Preventing biomedical research waste

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Abstract

An estimated 85% of efforts in biomedical research are wasted due to inefficiencies. This wastage represents a global financial loss of greater than US$200 billion per year, a barrier to practicing evidence-based medicine, and a considerable amount of carbon emission. Inefficiencies exist throughout the research life cycle, from strategic planning, design, execution, reporting, and publication. Medical writers and communicators are well-positioned to help prevent research waste and mitigate adverse effects on planetary health through actions related to good research practice, data stewardship, responsible reporting, and open science.

Introduction

An estimated 85% of biomedical research efforts are wasted due to inefficiencies, many of which are preventable. These inefficiencies span the life cycle of biomedical research from strategic planning, design, execution, reporting, and publication. Research waste represents a financial loss greater than US$200 billion globally per year and it interferes with the aim and practice of evidence-based medicine.[1,2] Considering the significant carbon footprint of the healthcare industry,[3,4] this wastage also has a considerable impact on planetary health.[5]

At the strategic planning stage, for example, research waste can occur when researchers ask questions or collect data on outcomes that are not relevant or necessary to clinicians and patients. This is compounded at the design stage when new studies are not informed by systematic reviews of the existing evidence, a shortcoming that has been noted in more than 50% of studies.[6] Research waste can also occur when study designs do not take adequate steps to reduce sources of bias. Other examples of research waste include the failure to fully publish study results, poor reporting, and the inability to re-use data. Given that relevant and essential research is the foundation of evidence-based medicine and healthcare, biomedical research waste translates into foregone benefits such as preventing illness or death, curing disease, promoting wellness, and fostering innovation. Furthermore, redundant studies translate into people and animals being unnecessarily exposed to risk and experimental procedures.[2]

In recent years, the issue of biomedical research waste has been gaining attention. The purpose of this article to provide an overview of various strategies to prevent research waste and how medical writers and communicators (MWCs) may contribute to these efforts.

How can we prevent research waste?

Four interlinked strategies that can help prevent research waste and contribute to a sustainable future are good research practices, data stewardship, responsible reporting (including transparency and disclosure), and open science (Figure 1). In this section, we discuss each of these strategies.

Good research practices

Good research practices help prevent research waste by ensuring that relevant and necessary questions are addressed by research efforts, and

that appropriate methodological standards (e.g. Good Clinical Practice[7]) are followed. Good research practices also encompass timely and accurate registration of study protocols, and such registration is linked to responsible reporting, transparency, and public disclosure.

Informing new research based on a synthesis of earlier research is a cornerstone of the scientific process; however, in practice, this is unfortunately not always the case. For example, an analysis of phase III randomised controlled trials published in 3 high-impact journals, (*The New England Journal of Medicine*, *Lancet*, and *JAMA*) between 2016 and 2018 indicated that less than half of the randomised control trials justified their undertaking with a systematic review.[8] Low rates of justifying research based on systemic review findings have also been reported in high-impact journals for orthopaedic trauma (between 2015 and 2018; 33%),[9] urology (between 2014 and 2019; 54%),[10] and ophthalmology and optometry (until 2018; 22%).[11]

> Research waste represents a financial loss greater than US$200 billion globally per year, interferes with evidence-based medicine, and has a considerable impact on planetary health.

To address this source of research waste, along with the continued failure of published studies (48.6%) to assess new research findings in the context of existing evidence,[12] an international network to promote evidence-based research (EBR) was established in 2014. EBR is defined as "the use of prior research in a systematic and transparent way to inform a new study so that the research is answering questions that matter in a valid, efficient and accessible manner." The EBR approach also includes consulting clinicians and patients to determine what are relevant and necessary research questions and clinical outcomes.[13]

While research funders and regulators have key roles in ensuring the EBR approach is implemented in practice,[14] MWCs who are involved in grant applications can also contribute. For instance, while funders currently differ with regards to explicitly justifying the need for new studies based on systematic reviews,[15] MWCs can act as early-adopters and educate their colleagues or clients on EBR and advocate for this approach. Furthermore, MWCs have a critical role in writing clear study protocols that adhere to good research practices, ensuring timely and accurate registration of study protocols, and implementing good documentation practices (Table 1).

