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Rapid, accurate publication and dissemination of clinical trial results: Benefits and challenges

Brief title: Rapid, accurate publication of clinical trial results

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Abstract

Large-scale clinical trials are essential in cardiology and require rapid, accurate publication and dissemination. Whereas conference presentations, press releases, and social media disseminate information quickly and often receive considerable coverage by mainstream and healthcare media, they lack detail, may emphasize selected data, and can be open to misinterpretation. Preprint servers speed access to research manuscripts while awaiting acceptance for publication by a journal, but these articles are not formally peer reviewed and sometimes overstate the findings.

Publication of trial results in a major journal is very demanding but the use of existing checklists can help accelerate the process. In case of rejection, procedures such as easing formatting requirements and possibly carrying over peer review to other journals could speed resubmission.

Secondary publications can help maximise benefits from clinical trials; publications of secondary endpoints and subgroup analyses further define treatment effects and the patient populations most likely to benefit. These rely on data access, and although data sharing is becoming more common, many challenges remain.

Beyond publication in medical journals, there is a need for wider knowledge dissemination to maximise impact on clinical practice. This might be facilitated through plain language summary publications. Social media, websites, mainstream news outlets, and other publications, although not peer reviewed, are important sources of medical information for both the public and for clinicians. This underscores the importance of ensuring that the information is understandable, accessible, balanced, and trustworthy.

This report is based on discussions held on December 2021, at the 18th Global Cardiovascular Clinical Trialists (CVCT) meeting, involving a panel of editors of some of the top medical journals, as well as members of the lay press, industry, and clinical trialists.

Keywords: preprint services, press releases, secondary analyses, data sharing, plain-language summary

Introduction

An important task for clinical trialists is writing up the main trial results for publication. The process is fraught with competing requirements, such as publishing results quickly while also following comprehensive trial reporting guidelines. The paper needs to be readable and avoid being too technical, but yet be detailed and accurate. The clinical implications of the findings need to be discussed, but assertions or inferences that go beyond the trial results should be avoided. In addition, in many journals, authors must adhere to formatting requirements and stay within the journal's word limit. These pressures are magnified when trying to publish the main results in a high-tier journal to coincide with the first presentation during a late-breaking trials session at a major international meeting.

This paper looks at the advantages and disadvantages of the many venues through which clinical trialists disseminate trial results, including conference presentations, press releases, social media posts, and preprints. We also review the process of publishing trial results in major journals, including the use of trial reporting guidelines and defining authorship rules.

Clinical trials are labour intensive and costly, and it is critical to maximise knowledge acquired from the collected data. After the main publication, secondary publications including subgroup analyses and meta-analyses of multiple trials, are valuable ways to do this. Such secondary analyses rely on access to the data and hence are mainly written by the trial investigators. However, data sharing is becoming increasingly common which facilitates analyses and insights from independent investigators who may perform conventional secondary or meta-analyses of the data.

Beyond results-based publications in scientific journals there is also a need for translation of their relevance into clinical practice for both patients and physicians. Clinical guidelines

provide important avenues for interpretation of evidence from multiple trials to ensure that optimal strategies make their way into routine practice. Guidelines distil evidence, although greater effort is needed to make them more user-friendly, timelier, and less cumbersome.

Finally, it is also useful to monitor the impact of a trial publication. Citations, downloads and other impact metrics can be used to assess the reach and value to clinical practice. Detailed reports collected by Altmetric[®] and other services and posted on many journal websites can be used to determine who is talking about the research, what is being said, and what the research is being used for.

Social media is an important avenue for information dissemination and discussion for both the lay public and for clinicians. However, it is difficult for such brief sound bites to provide the balance and nuance required of a complex dataset. Considering the increasing body of medical information available from many internet sources, and the potential for misinformation, it is essential that researchers disseminate accurate and accessible information. Plain language summary publications have the potential to be credible and reliable sources of information for patients and the public to improve health literacy on a societal level.

In December 2021, the 18th Global Cardiovascular Clinical Trialists (CVCT) (www.globalcvctforum.com) meeting hosted a panel of editors of some of the top medical journals in the world, as well as members of the lay press, industry, and clinical trialists. This paper is based on those discussions and aims to review the process of publishing clinical trial results, to maximise the information derived from trials, and to discuss strategies to ensure accurate and accessible dissemination to the widest audience possible, especially to treating-clinicians and their patients (Graphical Abstract). The full session presentations and video recording can be accessed on the CVCT website.

Releasing information before journal publication

Press releases and social media posts

For many reasons, there is urgency to disseminate information from major clinical trials. Companies listed on the stock exchange have an obligation to publicly announce topline results as soon as they are available. Announcements often occur through press releases. Mainstream news media coverage of health research relies on the content of these limited materials. However, the treatment effect or importance of findings can be exaggerated, potentially misinforming the public and undermining public trust in science. A study assessing observational studies found that 22% of press releases made exaggerated causal claims based on correlational findings compared with those reported in the original research paper.¹ An analysis of press releases from 2010 reporting the findings of randomised trials identified “spin” (emphasizing a beneficial effect of treatment) in 47%, and overestimation of trial findings in 27%.²

