ENTRUST-PE
Enhancing Trust in Pain Evidence

White paper

ENTRUST-PE: An Integrated Framework for Trustworthy Pain Evidence.

Authors: The ENTRUST-PE Network

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Abstract

The personal, social and economic burden of chronic pain is enormous. Yet patients with chronic pain, clinicians and the public are often poorly served by an evidence architecture that contains multiple structural weaknesses which reduce confidence in treatment practice. Weaknesses include incomplete research governance, a lack of diversity and inclusivity, inadequate stakeholder engagement, poor methodological rigour and incomplete reporting, a lack of data accessibility and transparency, and a failure to communicate findings with appropriate balance. These issues span pre-clinical research, clinical trials, systematic reviews and impact on the development of clinical guidance and practice update. Research misconduct and inauthentic data present a further critical risk. These problems are not unique to research in pain but, combined, they increase bias and uncertainty in research, waste resources, drive the provision of low value care, increase research and healthcare costs and impede the discovery of potentially more effective interventions, all of which negatively impact people living with pain.

This White Paper summarises the discussions and recommendations of the ENhancing TRUSTworthiness in Pain Evidence (ENTRUST-PE) network project, which received funding from the European Commission in 2023 (ERA-NET NEURON Consortium) An international and interdisciplinary group from the pain research community met on multiple occasions with the objective of developing a novel integrated framework for enhancing and facilitating the trustworthiness of evidence for pain. The resulting framework conceptualises Trustworthy research as being underpinned by 7 core values: 1. Integrity and Governance, 2. Equity Diversity and Inclusivity, 3. Patient and Public Involvement and Engagement, 4. Methodological Rigour, 5. Openness and Transparency, 6. Balanced Communication, and 7. Data Authenticity. We propose that each of these core values should drive universal actions and behaviours in researchers and stakeholders across all roles and stages of the research process. In this paper we summarise the challenges addressed by each core value, make recommendations for each key stakeholder group in the research ecosystem in order to enhance the trustworthiness of pain research and present the case for systems-level change.

Background

The ultimate goal of research in the field of pain is to develop an evidence base that affords us a deeper understanding of the phenomena of pain, how it is experienced, its many impacts and how it might be reduced, prevented or managed to improve the lives of those who live with pain. Research in pain encompasses a broad range of disciplines, methodologies and activities and provides the process and methods to develop a diverse body of evidence to ensure that knowledge and understanding exists in a state of incremental, and sometimes revolutionary, improvement. But to be successful in this crucial enterprise, research in pain must first be trustworthy.

The Challenge

The global personal, social and economic burden of pain is enormous [1,2]. Yet patients experiencing pain, clinicians and the public are often poorly served by an evidence base that contains multiple structural weaknesses that reduce confidence in treatment practice. Weaknesses in research evidence include incomplete research governance [3], inequity and discriminatory practices [4,5], inadequate stakeholder engagement [6,7], poor methodological rigour, questionable research practices, incomplete reporting [8], a lack of data accessibility and transparency [9], and a failure to communicate findings with appropriate balance [10]. These issues span pre-clinical research [11–13], clinical studies [8,14] and systematic reviews [15–17] and adversely affect the development of clinical guidance and practice update. Research misconduct presents a further critical and risk [18]. These problems are not unique to research in pain but, combined, they increase bias and uncertainty in research, waste resources, drive the provision of low value care, increase research and healthcare costs and impede the discovery of potentially more effective interventions, all of which negatively impact people living with pain. For evidence from pain research to be trustworthy, weaknesses must be acknowledged and addressed.

These challenges are neither new, nor unique to pain research. In 1994 Doug Altman raised the alarm regarding untrustworthy research in his provocative commentary “The scandal of poor medical research” [19], In 2009 Chalmers and Glasziou highlighted [20] the issue of “avoidable research waste” and in 2014 the Lancet published a special series on the challenge of research waste in biomedical research that identified the key issues and proposed solutions for improving research prioritisation, regulation, study design, conduct and reporting [21–26]. Because many of these challenges persist, and new challenges are emerging, there is a need to consider how we can best act to enhance and ensure the trustworthiness of pain research.

The ENTRUST-PE project

The ENhancing TRUSTworthiness in Pain Evidence (ENTRUST-PE) network received funding from the European Commission in 2023 (ERA-NET NEURON Consortium) to address these challenges. The funding supported an international network of members from the pain research community to meet over the course of one year. The primary goal of the project was to develop a novel integrated framework for enhancing and facilitating the trustworthiness of evidence for pain.

There is a rich body of existing work ongoing efforts aimed at enhancing research governance, including regulatory oversight, establishing core outcome sets, improving the quality of methods and reporting in pre-clinical and clinical research and evidence synthesis, increasing openness, identifying spin and miscommunication, supporting meaningful patient and public involvement, and screening for potential research misconduct (see supplementary tables for examples). Yet engagement with these resources is inconsistent in pain research. This underutilisation may reflect a lack of consistent community awareness, support or engagement. Therefore, a secondary goal of the project was to curate and signpost a selection of these resources for the pain research community.

Methods

An interdisciplinary network group was convened consisting of 25 members from the European Union the USA and Australia. Network members were included on the basis of experience and expertise and spanned the full range or research disciplines and career stages, including early career researchers. This included a patient partner, expertise in equity and inclusivity in research and the inclusion and involvement of people with lived experience and the public in the research process. It also included a range of clinical disciplines and expertise in preclinical and mechanistic research, clinical research including observational and experimental methods, qualitative and quantitative methods, and clinical trials and systematic reviews. The network included members with statistical expertise, including in the detection of fabricated or inauthentic data, and members with experience in senior journal editorial/ publishing roles. Lastly, the network also included members who investigate the factors that contribute to robust research and to development and implementation of approaches to improve the trustworthiness and quality of research.