Data stewardship

Stewardship refers to caring for and managing a resource. Data stewardship is an essential component of sustainable research practices and in recent years, it has become embedded in the requirements of research funders and scientific journals.[16]

In practice, data stewardship involves establishing procedures for managing data before, during, and at the end of a research study, and ensuring that data are FAIR (findable,

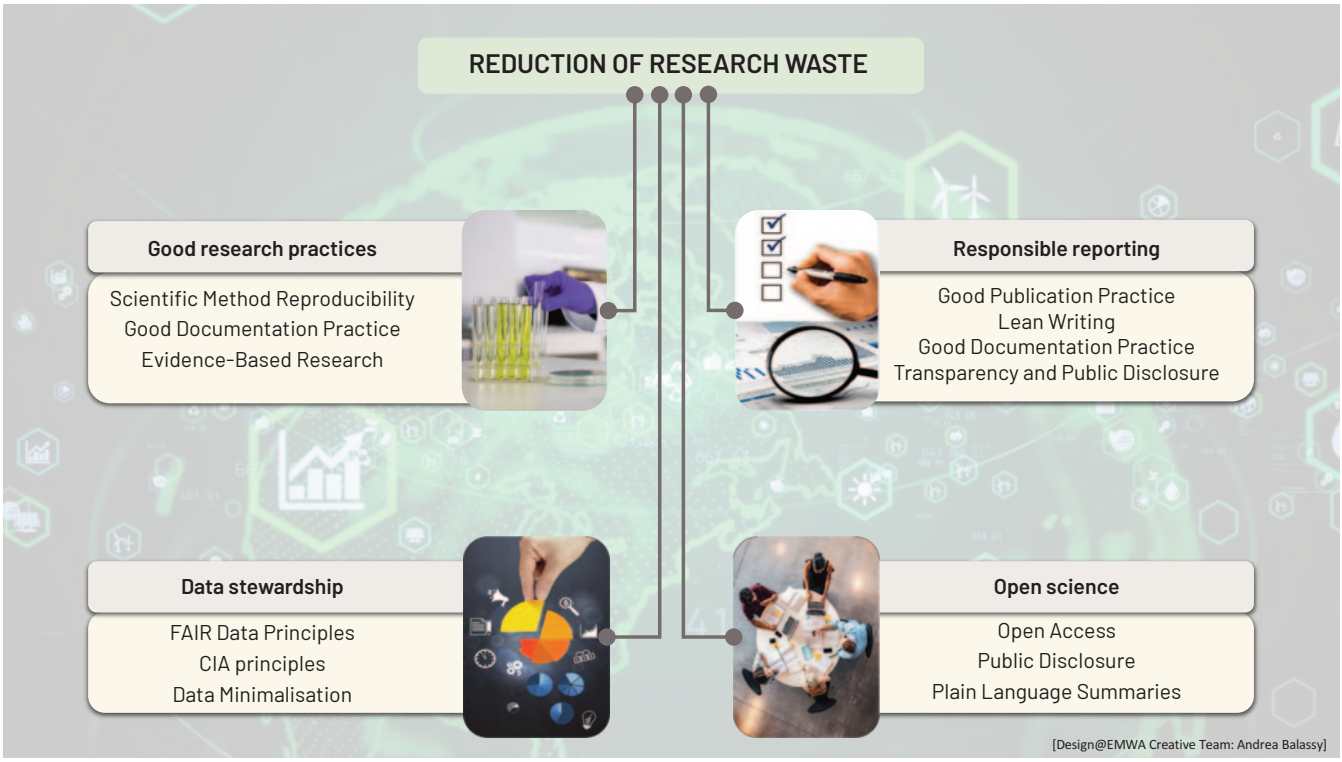

Figure 1. A schematic representation of how the reduction of research waste is based on actions/policies/standards related to good research practices, data stewardship, responsible reporting, and open science