A striking example of the variability of press releases was evident in four press releases announcing the results of the ROCKET-AF trial³ on the day it was presented at the American Heart Association (AHA) Scientific Sessions in 2010.⁴ In that study, rivaroxaban demonstrated non-inferiority compared to warfarin in the intention-to-treat (ITT) analysis and superiority in the pre-specified per protocol analysis.³ Press releases from the drug companies focused on the “superiority” in the per protocol analysis, not mentioning until the second paragraph the failure to achieve superiority in the ITT analysis. The academic leadership running the trial mentioned both analyses in the first paragraph, whereas the AHA stated the drug was as effective and did not mention superiority. Experts agreed that the most appropriate interpretation was that rivaroxaban was as effective as warfarin.⁴

Such press releases can have a major impact; first impressions are important, and headlines are written from the first paragraph. Superior makes a better story than “as effective”. However, readers should be aware that press releases are primarily marketing tools and may overstate or fail to include relevant details reported in conference presentations or journal publications.⁵ Interestingly, when the full results of ROCKET-AF were published³ several months later, the abstract described the results of both analyses, but in contrast to the company press releases, concluded only that rivaroxaban was non-inferior to warfarin, making no claim of superiority.

The need for rapid dissemination of pivotal trial results is often driven by the stock market. For a new, potentially blockbuster drug, or for a start-up company’s first product, positive or negative/neutral trial results can have a substantial impact on the manufacturer’s stock price. To prevent insider trading, the SEC requires that any possible market-moving clinical data be released promptly and simultaneously to the public and shareholders, with no early access to research results for any parties. These industry press releases often provide limited information; for example, companies often announce that the trial has met its primary endpoint but disclose little other information. This may be done partly to balance the requirements of medical journal editors, conference leaders, and trialists, who may not want the data to be revealed ahead of the publication or conference presentation.

There is a potential for the limited information in press releases to have a negative impact on patient care, which underscores the need for rapid publication of the full trial results after the initial announcement. An analysis of 100 press releases related to phase 3 oncology trials found a median of 300 days to reporting of complete results.⁶ Of these, 70% reported positive results but only 31% described their magnitude. Importantly, it took longer for publication of negative trial

results (median 407 days) than positive ones (median of 272; $P < 0.001$). Posting on preprint servers (see below) and uploading results on sites such as ClinicalTrials.gov can be considered. However, there are important concerns regarding the accuracy of these messages in the absence of peer review. Reducing the time involved with rigorous peer review of publications should be collectively sought by journal editors, trial sponsors and authors writing, revising, and approving the text.

Medical conference presentations

Presentations at medical conferences are another method of getting clinical trial results out more quickly. These provide more detail than press releases, but the data presented have not been peer reviewed and are selected by the presenter. Journal editors are increasingly coordinating online, peer-reviewed publication with conference presentations to help mitigate this problem by providing sufficient detail required for reliable conclusions. To protect the information, many journals have embargo policies to prevent release of the data which are coordinated with the late-breaking abstract presentations.

Unlike initial press releases, press coverage of medical conferences typically provides more detail regarding the results of a trial. These news stories reflect the reporter's view after the full presentation and a question-and-answer session with the principal investigator. These professional medical writers attempt to capture accurately the main findings. When a simultaneous publication is not available, reliance on the slide presentation might be supplemented by interviews with experts who were not involved in the trial. This level of communication goes well beyond an initial topline press release, and generally captures the major key messages of an initial presentation.

Preprints

Use of preprint servers has become increasingly common in the medical research community. These online platforms are dedicated to the distribution of preprints, research manuscripts that have yet to undergo peer review and acceptance for publication by a journal. Preprints have been used for almost a decade in other scientific areas. In 2019, www.medRxiv.org, was launched as a publisher-neutral, not-for-profit preprint server for health sciences operated by Cold Spring Harbor Laboratory and managed by the BMJ and Yale.

The use of preprints remains controversial, with proponents describing the potential benefits of early access to the data, and others who have concerns and recommend these articles be viewed with caution. Preprints ensure prompt sharing of ideas and information and foster feedback and collaboration among scientists, and they are also generally freely accessible.⁷ Other potential advantages are shown in Table 1.

By contrast, there are concerns that posting preprints before peer review will lead to dissemination of unchecked and possibly even harmful information (Table 1). Preprint servers have improved over time and most use screening checks. However, their requirements regarding transparency and rigor of research are not as strong as those of highly cited journals.⁸ To combat concerns around the potential for harmful information, screening for the medRxiv preprint server includes confirmation from a clinician that posting the manuscript will not pose a potential risk to patients or the public,⁹ which is likely far less reliable than the full review process in peer-reviewed journals. In addition, although cautions regarding the lack of peer review and the preliminary nature of preprints are posted on the home page of preprint servers, not all servers display these warnings on the online and the pdf version of the manuscript itself.⁷

One of the main challenges for readers is that preprints are not removed if the paper is eventually published in a scientific journal, thus leaving two different versions of the same paper online.¹⁰ Among preprints that went on to be published in peer-reviewed journals, several analyses suggest minimal differences between findings in the preprinted and published versions.^{11, 12} One analysis of 67 COVID-19-related studies found that preprints and their subsequent journal publications were largely similar in reporting of study characteristics, outcomes, and spin.¹¹ Discrepancies between reporting of results most often involved differences in level of detail. In another analysis, 94% of 44 preprint–journal article pairs reported concordant primary endpoints, and 98% reported concordant study interpretations.¹² The consequences of these discrepancies are unknown and may be not negligible.

