effort, and data linkage and data sharing on a national basis are potential opportunities of these health delivery arrangements in a digital age.

Data, in this context, are defined as 'discrete pieces of information' (Lowrance, 2002: 3) such as birthweight, blood pressure, dates of hospital stays, results of tests that were carried out – which are usually original observations, measurements and analyses entered into a patient record or database. They are recorded primarily for purposes of responding to patient need in terms of diagnosis, assessment, treatment and monitoring. However, the increasing use of electronic patient records opens up new potential for secondary uses of the original data. Digital records by nature of their medium enable, for example, remote access, searchability and interrogation. Patient records can be: 'screened for quality, corrected, linked to other data, combined with other data, translated into other technical or natural languages, and otherwise moved around and manipulated in complex ways' (Lowrance, 2002: 3). Developing new ways of working with these data (rather than an increase in collecting data) can reduce some of the expenses and the obstacles involved in carrying out research. Black (2003: 37) identifies the following areas which could benefit:

- the natural history and development of diseases;
- the causes of diseases;
- the value of health care interventions;

- the equity of health care;
- trends in the use of health care.

Higgins (2003: 8) adds that secondary data can also be helpful in terms of service planning and in the operational management of the health service. However, complex issues of patient choice and various forms of consent need to be taken into account. These might include: the question of the extent to which informed patient consent is necessary; the potential use of patient-identifiable data; opting in or out of electronic systems and the ease of doing so; and the accuracy and security of electronic clinical records.

This potential for secondary use of routinely collected patient data for research purposes has prompted a series of high profile reports in the past five years (AMS, 2006, 2011; UKCRC, 2007). There is general agreement that the public needs to be involved in the debate on using clinical data for research purposes in order for it to progress and that without this, regulatory and advisory bodies will make assumptions about what the public might find acceptable.

Below we present an analysis of three themes identified from a critical review of the underpinning discourse and knowledge assumptions evidenced in policy documents and research studies that have addressed the use of routinely collected patient data for research purposes. These are: the virtually unanimous claim that all health research is to the benefit of civic society; choice and the extent to which this includes patient choice over data use; rights and responsibilities of patients with regard to data use. The article concludes by looking at the relevance of these themes to the neonatal context and the implications for the design and process of our forthcoming research study. It is proposed that a model of 'ethics of care' might provide a means of contextualizing resultant data.

Methodology

A critically reflective literature review approach was adopted because we were concerned to move beyond description or summary of relevant literature and take a more evaluative approach, not just of evidence but of argument (Hart, 1998). The identification of underpinning discourses and knowledge assumptions was central to the rationale for why the review was being undertaken in the first place. Much of the relevant literature, as will become apparent, is not empirical but rather derives from policy, attends to practice and is in many respects overtly rhetorical in its approach (Rife, 2010). Disentangling empirically derived claims from policy, opinion and ethical inquiry was a key concern. A critical review technique was, therefore, highly appropriate in being sensitive to context and discourse while possessing the scope to be integrative in the kinds of literature that are included and the conclusions drawn. It also permits a degree of reflexivity in its construction which means that the underlying intent of the review and its authors can be overtly situated in the review thus allowing their influence to be transparent as part of the reviewing process (for example in the choice of literature that is considered).

An electronic search was undertaken spanning a number of databases: MedlinePlus; PubMed; HubMed; GoPubMed; Science Direct; Web of Knowledge; Social Science Citation Index; Social Science Research Network and such generic search engines as all4one and Google Scholar. This took place between February and April 2010. Searches

were restricted to English language papers, and required the use of multiple keywords and keyword combinations including: 'patient attitudes' or 'public attitudes', 'medical records' and 'research', 'privacy' and so forth. While this method provided 134 articles that had some relevance to our study, it proved difficult to locate literature that fitted our requirements entirely, and almost half these articles were rejected as being too tangential to our concerns. As the AMS (2006: 70) report points out, there is only a small body of research on public awareness of, and attitudes to, the use of health information for research purposes. Moreover, there is a lack of comparability and specificity to research in this area (AMS, 2006: 70) with research questions, methodologies and samples varying dramatically. We thus implemented a second approach to searching the literature: a 'snowball' sampling technique (Babbie and Benaquisto, 2002: 166). Working from the bibliographies and citations of found literature, we were able to locate those studies, as well as the grey literature, that more precisely fitted our requirements. The majority of the literature focuses predominantly on England and the NHS. In some respects, says Higgins (2003: 8), the English system of health records and the single NHS number are 'the envy of the world'. However, a number of countries are tackling similar issues – notably Scotland, Canada and the Scandinavian countries – and have produced interesting and relevant studies which we have drawn on here.

In all, we analysed 47 pieces of commentary in a variety of academic journals, 13 pieces of relevant empirical research and 18 pieces of grey literature. In order to reflect critically on this commentary and these empirically derived claims, we drew on a range of work on ethics, trust, professional discourse and informed choice that we were familiar with from our own disciplinary backgrounds in sociology and social work. This enabled a dynamic, recursive and reflexive critique of some of the assumptions inherent in the identified literature, not least how and why research is undertaken. Through detailed reading and re-reading, we organized the literature under the three main themes found in this article: 'protection, promotion and prevention', 'choice' and 'rights and responsibilities'. The following results section presents these identified concepts.

