MMR and the development of a research governance framework in UCL

1. Introduction

In May 2010, the General Medical Council found Dr Andrew Wakefield guilty of serious professional misconduct and erased his name from the medical register[i]. The GMC's findings related mainly to his clinical misconduct, notably through unnecessarily causing three young and vulnerable children to undergo the invasive procedure of lumbar puncture; and through collecting blood from a group of young children at a birthday party. However, the GMC Panel also raised a range of issues relating to Dr Wakefield's research conduct.

A journalist working for the Sunday Times suggested in a series of articles published in the BMJ in January 2011 that the GMC's findings amount to evidence of research fraud[ii]. The BMJ called on UCL to investigate these claims. UCL was conscious that any such investigation should be independent, robust, fair both to the initiator of the complaint and to the respondent(s), and conducted according to a transparent process. To that end, detailed advice was sought from the UK Research Integrity Office in respect of the scope, remit and processes for such a review. That advice in turn prompted a range of further concerns about the feasibility of any such inquiry, given the passage of time since the initial allegations. Independent advice was sought from a senior legal figure and the prospect of a detailed inquiry into alleged research fraud rejected for a number of reasons.

In essence, it was concluded that UCL would lack sufficient authority to require respondents or potential witnesses to contribute to any hearing or to provide evidence to inform the inquiry's processes, as the majority of the main characters are no longer in UCL's employ. Lacking any legal powers of compulsion, UCL would likely encounter reluctance or refusal to contribute from one or more respondents. Secondly, there is no formal complaint or complainant to trigger th s encou.--6.7 (o t)-6.7 (r)-5.9J 0 -1u.--6.7(es)8.9 (,)4.2 (-2nr)-5.9Jh1t -2nrcuiryt,1. evidence may be affected by failing memory. Although there is a good body of written evidence relating to the events in question still available (not least the documents made available to the GMC inquiry), documentary and laboratory materials relating to specific research projects and publications will be unlikely to be complete (or be obtainable by any such inquiry). The net result would likely be an incomplete set of evidence and an inconclusive process costing a substantial sum of public money.

However, the GMC's findings have serious implications both for UCL's own internal research governance and processes and for the research governance policies of health and higher education institutions across the UK and beyond. This paper will examine those issues and their implications for research governance policy and practice. It will look at how UCL has responded to date to the challenges of the incident and its aftermath and will attempt to draw some more general conclusions that may be of value to the wider scientific community.

Due to the informal nature of this process, no written note was taken of the meeting. In the week that followed, the Vice-Dean met again with staff engaged in the research in the department of Paediatric Gastroenterology where they examined the children's records and the relevant biopsy book and ethics committee records.

As this was an informal inquiry, the process lacked the usual features of an effective investigation of a complaint of misconduct. There were no terms of reference set out, no defined investigatory panel, no gathering of documentary evidence, no formal presentation of allegations nor any representation from the complainant himself. Two of those accused of misconduct were involved in the process of gathering the evidence from the children's files, which would not now be permitted under UCL's formal procedures. The rapid, informal investigation culminated in written statements being provided by the staff involved and by the Vice Dean on behalf of the Medical School. These statements were subsequently published in the Lancet in March 2004 and confirmed that aspects of funding, ongoing litigation, and overlap of children with another Legal Aid Board funded pilot project were not, and should have been, disclosed to the journal.[iv]

3. UCL Research Governance Framework 2004 to the present

UCL Research Governance is enshrined in three documents: the *code of conduct for research*; the *procedure for investigating and resolving allegations of misconduct in academic research*; and the *declaration of interest policy*[v]. Although these or equivalent policies were in place by 2004, all three have also undergone significant revision since then.

Together, the documents constitute a framework to support UCL's research strategy and to ensure that research conducted by members of staff, honorary staff, students and individuals who collaborate with UCL conform to good practice and ethical expectations. The research

If Wakefield's case were to have emerged in 2012, UCL would expect the journalist's concerns to have formally been expressed as a complaint, triggering an investigation under the *procedure for investigating and resolving allegations of misconduct in academic research.* In brief summary, the procedure requires that any allegation of research misconduct sh-6 (a) 4.435 0da007 Tbem tng an ion 2.7 (g)-io ton ai6 (e)]TJ -0.00d .6 (')2.6 (-6.6 (i)2.2 (r).6

4.2 The grant from the Legal Aid Board was used for purposes other than those originally agreed (for example, funds were used to support staff costs rather than, as stated, for diagnostic tests). Most grant funding bodies permit some defined, limited divergence in expenditure from the approved grant application, provided the change is justifiable and does not compromise delivery of the grant objectives. Nonetheless, the scope for unauthorised divergence was deemed greatest for awards held outside the formal grants administration system, and this issue was subjected to the audit set out in 4.1 above.

4.3 Wakefield violated conditions attached to his honorary contract of employment with the Royal Free Trust. This is an area where, nationally, procedures have been improved substantially since 2004. Nonetheless, the decision about conditions for honorary contracts is taken by NHS Human Resources departments and does not link to an understanding of the study protocol in question; nor can staff whose Trust honorary contract relates solely to research (rather than clinical) activity be readily identified. In response, UCL has set in motion a review of job planning and appraisal arrangements

excessive controls on the approval process. That same balance is one that challenges every UK organisation involved in biomedical research.

5. Good practice lessons

UCL's specific experience of the MMR issue reflects the general need for all institutions engaging in biomedical research to have in place a robust and effective research governance infrastructure. Some of the key lessons prompted by UCL's experience include:

5.1 The need for policies and procedures to be clear and comprehensive, setting out in detail the notification of concerns, preliminary vetting of allegations and the escalation of complaints to a relevant second-stage panel (or other body). That panel requires a membership that is appropriately skilled to consider the

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5.5 New scientific discoveries are regularly embraced by – and contribute to the welfare of – our society. It follows that society has a significant stake in the ethics and activities of its scientists. Particularly at the frontiers of science, public involvement is critical to the building of greater trust between society and its researchers and academic institutions ignore that involvement at their peril. It is incumbent on institutions to embed into their governance procedures a clear and prominent role for the consideration of matters of public interest and to subject such matters to particularly careful and focused scrutiny.

5.6 Institutions have a second responsibility which is to the wider promotion of science. Governance procedures must be clear, robust and well communicated, but they must also avoid any inhibition of legitimate scientific investigat5 (g)-11.s/.6 (on(d36 (s)-2 (e)-5.9eons)-2 (i)2.6

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governance processes and procedures are properly embedded into the management infrastructure of the organisation.

Secondly, to test and re-test those procedures (whether called upon in practice or not) to ensure that they are robust and workable (without impeding legitimate academic research aspirations), and reflect best practice from other organisations. To that end, institutions should be encouraged to think self-critically about their own framework, to review processes and procedures annually, and to share anonymised cases with other related organisations. Only by consciously and actively raising the profile of research governance issues across - as well as within – institutions, will the UK biomedical sector develop a framework that is truly fit for purpose. UCL is committed to working with the research community - including our NHS partners, other universities and UKRIO - to achieve this.

[i] GMC, Andrew Wakefield: determination on serious professional misconduct and sanction, 24th May 2010

[ii] Deer, B, How the Vaccine Crisis was meant to make money, BMJ 2011, -39.anieec 0 Tw 34.717 1812 3- T