Unfortunately, many preprints are not subsequently published, and these may be the ones with methodological flaws, biases, and other limitations.^{8, 9, 13} In a review of every research article posted to medRxiv preprint platform in September 2020, 77% were published within 2 years, and articles were published a median of 6 months after preprint posting. Importantly, 96% of these published articles reported findings that were concordant with the preprinted article.¹³ Although the rate has been improving, the non-publication, or late publication, of preprint articles is a serious concern that needs to be addressed.

The “open peer review” process has been cited as a means for authors to obtain rapid feedback on their work. Of almost 10,000 postings on medRxiv during 2019-2020, only 9% had received comments on the preprint server,⁹ although discussions through Twitter and other social media channels are more common. In addition, this process has been effective in identifying faulty research that has led to retraction of studies.¹⁴ Of note, traditional peer-reviewed journal

articles are also not immune to errors or even fraud leading to the need to retract published papers.¹⁴

In a survey of researchers, the top concerns regarding preprint publication centred around the premature media coverage and public sharing of information before peer review.⁷ Authors may also worry that preprints will interfere with journal acceptance, but despite the policies of most journals that a paper cannot be published elsewhere, many journals currently allow papers to be posted on preprint servers.⁷ In a recent assessment of preprint policies of the 100 top-ranked clinical journals, it appears that 86% explicitly allow preprints, whereas 13% make a judgment on a case-by-case determination.¹⁵ In fact, the AHA journals and the *European Heart Journal* do not consider preprints as prior publication.^{16, 17} The journal perspective is that the preprint paper is not a prior peer-reviewed publication with editorial input, and therefore, it is not a cause for immediate disqualification.

Publishing primary results

Improving publication rates of clinical trial results

The rate of timely publication of trial results has improved, but remains slow.¹⁸ A review of 1,429 heart failure (HF) studies registered on clinicaltrials.gov found that 44% remained unpublished within at least 2 years of trial completion.¹⁸ Among trials completed after 2007 (when 1-year submission of results was mandated in the USA), the 1-year publication rate was only 20%. In another analysis, the median time from study completion to publication was 559 days.¹⁹

There are a number of reasons why studies remain unpublished, not least of which is the workload for the people involved.²⁰ A systematic review of 38 reports on reasons given by investigators for not publishing their studies found that the main reason was lack of time or low priority.²⁰ Some of the other reasons included studies that were not meant for publication, such as feasibility or pilot studies and preliminary work, or studies of poor quality, unimportant or negative result, journal rejection or fear of rejection, and manuscript in preparation/under review.

Despite barriers, there may be several ways to facilitate more rapid publication of trials. From the investigators' perspective, adequate trial resources, potentially including writing services, to fund manuscript preparation and dissemination of the results may help reduce the burden on the primary investigator. This remains a problem for investigator-led clinical trials that may not have adequate funding or infrastructure.

Journals can help by reducing some of the repetitive tasks required of authors. They could forgo the need for rigid formatting requirements on initial submission, which can be implemented once the journal has shown interest. If a paper is rejected after peer review, with the authors' agreement, this could be carried over when submitted to a new journal and not repeated; this reduces the burden on authors, but also on peer reviewers, who are generally volunteers. Journals have been increasingly taking these steps, easing formatting requirements, and carrying over peer review, although mainly to sister journals within the same publishing company. Journals might also collaborate more by sharing the names of their reviewers with subsequent journals; this can help speed up peer-review and reduce the chance of reviewers reading the same paper again unless it has been substantially revised. Some journals will have 4 or 5 reviewers who may have contrary views. Generally, if journal editors select reviewers appropriately, then there should typically be no need to have more than three reviewers for any one manuscript.

Securing qualified reviewers may be challenging and may delay the timely publication and dissemination of trial results. Journals may consider hiring a core group of paid professional peer reviewers and remunerating researchers or providing them with credits for open access publication.²¹ Journals may also consider inviting twice as many peer reviewers as required, upon submission, and proceeding with the first few that consent to review. Multiple review cycles to satisfy each reviewer can delay publication and increase author burden, without necessarily yielding significant gain. Ideally, a single review cycle should be recommended, and should be possible in most cases. If a major revision is required, review cycles should not exceed two. Strong editorship may help limit the review cycle.

Journals and authors may have differing viewpoints on definitive conclusions. Authors argue that a focus on the statistical outcome of the primary endpoint alone fails to do justice to the totality of evidence in a trial and provides little context relative to other trials. Although most journals have moved to reporting hazard ratios and confidence intervals, some journals still focus on $P < 0.05$ for a positive conclusion, which may not capture the totality of evidence.

Furthermore, the word count limit often severely restricts the ability to delve into the nuances. A few journal editors argue that the initial publication of study results should present the primary findings without speculation, and that other vehicles, such as editorials and secondary publications, provide opportunities to delve into the nuances. Other journals are more flexible and allow reporting informative details, beyond the primary findings.