The ENTRUST-PE network met on 6 occasions from September 2023 to August 2024 including a 2-day in-person meeting at Brunel University London. In that meeting and in subsequent online meetings, specific network members, and an invited speaker with expertise and leadership in research integrity and reproducibility presented to the broader group on topics in which they had specific expertise. These were:

- Research Integrity
- Equity, equality and diversity
- Patient and Public Involvement and Engagement
- Methodological Rigour and Transparency (in pre-clinical, clinical mechanistic, clinical primary and qualitative research and in evidence synthesis)
- Open science practices
- Balanced communication and spin
- Research misconduct and data authenticity
- Editorial challenges and processes.

In each presentation speakers were asked to: 1. Provide a broad overview of the issue relating to trustworthiness to be addressed, 2. Summarise any direct evidence of how that issue affects pain research specifically, propose the characteristics of optimal practice, 3. Present existing tools and processes available to achieve them. 4. Identify any barriers to success and propose solutions. These presentations preceded a group discussion around each area in order to move to consensus on specific recommendations to include in the framework.

Following meetings, the project-lead (NO'C) drafted aspects of the developing framework and shared them with the network group for feedback and discussion. During subsequent meetings, specific aspects of developing and finalising the framework were discussed further, as were plans for the dissemination of the framework, the development of visual aids to promote the framework and the strategies for engaging a range of stakeholders with the framework from across the pain research community. The network discussed and agreed on a series of core values relating to each component of the framework and a series of proposed behaviours and actions in the short- and long-term that would drive practice and standards towards those core values.

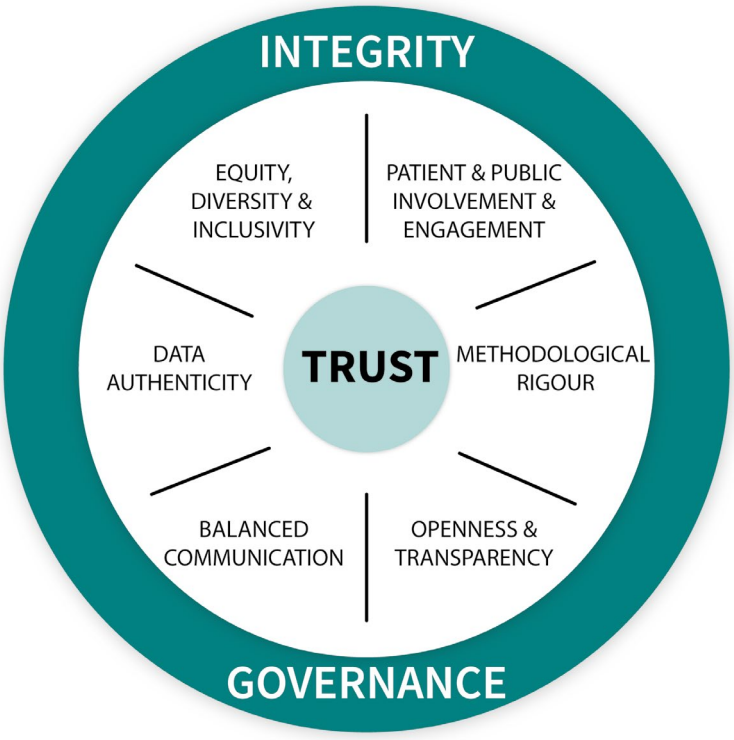
The following sections will outline: a description and explanation of the proposed core elements and values of trustworthy evidence, threats to each, characteristics of good practice for each component, specific tools or guidance that can assist in the achievement of good practice, and summary recommendations for different stakeholders in the research process. Where examples are used they are intended to be illustrative but not comprehensive.

What is Trustworthy Evidence?

Although there is no universally accepted definition of trustworthiness as it applies to research, the Oxford English Dictionary defines "trustworthy" as "Worthy of trust or confidence; reliable, dependable." [27]. Google dictionary defines "trustworthiness" as "the ability to be relied on as honest or truthful", giving the example "he has to prove his trustworthiness to you"[28]. Ignoring the unfortunate gender identifier, that example prompts reflection on where the burden of proof lies for trustworthiness, suggesting that it is for researchers themselves to demonstrate the trustworthiness of their research.

We conceptualise the construct "Trustworthiness" of research to be underpinned by the following core elements: Integrity and Governance, Equity and Inclusivity and Patient and Public Involvement and Engagement, Methodological Rigour, Openness and Transparency, Balanced Communication and Data Authenticity. Figure 1. Presents a visual model of the core elements. Integrity encapsulates all the other core elements which, in turn, underpin the concept of trust.

Figure 1. Core elements of trustworthy evidence.



For each element of the framework the network proposed a set of core values, which should drive some universal actions and behaviours in researchers across all roles and stages of the research process. These are presented in table 1.

Table 1. Core Values of the ENTRUST-PE framework and desired universal actions and behaviours

Element	Core Value	Universal Actions and Behaviours
Governance and Integrity	Research and researchers demonstrate high standards of research integrity and governance.	• Value, follow and promote the principles of research integrity. • Comply with best standards of research governance. • Consider markers of integrity and good governance as key quality indicators for research.
Equity, Diversity and Inclusivity	Research is equitable, diverse and inclusive.	• Prioritise inclusivity, diversity and equity in the design, conduct and reporting of research. • Value and promote anti-discriminatory practices as a key quality indicator for research. • Cultivate equitable, diverse and inclusive research environments/ communities.
Patient and Public Involvement and Engagement	Research is undertaken in partnership with the public and people with lived experience.	• Embed Patient and Public Involvement and Engagement throughout the research process. • Value Patient and Public Involvement and Engagement practices as a key quality indicator for research.
Methodological Rigour	Research is designed and conducted to optimise methodological rigour (appropriate to the question) and reported completely and transparently.	• Value, conduct, educate and promote high quality, methodologically rigorous research (process). • Value, conduct, educate and promote high quality, methodologically rigorous research (process).
Transparency and Openness	Research is as open and transparent as possible.	• Value and promote transparency of methods and compliance with accepted best standards of reporting. • Adopt and promote Open Research practices and FAIR principles as the norm. "As open as possible, as closed as necessary." [29,30]
Balanced Communication	Research is communicated with balance.	• Report all planned results regardless of the findings. • Make clear the distinction between exploratory and confirmatory research. • Make clear the distinction between reasonable interpretation of the data and speculation. • Be aware of markers of unbalanced communication and call attention to them.
Data Authenticity	Inauthentic data are identified and excluded from the literature.	• Be vigilant to markers of potential inauthentic data and research misconduct, call attention to them and take action. • Commit to timely action to remove inauthentic data from the literature. • Commit to timely correction of errors in the published literature.

