Improving Value and Reducing Waste in Research

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Objectives

• Tell a couple of stories about the emergence of ‘research waste’ and ‘adding value’ as concepts
• Introduce the main themes in these concepts
• Broaden the focus of these concepts
• Consider more systemic sources of waste
• Predict the end of civilisation
The classic story

The 4 C’s:
Context, Conflict, Climax, Closure

Main character and supporting characters

A crisis arises disturbing the main character’s world view and sense of self

The character takes action and resolves a series of challenges (the plot)

These actions result in a resolution of the main character’s crisis and a resetting of their world view
Characters

The 4 C’s:
Context, Conflict, Climax, Closure

Iain Chalmers

Paul Glasziou
Conflict

• 85% of healthcare research activity is ‘waste.’

• much research confers no discernible benefit to people in need of health care, carers and the professionals who deliver it
Conflict
Nice story….but

‘The Hero’s Journey’

Common narrative structure if we want the audience to adopt a new idea
The New Idea?

From research waste...

...to adding value
Research Waste

Questions relevant to clinicians and patients?
- Low priority questions addressed
- Important outcomes not assessed
- Clinicians and patients not involved in setting research agendas

Appropriate design and methods?
- Over 50% of studies designed without reference to systematic reviews of existing evidence
- Over 50% of studies fail to take adequate steps to reduce biases—e.g., unsealed treatment allocation

Accessible full publication?
- Over 50% of studies never published in full
- Biased under-reporting of studies with disappointing results

Unbiased and usable report?
- Over 30% of trial interventions not sufficiently described
- Over 50% of planned study outcomes not reported
- Most new research not interpreted in the context of systematic assessment of other relevant evidence

Research waste
Ensuring Value in Research (EVIR)

### Relevance and expressed need
- Set justifiable research priorities
  - Priorities are set involving those who use and are affected by health research
  - New research should be set in the context of a systematic review or rigorously determined evidence gap

### High quality research that minimises bias
- Design, conduct and analysis are robust and appropriate
  - Designed using advances in research methods and taking steps to reduce bias
  - Studies registered at inception
- Regulation and management are proportionate to risks
  - Actively manage research in a risk proportionate way
  - Protocols, methods and materials should be made available early

### Open and transparent research and research funding
- Complete information on methods and findings are accessible and usable
  - Methods, interventions and findings reported in full
  - Support replication and reuse of data
- Findings are appropriately and effectively disseminated
  - Findings should be set in the context of previous evidence and systematic reviews
  - Disseminate knowledge to end users. Usage of new knowledge should be supported and facilitated
Value = useful

• Usefulness:
  • answering a priority question
  • using the correct design to answer the question
  • in a timely (rapid) manner
  • to test interventions
  • that may improve health and healthcare
  • published openly, in full, unbiased
MRC Framework for Evaluating Complex Interventions

Kathryn Skidmore, Lynsay Matthews, Sharon Anne Simpson, Peter Craig, James Baird, Jane M Blundell, Kathleen Anne Boyd, Neil Craig, David P Franch, Emma McIntosh, Mark Petticrew, Jo Yogaft-Mallan, Martin White and Laurence Moore

A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance.

Complex interventions are commonly used in the health and social care services, public health practice, and other areas of health and economic policy that have consequences for health. Such interventions are delivered and evaluated in different contexts, often in a multifaceted manner. Examples include new policy interventions, the implementation of a healthcare programme, and a change in national policy. The UK Medical Research Council (MRC) published a framework for researchers and research funders on developing and evaluating complex interventions in 2000. This update document contains amendments to the original framework and describes how the framework should be used.

Summary Points

- Developing a new framework is necessary to ensure that interventions are evaluated effectively.
- The new framework provides a structured approach for evaluating complex interventions.
- The framework takes into account recent developments in theory and methods and the need to maximise the efficiency, effectiveness, and impact of research.

Development of the Framework

The original framework was developed in consultation with stakeholders and researchers. The update framework was developed by revising and updating the original framework, and includes new guidance on evaluating complex interventions in different contexts.

- A gap analysis to identify developments in the methods and practice since the previous framework was published.
- A full day expert workshop, in May 2016, of 36 participants to discuss the topics identified in the gap analysis.
- The framework was refined in April 2017, when stakeholder workshop by the Advisory Group on Social Media, Social Science and the Internet.
- Further development work was completed in 2019, and the updated framework was published in 2021.