The increasing use of online supplements and appendices provides an important medium to provide critically important information, such as additional results, the trial protocol, and the statistical analysis plans. This information may help with the peer review and editorial decision processes and remains available to readers.

Trial reporting guidelines and checklists

The EQUATOR Network (Enhancing the QUALity and Transparency Of health Research, www.equator-network.org) is a repository of guidelines for reporting different study types (as of February 2022 this holds 486 reporting guidelines). For clinical trials, the CONSORT statement and its extensions are designed to standardise the reporting of randomised trials.²² Beyond CONSORT, there are extensions such as the CONSERVE guideline for dealing with trial disruptions from COVID-19, natural disasters, and other causes.²³ These guidelines and checklists are required by many journals, and they provide tools and templates to enhance the quality of trial results reporting. However, using checklists can add a substantial burden to the submission, and it is not clear just how useful extensive checklists are. The journals may need to test the value of checklists with their authors, and potentially re-develop them to make the submission process more efficient. Making checklists optional rather than compulsory may be an option.

Authorship roles and rules

Authorship affords public recognition of those who have contributed to the work. For many individuals and academic institutions, authoring papers is a measure of performance for promotion, obtaining grant money, and benchmarking a university's ranking and prestige. However, including too many authors invites the risk of devaluing authorship, and there are ethical issues and dangers involved in cases of retractions.

Authors represent the intellectual input that has gone into the publication, but they are also responsible for assuring the reader that the data are valid.²⁴ The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following four criteria: substantial contributions to the concept and interpretation of data for the work, AND

critically revising the work, AND approving final version to be published, AND agreement to be accountable for all aspects of the work.²⁴

Often, high enrollers in a trial are included as co-authors since this may be one of the major incentives to enrol. In addition, the directors of core laboratories or the clinical events committee are occasionally included as co-authors. Publications with vast numbers of authors cannot possibly be developed by all those authors. Authorship is preferably restricted to a core group of the writing committee and contributors. Using a group name is a possibility. Important contributors to the trial (and not necessarily to the manuscript) should be recognised and made searchable on PubMed, which is all that should be needed to support a contributor's career. Journal editors, trial steering committees, sponsors and lead authors should support this policy and limit the authors of a publication to those who take accountability and actually contribute to the development of the manuscript.

While ghost-writing should be avoided, drafting a trial report publication may occasionally require the assistance of a medical writer.²⁵ The named authors of the paper have to be involved in the development process and are the ones who have to be accountable for the content. Medical writers need to be acknowledged for their work in the submitted manuscript, but they do not qualify to be authors on a publication.

The reputation of prolific authors, a small group of whom lead a large proportion of industry-funded trials in each field, can be a distraction and may bias the reviewing process and manuscript acceptance. Blinding reviewers to the identity of the authors can help minimize biased reviews.²¹ Well-known authors from reputable institutions are less likely to have manuscripts accepted when reviewers are blinded to their identity.²⁶ Further research is needed

on potential biases and issues related to the role of trial leadership in the complex clinical trials ecosystem.

Publications to maximise scientific knowledge from clinical trials

The value of secondary analysis publications

Publication of secondary analyses is an important step to maximise the output from often long and costly clinical trials. It should be clearly stated whether these analyses were pre-specified or exploratory as this helps both journal editors and peer reviewers assess the validity of the findings.

Secondary results are important in understanding the quality and generalisability of the results of a specific trial. This can be accomplished by examining the internal consistency within the trial using subgroup analyses and by examining the external validity of the trial compared to other related trials. Secondary analyses are also hypothesis-generating and can advance science by examining secondary or exploratory endpoints, or by helping to elucidate the mechanism of action of a medication. These analyses can help expand personalised medicine by identifying patient phenotypes to define responder profiles. Insights through machine learning and artificial intelligence can only be obtained from secondary analyses. Finally, there is a role for reverse translational analyses that can look for signals to help understand the pathophysiology of the disease itself.

Some useful subgroup analyses relate to geographic differences in populations, healthcare systems, and patient phenotypes. For example, in the EMPEROR-Reduced trial,

patients from Europe appeared to benefit less from empagliflozin treatment.²⁷ Subgroup analysis of regions in the TOPCAT^{28,29} and PLATO³⁰ trials also revealed geographic differences.

Secondary analyses of device trials have helped to identify the patients who would benefit most from cardiac resynchronization therapy.³¹ Data from the EMPEROR-Reduced trial were used to develop a risk assessment tool that added N-terminal pro B-type natriuretic peptide (NT-proBNP) and high-sensitivity cardiac troponin T (hs-cTnT) levels to other clinical variables to enhance the assessment of patient absolute risk.³² Subgroup analysis of patients in the EMPHASIS-HF study showed that despite the potential for hyperkalaemia, eplerenone was effective and could be used safely in patients at risk of worsening renal disease (including older patients and those with diabetes).³³

These types of secondary analyses improve the ability to identify patients who are likely to benefit most from specific treatments and can help when developing guidelines and making individual patient management decisions. However, secondary analyses should be conducted cautiously, with consideration of the statistical impact of doing multiple analyses. Exploratory analyses should be regarded with particular caution, as analytic plans can be biased, and reporting can be selective. Pre-specified secondary analyses of good quality can provide valuable training opportunities for fellows and future trialists. To facilitate these useful analyses and maximise the information obtained from clinical trials, industry-sponsored trial databases should be freely accessible (see discussion of data sharing below).