The following sections provide background to each core component of the framework and present some recommendations for specific actions and behaviours for different stakeholders in the research ecosystem. This includes recommendations for consumers of research. This is a highly diverse group and will include researchers, the media, patients and members of the public with a spectrum of depth of knowledge and understanding of both pain and research methods. It may therefore not always be possible for individual consumers to make an informed judgement for all of the recommendations. In that light, our recommendations aim to sign-post readers to features of research that consumers may look for, but individual consumers should consider the limits of their knowledge, and approach each recommendation pragmatically.

Governance and Integrity

Research governance and the integrity of research are inextricably linked. While definitions may vary slightly there is broad agreement on core principles. The UK National Institute of Health and Care Excellence (NICE) defines research governance as "the broad range of regulations, principles and standards of good practice that ensure high quality research." [31]. This encompasses systems and processes that aim to protect participants and research staff and ensure accountability and research quality [32]. These include research ethics structures and processes, data stewardship requirements and a range of regulatory structures relating to research on animals, human tissue, development and testing of health technologies. Governance structures will vary by location, discipline and institution [32].

There is a responsibility for researchers to be familiar with and to adhere to the principles and processes of good governance. As members of the research community we, our institutions and regulatory bodies should also reflect critically on whether our existing structures and processes are themselves trustworthy and promote the completion and implementation of trustworthy research, with the aim of identifying and mitigating fragilities. An example of a potential fragility that arose from network discussions was the role of research ethics committees and the perception that while they may routinely focus on harm reduction (non-malfeasance) in clinical research they may not routinely offer adequate consideration to aspects of justice.

Research Integrity means conducting research in a way that demonstrates that others can trust and have confidence in the methods used and the findings that result [33,34]. The vital importance of research governance and integrity has received increasing recognition in the last decade, prompting governments, research institutions, funders and publishers to develop policies and tools to define and support best practice (see Supplementary Table 1 for some relevant examples).

These policies can be seen as driven by core values. The Singapore Statement, developed in 2010 by the World Conference for Research Integrity (WCRI) [35] identifies four principles of Research Integrity: **Honesty** in all aspects of research, **Accountability** in the conduct of research, Professional **Courtesy and Fairness** in working with others and **Good stewardship of Research** on behalf of others. The Canadian Framework for the responsible conduct of research [36],The UK Research and Innovation (UKRI) [37] and the Australian National Health and Medical Research Council (NHMRC)[38] policies on the governance of good research practice establish core principles of honesty, rigour, transparency and open communication, care and respect and accountability. The NHMRC document also includes "Recognition" of indigenous peoples to be engaged in research and "Promotion" of responsible research practices. The US National Institutes of Health (NIH) identify the shared values of Honesty, Accuracy, Efficiency and Objectivity [39] and the European Code of Conduct core principles are Reliability, Honesty, Respect and Accountability [40]. All speak to the notion that research should be conducted to high standards of methodological and ethical practice. In a recent scoping review of responsible research systems and cultures, Field et al. highlight that Transparency, Harm Minimisation, Capacity Building and Reflexivity are emerging dimensions of responsible research conduct [41].

Most policies allude to the development of a positive and supportive research culture that is aligned with those values. The Royal Society (UK) defines research culture as encompassing 'the behaviours, values, expectations, attitudes and norms of our research communities' [42]. Research cultures exist at local (for example an individual lab or research group), institutional, disciplinary and global levels. Research cultures are multi-layered and are essentially co-created by policy-makers, professional bodies, industry and commercial interests, institutions, academic departments/ laboratories, academic leaders and researchers at all career stages, publishers and editors [43]. As such, all agents within the research ecosystem have a role in fostering and promoting such a culture both locally and more widely [43]. This presents an opportunity for reflection. We need to scrutinise where our research cultures might fail to

reflect these values, and ensure that the research questions we ask, the processes that we follow and the behaviours that we model and promote align with these core values and contribute to a positive research culture, and be vigilant, and call attention to examples of potential influences that might steer research away from them.

Problems of research integrity and a lack of engagement with the policies described above are contributors to the frequent failure of research findings to be reproducible. Munafo et al. (2017) [44] published a manifesto for reproducible science that outlined key challenges and potential solutions to improve reproducibility, many of which we discuss here. These include proposals to improve methods, reporting, transparency, peer review and how research practice is incentivised. In 2023, the UK Parliament House of Commons Science, Innovation and Technology Committee published the findings of an inquiry into research reproducibility and integrity [45]. They recommended that research institutions, publishers and researchers should work alongside each other to create an environment which champions research integrity and reproducibility. They concluded that all disciplines face challenges that limit the reproducibility of research, though the scale of the issue is difficult to quantify. The report identified specific threats that included academic career incentives that value outputs and perceptions of novelty over rigour and reproducibility, career instability, inconsistent approaches to research integrity training, a common lack of adequate statistical expertise on project teams and suboptimal publishing behaviours that value novelty over confirmatory studies. Key recommendations from the inquiry for a range of stakeholders included:

- refocusing researcher incentives to value reproducibility
- the development of adequate statistical expertise in research teams
- greater emphasis on research integrity and reproducibility in research training
- more secure contracts for post-doctoral researchers
- ensuring open access to research, encouraging open research practices
- ensuring publication of negative results and funding for replication research
- timely action from publishers to correct errors and retract problematic papers
- The inquiry acknowledged that most reproducibility issues are not the result of deliberate bad practice but that many incentives faced by researchers act against reproducibility

Researchers operate within a broad and complex ecosystem of relationships and power brokers that contains myriad pressures, politics and incentives that positively or negatively affect behaviours. Figure 2 illustrates a simple model of this complexity. Researchers work in local communities and broader research communities with their own norms, standards and expectations that inform and drive their behaviours. Peers and mentors may model, and local leaders may demand or create incentives and pressure towards both good or poor practice. Research Institutions, industry employers, regulators, research funders, sponsors, policymakers and editorial and publishing organisations and processes may do likewise. Moving towards more trustworthy evidence requires action and change at all these levels.

