Post title:

Consent in an acute clinical research setting - what should that look like?

Main post content:

Consent to an intervention serves to recognise a person’s autonomy, be that in clinical care - or in the research that informs that clinical care. Consent is not valid unless it is given voluntarily, on the basis of sufficient information to make the decision, and by someone who has the capacity to understand that information and utilise it to [inform their decision](https://www.nhs.uk/conditions/consent-to-treatment/).

How consent is provided and documented depends on the setting and context. Sometimes consent will need to be very specific, to ensure that particular risks and benefits of say, an operation, or participation in a research study have been considered and weighed in the balance. In such examples it might be evidenced by a signature on a consent form. At other times, consent might be just as considered and freely provided, but relate to a broad or open-ended activity, for example, providing blood samples for future, as yet undetermined, research studies.

In acute clinical settings, consent will often be woven into a consultation. For example, the parents of an unwell neonate will usually demonstrate their consent for clinicians to seek a diagnosis, implement appropriate care of their child through various ongoing interactions with the clinical team, instead of providing specific written confirmation for each particular aspect of this pathway. Thus, in some contexts, a signature on a consent form might be the only evidence that legitimate activity has taken place, whilst in others, the clinician’s duty of care and the trustworthiness of the setting in which they work, will complement verbal or inferred consent from a clinical encounter to provide this legitimacy.

So what of the consent required for research in acute clinical care? The governance systems for research studies usually insist on specific, written consent, but where research forms an integral component of the clinical investigations, broad verbal consent may be a more appropriate recognition of autonomy. In our roundtable response to [McDermott et al’s paper](https://jme.bmj.com/), we suggest that the Human Tissue Authority’s (HTA) insistence on [specific written consent](https://jme.bmj.com/) in an acute diagnostic setting may actually do the opposite of what such type of consent aims to promote, and indeed also has the potential to cause harm. McDermott et al sought to research whether the rapid determination of a particular genetic variant on the neonatal intensive care unit was helpful in identifying babies who are predisposed to [permanent] deafness as a side effect of antibiotic treatment - treatment that is often commenced routinely soon after admission in this setting. A rapid result would enable different antibiotics to be utilised in the minority of children who have this genetic predisposition. Specific written consent for this test (from a parent) would not be practical, in part because a barrage of clinical tests and investigations need to be performed within minutes, so separating one test for a specific signed consent may slow down other crucial activities.

The HTA was set up following high profile organ retention scandals where it became clear that body parts and tissues had been retained in hospital departments often without relatives’ knowledge. Following a new [Human Tissue Act (2004)](https://www.gov.uk/government/organisations/human-tissue-authority), the HTA was set up to ensure that human tissue is used safely, ethically and with “proper” consent. Written consent from a “qualifying” relative is required in the context of *research* on DNA extracted from human tissue, in this case a parent, although for routine clinical care, verbal consent is appropriate. The issue of consent pertaining to the point of care test (POCT) being researched by McDermott et al is interesting because the DNA test in question has been available as part of routine clinical care for many years, but results were usually too slow to help guide urgent clinical care. Their research question is whether such a POCT allows more timely clinical decisions to be made, not which particular DNA variants cause deafness if certain antibiotics are used.

We therefore argue that broad, verbal consent for a package of care (that includes the POCT) is appropriate in this setting and that this is more likely to foster trustworthiness and “proper” consent than singling out the POCT for specific, written consent. We also contend that to insist on categorising an activity as either research or clinical practice, with different consent rules for each, is not feasible in many 21st century settings where [hybrid clinical research](https://www.tandfonline.com/doi/full/10.1080/14737159.2019.1672540) practices are commonplace.

What we can all agree on is that we that we want to ensure that patients or their proxies provide consent to an investigation, treatment or research participation. The difficulty of defining what this looks like in different contexts has been eloquently highlighted by others, including the impossibility of providing *all* the information about a particular activity, and that specificity will not necessarily improve the [quality of consent](https://www.cambridge.org/core/books/rethinking-informed-consent-in-bioethics/86303F0B7A7B1922DF91C7B1A8982957). A signature on a consent form is not a solution: actual consent is the evidence of autonomous decision-making and, as Grubb has helpfully asserted, might include “where the patient does not demonstrate his agreement providing that *the state of mind* was, in fact, that he agreed [and that]…unexpressed [*actual* consent is valid consent](https://global-oup-com.eres.qnl.qa/academic/product/principles-of-medical-law-9780198732518?lang=en&cc=in).’

Paper title:

# Using biomarkers in acute medicine to prevent hearing loss: should this require specific consent?

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None

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