Paper 3: Increasing value and reducing waste in biomedical research regulation and management

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On behalf of the authors

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Three ways in which research regulation is compromising the interests of patients

1. Promulgation of double standards on informed consent to treatment

2. Acquiescence in unnecessary and poorly designed research

3. Failure to take steps to reduce biased under-reporting of research

Iain Chalmers

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- Regulation and legislation
- Governance and management

Responsive –
Reactive –
Protective
Effective??

- Ethical practice demands that clinicians seek to resolve uncertainty
- Ethical research demands that individual consent is obtained if a treatment is determined by a research protocol
- EU clinical trial regulations demand that individual consent is obtained, even if the study design is cluster randomisation

Consequences

‘***permission*** to give a treatment to half his patients (-), but that he did not need permission if he decided to give the treatment to all his patients (-)

Ref 14 Smithells

Current research regulation is obstructing the professional duty to help resolve uncertainties about the effects of treatments – Iain Chalmers

The evidence base----

‘ in view of the extent of waste and inefficiency that we report in the regulation and management of research worldwide, we are surprised by the paucity of qualitative and qualitative research documenting and investigating solutions to it—’

Recommendation 1

People regulating research should use their influence to reduce other causes of waste and inefficiency in research

Recommendation 2

Regulators and policy makers should work with researchers, patients and health professionals to streamline and harmonise the laws, regulations, guidelines and processes that govern whether and how research can be done, and ensure that they are proportionate to the plausible risks associated with the research

Recommendation 3

Researchers and research managers should increase the efficiency of recruitment, retention, data monitoring, and data sharing in research through the use of research designs known to reduce inefficiencies, and do additional research to learn how efficiencies can be increased

Recommendation 4

Everyone, particularly individuals responsible for health-care systems, can help to improve the efficiency of clinical research by promoting integration of research in everyday clinical practice

Conclusions

- Less research is done
- Research too late to matter or be relevant
- Participant retained in studies that will not answer the questions
- Professionals deterred from careers in research
- Everyone involved in research should be accountable for the efficiency and effectiveness of their research – it is a collective responsibility

Progress and solutions in the UK

- **The IRAS partnership**
- **Agreements and defined boundaries across regulators**
- **NIHR**
- **One ethics committee approval**
- **Health Research Authority**

[Integrated Research Application System
National Institute for Health Research]

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