These incentives that discourage best practice have long been recognised. In 2013 the San Francisco Declaration on Research Assessment (DORA)[46] was launched to draw attention to this issue; it made recommendations to ensure that research is evaluated on its own merits and in a way that promotes research excellence. The declaration is supported internationally and at the time of writing has over 23000 individual and organisational signatories in 161 countries. The 2015, the Leiden Manifesto cautioned against the overreliance on and misuse of research metrics such as the H-index and journal impact factors in evaluating research and researcher performance [47]. In 2020 the Hong Kong Principles for assessing researchers [48] aimed to establish principles to ensure that researchers are explicitly recognized and

rewarded by their institutions for behaviours that strengthen research integrity. Table 2 illustrates those principles in full. In 2022 the international Coalition for Advancing Research Assessment (CoARA) [49] published an agreement for research assessment reform with the goal of changing assessment practices and incentives to maximise the quality and impact of research.

Table 2. The Hong Kong Principles for assessing researchers [48]

Principle 1:	Assess researchers on responsible practices from conception to delivery, including the development of the research idea, research design, methodology, execution, and effective dissemination
Principle 2:	Value the accurate and transparent reporting of all research, regardless of the results
Principle 3:	Value the practices of open science (open research)—such as open methods, materials, and data
Principle 4:	Value a broad range of research and scholarship, such as replication, innovation, translation, synthesis, and meta-research
Principle 5:	Value a range of other contributions to responsible research and scholarly activity, such as peer review for grants and publications, mentoring, outreach, and knowledge exchange

The recent European Commission-funded "Standard Operating Procedures for Research Integrity (SOPS4RI)" project has developed tools to help Institutions that conduct research [50], and research funding organisations [51] to promote research integrity. For research active institutions, core recommendations include: creating an environment that fosters integrity and minimises misconduct and questionable research practices; offering quality mentoring and supervision and formal research integrity training to researchers at all career stages; ensuring robust structures to promote and ensure research meets ethical requirements; providing training and infrastructure to support robust data management; encouraging responsible collaboration; promoting responsible communication of findings including the use of preregistration, preprints, and online repositories; guidelines for the attribution of authorship for handling authorship disputes; open access; expectations about the use of reporting guidelines; procedures for avoiding predatory journals; strategies for responsible peer review practices; mechanisms to support and acknowledge public communication of research findings; transparency around declarations of interest; and clear policies for dealing with breaches of research integrity.

Although policies and incentives are of great importance to promote a culture of research integrity and good governance, ultimately the behaviours of individual researchers will, at least to some extent, define our success in that goal. Researchers have a shared responsibility to conduct their research with integrity, to meet contemporary standards of best practice, to model and promote those behaviours and to recognise and confront poor practice. Network discussions recognised that researchers routinely hold multiple roles in the ecosystem and hold different power in each. Researchers will commonly be leaders, mentors, peer reviewers, funding panel members, editors, institutional managers, consumers of research and people with pain. This provides an opportunity for researchers to promote and model the values of trustworthy evidence consistently through their actions across each of these roles to encourage systems-level change by advocating for systems that facilitate and support research conducted to high standards of integrity.

Declarations and conflicts of interest

Conflicts of interest are a fundamental research integrity issue. They have been defined by United Kingdom Research and Innovation (UKRI) as "a situation in which an individual's ability to exercise judgement or act in one role is, could be, or is seen to be impaired or otherwise influenced by their involvement in another role or relationship." Like all fields, the health research ecosystem is influenced by various different agendas that may explicitly or implicitly influence the research process. These will include commercial and financial, professional, regulatory or personal interests which can all create potential conflicts of interest. [52] In terms of these, commercial and financial interests have received the

most attention in regard to the potential for creating conflicts of interest. It is clear that industry and commercial actors seek and maintain extensive relationships with the research community and other relevant stakeholders including professional organisations, clinical education providers, regulators, guideline developers and patient groups, with varying levels of transparency [53–56] all of which may influence the research that is done, its design and conduct, its interpretation and how that is used to inform patient care. Such interests are relatively well understood, including direct or indirect payments or funding/ sponsorship, gifts, employment and shareholdings [56], though the rules and compliance with them vary across journals and institutions. Although industry involvement and collaboration are fundamental features of the research landscape, McLeod et al. point out that the profit motive is central to industry involvement in research and that this necessarily includes its interactions with "seemingly independent researchers and clinicians" [21]. Industry sponsorship is associated with more favourable efficacy results in drug and device trials [57].

Non-financial interests might include the interests of certain professional groups, personal and professional identity, strong personal investment in specific theoretical models or models of care, bias towards a specific outcome amongst researchers or broader personal beliefs and values [56]. These are less frequently addressed or reported in health research and are arguably less well understood or easy to identify, but like financial interests can adversely influence the choice of research that is undertaken, its design, analysis, interpretation and communication. All interests affect what we might label "researcher equipoise", that is, researchers' beliefs, wishes and personal position in relation to the research question and its possible answer. Recent years have seen many journals, funders and guideline developers move to strengthen their policies on these declarations of interest, but at all levels of the ecosystem, vigilance and structures are needed to minimise the potential negative influence of vested interests.

