Clinical uncertainty and the consequent ethical responsibilities for today's doctors

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Abstract

Clinical uncertainty continues to matter today, causing harm and waste in healthcare. Managing and resolving this through the empirical findings of research are the foundations of modern medicine's successes. Doctors therefore have an ethical duty to help contribute to the identification and resolution of clinical uncertainty through facilitating and contributing to research, a point clearly put in sharp perspective by the recent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Ethical codes support this, but endorsement is far from emphatic given its clinical importance and future revisions should urgently address this omission.

Keywords Clinical uncertainty; COVID-19 pandemic; ethical codes; medical education; medical research; research ethics

Medicine is a science of uncertainty and an art of probability.

William Osler

Uncertainty, current ethical codes and research

Clinical uncertainty matters to everyone. It has caused, and continues to cause, widespread major harm and waste. Empirical data derived from research have been the key to its resolution (*Viva la evidence* https://www.youtube.com/watch?v=QUW0Q8tXVUc) but we do well to remember that it is only in the last two centuries, as a charitable estimate, that doctors turned to research evidence to try to solve the many uncertainties in their medical practice and, as David Wootton wrote, stopped killing their patients. The subsequent successes of this approach now mean that healthcare and research are inextricably interwoven, with all the consequent benefits and tensions. The SARS-CoV-2 pandemic, with its accompanying uncertainties, indicates clearly that this complicated relationship will continue.

Yet, with scant reference to uncertainty and the limited duty to promote research, ethical codes do not fully recognize that the resolution of the uncertainties of medical practice is one of the major challenges for all today's healthcare practitioners. One reference can be found in the CanMEDS framework of the Royal College of Physicians and Surgeons of Canada (https://www.royalcollege.ca/en/canmeds/canmeds-framework/canmeds-role-scholar.html):

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Key points

- Clinical uncertainty continues to matter today, causing harm and waste
- Acknowledging, managing and resolving this uncertainty through the empirical findings of research are the foundations of modern medicine's successes
- Doctors have an ethical duty to help contribute to the identification and resolution of clinical uncertainty through facilitating and conducting research
- Ethical codes support this, but endorsement is far from emphatic given its clinical importance

Through their engagement in evidence-informed and shared decision-making, they recognize uncertainty in practice and formulate questions to address knowledge gaps.

One past reference in the UK General Medical Council 2005 guidance clearly placed a duty upon all those involved in healthcare to take this on and resolve uncertainty, but this was (for no clear reason) removed in the updated guidance:

Doctors must work with colleagues and patients ... to help resolve uncertainties about the effects of treatments. (para 14f) (https://www.bmj.com/content/346/bmj.f2626/rr/649454).

Promoting or contributing to research is at one end of the spectrum a clear duty (an obligation):

Physicians have a duty to promote research, and to create new knowledge and ensure its appropriate use. (American Board of Internal Medicine and European and Federation of Internal Medicine Physicians charter) https://abimfoundation.org/wp-content/uploads/2015/12/Medical-Professionalism-inthe-New-Millenium-A-Physician-Charter.pdf

While at the other end of the spectrum it is an exhortation to best practice, no more than an option:

A doctor should according to his or her competence contribute to the development and mediation of medical knowledge. (Norwegian Medical Association Code of Ethics for Doctors para 10 and 11 https://www.legeforeningen.no/om-oss/etikk/etiske-regler-koder-deklarasjoner-og-lignende/code-of-ethics-for-doctors-/).

All doctors should be encouraged to engage in the delivery of clinical research as part of direct clinical care. (UK General Medical Council Normalising research — Promoting research for all doctors https://www.gmc-uk.org/education/standards-guidance-and-curricula/position-statements/normalising-research—promoting-research-for-all-doctors).

However, contrary to these positions, a duty to identify and resolve personal uncertainty can be derived indirectly from other duties found in the following ethics codes and guidance:

• The duty to be clinically competent — unanimously, ethical codes and guidance make clinical competence a

clearly defined duty for practising doctors. If it is accepted that uncertainty has harmed patients, this logically must lead to a duty to identify and resolve any uncertainty a doctor meets in practice. Resolving uncertainty must, therefore, be a duty of competent practice.

- The duty to practice evidence-based medicine this requires doctors to seek best evidence to resolve uncertainty and then incorporate this knowledge into practice.
- The duty to continue learning one key goal of this is to develop the necessary skills to identify and resolve uncertainty and so provide care based on the best available evidence.