Abbreviations: CIA = confidentiality, integrity, accessibility; FAIR = findable, accessible, interoperable, reusable.

accessible, interoperable, and reusable) for humans and machines. It also involves meeting legal and ethical requirements for upholding confidentiality and privacy of participants as well as ensuring that the wish of patients to have access to their own data and have their data reused are fulfilled.[17,18]

Benefits of good data stewardship include increased research transparency and ease of replication, and accelerated discovery and innovation as data sharing is possible and feasible. Good data stewardship goes beyond individual researchers and involves organisations. An illustration of this is the recent collaboration to improve the interoperability between two key clinical terminology vocabulary systems: the Systematised Nomenclature of Medicine – Clinical Terms (SNOMED CT), which is used by physicians and other healthcare providers; and Medical Dictionary for Regulatory Activities (MedDRA), which is used by regulatory authorities such as EMA. Thanks to this commitment, SNOMED-based data in electronic health records/databases and MedDRA-based data in regulatory databases can be exchanged seamlessly from one to the other. As such, for example, adverse event data in electronic health records can now be converted into MedDRA and used by EMA for pharmacovigilance tasks; conversely, adverse event data in MedDRA can be converted into SNOMED CT and used to inform clinical decision-making.[19]

Finally, data stewardship also means data minimisation, that is, only data that are necessary for the research purpose should be collected.

The European Health Data Space (EHDS) is another example of data stewardship. It "aims to make full use of digital health to provide high-quality healthcare and reduce inequalities. It will promote access to health data for prevention, diagnosis and treatment, research and innovation, as well as for policymaking and legislation."[20] Finally, data stewardship also means data minimisation, that is, only data that are necessary for the research purpose should be collected. Less data means less computing power is needed for storage and analyses.

While MWCs may not be directly involved in data collection and management per se, they can ensure that data stewardship is considered in the study design and that requirements regarding FAIR data management practices are adequately addressed in grant applications. MWCs can also provide the public with accurate information about data sharing and address concerns about confidentiality and privacy. Furthermore, when writing laboratory manuals and study protocols, MWCs can advocate for data minimalisation to ensure that only absolutely necessary data and samples are collected (Table 1).

Responsible reporting

Responsible reporting, transparency, and public disclosure are closely intertwined when it comes to dissemination. Dissemination of research results regardless of the outcomes is one of the ethical principles written in the Declaration of Helsinki.

> *Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and*

Table 1. Recommended actions for medical writers and communicators to help prevent research waste

Strategy	Recommended Actions	
Good research practices	• Advocate for scientifically sound, efficient clinical trials • Advocate for following the EBR approach • Adhere to the GCP principles	• Advocate for clear and easily implementable protocols • Ensure timely and accurate registration of study protocols • Follow good documentation practices
Data stewardship	• Advocate for data minimisation • Educate clients on adherence to FAIR data management as part of funding requirements	• Educate public/patients about FAIR data management through medical communications
Responsible reporting	• Ensure timely posting of results publicly • Write clear, accurate, fit-for-purpose documents • Protect personal data through proactive anonymisation, thereby producing "redaction-friendly" documents	• Practice "lean writing" • Follow good documentation practice • Extend reach to patients and public via plain language summaries
Open science	• Report scientific information accurately and responsibly • Advocate for publishing negative results • Develop a publication plan • Advocate for publication in open access journals	• Adhere to reporting guidelines (EQUATOR) • Avoid predatory journals • Adhere to good publication practice, including transparency of involvement of MWCs in a publication

Abbreviations: EBR = evidence-based research; EQUATOR = Enhancing the QUAlity and Transparency Of health Research; FAIR = findability, accessibility, interoperability, and reusability; GCP = Good clinical practice; MWC = medical writers and communicators.