It is important to acknowledge the distinction between declarations of interest and conflicts of interest, whereby a third party determine whether a declared interest represent a conflict. Such interests do not necessarily cause a material conflict but present the potential for it, and whether an interest presents a conflict is a matter of judgement for all consumers of research. As such, the accepted norm in research is for full and open declaration of interests to allow the reader to make an informed judgement [56], and failure to do so may be considered a form of misconduct. This responsibility applies to research authors, peer reviewers and journal editors [58].

Beyond transparent declarations of interest, there is value for researchers in critically examining their own interests, preconceptions, biases and beliefs and how they might exert an influence on our research. It is naïve for researchers to presume they are objective despite such interests. Jamieson et al. [59] have recently advocated for the adoption of the principles of reflexivity, a common feature of qualitative research, into quantitative research methods. They define reflexivity as "the process of engaging in self-reflection about who we are as researchers, how our subjectivities and biases guide and inform the research process, and how our worldview is shaped by the research we do and vice versa." (page 2). Their argument starts from the acknowledgement that no research is purely objective or untouched by the perspective and behaviours of researchers, and that all research presents researchers with multiple choices (or degrees of freedom) that can be influenced by their positionality and that can, in turn, influence research results and their interpretation. They propose that researchers, both quantitative and qualitative, should engage in reflexive practices and that making this process transparent and clear, including the incorporation of reflexive statements in study registrations, protocols and final reports, might mitigate against the influence of unchecked assumptions and biases, reduce the risk of questionable research practices and enhance the "credibility and verifiability" of research. This proposal, for routine reflexive/ positionality statements in research has been challenged. Savolainen [60] argue that while positional bias and cultural underrepresentation in research are serious issues, and the practice of reflexivity is valuable, specific positionality statements are problematic as: 1. It is not possible to construct credible positionality statements as they are themselves constrained by the researchers' positionality; 2

reducing bias in research is not dependent on the biographical details of scholars and 3. The process of personal disclosure involved undermines the norms and practice that safeguard impartiality in research. At the time of writing, we are not aware of the adoption of these practices in any quantitative pain research.

The network had extensive discussions around the issue of positionality and the value of formal statements. The network agreed that it is essential that researchers reflect honestly and carefully on their biases and positionality throughout the research process. However, views varied on the best ways to undertake and report this process and on the value of formal positional statements for all research. Discussions explored uncertainty about how to choose which characteristics to represent and exclude and whether information around positionality would be better embedded in the methods and limitations sections of research reports or as a separate statement. There was a view that this is an area in need of further enquiry in order to develop robust and meaningful guidance. As a result we did not report a formal positionality statement for this project.

Publishing integrity

Editors and publishers hold substantial power in the research ecosystem by virtue of their gatekeeper role in terms of published research literature. The Committee on Publishing Ethics (COPE) [61] and the International Committee of Medical Journal Editors (ICMJE) offer guidance and recommendations for best practice in academic publishing, addressing key research integrity issues including [62] authorship, conflicts of interest, data and reproducibility, ethical oversight, intellectual property, peer review, and post publication issues including allegations of misconduct, errors and corrections. There is however, no obligation for editors and publishers to sign-up to or require authors compliance with these recommendations, nor to comply with them if they are signatories. The Centre for Open Science produced guidelines for transparency and openness promotion "The TOP guidelines" in Journal Policies and Practices in 2014 [63]. However limited knowledge of how to implement policies and multiple pressures, including commercial interests of publishers, the practical challenges of time and resource in the context of multiple and growing indicators of quality that demand editors' attention and the increasing challenge of securing peer reviewers may all act as barriers to action to improve policies and practice

Recent years have seen the emergence of new threats to the integrity of scientific publishing in the form of so-called predatory journals/ publishers and paper mills. Paper Mills have been defined by COPE as "profit oriented, unofficial and potentially illegal organisations that produce and sell fraudulent manuscripts that seem to resemble genuine research" [64]. Their activities may range from providing data to ghost-writing full manuscripts and paper submission, often at scale [65]. The rise of paper mills presents a self-evident threat to the trustworthiness of our evidence through obfuscation of authorship and contribution, and the proliferation of inauthentic data in our evidence base. A 2022 report from COPE and STM [66] based on an analysis of >53000 papers across a range of subject areas estimated that most journals will see at least 2% of fake papers submitted, with that number increasing sharply after paper mills have achieved successful publication. The report recommends a major education exercise to raise awareness with editors; changes to the incentives for researchers from institutions and funders that might encourage paper mill use; investment in tools and systems to identify suspect papers; and a review of retraction processes to allow for speedier removal of papermill papers from the literature. The emergence of generative Artificial Intelligence technology offers a potentially potent accelerant to the generation of fake manuscripts

The "UNITED2ACT" consensus statement [67] followed a virtual summit and include international signatories including researchers, publishers, research funders and COPE. It recommends 5 collaborative multi-stakeholder actions to confront the threat including: 1. Education and awareness resources for

researchers, journal editors, reviewers, journals, and publishers, 2. Improvements in the process of post-publication corrections, 3. Research into paper mills, 4. The development of trust markers to verify legitimate authors, reviewers and editors and 5. A continued dialogue between stakeholders about the systematic manipulation of the publication process.

The term "predatory" has been applied to open access, profit-driven journals and publishers who fail to provide legitimate editorial or publishing services or to adhere to other expected standards of editorial and publishing practice including legitimate peer review [68,69]. A consensus definition developed by Grundiewicz et al. states: [70] "Predatory journals and publishers are entities that prioritize self-interest at the expense of scholarship and are characterized by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices."

There has been an explosion of such journals in recent years as an unwanted consequence of the open access agenda. A study in 2014 [71] found that amongst 996 publishers of almost 12000 "journals", the volume of publications from predatory journals across all scientific disciplines rose from 53,000 in 2010 to 420,000 in 2014. Biomedicine accounted for around 70,000 of those publications. A 2019 review of predatory publishing in Anesthesiology [72] identified 212 "journals" from 83 publishers. While many publishers reported their location as the US, in 43% of cases this was considered unreliable after checking with Google Maps. Only 6 journals were indexed on PubMed and many provided incomplete, inconsistent or inaccurate information regarding editorial policy and practice. Like paper mills, these exploitative entities create a growing threat to the evidence-base through the propagation of poor quality and fabricated research. To help researchers to better navigate journal choice and avoid predatory publishers, the cross-industry "Think, Check, Submit" initiative [73] has created checklists to help researchers identify trusted journals and publishers for their work.