Identified themes

Protection, promotion and prevention

Research benefits? The overwhelming majority of the literature that we examined assumes that the use of medical records as data to inform research provides categorical benefits to society. The report produced by the UKCRC (2007: 6) points out the 'enormous benefits for all types of clinical, public health and health services research and for many aspects of patient care' that can emerge from the use of electronic patient data. Verity and Nicholl (2002: 1210) stress the 'effective protection of public health' that results from the use of large-scale databases of health records in terms of disease surveillance. In the neonatal context, the recent document *Toolkit for High-Quality Neonatal Services* (DoH, 2009: 22) includes as one of its principles for 'quality' services, the need for 'high-quality data' to provide 'accurate information to all clinicians, researchers and patients' for improved outcomes of care. There are tensions, however, when it comes to what many health professionals and researchers see as the 'complicated patchwork' (UKCRC, 2007: 3) of

legislation – or rather, the bureaucratic interpretations of this legislation – which is designed to protect patient confidentiality (although the extent to which the legislation guarantees patients' privacy is debatable). Souhami (2006: 315) opines that problems associated with informed consent and de-identification of data are 'damaging our population based research – an "own goal" at a time when a national system of health records would give us unequalled opportunities for research to improve health'.

That literature which emphasizes the necessity of maintaining high standards of confidentiality does so while stressing the potential benefits of using routinely collected clinical data, and large-scale databases, to inform health research. Strobl et al. (2000: 890, emphasis added), for example, argue that there is 'a need to find a balance between facilitating *important* research and protecting the confidentiality of patients'. Cayton and Denegri (2003) are alone, in the identified literature, in their critical stance. The authors are highly opposed to calls for patient data being used for research without individual patient consent (in the form of general and advance consent which is consistently applied). Even if patients agree to their records being used – and the authors acknowledge the likelihood of this since 'public altruism is strong' (Cayton and Denegri, 2003: 34) – they need to be aware that *not* all research is 'good' research: objective, independent or beneficent. They take as an example the case of Alzheimer's research, pointing out the risk of information from genetic studies being sought by insurance companies and the resulting potential for serious discrimination. As the authors make clear: 'The pursuit of knowledge may be an end in itself for science, but the application of knowledge is of real public and private consequence' (Cayton and Denegri, 2003: 34).

Informed consent and de-identified data. A significant proportion of the identified literature focuses on the fact that informed consent is not always possible or even desirable when it comes to research using data which were initially collected for direct patient care. Such practice is likely to be quite different from traditional medical research where doctors and researchers will have contact with the patients involved and can obtain consent from them directly (Souhami, 2006: 315). Study populations may comprise thousands of people, some of whom will have moved or died (Souhami, 2006: 315). Seeking informed consent may upset patients, particularly those recently diagnosed with a serious disease (O'Brien and Chantler, 2003: 37). Moreover, the very act of having to seek consent could bias research findings as particular groups – such as the unemployed, severely ill and students – are particularly difficult to contact or more likely to opt out (Haynes et al., 2007: 302). Al-Shahi and Warlow (2000: 1031) state that having to seek informed consent to use identifiable data 'would jeopardise the methodological integrity of research and audit'. This, they point out, 'would not just hinder the progress of medical knowledge but might lead to completely incorrect conclusions' (2000: 1031). Chalmers and Muir (2003: 725) agree that such data, 'skewed by unquantifiable biases', are 'often not worth the cost of collection'.

While de-identified data have their uses, this is not an option for research which seeks to make links between databases, or even *within* a database (for example linking several episodes regarding a particular patient) (Black, 2003). Black (2003) also stresses the importance of taking into account such factors as age, sex and socio-economic status. Haynes et al. (2007: 302) point out the potential for research conclusions to be flawed

should such variables not be included in data analysis. In addition, Iversen et al. (2006: 167) raise the fact that it may be useful to be able to re-contact participants – perhaps years after a study – should new, important information about their conditions arise.

Legislation does not, in fact, present ‘insurmountable obstacles’ to the use of identifiable data without consent (Souhami, 2006: 316). Iversen et al. (2006: 165) concur that the ‘substantial impact’ on health research caused by such legislation as the Data Protection Act 1998 is less to do with the legislation per se than the way that ‘those who control access to healthcare data are not allowing ... legitimate and sensible exceptions to be put into practice’. They go on to describe their own difficulties with gaining approval for their research. Metcalfe et al. (2008) discuss the setbacks to their research that were wrought by their encounters with the Patient Information Advisory Group (PIAG)² whose ‘judgement’ has been deemed by some to be inconsistent and problematic.

