original article

Informed consent in research

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The developments in the protection of human participants in research evolved following the Nuremberg trial of Nazi doctors leading to the Nuremberg Code (Annas & Gordin, 1992; European Commission, 2010; Faden, 1989), which highlighted the following safeguards and is the basis for subsequent ethical codes and guidelines internationally;

- *The voluntary consent of the human subject is absolutely essential*
- *Favorable risk-to-benefit analysis*
- *The right to withdraw without repercussions*

Informed consent has been described as 'a precondition for autonomous decision-making' (Biggg, 2010). The social values most notably stated as being promoted by the requirement of informed consent are autonomy and trust (O'Neill, 2002). However there is no statute based law of consent in the United Kingdom (UK). Practical guidance in terms of the practical operation of consent is led by guidance from professional organisations for healthcare professionals. Importantly, consent is commonly regarded as the cornerstone of medical law and ethics (Agich, 1998).

The benefits of informed consent in relation to research on human participants can be seen as respect for participants, engaging the participants with the study and enhancing the researcher-participant relationship, which may reduce discontent and litigation. However a universal insistence on consent can introduce selection bias (a systematic error in a study based on the processes used to select the study participants) and participation bias (caused by differences between participants and non-participants), which will limit recruitment of study participants and may affect the generalisability of the study findings by reducing the statistical power of the findings (Kho, Duffett, Willison, Cook, & Brouwers, 2009). The requirement, may overburden limited resources in terms of time and financial costs.

Informed consent in the context of research on human participants evolved in a different but parallel sphere to informed consent to medical treatment. Before the contemporary era, many people were used in research not only without their knowledge but also, sometimes against their expressly stated wishes (Mallardi, 2005). Two central aspects play a crucial ethical role in the recruitment of participants to research studies. These are that the consent to participate is fully informed and freely given. The informed consent process has been seen as necessary both to protect individuals from harm, safe-guarding their well being, and to protect the basis of autonomy as a right in itself by allowing potential participants an autonomous choice (Ursin, 2009).

Elements of informed consent

For consent to be valid the process of information giving in itself is not enough. The element of understanding is the basis of this validation. The information given needs to be

adequate for the research participant. It must include the purpose of the study, any significant risks to the participant and details of financial aspects of the study that could highlight potential conflicts of interest. Information is imparted by speaking with the participants as well as using information sheets. Literacy and language can be major barriers in understanding for potential participants. According to Flory, Wendler and Emanuel generally 75% of participants understand the purpose of a study (2007). Appelbaum described the therapeutic misconception leading research participants to believe their participation in the study will benefit them in the same way as clinical care (Appelbaum, Lidz, & Grisso, 2004). Attention must be paid to ensure potential participants understand the underlying reasons for research. The amount of information imparted in the consenting process may lead to information overload, which will in turn affect understanding. The type of research study will dictate what, how and how much information should be provided in the consenting process. But it is important to note that complete understanding by the participant cannot be guaranteed. However it must be of an adequate level for the participant to make a decision.

Informed consent must also be given freely. Voluntariness demonstrates the autonomous participant has not been controlled in any way into agreeing to consent. It has been recognised that decisions are rarely made free from external control (Kottow, 2004). This notion is well defined by Faden and Beauchamp (Faden, & Bauchamp, 1989). They recognise that not all external controls and influences are controlling. Accordingly they state that coercion is always fully controlling and thus is not compatible with informed consent, whereas persuasion, not being controlling is compatible with informed consent. It is important that a power imbalance of researcher and participant does not play a role in manipulating the voluntary nature of the informed consent process. Furthermore the study information sheet must make it clear that participants do not have to take part if they do not wish to do so and that they can withdraw from the study at any time without that decision affecting their usual care. Studies have revealed that this element of the consent process is poorly understood and undermines the voluntariness of research participants as they may continue to participate in a study even after they decide they would rather no longer be part of the study (Flory & Wendler, 2007).

The final required element is competence. Competence is defined as a participant having decision-making capacity to utilise the information they have been given to make a free and voluntary decision. In those participants identified as lacking capacity and children generally under the age of 16, proxy consent may be sought. In healthcare settings, the healthcare team will have had time to assess competence in the course of their usual clinical care. This is a more problematic assessment in the research environment if participants are recruited without the involvement of usual healthcare providers. It is also the case that potential participants may not be able to exercise their decision-making capacity whilst in, for example, prison. The setting needs careful consideration when seeking informed consent.