The value of meta-analysis publications

Meta-analyses of trials represent secondary analyses that can also help to maximise the knowledge gleaned from important clinical trials. For example, a meta-analysis of the EMPEROR-Reduced and DAPA-HF trials showed that sodium-glucose cotransporter 2

inhibitors as a drug class significantly reduced cardiovascular mortality, but when taken individually, the two trials gave an equivocal picture.³⁴

There are pros and cons to pooled trials and meta-analyses. Generally, any one trial may be too small and lack generalisability, therefore, combining evidence from related trials can provide useful information. However, there are concerns around meta-analyses, including the “breadth” or similarity of the trials (patients, treatments, outcomes), the “quality” of trials (less rigorous methodology), and the “representativeness” or ability to identify all eligible studies (risk of publication bias).^{35,36} Although meta-analyses are increasingly being conducted, they should be critically evaluated. When studies are too heterogeneous the data should not be combined, but rather a systematic review should be conducted, and the individual studies evaluated.

In contrast, meta-analyses of individual patient-level data from clinical trials can be very useful because additional analyses not conducted in the original publications can be performed. Patient level meta-analyses are more likely to be published in high-tier journals³⁷ and are fostered by data sharing. Regardless of the type of meta-analysis, it should be registered on the PROSPERO platform (www.crd.york.ac.uk/PROSPERO/), and authors should follow the PRISMA³⁸ recommendations and MOOSE³⁹ reporting guidelines.⁴⁰

Impact of data access and data sharing on publication of optimal clinical trial knowledge

Limitations on access to clinical trial databases can be a barrier to optimal use of the knowledge gleaned from clinical trial results. Wide sharing of clinical trial data involves challenges but can also afford substantial benefits (Table 2).^{40,41}

Research partnership and data access agreements between industry and trial investigators vary from trial to trial. In some cases, the sponsor develops and controls the database, and the researchers may have little or no access, despite assuming authorship and responsibility for

publications. For other trials, the sponsor may fund an academic research centre, affording researchers full control of the database, analyses, and publications. In general, most major CV trials fall somewhere between these two extremes.

Data sharing can pose unique challenges for young investigators and investigator-led clinical trials that do not have industry support or extensive infrastructure. There are costs to de-identify data and transfer it to a sharing platform. Although there are reasons why data sharing might not be embraced by sponsors who have invested decades in a research project, data sharing should be encouraged, setting transparent mechanisms of data access and sharing, with coordination by the academic trial steering committees.

Journals have been working on data sharing policies for over a decade with the goal of ensuring high-quality review of evidence and maximizing confidence in industry-generated data.⁴² In 2017, the ICMJE proposed that clinical trial reports include a data sharing statement, and those initiated after 2019 must include a data sharing plan in the trial registration.⁴³ The *European Heart Journal* currently takes a moderate stance; given that mechanisms to mandate data sharing are not yet available, they encourage authors to make data available and require a data sharing statement in trial reports.⁴⁰ As a minimum, to increased transparency it may be suggested that editors mandate that the publication describes with which stakeholders the database resides.

Funding bodies play a major role in promoting and facilitating data sharing. For example, the National Institutes of Health (NIH) sees data sharing as an important resource to maximise the full value of the public investment in research studies. A new policy, beginning in January 2023, will mandate data sharing within two to three years after completion of the trial.⁴⁴ The NIH provides platforms such as BioLINCC for biologic specimens and data and BioData Catalyst,

which serve as data repositories and provide tools for analyses. Other common clinical data sharing platforms include Clinical Study Data Request (CSDR), Project Data Sphere, Vivli, and the Yale Open Data Access (YODA) Project.⁴⁵

In general, journal editors agree on the benefits of sharing data from clinical trials but acknowledge that data sharing has legal and ethical ramifications and is a costly undertaking. However, when funding agencies provide the infrastructure and make it a requirement, as has been the case with the NIH initiatives, it has had some success.^{46, 47} More success may be achieved if data sharing and analyses are coordinated by the academic trial steering committees. Currently, there continues to be a need for a workable mechanism for researchers to apply for data access with a specific outline of their research questions and for those holding the database to screen these applications.

Expanding the dissemination and translation of trial results to a wider audience

Publishing the results (primary or secondary) of clinical trials in medical journals is only the first step in maximising the information gleaned from each trial. The information has to be assessed and added to the existing body of evidence on the topic and used subsequently to inform expert consensus in the development of clinical management guidelines. Ultimately, the goal needs to be dissemination and translation into routine clinical practice to improve health outcomes.

Clinical trial results need to be communicated to practicing cardiologists, but also to specialists in other fields, primary care practitioners, other healthcare professionals, and individuals with (or at risk for) the condition. Presentations at congresses are an important forum

to allow more detailed discussion of the trial and its results. Journals have in place additional strategies to disseminate publications, including podcasts, webinars, videos, slides, and social media. Making articles open access can help in dissemination.