Professional discourse. The majority of the literature we have analysed is written by clinicians, health researchers and government advisers. In terms of wording, language is often strong and forceful: warnings that bureaucratic intervention will ‘jeopardize’ research, putting society ‘at risk’. This could be seen as offering a potent counterpart to policy and legislation that is complicating the process of research from patient data. Conversely, repeated references to ‘care’, ‘protection’ and ‘progress’ can be seen as professionalism in its most patriarchal, protective guise (Kuhlmann, 2006). Notably, as Brown et al.’s (2008) work illustrates, the way that the use of medical records for research purposes is reported in the press mirrors the issues discussed here.

Brown et al. (2008) searched the content of UK national newspapers over an 18-month period and found that the majority of articles that included mention of the use of patient data for research did so without controversy, in the context of reporting findings from new scientific research. Those articles that *did* report ‘controversies’ tended to focus on the issue of bureaucratic restrictions hampering important research. As such, it could be argued that the media reporting contributes to a hegemonic discourse – one whose assumptions ‘seem natural and unmarked’ (Shirley and Padgett, 2006: 28). Alternative discourses – such as those highlighting the fact that research from patient data is not always in the public interest – are thus marginalized or obscured (see Lewis, 2006).

Public attitudes. Brown et al. (2008) found that doctors, researchers and government spokespeople consistently spoke in patients’ ‘best interest’ and rarely were patients quoted directly. While we were able to locate a number of studies that did question the public directly about their attitudes towards the use of patient records for research purposes, it is generally acknowledged in the literature that more work needs to be carried out in this area. In so doing, however, it is perhaps important to be mindful of not simply reproducing the prevailing discourse. In one study which directly questions public views on how patient information is used (NHS Information Authority in conjunction with the Consumers’ Association and Health Which?, 2002: 21), a question offers participants the following list of ways patient information is currently used and asks them to rank them in terms of importance:

- to treat a health problem I have;
- run health services efficiently;
- to check quality of care provided;
- to train doctors/nurses;
- compare results of treatments;
- to develop new treatments;
- to protect public health;
- plan for future demands on the NHS.

The assumptions that research from patient data will ‘protect public health’ and contribute to the running of efficient health services is inherent in the question, and these are undoubtedly issues that few would argue with when presented in this manner. Such a question does not allow for any exploration of the fact that patient data might not always be used to such positive ends. Lay perspectives may well prove the case that the routine use of patient data for research purposes is seen as essential for the protection of society, the promotion of collective well-being and the prevention of harm. Alternatively, such perspectives may produce a different narrative that questions, curbs or reframes the terms of the debate. Without meaningful exploration of patient beliefs and attitudes their divergent and/or interlocking narratives with those of professionals and policy-makers cannot be exposed.

Choice

Safeguarding privacy. ‘Choice’ is the second theme identified from the literature and this includes: the degree of choice patients have over giving consent for their clinical data to be used for research purposes; what influences these choices; and how ‘informed’ these choices are. In terms of UK policy, the legislation and codes of practice that address issues of data protection and confidentiality can be viewed as providing reassurance to the public in terms of safeguarding their privacy (Higgins, 2003; Montgomery, 2005). Montgomery (2005: 191) stresses the benefits of the Data Protection Act 1998. Stipulations such as information held being ‘fit for purpose; relevant and not excessive ... accurate and up to date’ means, argues Montgomery (2005: 191), that it ‘can only be used in the way that patients want and expect’.

However, not all commentators are as positive. Strobl et al. (2000) point out the variety of interpretation that such legislation is subject to. For instance, the first of the 1998 Data Protection Act’s eight principles stipulates that ‘personal data shall be processed fairly and lawfully’ which may be seen as subjective and vague rather than reassuring. The Human Rights Act 1998 also appears to give patients rights to privacy and confidentiality. However, O’Brien and Chantler (2003: 36) point out that the law ‘provides no absolute protection for medical information’. Indeed, while the Human Rights Act 1998 includes article 8, the right to respect for ‘private life’, this may be overridden for ‘the protection of the public health’.

In the UK, the ‘NHS Spine’ is currently being rolled out and has caused some concern in terms of patient privacy (Dunt, 2010). Part of the ‘Care Records Service’, this is an electronic system of managing patient records. The ‘Summary Care Record’ is a major part of this development and involves uploading medical records onto a centralized database. This

is linked to the 'Secondary Uses Service' which uses these data anonymously for reports, research and public health delivery. It is possible to opt out of the Summary Care Record, though initially there was no opt out form included in patient information packs. After concerns were raised about this – by John May from the BMA's Patient Liaison Group (Dunt, 2010) among others – this was remedied. However, if a patient does not opt out of the Summary Care Record, they cannot opt out of the Secondary Uses Service; nor can they have their record deleted at a later date (Eydmann, 2010). This has led to campaigners against the initiative claiming that the Department of Health is 'manufacturing consent' (Dunt, 2010).

Informed consent. The identified literature tends to focus on informed consent: when and how this should be obtained (if at all). Thus when patient choice is discussed it is, for the most part, in relation to informed consent. There are, however, many varieties of consent relating to this issue: implicit consent; blanket consent or the option to consent each time data are requested for use; only consent if data are non-identifiable; only consent with regards to aggregated data; and so forth. The research which has been undertaken on lay perspectives of the use of clinical data for research purposes (while limited) does include a number of studies which attempt to distinguish between various models of consent and to gauge public opinion on these.