Codes have a cautious approach to research itself, focusing on the primacy of the participant (their individual rights) and their protection rather than the importance of, and ethical duty to promote, research to improve care. Paragraph 8 of the World Medical Association's Declaration of Helsinki states:

While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects. (https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/)

This simple statement hides a complex, subtle, balance, usually interpreted in favour of the research participant, with little consideration for patients who will benefit from any new knowledge derived from the research studies. Redrafted, might this be considered as:

While the primary purpose of medical research is to generate new knowledge to the benefit of current and future patients, this goal can never take precedence over the rights and interests of individual research subjects.

Setting us a far more difficult task of balancing the interests of both research participants and other patients.

How today's doctors can honour these ethical duties

Accept uncertainty in practice and be able to resolve it

The first step must be to acknowledge and address uncertainties in everyday practice, to learn to be comfortable with this as a normal companion of practice (which must, however, be challenged). This can be difficult, particularly early in a medical career when uncertainties may be blamed on ignorance and inexperience, with consequent attempts to hide or deny it. It is believed that there is one certain answer and, like the drowning man, the training doctor may cling to the life raft of the apparent certainty in medical texts. This approach got them through their undergraduate days and why the raft floated was of no concern. The apparent further certainty of exams on the way to consultant certification may not be the best preparation for further practice and its accompanying uncertainty. As a result, the practising clinician faces this 'broad medical uncertainty' ill prepared. How to address and resolve this must be incorporated into training so doctors can:

- define the uncertainty as a question
- search the current literature for best evidence to answer
- · critically appraise relevant studies
- integrate the evidence from these studies

- evaluate outcomes
- · share the results and experience.

Work with others

All individuals with legitimate interest — patients, public and professionals — should be involved in making decisions around healthcare, and this means that clinical uncertainty must be shared with others involved.³ Only in this way will care and research be aligned with the values and preferences of patient groups and the community. Many existing groups can help. Examples are the:

- National Institute for Health and Care Research INVOLVE initiative
- James Lind Alliance
- Patient Focused Medicines Development (PFMD) initiative
- European Patients' Academy on Therapeutic Innovation (EUPATI)
- European Communication on Research Awareness Needs (ECRAN).

Specialties also have their own groups. As an example, 'Generation R' is an alliance of UK Young People's Advisory Groups to support the design and delivery of paediatric health research in the UK to make sure that it is relevant to children, young people and their families. In these partnerships contributions should be:

- conscientious all must be willing to talk and listen with civility and respect
- evidence informed arguments should be supported by appropriate and reasonably accurate factual claims
- balanced arguments should be met by contrary arguments
- substantive arguments should be considered sincerely on their merits, not on how they are made or by who is making them
- comprehensive all points of view held should receive due attention and consideration
- transparent about the grounds for decisions
- with procedures for revising decisions in light of challenges.

Commit to continuing research

Research is now established as the most reliable way to resolve uncertainty and it must therefore follow that doctors have a duty to conduct and promote it. They can help by:

- knowing how to reliably access current literature in this way uncertainty can be resolved or deficits in current knowledge (and the need for further research) identified. Doctors can pay a key role in helping their patients do this as well
- telling patients about research, its importance and possible opportunities to participate surveys have shown that <20% of patients would feel confident enough to ask their doctor or medical specialist about taking part in a research study; however, clinicians are not yet very good at taking the lead and presenting research opportunities. The professional can actually be a barrier. The possible benefits for patients joining a research study (or at least the lack of harm) and the better outcomes in evidence-based

- and research-active units care would add empirical support to this argument.
- **contributing to research** this does not require the practising doctor to be the lead researcher with all its consequent demands in today's regulated research world (a role that requires specific training, resources, patience and humour). The SARS-CoV-2 pandemic has provided a model of how all can contribute so adaptive trials can be rapidly set up and completed to address the uncertainties that emerged from this new disease (the RECOVERY trial https://www.recoverytrial.net/). Doctors can play an important part in recruitment to these studies.
- **contributing to the oversight of research** looking back into past research disasters and misconduct it is evident that independent expert clinical or scientific review would

have been best able to identify and prevent the consequent harms. It would seem self-evident that this requires expertise; it is therefore crucial that today's doctors are willing and prepared to contribute their expertise to the oversight of research, while not drowning out other voices (doctors should wear their expertise lightly).

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