Mainstream media and social media

Mainstream media and social media are popular ways to disseminate medical journal articles of interest to scientists, business professionals, the general public, and patients. Articles of greatest interest are those that present novel findings, suggest immediate changes to clinical care, improve patient outcomes, or address core societal issues such as health disparities and healthcare inequities. For example, in 2020-21, some of the top cardiology news stories involving clinical research presented at the AHA scientific meetings or published in the association's peer-reviewed journals included research about coffee and HF risk, racial disparities in cardiovascular disease, and research discussing hypertension.

Social media now plays an important role. In 2020-21, there were 4,670 media stories, yet over 4 million Twitter posts based on studies published in the journal *Circulation* alone. Whether the wider media coverage prior to publication dampens enthusiasm, or helps generate more interest in the publication remains to be properly investigated. The number of social media posts regarding some of the top articles, particularly those from members of the public, illustrate that it is not just physicians and scientists who want to engage in the discussions. Of note, caution around social media posts is warranted, as misinformation can be introduced and circulated by those with strong biases or competing interests. Social media may provide some insight or education, but it may also feed into people's prejudices.

The COVID-19 pandemic revealed the critical importance of investing resources in improving health communication. More work is needed to educate the public around the

principles of evidence generation and assessment. One suggestion is use of a colour-coded scheme for grading medical evidence in mainstream and social media.⁴⁸ In simple terms, green would indicate robust well-conducted randomized clinical trials, yellow would indicate weak randomized clinical trials and observational studies, while red would indicate misleading or false information.

Altmetrics and other impact metrics

Measures of activity around a publication have now gone beyond recording citations alone. For example, Altmetric (www.altmetric.com) provides additional quantitative and qualitative data and is often included on journal websites. The additional measures can include mentions in non-journal-based documents such as public policy documents, blog discussions, mainstream media, social media networks, and Wikipedia citations. These metrics provide insight into how publications are being discussed and used by both the scientific community and the general public. They are becoming widely used as indicators of influence and performance in academia, and by libraries, publishers, and individuals. For example, the 2021 European Society of Cardiology guidelines for the diagnosis and treatment of acute and chronic HF³¹ were viewed over 937,000 times in just 5 months. With a score of 1332, the article is among the top 5% of all research outputs scored by Altmetric (20,236,922). There was broad reach beyond the scientific community with the guidelines being picked up by 27 news outlets, referenced in 1 policy source and 2 Wikipedia pages, and tweeted 1615 times. Of interest, 78% of Twitter mentions were from members of the lay public.

Plain language summary publications

Plain language summaries help to engage and motivate both patients and healthcare professionals, and they increase the efficiency and value of the healthcare system by ensuring that patients understand the disease and its treatment and thus use resources appropriately.

Dissemination of critical information can be hindered by lack of access to subscription-only journals. Although many of the main publications of major randomized trials are open access, usually thanks to the contribution of the sponsor, some remain available only behind a pay wall. Ideally, sponsor–publisher agreements should progress toward mechanisms that generalise access to such main major publications. Alternatively, or in addition, a 2- to 3-page plain language summary publication may be made free to all, simultaneous with the main publication.

The use of technical language can also be a barrier to dissemination. Terms that are well known and accepted by cardiologists may not be familiar to specialists in other healthcare fields, patients, or the general public. Low health literacy has been associated with poorer health and higher mortality, and as such, communication of medical information using scientific jargon or a complex format is a barrier to good health.⁴⁹ With an increasing volume of information available through multimedia channels, there is a need to improve access to reliable medical information that can facilitate physician–patient communications. This is a gap that can be filled by plain language summaries (PLS) and plain language summary publications (PLSP).

According to the International Plain Language Federation, “a communication is in plain language if its wording, structure and design are so clear that the intended readers can easily find what they need, understand what they find, and use that information.”⁵⁰ There are a number of plain language strategies currently in place, and these are expanding. Many journals are

providing visual abstracts and plain language summaries to accompany manuscripts. European clinical trial regulations require lay summaries of trials, and PLSPs are stand-alone, peer-reviewed publications that are designed to be freely accessible plain language summaries of existing manuscripts, which highlight the key findings. They have clear visuals and infographics to explain the data and focus on the needs and the impact of the findings for patients (Figure 1).

By reaching out, for example, to primary care physicians, who vastly outnumber cardiovascular specialists, PLSPs can make information more accessible and understandable to a wider clinician audience, and this type of publication is increasingly being used by patients and patient organisations. While very valuable, currently only a few publishers of medical journals are providing this publication option.

There may be a need for guidelines with plain language summaries. It can be a difficult task for most physician trial authors and experts at medical journals to understand how best to deliver the information to the public. Non-scientific journalists may be more appropriate as authors versus people whose profession is to communicate in more technical terms. However, one should be cautious that plain language does not lead to over-simplification of trial findings and their implications for practice, making them seem simpler than they really are.

Patient partnerships have proven to be invaluable throughout the clinical trial process, from trial design and conduct to interpretation, dissemination of results, and ongoing post-trial initiatives and communications.⁵¹ Patient authors may be able to explain the data in lay terms and describe the impact of the data on themselves and others with a specific condition.

Summary and recommendations

A summary and recommendations to maximise the yield from clinical trials, and to facilitate publication and rapid, accurate dissemination of results is provided in Table 3.