Levitt and Weldon's (2005) work explicitly addresses these issues, albeit in the context of genetic research and UK Biobank. The authors explore the limits of informed consent in their focus group research looking at public perceptions of privacy and trust, data collection and storage, medical databases and UK Biobank. Levitt and Weldon (2005: 317) argue that health professionals equate informed consent with 'consumer choice'. They cite O'Neill who states that, for health professionals, 'Informed consent is seen as offering *necessary and sufficient ethical justification*' (O'Neill, cited in Levitt and Weldon, 2005: 317, emphasis in original). However, Levitt and Weldon (2005: 317) found that for their focus group participants, 'the requirement of informed consent was not an ethical trump card'. They felt that wider social and ethical issues still needed to be taken into account.

Participants in the study assumed that they would have a choice whether or not to donate genetic data, but they were aware of the limitations of this choice:

'Choices' might not be made freely, individuals might not have the information about future uses needed to make informed choice, those to whom the sample was going could not be trusted to use it well and some choices are undesirable. (Levitt and Weldon, 2005: 317)

Informed choice. It is debatable whether patients fully understand the choices that they are required to make regarding consent for their health data to be used for secondary purposes. Research carried out by NHS Information Authority (NHSIA) in conjunction with the Consumers' Association and Health Which? (2002: 27) looks at the public's views on consent and confidentiality of patient information. Through a large-scale survey it found that the forms of consent that the public would choose are evenly split. Thirty-five per cent of participants wanted to be asked for consent each time information is shared, including for treatment; 29 per cent thought it appropriate that consent be given on a one off basis for all uses; 30 per cent wanted to be asked for consent each time information

might be used for purposes other than treatment. However, the authors note that these findings were inconsistent with those garnered from a separate question which looked at attitudes to a published sharing agreement (45 per cent of participants chose the published sharing agreement as a safeguard). Two possible reasons are given for this inconsistency, both relating to a lack of understanding: the first suggests that participants may not have fully understood the implications of the published agreement; the second suggests that respondents did not fully understand the implications of collecting consent each time information would be shared.

Young et al. (2006: 328) stress the significance of the relationship between knowledge and understanding rather than the degree of information provision in making informed choices. They highlight the distinction between

informed choice as a statement of personal preference, with presumptions of individual rights of expression, and informed choice as a consequence of understanding, with presumptions of what might be adequate or required levels of knowledge in order to exercise it. (2006: 328)

This is particularly pertinent given the seeming propensity for the issues surrounding data sharing for research being presented in a very particular way through professional normative discourse. For example, Kuhlmann (2006: 617) argues that despite the current emphasis upon patient choice and decision making, the reality remains that patients have 'very little influence' in wider processes within the health service. In Levitt and Weldon's (2005: 317) study, it was generally understood that the notion of patient 'choice' is not unproblematic. Notably, the only exception to this view came from a health professional who argued that 'medical research is important and that giving people the right to choose ensures that ethical concerns have been dealt with' (Levitt and Weldon, 2005: 317).

Rational decision making? Professional model of ethics draw from Kantian or utilitarian models and can over-rely upon 'the mechanical application of rights-claims and adherence to duties' (McBeath and Webb, 2002: 1018) alongside 'ideas of closure, competency and control within the relatively determinate universe of a legal-rational administrative or economic systems' (2002: 1016). They also presume rational decision making (Young et al., 2006). Such a framework does not take into account the more nuanced aspects of human relationships and emotional experience that are bound up with the choices that patients make.

From the studies identified here, it appears that patients' relationships with their health care professional are likely to hold considerable sway over the choices they make regarding secondary uses of their health data. In their qualitative research looking at this issue, Nair et al. (2004: 25) found that trust in individual doctors remained an important facet in influencing whether they would want their records to be used for other purposes. One patient stresses, 'I like Dr XX ... if that is going to help her, hey why not?' Another says, 'If you trust the doctor, I don't think it would worry me how much [data] you needed, and I do trust the doctor' (Nair et al., 2004: 25).

That literature which does not engage with public opinions also tends to recognize the crucial importance of trust in this debate, not least because of the potential risks involved in data sharing:

[S]ensitive health information might be released to unauthorised users and result in the research participant being stigmatised, emotionally harmed or financially disadvantaged (for example, being refused life insurance or being charged higher premiums). In medical research involving genetic analysis, there is a risk that research will provide information about familial disease susceptibility to other family members who do not want to know about it. (Wellcome Trust, 2008: 7)

However, it sees the answer to this as putting in place secure, scientific ‘systems’ which will increase public confidence. Smith (2005) provides a useful critique of this reliance on confidence in systems and procedures in health and social care that has emerged through the modernization agenda. She claims that seeing people as consumers of services, and focusing on providing a fast, efficient service can result in the neglect of ‘the needs of service users who are vulnerable, distressed, in pain, dependent on the intervention of others and facing uncertain outcomes’ (Smith, 2005: 311). It is during this vulnerable time that we most need to be able to trust others; as such, trust has moral and affective characteristics (Smith, 2005).