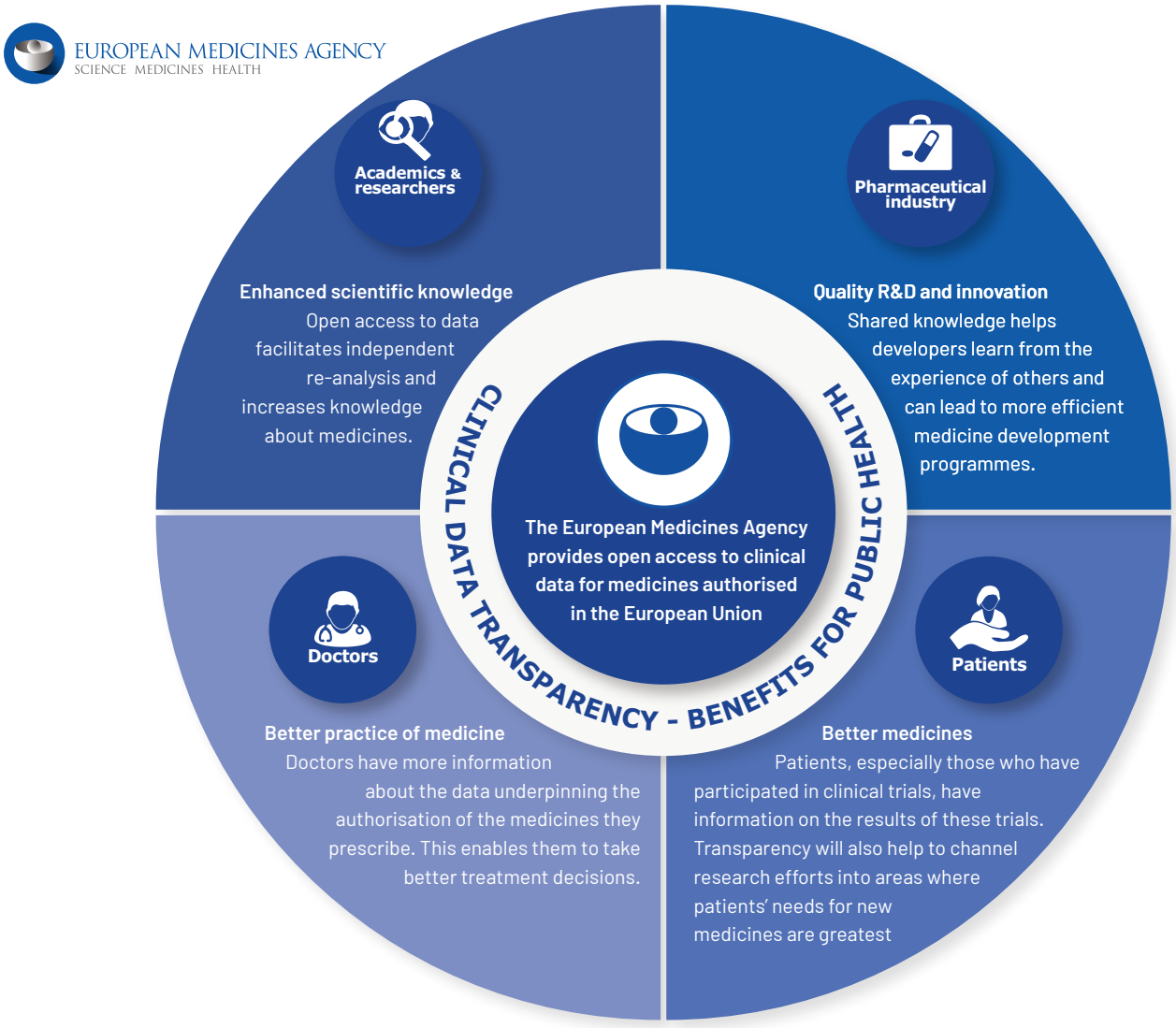

Figure 2. Benefits of clinical data transparency in clinical research
Used with permission from the European Medicines Agency and adapted for readability[24]

> *accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available.*[21]

Dissemination comprises a range of research documentation. For example, the study protocol and related material such as trial registration, statistical analysis plans, and clinician training resources; various summaries for different stakeholders; data manuals; and primary and secondary publications.