Further and emerging threats to the integrity of academic publishing include authorship manipulation, which has many forms including "gift authorship" in which named researchers did not meet the criteria for a legitimate author contribution [74] , authorship and citations for sale [75,76], ghost writing in which 3rd party, often commercial entities, write papers without presenting as authors, which are then attributed to academics [74] and fake peer review, in which authors manipulate the peer review process by nominating fake reviewers, "friendly reviewers", or even themselves, and sometimes at scale [78]. As with paper mills, these practices require vigilance and the development of coordinated solutions by and for editors and publishers.

Enhancing Trust: Governance and Integrity
Core Value: Research and researchers should demonstrate high standards of research integrity and governance. Universal Actions & Behaviours: • Value, follow and promote the principles of research integrity. • Consider markers of integrity and good governance as key quality indicators for research.

The network considered that it should be expected that researchers across all roles should be knowledgeable about the core principles and practice of research integrity and governance and value, follow and promote those.

In terms of specific targets and actions the network proposed the following actions that can be taken immediately:

Researchers

- Act consistently in alignment with the principles and values of research integrity. They should be aware of local and wider research integrity and governance policies and act in alignment with those.
- Consider their own positionality, interests and biases and how they may impact the research process and clearly declare all interests (financial, professional and personal).
- Clearly declare all interests (financial, professional and personal).

Institutions

- Provide meaningful training to all research active and research-adjacent staff to promote the values of research integrity and good governance.
- Provide and maintain structures, policies and support to facilitate optimal research governance and assess and incentivise research and researchers in line with the Hong Kong Principles [48].

Research Funders

- Ensure that the values and practices of optimal research integrity and governance are key pre-requisites to funding success, by requiring key details to be included in funding applications and post-award monitoring of adherence.

Regulators and Policymakers

- Review, ensure and rigorously implement policies and processes that incentivise and safeguard research integrity
- Ensure full transparency of declarations of interest across all processes.
- Ensure that the values and practices of research integrity and governance are key criteria for regulatory approval and the adoption of research into policy.

Editors, publishers and peer reviewers

- Require and evaluate full transparent disclosure of Declarations and Conflicts of Interest.
- Consistently consider and value indicators of research integrity practices in the editorial process and require full clarification from authors where any practice is unclear.

The network proposed the following actions that can be taken in the medium and/or long term:

Research Funders

- Prioritise funding for high quality meta-research as a form of monitoring of research practice in the community across all elements of the framework.

Consumers of research

- Look for information regarding ethical approval of the research.
- Look for information on declarations of interest and sources of financial support. Consider whether they might represent a conflict.

Key resources and information to support Research Integrity can be found in Supplementary Table 1.

Equity, Diversity and Inclusivity

In 2023, the editors of eight international pain journals concurrently published a commentary titled "Promoting inclusion, diversity and equity in pain science" [5]. This commentary acknowledged the long history of discriminatory and oppressive practice in science and medicine and how this is clearly reflected in the study, science and practice of pain. It is perhaps unsurprising that systematic inequities and injustices that have been long observed in society globally will be reflected in the research and clinical practice conducted in those societies. But the negative consequences of these inequities, and the risks of failing to act to address them are serious and far-reaching.

Beyond the fundamental injustice, these consequences include creating and sustaining a research community and career structures that systematically underrepresent or exclude minoritized and marginalised groups, with clear impacts on the diversity of perspectives that can be brought to the questions that we choose to ask, the understanding and wisdom that we use to frame those questions, the methods we apply, which groups we generate evidence for and the ways that we interpret and implement evidence in practice. The resulting lack of representation and diversity of knowledge has and will continue to result in research that fails to reflect and inform the needs of all groups, research practices that cause substantial harm to minoritized groups, and research that reinforces or misses opportunities to challenge discriminatory beliefs and practices in pain care [4,79,80].

This is not an academic consideration. Clear, non-exhaustive examples of harm and unjust practices can be found in the systematic exclusion of women and racialised groups from science as a profession and from research participation, of older people from studies exploring pain therapies, and of the failure of research to challenge and address racist and discriminatory beliefs and practices in healthcare that have resulted in the under-estimation and under-treatment of pain for people from those groups [4,5]. In a recent systematic review of representation in low back pain clinical trials [81], 76% of trials did not report any data on race and ethnicity and no study reported data on gender or sexual minority status. In US-based trials that reported data, Black participants were the only racialised group whose composition were comparable to census estimates, and ¼ of trials excluded adults over 65.

It is important to recognise that commitment to equality, diversity and inclusion needs to be embedded into the design of non-human pre-clinical research (whole animal, cells and tissue models). Under-representation of sex and age is an important problem in pre-clinical pain research, with animal research heavily dominated by studies with exclusively male animals [12,82–84] and only a small minority of studies including female-only or mixed-sex populations. This is both remarkable and highly problematic for a condition (persistent pain) that disproportionately impacts women [85]. Homogeneity is found with regards to age, species and strain of animals, further limiting generalisability and reproducibility [86]. Careful consideration should be given to animal characteristics, including the choice of species, strain [87], sex [88], and age [89] in relation to the clinical condition being modelled, because these factors influence what conclusions can be drawn. Several funders have instituted policies and guidance to ensure the use of both sexes as default e.g., US National Institutes of Health [90] and the UK Research Innovation Medical Research Council [91]. The UK's National Centre for the Replacement, Refinement and Reduction of Animals in Research, Experimental Design Assistant [92] ensures consideration of all factors to support researchers to design robust and reliable animal experiments.