‘Rights and responsibilities’

No rights without responsibilities? The idea of ‘rights and responsibilities’ is the third concept identified from our critically reflective approach to the literature review and one which also has much influence over patient choice. Although patients hold the right to refuse researchers access to their medical data, much of the identified literature also presupposes that they simultaneously have a responsibility towards ‘helping’ others: that is much health research not only depends on but also implicitly *assumes* varieties of ‘altruistic participation’ (Cayton and Denegri, 2003: 33). Again, there is an emotional element to this concept which is not explicitly addressed in the literature.

The modernization agenda emerges from a Third Way political philosophy³ which has placed greater accountability upon individual citizens. Ledwith (2001: 171, emphasis added) sees this agenda as having ‘transformed rights into responsibilities by transferring the collective responsibility of the welfare state to the individual, the family and the community as a *moral* responsibility’. A report from NHSIA in conjunction with the Consumers’ Association and Health Which? (2002: 4) clearly states: ‘People have more rights and responsibilities’ in the NHS. The report goes on to discuss the potential risks involved in the sharing of health information (including how people are treated; ability to get jobs, mortgages, life insurance). It states that one way to minimize such risks is ‘to have informed patients exercising as much control as possible over who sees their medical information’ (2002: 5). Thus it becomes patients’ responsibility to manage how their medical data are used. O’Brien and Chantler (2003: 36) see this as a positive move: ‘Enabling patients to decide how information about them is disclosed is an important element in autonomy and helps patients engage as active partners in their care.’

In the UK, the newly elected conservative-led coalition government has only emphasized the responsibility of patients as a recent White Paper illustrates:

In future, patients and carers will have far more clout and choice in the system; and as a result, the NHS will become more responsive to their needs and wishes ... We are also clear that increasing patient choice is not a one-way street. In return for greater choice and control,

patients should accept responsibility for the choices they make, concordance with treatment programmes and the implications for their lifestyle. (Department of Health, 2010: 16)

Nettleton (1996: 35), however, is concerned about the additional pressure this 'consumer-led' model of medicine causes, especially to women. Because of their role as carers, and as the main recipients of health care, women are held the most accountable for the health not just of their family but of the community. So in a model where 'people are increasingly being encouraged to monitor and maintain their own health ... and people are being invited to voice their views about health and health care', women will be expected to shoulder much of this 'moral' responsibility. These morals can be seen to be transmitted through the processes of normalization and integration; thus the moral codes promoted through this model of health care are presented as unquestionably 'neutral forms of care, helping and good works' (Webb and McBeath, 1989: 501).

Altruism. Through these processes, and through the framing of all health research as progressive and as benefiting society, patients are encouraged to feel that they are doing 'good' by allowing their data to be used for research. However, as Cayton and Denegri (2003: 34) wryly observe (in the context of Alzheimer's research):

They would be much less enthusiastic if they knew, as was recently proposed, that the social, medical and genetic data they contributed might be combined in an academic study funded by the insurance industry so that it could discriminate more effectively against them and their families.

This rehearses the point made earlier that 'informed' consent is not always *informed*. It does appear, though, from the available literature, that the majority of patients *are* willing to allow their (often identifiable) data to be used for research, with numbers varying slightly according to context. McKinney et al.'s (2005) study into the feasibility of obtaining parental consent for patient identifiable data to be submitted to a national database took place in paediatric intensive care units across England. The refusal rate was extremely low at less than 1 per cent. Baker et al. (2000) questioned a random sample of patients with asthma or angina and found that approximately 10 per cent of patients would refuse consent to data collection from their records for research purposes. Nair et al. (2004), in their study in Canada, similarly found that the majority of patients questioned were happy to have their medical information used for research purposes, commenting on the necessity of health research for benefiting future generations. However, they also wished be consulted first, even if their information was de-identified.

The literature examined here tends to understand informed consent as allowing people to be 'generous' with their medical data; to have the sense that through their own – often difficult, if not traumatic – experiences they are helping others. Cayton and Denegri (2003: 33) discuss the propensity for dementia patients to donate brain tissue for research into this condition. Such an act can obviously not be for personal gain, but in order to benefit others in the future. The Independent Review Group on Retention of Organs at Post Mortem in Scotland found that parents often wanted to be asked about the use of a child's organs for research after death, not so that they could refuse, but so that they could say yes and feel that their experiences could help other families in the future (cited in O'Brien and Chantler, 2003: 37).

Emotion. As discussed earlier, such choices are inevitably going to be bound up in considerable emotion. This is very much at odds with the western-style code of conduct which is assumed to influence patients' moral decision making. Western approaches to ethics 'place the individual moral agent in the centre of the picture, rationally weighing up the balance of individual duties and rights' (Banks, 2008: 1243). Drawing on alternative approaches to the Kantian/Utilitarian models of professional ethics with their abstract principles and 'universal' values can enable attention to be paid to 'the situated nature of values and conduct, as embedded in families, relationships, communities and cultures, and take account of commitments to specific others, motives and emotions' (Banks, 2008: 1243).