The update framework provides a comprehensive guide to evaluating complex interventions, and is intended to support researchers and funders in developing and evaluating such interventions.
MRC Framework for Evaluating Complex Interventions

Core Elements:
- Consider context
- Develop, refine and (re)test programme theory
- Engage stakeholders
- Identify key uncertainties
- Refine the intervention
- Economic considerations

Feasibility:
Assessing the feasibility and acceptability of the intervention and evaluation design in order to make decisions about progression to the next stage of evaluation.

Evaluation:
Assessing an intervention using the most appropriate method to address the research questions.

Implementation:
Deliberate efforts to increase the impact and uptake of successfully tested health innovations.

Develop the intervention:
Either developing a new intervention, or adapting an existing intervention for a new context, based on research evidence and theory of the problem.

Identify the intervention:
Choosing an intervention that already exists (or is planned), either via policy or practice, and exploring its options for evaluation (evaluability assessment).
Throughout, [they] emphasise *usefulness [value]* of evidence, rather than bias minimisation, as the key goal of complex intervention research and the main criterion for prioritising research questions and making methodological choices.
Research waste and adding value

Main themes in these concepts
What makes a problem a priority?

- Problem epidemiology (incidence etc.)
- Problem burden (HRQoL etc.)
- Clinical and/or patient priority
- Systematic reviews?
- Clinical or other guidelines exist/have gaps
- Cost burden
- Timing?
- Tractability?
- Potential impact…
Importance of Systematic Reviews

- Antman et al. 1992 *JAMA* Cumulative Meta-Analyses of 33 Trials of Intravenous Streptokinase for Acute Myocardial Infarction
- In 1973, after 7 trials and 2,432 participants the case for thrombolysis was proven
- Between 1973 and 1988 34,542 participants were unnecessarily included in another 26 trials
- Some of these participants died by being randomised to a non-thrombolysis group
Why do high quality research methods matter?

The importance of reporting quality

The EQUATOR network now has 580 reporting guidelines!
The importance of reporting quality

**RESEARCH METHODS & REPORTING**

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide

Tammy C Hoffmann associate professor of clinical epidemiology\(^1\), Paul P Glasziou director and professor of evidence based medicine\(^2\), Isabelle Boutron professor of epidemiology\(^3\), Ruairidh Milne professorial fellow in public health and director\(^4\), Rafael Perera university lecturer in medical statistics\(^5\), David Moher senior scientist\(^6\), Douglas G Altman professor of statistics in medicine\(^7\), Virginia Barbour medicine editorial director; PLOS\(^8\), Helen Macdonald assistant editor\(^9\), Marie Johnstone emeritus professor of health psychology\(^10\), Sarah E Lamb Kadokie professor of trauma rehabilitation and co-director of Oxford clinical trials research unit\(^11\), Mary Dixon-Woods professor of medical sociology\(^11\), Peter McCulloch clinical reader in surgery\(^11\), Jeremy C Wyatt leadership chair of ehealth research\(^11\), An-Wen Chan Phelan scientist\(^14\), Susan Miche professor\(^15\)

### TIDieR (Template for Intervention Description and Replication) Checklist:

<table>
<thead>
<tr>
<th>Item number</th>
<th>Brief name</th>
<th>WHO PROVIDED</th>
<th>WHERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Provide the name or a phrase that describes the intervention.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Describe any rationale, theory, or goal of the elements essential to the intervention.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WHEN and HOW MUCH**

- Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.

**TAILORING**

- If the intervention was planned to be personalised, élaborated or adapted, then describe what, why, when, and how.

**MODIFICATIONS**

- If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).

**HOW WELL**

- Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.

- Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.
But are these ideas too narrow?
Defined by something it is not?

- If Adding Value is merely *not being wasteful*, is it really a ‘thing’?
  - Or actually an ‘anti-thing’

- See atheism, amoral, ethnic minority etc.
Mainly about experimental research

Austin Bradford Hill

... I have no wish, nor the skill to embark upon a philosophical discussion of the meaning of 'causation'
Mainly about experimental research

1. Consistency
2. Specificity
3. Temporality
4. Biological gradient
5. Plausibility
6. Coherence
7. Experiment
8. Analogy

Bradford Hill “causation” criteria

1. Consistency: Same finding observed by different persons in different places with different samples.

2. Specificity: Causation is likely if seen in a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship.

3. Temporality: The effect has to occur after the cause. If there is an expected delay between the cause and expected effect, then the effect must occur after that delay.

