**A submission to the Cooksey Review by the Ethox Centre, University of Oxford**

The translation of medical science into clinical practice requires translation across two boundaries. It requires translation both *from the laboratory to the clinic*, that is, into the practice of health professionals, and also thereafter *from the clinic into the lives of patients* and their families. This second, essential phase of translation is often forgotten in the discussion of translational medicine. The success of these two phases of translation is however interlinked: public perceptions about the credibility and trustworthiness of scientific practice and its influence on the health service will, for example, be a key factor in the extent to which innovations are accepted not only by health professionals but also by patients.

Successful innovation and translation across each of these boundaries require high quality science and well-structured clinical services. They also require:

- The development of models of well-constructed and appropriate **law and guidelines**
- Good quality empirical evidence about the **social context** in which medical research takes place, and the social implications of proposed innovations
- Identification and analysis of the **ethical implications** of the science and/or the proposed innovation in the context of the empirical, economic and regulatory research

High quality ethical, legal and social science (ELSI) research can be a key facilitator of successful and appropriate translation of medical science into practice. It can:

- enhance evidence-based decision-making
- enable the development of appropriate and sensitive regulation
- anticipate and identify potential ethical, legal and social barriers to translation and make recommendations for how these might best be addressed

If basic and clinical research is to be translated into equitable and effective health care it is therefore crucial that close links are forged between scientists, clinicians and those working in ethics, law and the social sciences. Advances in medical science, as well as social, legal and political developments, lead to new ethical issues and new contexts for the delivery of health care. It is important that research is carried out into these ethical issues, and that this research takes place in close collaboration with medical scientists, health professionals and patients and is informed by high quality legal and social research. The absence of genuinely embedded ELSI research can undermine translation, leading ELSI issues to be identified and addressed post hoc. This has potential to lead to:

- Public distrust and negative public and media reaction
- Misunderstandings
- Poor clinical take-up
- Harms to patients and families
- Waste of resources and scientific effort

- Clinicians/scientists and policy-makers being unable to justify practice on ethical grounds when asked

We therefore believe that significant research funding for the ethical, social and legal issues relevant to medical research (both clinical and basic science) should be closely connected with funding for the medical research itself. To ensure high standards in science and clinical practice, and evidence-based value judgments, the ELSI issues must:

- be **identified** through empirical research and close working relationships between ELSI researchers and scientists, clinicians and patients
- be properly **analysed** by ELSI researchers who have a good working understanding of medical research and health care practice
- **inform practice** in research and clinical services through feedback, publication, training and policy development

It is our view that in order to ensure that the key priorities for health objectives referred to by the Cooksey consultation are met, consideration of ethical, social and legal matters should be included at all stages of the development and implementation of health innovations.

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