Gilligan (1982), in her development of an ethics of care, sets out an alternative – 'female' – approach to moral reasoning which takes into account personal relationships, care and responsibility. Again this model recognizes that decisions made by patients – or family members of patients – with regard to the use of health data for research purposes are always going to be bound up in emotional experience, as well as being shaped by cultural and societal expectations.

Conclusion

It remains the case that we rely on 'experts' and 'expert knowledge' to safeguard our well-being. However, in the literature examined, not only does the application of this knowledge remain unchallenged, the reliability of data collected from health records is not questioned. Rather, authority is invested in the data as 'expert'. This is diametrically opposed, says Braude (2009: 182), to the 'tacit knowledge' or 'practical intuition' which is also needed to provide effective clinical care. Thus the emphasis on data as expert undermines human emotion or intuition; in presenting a particular discourse it also closes down communication.

The article has discussed the dominance of the medical profession in the debate around data sharing in relation to medical research. The debate is framed in a model of professional ethics which takes for granted a particular set of moral values, notably with regards to the advancement of knowledge and the 'greater good'. Yet Banks (2008: 1239) has highlighted the influence of the 'postmodern' turn and the management of risk within welfare professions which, among other consequences, has more recently assisted in:

A questioning of universal values, all-embracing foundational theories (including ethical theories) and the legitimacy and roles of 'expert' professional practitioners in relation to service users ... These factors are contributing to a continuing concern with professional power, legitimacy, credibility, conduct/misconduct and a questioning of the traditional professional-client relationship.

The forthcoming study, which will examine the question of consenting to the use of patient records for research in the neonatal context, will involve service users – parents of newborn babies who have required additional care – in the research process. Such a methodology offers the potential to tap into an alternative discourse to inform or challenge assumptions underpinning the research process. It can also recognize, if not challenge, the power imbalance between the health care professional and the patient.

As Smith (2005: 313) says, 'Greater sharing of knowledge, ethical dilemmas and decision-making between professionals and service users may encourage trust and moral responsibility between both parties.' While Kuhlmann (2006: 617) stresses that '[i]nformation does not automatically abolish asymmetries in health care systems', although it does have the potential to raise awareness of the debate.

The issues of 'choice' and 'rights and responsibilities' identified in the article are pertinent in the context of neonatal services and are likely to manifest in both practical and philosophical ways. The article has highlighted the vulnerability of patients and the emotional aspects of being asked for consent for data to be used for research purposes. The POPPY Report (2009) looks at the findings from a three-year research project into the needs of parents of babies in neonatal care. The emotional stress experienced at this time in parents' lives is very much in evidence. Parents often found themselves overwhelmed by information (POPPY, 2009: 11) and exposed to a large number of health professionals who were regularly reported as communicating in an insensitive way (2009: 11). Such experiences are likely to impact on parents' reactions to consent issues regarding their babies' data being used for research, particularly if, as is suggested in the article, experiential knowledge, relationships and trust in clinicians are key factors in individuals' decision making. It also seems highly probable – from the literature examined here – that parents of newborns would be keen to 'give something back' from their distressing experiences, and to have the opportunity to consent to their babies' data being used for research.

Through the themes explored here, however, there is indication that such 'choices' and the resultant decisions made are not straightforward. Rather, they are loaded with social and cultural assumptions of what is morally right. Traditional approaches to professional ethics have drawn on Kantian and utilitarian ideas and can be seen in evidence here in the suppositions over what is best for the progress of society. Recent criticism of such a model highlights its tendency to frame historically located and specific discourses as universally rational. As Bauman (cited in Clifford, 2002: 31) says, 'Modern societies practice moral parochialism under the mask of promoting universalistic ethics.' Feminist criticism would also point to the privileging of the socially advantaged, male viewpoint in traditional professional ethics (Clifford, 2002: 32). The future research study will explore with parents their moral and ethical views on the subject of consenting for their babies' data to be used for research, how they arrive at judgements about what kind of data might be used and whether individual consent is always required (or whether the use of patient data simply becomes part of the collective consequences of being a NHS patient). In order to locate the resultant ideas in an alternative discourse to the one identified here, a model of an ethics of care will be employed to underpin the future study. Drawing from feminist approaches to ethics, this challenges 'objective, rational and male' reasoning of traditional models (Orme, 2002: 800) and gives consideration to relationships and emotion in moral reasoning. As such, it offers an opportunity to explore a further dimension in terms of investigating patient attitudes to the issue of routinely collected medical data being used for research.

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Notes

- 1 All Members of the Medicines for Neonates Investigator Group have seen and approved the final version.
- 2 PIAG was established by the Health and Social Care Act 2001 (and recently replaced by the National Information Governance Board for Health and Social Care – NIGB – under section 158 of the Health and Social Care Act 2008). PIAG's role was to advise the Secretary of State for Health on cases in which it may be justifiable to make patient-identifiable information available to support essential NHS activities, without the consent of patients.
- 3 The Third Way is a political ideology which can be seen to have been enacted through policies notably by the Clinton administration in the United States and the New Labour government in the UK. Influenced by Anthony Giddens, the British sociologist, the Third Way aims to reconcile left-wing and right-wing politics.

