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Research Fraud and Misconduct

The incidence of research fraud and misconduct is at least 4%. It is estimated that 2% of all published papers should be withdrawn whereas only 0.2% are retracted[1]. Fraud reflects intent while misconduct covers a wide range of activities from carelessness to issues such as relevant data omission. Misconduct is described as being pernicious in nature and its effects can be profound. The consequences are that it can undermine public trust, misdirect funding, damage reputations, and risk public health and welfare. Flawed research can lead to bias in systematic reviews and erroneous clinical guidelines leading to patient harm. The absence of an agreed definition of research misconduct is a major challenge. It is difficult to determine between the difference between honest errors and poor research practice.

These issues were highlighted by an article in the Guardian earlier this year[2]. It stated that medical research is being compromised, drug development hindered, and promising research is being jeopardised due to a global wave of sham science. COPE (Committee of Publication Ethics) have issued its concerns about paper mills[3]. It states that paper mills are a threat to the integrity of scholarly record. Paper mills are the process by which manufactured manuscripts are submitted to a journal for a fee on behalf of a researcher.

UKRIO (UK Research Integrity Office)[4] has produced a working party report in May this year. The organisation established in 2006 aims to promote good governance in the conduct of medical research. It provides guidance on how to address poor research practice. It promotes and gives confidence to those involved in good research. It is committed to supporting research work of the highest integrity, quality, and efficacy. It begins by pointing out that research organisations are responsible for good practice in research being carried out under their auspices. It is important to increase the clarity and confidence in the processes and expectations for all those involved in research. Allegations of research misconduct should be taken seriously and investigated by the supervising organisation. It is more about destigmatising research misconduct and concentrating on putting the research programme back on track. More neutral terminology is recommended including initiators instead of complainants, and breaches of good practice instead of allegations of misconduct.
From the outset it is accepted that honest errors and differences in research methodology do not constitute research misconduct. The importance of a good research culture with better connectivity between research groups is encouraged. The Australian model is to shift the focus to correcting errors as it helps to raise concerns at an earlier stage.

The concordat to support research integrity is the UK's national policy statement that has been developed with the assistance of the UKRIO. Its 5 principles are –

a) upholding the highest standards of rigour and integrity in all aspects of research,

b) ensuring that research is conducted according to appropriate standards,
c) appropriate support for the research environment,
d) using timely, robust and fair processes, and
e) working together to strengthen research integrity.

A numbers of terms are defined. Fabrication is the making up of results. Falsification is inappropriately manipulating or selecting research processes. Plagiarism is the use other people's ideas, intellectual property , or written work. The fourth issue is failure to meet legal, ethical, and professional obligations include factors such as not obtaining proper consent, breach of duty of care for participants, misuse of the patients data, and non-disclosure of conflicts of interest. The fifth issue is misrepresentation of data in the presentation of a flawed presentation of the research findings.

It has long been recognised that organisations have struggled on how to deal with allegations of research misconduct. The sheer resource implications required to investigate a case are immense and involves drawing specialists away from their busy work schedules. It is a challenge to separate an honest mistake from research misconduct. Intentionality is very difficult to define.
Preventing research fraud is much more preferable to identifying and sanctioning it. This approach involves taking a number of important measures[5]. Researchers should be provided with a structure of proper supervision governance and guidance. The research project should be reviewed step-by-step. Outlying or surprise findings should receive added scrutiny. It should be continually emphasised that research integrity is the number one goal rather than publication at all costs. Research integrity is defined as doing research according to high professional and methodological standards. Institutions must provide their researchers with research integrity training and education. The specific needs differ between trainees undertaking a higher degree and post-doctorate senior researchers. The former require supervision policies, guidelines and positive interaction with their supervisor. The latter require support in the development of the strategic direction of their research and how to collaborate effectively with other research groups. Isolation must be actively avoided as it adversely affects research quality and meaningful output.

Governing bodies such as the medical councils give more general guidance. The GMC states that the research must be based on a properly developed protocol that has been approved by an ethics committee. There must be proper informed consent and confidentiality of the patient's personal information. The safety, dignity, and well being of the participants is paramount. The anticipated benefits of the research should outweigh the potential risks of the intervention. Conflicts of interest are of particular importance in relation to drug trials.

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Medical research should be undertaken and performed to the same standards as clinical practice. Researchers should be trained in the basics of research science. All data should be accurately recorded and be readily available for scrutiny. No data should be omitted. There should be clear lines of communication with the researcher's supervisor. The aim is to produce a high quality piece of work irrespective of whether or not it fits with the initial hypothesis. Properly conducted research with a negative result is an important contribution to medicine as it helps to prevent the adoption or continuation of useless therapies.

JFA Murphy,
Editor.

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