Traditionally, however, reporting of research results has consisted of submitting documents and datasets to regulatory authorities and disseminating results through biomedical publications. The former was cloaked in confidentiality whereas the latter was done voluntarily, usually when results were favourable. Indeed, a "negative" study is a strong predictor of nonpublication.[22] Also, although reporting guidelines exist, adherence has been an issue and a contributing factor to research waste.[23] Data transparency is about making research information, regardless of outcome, available to the public, hence public disclosure. This transparency promotes public trust. Research results are wasted if they do not translate into societal benefits, which is impossible without trust. The benefits of data transparency to promote innovation and enhance scientific knowledge that would translate into better practice of medicine and benefits for public health are detailed in Figure 2.[24]

Funders have a role in encouraging dissemination; for example, the UK National Institute for Health Research Health Technology Assessment programme policies include withholding the final 10% payment of a study grant until the full report has been made available.[14]

The onus to publicly disclose lies not only on the researchers but also on regulatory agencies and health authorities. EMA spearheaded data

transparency and public disclosure in 2016 with the launch of a clinical data website under EMA Policy 0070.[25] With this move, the agency went beyond disclosing their decisions through European public assessment reports; they also published the submitted documents on which they based their decisions. Since the launch of EMA clinical data website, 152 applications have been shared, including 10 on COVID-19 treatments and vaccines (as of end of December 2021).[26] Following EMA's example, Health Canada also started its own public disclosure portal in 2019.[27] In addition, two new electronic systems have been launched in Europe to centralise public disclosure of clinical trials, the Clinical Trial Information System (CTIS) for medicinal products and the European database for medical devices (Eudamed). Both are expected to be fully operational in 2022.

MWCs have a pivotal role preventing research waste through responsible reporting, transparency, and public disclosure. By ensuring accurate, complete, and easy to review documents, MWCs facilitate efficient and speedy reviews of manuscript submissions and regulatory applications. MWCs can protect personal data through proactive anonymisation, which facilitates the production of "redaction-friendly" documents. Through timely dissemination of both favourable and unfavourable results, MWCs help minimise duplicating efforts and repeating mistakes. Furthermore, public dissemination through biomedical publications support healthcare professionals in their efforts to practice evidence-based medicine. Lastly, in developing plain language summaries of research results, MWCs extend their reach beyond regulators and healthcare professionals to the patients and the public (Table 1).

Open science

Good research practice, data stewardship, and responsible reporting culminate in open science. According to UNESCO, open science is about making scientific knowledge openly available, accessible, and reusable for everyone. The term has its roots in the open access initiative of providing free access to scientific literature to everyone. Open science goes beyond biomedical journals; it extends to lab books, regulatory documents, datasets, open-source software, and open hardware. The aim is for scientific information to be effectively and reliably harnessed for universal benefit.[28]

Adopted by the Council in 2016, the EU's open science policy is among the strongest in the world. Under Horizon Europe, all publicly funded research should adhere to FAIR and open data sharing of results, using for example the European Open Science Cloud. Once fully implemented, the cloud will provide European researchers, innovators, companies, and citizens with a federated and open multi-disciplinary environment where they can share, find, and re-use data, tools, and services for research, innovation, and educational purposes.[29]

Good research practice, data stewardship, and responsible reporting culminate in open science.

MWCs have a big role to play in the open science environment. They enable timely and accurate reporting of research results in biomedical journals by following reporting guidelines and adhering to ethical principles and good publication practice. In doing so, they promote public trust in science (Table 1).

Conclusions

Research not shared is research wasted. And like all human activities, biomedical research has an ecological impact. We have identified four interlinked strategies that can help minimise wastage in terms of money, time, and resources during the life cycle of a biomedical research project. MWCs play an important role in all these strategies, as summarised in Table 1. In doing our part, we help minimise research waste, reduce the carbon footprint of research projects, and contribute towards a sustainable future for biomedical research and the planet.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers, clients, or EMWA.

Disclosures and conflicts of interest

Kimi Uegaki provides freelance medical writing and editing services to clients in academia and the biomedical/healthcare industry. Raquel Billiones is employed in the pharmaceutical industry.

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