4. Biological gradient: Greater exposure should generally lead to greater incidence. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence. Sometimes called the “dose-response” effect. Can be “U” shaped.

5. Plausibility: A plausible mechanism between cause and effect is helpful, but not required.

6. Coherence: There is coherence (agreement) between epidemiological and laboratory findings.

7. Experiment: Relationship can be investigated in an experiment. Not always possible.

8. Analogy: The effect of similar factors may be considered.
Assumes dissemination will lead to implementation

The “leaky” research pipeline

Research waste 1
Chalmers & Glasziou. Lancet 2009;374:86-9

>50% designed without reference to systematic reviews of existing evidence
>50% has avoidable research flaws / biases
50% of research is never published in full
50% is unusable or incompletely reported or both

Research waste 2

% sustainability?
As little as 14% of evidence is ever implemented

It takes a mean of 17 years to get research evidence implemented

SUPPORTED BY
National Institute for Health and Care Research
University of Exeter
Implies *individual researchers* are the wasteful actors

- What about systemic waste?
  - The type of research
  - Grant award systems
  - Peer review
  - Research methods education in universities
  - Elite overproduction…
# Type of Research

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<th>Method</th>
<th>2010 (n=223)</th>
<th>2013 (n=254)</th>
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</thead>
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<tr>
<td></td>
<td>n</td>
<td>%(*)</td>
</tr>
<tr>
<td>Secondary</td>
<td>33</td>
<td>13.4%</td>
</tr>
<tr>
<td>Primary</td>
<td>193</td>
<td>88.0%</td>
</tr>
<tr>
<td>Observational</td>
<td>187</td>
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<tr>
<td>Qualitative</td>
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<td>39.0%</td>
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<tr>
<td>Quantitative</td>
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<td>44.8%</td>
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<tr>
<td>Experimental</td>
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<td>11.7%</td>
</tr>
<tr>
<td>Type 1: RCT</td>
<td>10</td>
<td>4.5%</td>
</tr>
<tr>
<td>Type 2: nRCT</td>
<td>4</td>
<td>1.8%</td>
</tr>
<tr>
<td>Type 3: UCT</td>
<td>12</td>
<td>5.4%</td>
</tr>
</tbody>
</table>

Richards et al, WEBN, 2014; 2018

*% not equal to 100% as some reports included more than one method
Grant Award Systems

- Relentlessly competitive (in general)
- Example
  - Horizon Europe Health Cluster Patient Safety call 2021
- Costs per application?
  - 12 consortium partners, 32 named researchers, 12 partner meetings plus multiple internal meetings, 4 months writing and preparation, 45 pages plus administrative forms, 35,000 words, costs €€€€€€€
- Outcomes?
  - 43 applications (1.5m words; 344-516 organisations; 860-1290 personnel)
  - Five funded, several others ‘fundable but not affordable within allocated budget’
  - Value to waste ratio: 12:88
Peer Review

- Where do we start!
  - It doesn’t matter whether behind a paywall or ‘open’, academics pay exorbitant fees to publish and read their own (publicly funded) research
  - Publishers use free academic labour to peer review and edit journals and articles
  - Academic publishers’ profit margins are around 36% (higher than Apple, Google etc.)
  - The taxpayer picks up this cost
  - Does not prevent (encourages?) scientific misconduct – see Elisabeth Bik’s Wikipedia page and recent harassment by Didier Raoult regarding dubious conduct of COVID-19 hydroxychloroquine study
Research methods education in universities

- Does post-graduate research education lead to better value research?
  - Example 1: the UK NIHR-funded ‘MRes’ for nurses and non-medical health workers
  - Example 2: PhD education as academic apprenticeships
    - How many PhD graduates go on to have a research career?
Elite overproduction and the ‘End Times’

• Is research waste actually just another symptom of the end of our civilization?
Elite overproduction and the ‘End Times’

• Analysis of 100 historical crises
• Three consistent factors
  – Decline in wages
  – A wealth pump
  – Elite overproduction
• All three factors in universities as well as society
In summary

• The emergence of ‘research waste’ and ‘adding value’ as concepts has shaped a lot of current evidence-based practice orientated research worldwide.

• A broader analysis of systemic sources of waste persuades us to expand the adding value movement beyond this specific focus.

• However, according to Peter Turchin, are we all just doomed anyway?