References

- Academy of Medical Sciences (AMS) (2006) *Personal Data for Public Good*. London: The Academy of Medical Sciences.
- Academy of Medical Sciences (2011) *A New Pathway for the Regulation and Governance of Health Research*. London: The Academy of Medical Sciences.
- Al-Shahi R and Warlow C (2000) Using patient-identifiable data for observational research and audit: Overprotection could damage the public interest. *British Medical Journal* 321(7268): 1031–1032.
- Babbie E and Benaquisto L (2002) *Fundamentals of Social Research*. Ontario: Thomas Nelson.
- Baker R, Shiels C, Stevenson K, Fraser R and Stone M (2000) What proportion of patients refuse consent to data collection from their records for research purposes? *British Journal of General Practice* 50(457): 655–656.
- Banks S (2008) Critical commentary: Social work ethics. *British Journal of Social Work* 38(6): 1238–1249.
- Black N (2003) Secondary use of personal data for health and health services research: Why identifiable data are essential. *Journal of Health Services Research & Policy* 8(1): 36–40.
- Braude HD (2009) Clinical intuition versus statistics: Different modes of tacit knowledge in clinical epidemiology and evidence-based medicine. *Theoretical Medicine and Bioethics* 30(3): 181–198.
- Brown L, Parker M and Dixon-Woods M (2008) Whose interest? British newspaper reporting of use of medical records for research. *Journal of Health Service Research Policy* 13(3): 140–145.
- Cayton H and Denegri S (2003) Is what's mine my own? *Journal of Health Service Research Policy* 8(1): 33–35.
- Chalmers J and Muir R (2003) Patient privacy and confidentiality. *British Medical Journal* 326(7392): 725–726.
- Clifford D (2002) Resolving uncertainties? The contribution of some recent feminist ethical theory to the social professions. *European Journal of Social Work* 5(1): 31–41.
- Department of Health (DoH) (2009) *Toolkit for High-Quality Neonatal Services*. London: Department of Health.

- Department of Health (DoH) (2010) *Equity and Excellence: Liberating the NHS*. London: The Stationery Office.
- Dunt I (2010) *Privacy Fears Raised as NHS IT Project Ploughs Ahead*. Politics.co.uk. Available at: [http://www.politics.co.uk/news/health/privacy-fears-raised-as-nhs-it-project-ploughs-ahead-\\$1362552.htm](http://www.politics.co.uk/news/health/privacy-fears-raised-as-nhs-it-project-ploughs-ahead-$1362552.htm).
- Eydmann J (2010) *Information Self-Determination and the NHS Spine*. Bio Centre. Available at: <http://www.bioethics.ac.uk/news/information-self-determination-and-the-nhs-spine.php>.
- Gilligan C (1982) *In a Different Voice*. Cambridge, MA: Harvard University Press.
- Hart C (1998) *Doing a Literature Review: Releasing the Social Science Research Imagination*. London: SAGE and Open University.
- Haynes CL, Cook GA and Jones MA (2007) Legal and ethical considerations in processing patient-identifiable data without patient consent: Lessons learnt from developing a disease register. *Journal of Medical Ethics* 33(5): 302–307.
- Higgins J (2003) The Patient Information Advisory Group and the use of patient-identifiable data. *Journal of Health Services Research and Policy* 8(1): 8–11.
- Iversen A, Liddell K, Fear N, Hotopf M and Wessely S (2006) Consent, confidentiality, and the Data Protection Act. *British Medical Journal* 332(7534): 165–169.
- Kuhlmann E (2006) Traces of doubt and sources of trust: Health professions in an uncertain society. *Current Sociology* 54(4): 607–620.
- Ledwith M (2001) Community work as critical pedagogy: Re-envisioning Freire and Gramsci. *Community Development Journal* 36(3): 171–182.
- Levitt M and Weldon S (2005) A well placed trust? Public perceptions of the governance of DNA databases. *Critical Public Health* 15(4): 311–321.
- Lewis B (2006) Medical professionals and the discourse of professionalism: Teaching implications. In: Wear D, Aultman JM (eds) *Professionalism in Medicine: Critical Perspectives*. USA: Springer, 149–164.
- Lowrance WW (2002) *Learning from Experience: Privacy and the Secondary Use of Data in Health Research*. 28 November. London: The Nuffield Trust.
- McBeath G and Webb SA (2002) Virtue ethics and social work: Being lucky, realistic, and not doing one's duty. *British Journal of Social Work* 32(8): 1015–1036.
- McKinney P, Jones S, Parslow R, et al. (2005) A feasibility study of signed consent for the collection of patient identifiable information for a national paediatric clinical audit database. *British Medical Journal* 330(7496): 877–879.
- Metcalfe C, Martin RM, Noble S, et al. (2008) Low risk research using routinely collected identifiable health information without informed consent: Encounters with the Patient Information Advisory Group. *Journal of Medical Ethics* 34(1): 37–40.
- Montgomery J (2005) Personal information in the National Health Service: The demise or rise of patient interests? In: Lace S (ed.) *The Glass Consumer: Life in a Surveillance Society*. Bristol: The Policy Press, 187–206.
- Nair K, Williamson D, Holbrook A and Keshavjee K (2004) Patients' consent preferences regarding the use of their health information for research purposes: A qualitative study. *Journal of Health Service Research Policy* 9(1): 23–27.
- Nettleton S (1996) Women and the new paradigm of health and medicine. *Critical Social Policy* 16(48): 33–53.
- NHS Information Authority (NHSIA) in conjunction with the Consumers' Association and Health Which? (2002) *Share with Care! People's Views on Consent and Confidentiality of Patient Information*. Birmingham: NHSIA.
- O'Brien J and Chantler C (2003) Confidentiality and the duties of care. *Journal of Medical Ethics* 29(1): 36–40.