The role of Research Ethics Committees

In medical research, Research Ethics Committees have to approve research studies and the informed consent process for each study is assessed during this process. There appears to

be a lack of agreement as to how populations are to be assessed for understanding. Informed consent is being judged presently without an assessment of its success. Since the first Research Ethics Committee was formed in the United Kingdom in 1966 it has become a function of the committee to make assessments of the nature and adequacy of the consent strategies for each of the research studies reviewed (Gelling, 1999). Consent is usually obtained with the use of a consent form, which is signed by the research participant before their participation in research. In a review of the evolution of consent forms for research over a 25 year period, Albala et al. reviewed research protocols and consent forms reviewed by an Institutional Review Board in a major academic medical centre (Albala, Doyle, & Appaelbaum, 2010). They concluded that the length of consent forms have increased 'linearly by an average of 1.5 pages per decade.' The increase in length of consent forms may be problematic if the three stated elements of informed consent are to be satisfied.

Consent requirements: an ongoing debate

Within the realm of medical research, the different strategies of consent are the basis of much of the ongoing debate on informed consent. The differences are essentially obtaining individual informed consent or not obtaining individual informed consent. In using anonymised data, consent is not a legal requirement. This is based on the current interpretation of the legal framework. But in needing to access identifiable data consent is required.

Consent requirements are different in the case of emergencies and in research on vulnerable groups. In undertaking research in the emergency setting where the participants are unable to provide consent, an ethics review body will need to have approved the study protocol. In undertaking research on vulnerable adults alternatives to the standard consent process are considered appropriate. These are accepting consent from a proxy to make the decision on their behalf or to rely on an advance statement if one has been prepared (General Medical Council, 2013). Children are commonly viewed as a vulnerable group in relation to research. Usually a parent provides consent on behalf of the child, although obtaining the assent of the child as well acts as another means of protecting the interests of the child and it is encouraged. The best interest standard is usually upheld when making decisions on behalf of a child (Shah, 2013).

Legal perspectives

The legal significance of informed consent derives from two main areas of law - negligence and assault and battery. Despite the acceptance in both ethics and law, that a person should have choice about their participation in research there is no "…. specific statute-based law of consent in the United Kingdom, and the concept has developed through common law judgments. Similarly, there is no UK case law pertaining explicitly to consent in research." (Biggs, 2010). The requirements of the information expected to have been provided, to a research participant are different to that which is required to be given to a patient in order to obtain consent. This information element is different as potential participants need to be aware of their freedom to withdraw from a study at any time and that the research may not directly benefit them. Compounding this issue is the element of data as gathered in the research process and its

use and protection as a result of participation in a study.

The decision whether or not to participate in research has become a fundamental right in English medical law. In her book exploring the relationship between law and ethics, Hazel Biggs notes;

> *"Broadly speaking, obtaining consent from a research participant authorises a clinician or researcher to have physical contact with the participant. It also protects the rights of participants to exercise their own autonomy and retain control over what happens to them. …. More generally, legal authorisation is required for any intervention involving interference with the physical integrity of the body, its tissue and fluids, or access to personal data and records."*

In the absence of a legal right to privacy until the 1990s, researchers were encouraged to undertake research using patient information as a professional ethical duty without an emphasis on obtaining informed consent or approval from Research Ethics Committees (Foster, 2001). The introduction of the Data Protection Act 1998 and a social setting focusing on patient-centered health care altered this research backdrop. This new legal framework has been interpreted in the context of 'consent or anonymise' in which obtaining individual consent is held to be the only ethically appropriate way of justifying the use of identifiable data (and where annonymised data has had the identifiable data removed from the data of interest).

The most important laws governing medical research using personal data in the UK include:

- *Data Protection Act 1998*
- *Common law of confidentiality*
- *Human Rights Act 1998*
- *Section 60 of the Health & Social Care Act 2001*

Individual consent and the interests of society

There is a debate surrounding the abandonment of informed consent in the governance of certain new research technologies. In the case of large databases, bioethicists and policymakers are considering the relevance and importance of obtaining individual narrow informed consent (Rommetveit, 2011). In bioethics the tension has always been between common good and individual autonomy. This has been founded on the need to protect the privacy of individuals versus the public interest. The liberal framework, which protects individuals and places autonomy at the core of the need for informed consent, is being tugged at by a communitarian 'turn' in bioethics. This term is defined by Ruth Chadwick as a "… shift in bioethics over the last decade or so, involving greater emphasis on principles of solidarity, equity and public good, as opposed to the prominence of autonomy-based arguments." (Chadwick, 2011).