Where research is conducted is also highly relevant to issues of equity. In a review of the challenges of improving musculoskeletal health on low to middle income countries (LMICs) [93] the need to build local research capacity was identified as a key step to developing and testing models of care that are locally contextualised and culturally appropriate. Sharma et al. [94] argue that research conducted by, with and within LMICs is critical to improving global health and they outline key challenges to this including under-investment, limited awareness and research training, a lack of local research roles and career opportunities and the challenges of publishing in another language, a lack of editorial understanding of the local research contexts in LMICs and a failure of editors to recognise the relevance and impact of

research in LMICs. They issue a call to researchers to seek international collaborations and for journals and editors to consider equity, diversity and inclusion in editorial boards, in selecting peer reviewers, in offering support to researchers from LMICs and to facilitate mentorship activities. Critically, when developing these international collaborations, researchers need to create equitable partnerships where their LMIC colleagues' expertise is valued through co-principal investigator or co-investigator status, rather than limiting involvement to consultancy or collaboration.

In health research based in LMICS under-representation of authors from those countries in journal articles remains a serious issue as does equitable partnership with local stakeholders [95]. This lack of inclusion has led to calls for journals to require authors to submit structured reflexivity statements outlining ways in which equity has been promoted in the partnership that produced the research [96,97]. These principles hold for research in all settings and communities. There is a need to carefully consider where our research is conducted, by and with whom and the impact that this will have on the inclusivity, context and diversity of that research and the results it produces.

There are multiple ways in which inadequate equity and inclusion detract from the trustworthiness of pain research. Research about a population that systematically excludes affected groups within that population can seriously undermine generalisability and transferability. Research that applies simplistic, inaccurate and discriminatory approaches to measuring and reporting participant characteristics such as limited or missing categories to capture race risks reinforcing biases and stereotypes and drives unwarranted and inappropriate conclusions. Without the collection of important identity characteristics, research obfuscates that data from affected groups is missing. But there is a broader question of who do we want to consider our research trustworthy? The history of inequity, discrimination and harm in pain research and practice has engendered distrust in minoritised communities in relation to clinicians and researchers, and concern that and the research produced does not represent them or serve their best interests. As an example, the Black British Voices Project in the UK [98] found that less than 1 in 60 respondents felt fairly treated within the healthcare system and 87% of respondents expected to receive substandard care because of their "race". Trust must be earned through clear acknowledgement of past and current failures and by demonstrating our commitment, acting to address these problems now and in the future.

The Antiracism CoaliTION in Pain Research (ACTION-PR) group published a call to action in 2022 [4], calling on the pain community to act to dismantle racism in our research practices. In a series of papers they highlight, with specific examples how concepts of racialised identity are socially and politically constructed and have created and reinforced imbalances of power, inequity and oppression both in society and in pain research. They propose an antiracism framework to pain research that requires all stakeholders in pain research to proactively reflect on how racism can pervade our work in order to act to minimise it [4], discuss how this can be used to reframe the design of studies [80] and invite all pain research disciplines to commit to confronting racism with some key recommendations that broadly include building community partnerships and engagement, proactively addressing inclusivity in participants recruitment and engagement, diversifying research environments and careers, reframing research designs, and proactively considering antiracism principles in the dissemination of research findings [99]. Importantly anti-racism is defined as the "active process of eliminating racism by changing systems, organizational structures, policies and practices, and attitudes, so that power is redistributed and shared equitably" and presented as an alternative to the more passive "non-racism" which is limited to the passive rejection, opposition and disassociation from racism. Looking at equity and inclusivity more broadly than racism, it follows that anti-racism might be considered as a key part of a broader need for anti-discriminatory approaches that consider all minoritised and marginalised groups. Although the scholarship of ACTION-PR is framed through the lens of antiracism, predominately in Western countries (e.g., USA, UK), in every country, there is a group who experiences social and political oppression or stratification (e.g., caste systems). Therefore, similar principles of antiracism should be applied to these excluded groups in pain research.

The Action-PR group has subsequently created the Inclusion, Diversity, Equity, Antiracism, and Accessibility (IDEAA) guidelines that aim to increase transparency and equity in manuscript reporting [100]. These guidelines encourage researchers to adopt inclusive language, to apply accurate interpretations of constructs of racialised identity, ethnicity, sex and gender, to clearly make and report efforts to promote diversity and inclusion of study samples and to comprehensively report sample characteristics. At the time of writing, these modified guidelines have been adopted by the Journal of Pain [101].

In a recent review of the challenges of embedding a sex and gender perspective into pain research, Boerner and Keogh [102] identify the entrenched challenges of conceptual imprecision between sex and gender, a bias against the inclusion of women and female animals in research, a lack of attention to and clear reporting of sex and gender influences, challenges to binary conceptualisations of sex and a lack of clear methods for the consistent integration of sex and gender in pain research. In moving towards meaningful change and greater inclusivity they recommend adherence to guidelines on the reporting of sex and gender, the development of intersectional designs that take a systems-level approach to exploring these characteristics and partnership with external stakeholders and policymakers to help research in this area to translate to practice.

Palermo and colleagues [5] propose 4 general principles for authors, reviewers, editors and publishers to promote equity and inclusivity:

1. Promote inclusive and representative scholarship and fair, unbiased reviews.
2. Use language that is inclusive and minimises bias.
3. Include representative populations in pain research and comprehensively report data for demographic variables
4. Report demographic variables and use social frameworks for interpretations (that is, include measures of a combination of sociodemographic and social determinants to advance understanding of disparities in pain).

Returning to reflexivity, Jamieson et al. [59] and Macgregor et al. [103] make the case that reflexivity practices and reflecting on their own positionality in relation to research may help researchers to identify and address equity issues throughout the research process driven by hitherto unacknowledged biases and assumptions.

Enhancing Trust: Equity, Diversity and Inclusivity
Core Value: Research should be equitable, diverse and inclusive. Universal Actions and Behaviours: • Act to optimise inclusivity, diversity and equity in the design, conduct and reporting of research. • Value and promote anti-discriminatory practices a key quality indicator for research • Cultivate equitable diverse and inclusive research environments/ communities.