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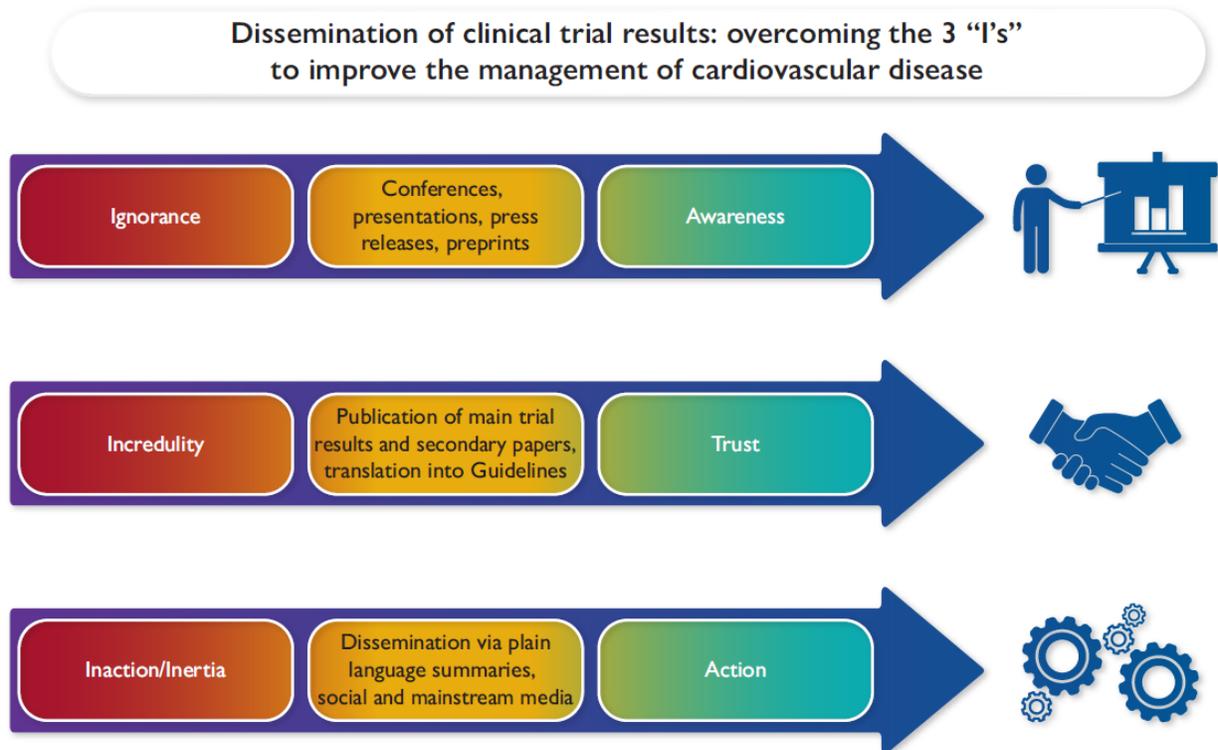
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Legends