In undertaking an exploration of the ethical and societal principles of the requirement for informed consent, stakeholders in the debate on informed consent were interviewed. The outcome of this study was that the presence of an improved level of background education in relation to research, trust in research practices and research participation combined with a societal shift to a more solidarity based model of society would provide the background seen as necessary for different consent strategies to be acceptable in undertaking research. A societal

shift to a more socially collective model of citizenship would be required for consent strategies to become less prescriptive as compared to individual opt-in strategies (Schofield, 2013).

Conclusion

Informed consent has become important due to historical developments, placing an emphasis on the individual. Alternative consent strategies based on a more societal model of citizenship combined with education and building up of trusting relationships will allow research to maximise its benefits whilst continuing to protect participants.

References

Agich, G. J. (1998). Human experimentation and clinical consent. In J. F. Monagle, & D. Thomasma (Eds), *Health care ethics: critical issues for the 21st century*. Gaithersburg, USA: Aspen Publications.

Albala, I., Doyle M., & Appelbaum P. S. (2010). The evolution of consent forms for research: A quarter century of changes. *IRB: Ethics and Human Research, 32*(3), 7-11.

Annas G. J., & Gordin M. A. (1992). *The Nazi doctors and the Nuremberg Code*. New York: Oxford University Press.

Applebaum, P. S., Lidz, C. W., & Grisso, T. (2004). Therapeutic misconception in clinical research: Frequency and risk factors. *IRB: Ethics Human Research, 26*(2), 1-8.

Biggs, H. (2010). *Healthcare research ethics and law. Regulation, review and responsibility*. Cavendish, New York: Routledge

Chadwick, R. (2011). The communitarian turn: Myth or reality? *Cambridge Quarterly of Healthcare Ethics, 20*(4), 546-553. doi:10.1017/S0963180111000284

European Commission (2010). *European textbook on ethics in research. European research area, Science in society*. Luxembourg: Publications Office of the European Union.

Faden, R. R., & Beauchamp, T. L. A. (1986). *History and theory of informed consent*. New York: Oxford University Press.

Faden, T. L. (1989). *A history and theory of informed consent*. Beauchamp Georgetown University: Oxford University Press.

Flory, J., Wendler, D., & Emanuel E. (2007). Informed consent for research. In R. E. Ashcroft, A. Dawson, H. Draper H., & J. R. McMillan (Eds), *Principles of health care ethics* (2nd ed). England: Wiley & Sons Ltd.

Foster, C. (2001). *The ethics of medical research on humans*. Cambridge: Cambridge University Press.

Gelling, L. (1999). Role of the research ethics committee. *Nurse Education Today, 19*(7), 564-569. doi:10.1054/nedt.1999.0349

General Medical Council (2013). *Good practice in research and consent to research*. Retrieved from: http://www.gmc.uk.org/static/documents/content/Good_practice_in_research_and_consent)

Kho, M. E., Duffett, M., Willison, D. J., Cook, D. J., & Brouwers M. C. (2009). Written informed consent and selection bias in observational studies using medical records: A systematic review. *BMJ, 338*(b866). doi:10.1136/bmj.b866

Kottow, M. (2004). The battering of informed consent. *Journal of Medical Ethics, 30*(6), 565-569. doi: 10.1136/jme.2003.002949

Mallardi, V. (2005). The origin of informed consent. *Acta Otorhinolaryngol Ital, 25*(5), 312-27.

O'Neill, O. (2002). *Autonomy and trust in bioethics. The Gifford Lectures*. Cambridge: Cambridge University Press.

Rommetveit, K. (2011). Tackling epistemological naivety: Large-scale information systems and

the complexities of the common good. *Cambridge Quarterly of Healthcare Ethics, 20*, 584-595. doi:10.1017/S0963180111000326

Schofield, B. (2013). *The ethical and societal implications of consent strategies in large-scale epidemiological studies* (Unpublished doctoral dissertation). University of Bristol, Bristol.

Shah, S. (2013). Does research with children violate the best interests standard? An empirical and conceptual analysis. *North-Western Journal of Law & Social Policy, 8*(2), 122-173.

Ursin, L. O. (2009). Personal autonomy and informed consent. *Medicine, Health Care and Philosophy, 12*(1), 17-24. doi:10.1007/s11019-008-9144-0

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