- Orme J (2002) Social work: Gender, care and justice. *British Journal of Social Work* 32(6): 799–814.
- POPPY (Parents of Premature babies Project) (2009) *Family-Centred Care in Neonatal Units: A Summary of Research Results and Recommendations from the POPPY Project*. London: NCT.
- Rife MC (2010) Ethos, pathos, logos, kairos: Using a rhetorical heuristic to mediate digital-survey recruitment strategies. *IEEE Transactions on Professional Communication* 53(3): 260–277.
- Shirley JL and Padgett SM (2006) An analysis of the discourse of professionalism. In: Wear D, Aultman JM (eds) *Professionalism in Medicine: Critical Perspectives*. USA: Springer, 25–42.
- Smith C (2005) Understanding trust and confidence: Two paradigms and their significance for health and social care. *Journal of Applied Philosophy* 22(3): 299–316.
- Souhami R (2006) Governance of research that uses identifiable personal data. *British Medical Journal* 333(7563): 315–316.
- Strobl J, Cave E and Walley T (2000) Data protection legislation: Interpretation and barriers to research. *British Medical Journal* 321(7265): 890–892.
- UKCRC Advisory Group to Connecting for Health (2007) *Report of the Research Simulations*. London: UKCRC.
- Verity C and Nicholl A (2002) Consent, confidentiality, and the threat to public health surveillance. *British Medical Journal* 324(7347): 1210–1213.
- Webb SA and McBeath GB (1989) A political critique of Kantian ethics in social work. *British Journal of Social Work* 19(1): 491–506.
- Wellcome Trust (2008) *Data Sharing Review: Use and Sharing of Personal Information in the Public and Private Sectors, Response by the Wellcome Trust*. Available at: <http://www.justice.gov.uk/docs/The-Wellcome-Trust-Data-Sharing-Response.pdf>.
- Young A, Skipp A, Carr G, Tattersall H and Hunt R (2006) Informed choice and deaf children: Underpinning concepts and enduring challenges. *Journal of Deaf Studies and Deaf Education* 11(3): 322–336.

Author biographies

Victoria Foster, PhD, is currently a Research Associate at the University of Manchester working on the project ‘Understanding parents’ attitudes towards the use of NHS data for research purposes in the context of neonatal services’. She has a background in Sociology and Social Policy and is particularly interested in innovative, participatory research methods. Her ESRC funded doctoral research employed a participatory arts-based methodology to look at women’s experiences of mothering in poverty and she was awarded an ESRC Postdoctoral Fellowship to follow up this work.

Alys Young, PhD, MSc (Oxon), MA (Cantab.), CQSW, is Professor of Social Work Education and Research at the University of Manchester, UK and visiting Professor in the Department of Deaf Studies at the University of Witwatersrand, Johannesburg, South Africa.

STROBE Statement—checklist of items that should be included in reports of observational studies, followed by a table showing how the current study conforms to the STROBE statement.

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

Continued on next page

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

STROBE Checklist: How to avoid missing half the evidence: comparing the use of generic and specific electronic search terms used to identify health outcomes for a systematic review.

STROBE Item No.	Authors comment
1 (a)	Done – see abstract, main article
1 (b)	Done – see abstract, main article
2	Done – main article
3	Done – main article
4	Done – main article
5	Done – a literature search is internet based rather than set in a specific location so we gave details of the databases searched and the review that the searches were conducted for. Main article
6 (a)	Done – main article
6 (b)	Not applicable – the study includes no matching of the kind described in STROBE.
7	Done – main article
8	Done – main article
9	Done – use of multiple reviewers during search and selection process.
10	Not applicable - the study did not require a power calculation as it includes no participants (in the conventional use of the terms). The text does state that the two searches were field tested during an actual systematic review – main article and protocol.
11	Done – main article.
12 a to e	Done – main article.
13	Done – figure 1 and text in main article.
14 a	Done – table 1, main article.
14 b and c	Not applicable
15	Not applicable
16	Done in so far as applicable (the study does not involve estimates, statistical adjustment or missing data as described by STROBE). Main article.
17	Done – main article.
18	Done – main article.
19	Done – main article.
20	Done - main article.
21	Done - main article.
22	Done - main article.