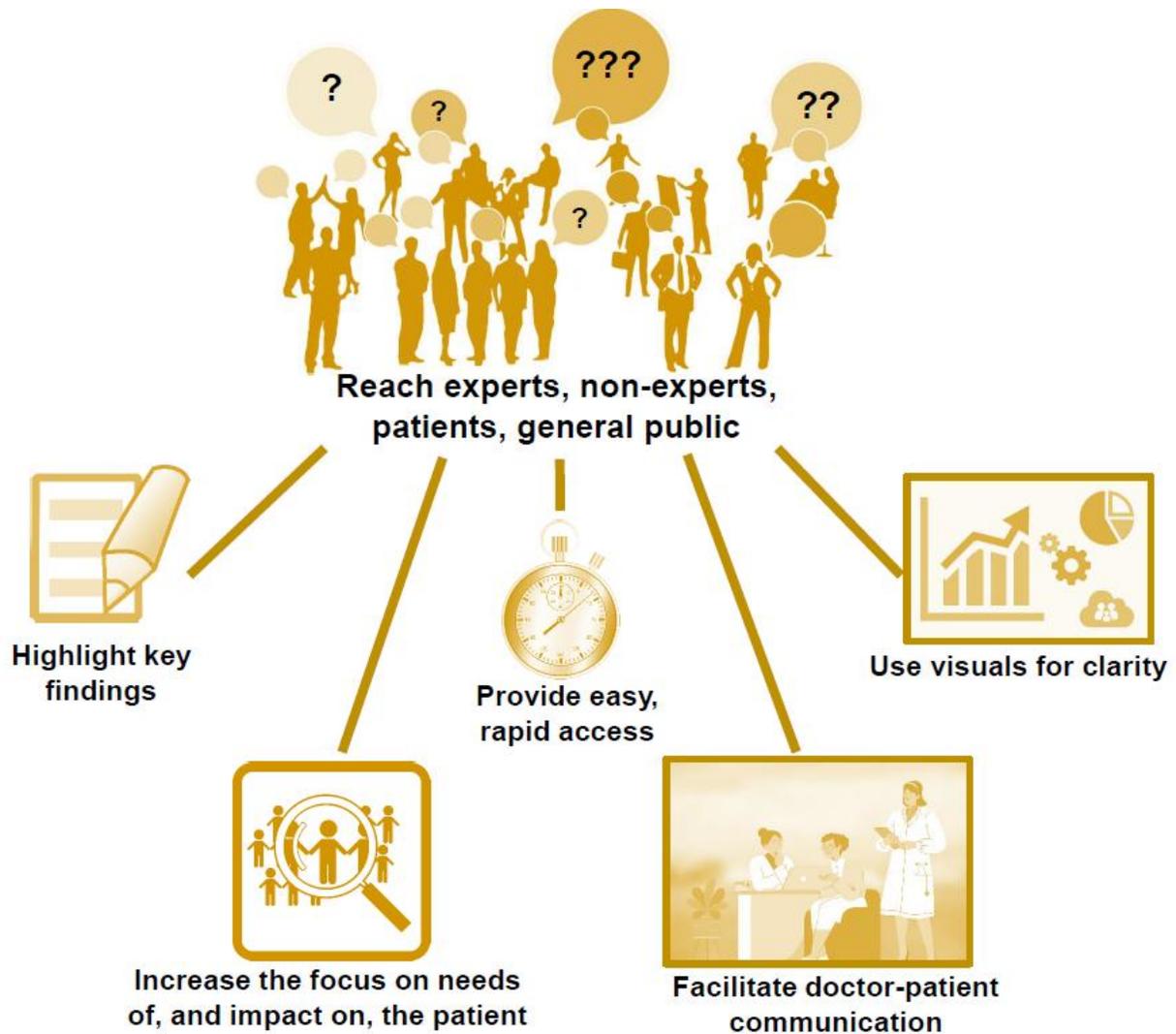
Graphical abstract

Dissemination of clinical trial results: Overcoming the 3 “I’s” to improve the management of cardiovascular disease



Figures

Figure 1: Characteristics of effective communication through plain language publications



EURHEARTJ-D-22-02705R2 - Rapid, accurate publication and dissemination of clinical trial results: Benefits and challenges

Table 1: Advantages and concerns associated with the use of preprint servers in medicine

Potential benefits	Concerns
<ul style="list-style-type: none">• Rapid sharing of new information• Establishes the authorship and ownership of the information while papers are being peer reviewed• Facilitates prompt scientific feedback and enhances collaboration among scientists• Demonstrates scientific productivity• Makes “less publishable” studies more readily available, such as negative or neutral studies or qualitative research• Fosters more complete reporting, such as providing links to registry results, protocols, and other supplementary materials	<ul style="list-style-type: none">• Posting research prior to peer review can lead to harmful information being disseminated to the medical community• Premature media coverage can spread misinformation• The persistence of preprints can lead to 2 different versions of a paper being online, which may have clinically relevant differences after peer review• Authors may worry about how preprint publication will impact journal acceptance

EURHEARTJ-D-22-02705R2 - Rapid, accurate publication and dissemination of clinical trial results: Benefits and challenges

Table 2: Potential benefits and challenges associated with data sharing

Potential benefits

- Increases confidence and trust in conclusions from clinical trials
- Enables the independent confirmation of results which is an essential tenet of the scientific process
- Fosters the development and testing of new hypotheses
- Enhances feasibility of patient-level meta-analysis
- Helps define criteria to harmonise outcomes across trials
- Speeds progress by maximizing knowledge from each trial and avoiding repetition
- Helps fulfil ethical obligation to study participants

Potential challenges

- Scholarly credit must be given to those who gathered the data in addition to those who are publishing the analyses
- Steps are needed to preserve rights of the initial investigators regarding priority and intellectual property. E.g., sufficient time to publish planned post hoc analyses
- Mechanisms are needed to manage data requests in a timely manner and ensure that analyses are accurate and appropriate
- Concerns around re-identification of de-identified participant-level data must be addressed
- There are requirements for funding and licensing policies related to the creation and maintenance of open data repositories

Adapted from references.^{40, 41}

EURHEARTJ-D-22-02705R2 - Rapid, accurate publication and dissemination of clinical trial results: Benefits and challenges

Table 3: Strategies to maximise the yield from clinical trials, and to facilitate rapid, accurate publication and dissemination of results

-
- Clinical trial results should be rapidly published and disseminated
 - If press releases are issued, they should accurately reflect the overall trial findings
 - Conference presentation and subsequent news coverage should maintain balance
 - Preprint servers can provide early access to trial results, facilitate awareness, prompt scientific feedback, and enhance collaboration when used appropriately
 - The value of preprints might be enhanced by placing on every page a statement of caution regarding the preliminary nature and lack of peer review. Preprint platforms should direct readers to the corresponding paper after publication in a peer-reviewed journal
 - The quality of clinical trial reporting can be increased, and journal acceptance facilitated, by use of reporting guidelines such as CONSORT
 - If a paper is rejected by a journal, peer review could be carried over with resubmission to another journal (with author agreement)
 - Journals should not require special formatting, unless interest in the paper is expressed
 - Authors should be prepared to take full responsibility for all aspects of a paper, including having access to data analyses
 - Secondary analyses and meta-analyses can be useful to maximise the knowledge yield from a clinical trial
 - Data sharing is needed to ensure full use of the clinical trial data and fulfil the ethical obligation to trial participants
 - Trial results should be disseminated beyond scientific journal publications using mainstream outlets, social media, and plain language summary publications
-