The network considered that it should be expected that researchers across all of their roles should be knowledgeable about the issues of inequity and poor inclusivity, understand the recommendations for more inclusive, anti-discriminatory practices and values, and follow and promote those.

The network proposed the following specific actions that can be taken immediately:

Research Institutions, Funders, Editors

- Establish and adopt guidance and recommendations for researchers and reviewers for embedding equity and inclusivity in research.
- Promote and implement guidelines for reporting all research in an equitable and inclusive

manner [97].

- Value and incentivise good practice in equity and inclusivity by making them key quality indicators of research, academic practice and promotion criteria
- Encourage recruitment of minoritised groups in research along with detailed reporting of important demographic variables for all study samples.
- Support funding and calls for papers that promote the inclusion of minoritised groups as researchers through positive action.

Regulators and Policymakers

- Review, ensure and rigorously implement policies and processes that incentivise and safeguard appropriate equity, diversity and inclusivity in pain research.
- Ensure that appropriate equity, diversity and inclusivity practices in research are key criteria for regulatory approval and the adoption of research into policy.

Peer-reviewers

- Prioritise equity and inclusivity in conduct and reporting as an important quality indicator when reviewing research and request/ require that information where it is not clearly presented.

Researchers

- Plan and adopt strategies to maximise inclusivity at the very start (conception and planning) of the research process engaging positively with potential community partners from the start and throughout and clearly report these activities, and where such efforts were not made, with specific reasons.
- When reporting research:
  - adopt inclusive language,
  - apply accurate interpretations of constructs of race, ethnicity, sex and gender
  - clearly make and report efforts to promote diversity and inclusion of study samples
  - comprehensively report sample characteristics [97]
- Consider their own positionality as it relates to issues of inclusivity and equity in the research.
- Make a start today.

Consumers of research

- Reflect on what information is provided about who was and was not included in the research.

The medium- to long-term vision is for these anti-discriminatory practices to be normalised and fully embedded in the design and reporting of all research and for detailed reporting of important demographic variables to be mandated for all study samples.

Key resources and information to support Equity and Inclusivity in research can be found in Supplementary Table 2.

Patient and Public Involvement and Engagement (PPIE)

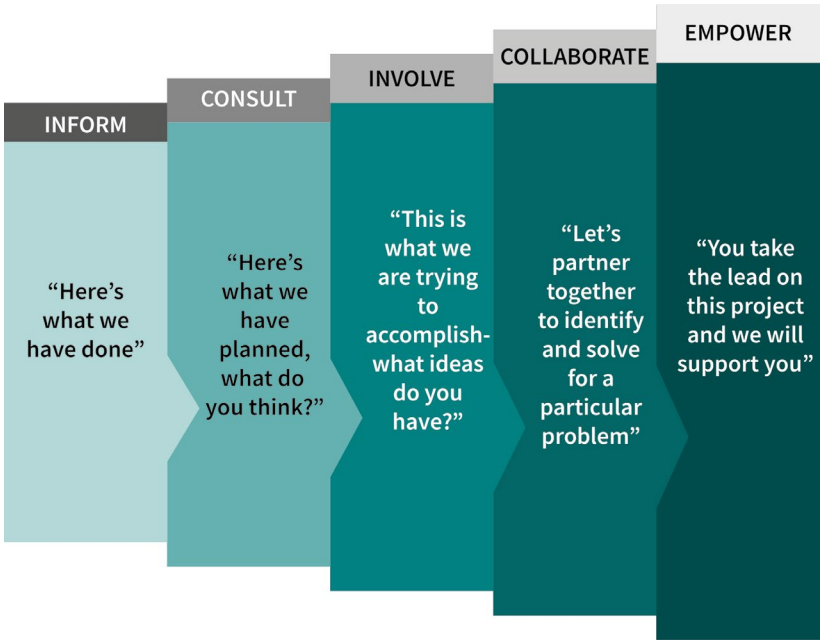
There is growing acknowledgement today that involving patients, people with lived experience (PLE) of a condition and the public is a highly desirable process in research, indeed that it is the right thing to do [6]. When implemented well, PPIE addresses the limitations of the "Researcher as Gatekeeper" paradigm [6], improving the likelihood that we pursue relevant research questions , reduce research waste, measure outcomes of relevance to patients and affected communities, and translate that knowledge more effectively. PPIE affords us the opportunity to access the lived experience of pain as a valuable and valid way of knowing pain. As Smith and Belton argue [104], PLE bring expertise in the experience of pain, seeking care, and managing their pain in their lives. This creates the potential to challenge existing paradigms and assumptions, which can lead to innovative approaches and solutions. These benefits of PPIE apply across the research pipeline, from pre-clinical/ laboratory-based research to clinical and community-focused studies. Although PPIE has been less common in preclinical research, with researchers often believing there are limits to patient and community capacity, less scope for research to be beneficial and that research questions, design, and data are too complex, a recent scoping review concluded that PPIE is both feasible and potentially beneficial in this area [105].

In a recent scoping review of frameworks for supporting PPIE, Greenhalgh et al. [106] summarised 3 key arguments for this involvement: 1. Normative/ Emancipatory: that patients have a right to have an input to research on their condition and that reducing the known power imbalances between researchers and patients is a moral duty of researchers, especially with oppressed and seldom-heard groups. 2. Consequentialist/ efficiency-oriented: By bringing a real-world and lived-experience perspective, PPIE improves the efficiency and value of research via a number of mechanisms: increasing its relevance to patients; improving recruitment and retention rates; extending the range of people represented in research; and improving dissemination of findings beyond academic audiences. 3. Political/ practical: that forming alliances with patients and the public is a defining feature of contemporary science, increasing the accountability and transparency of research and may be an effective way of attracting resources. (106)

PPIE can take many forms, has many names, and a diverse range of frameworks have been used to support PPIE in clinical research. Greenhalgh [106] grouped these into five broad types: 1. Power-focused frameworks that focus on understanding and challenging power differentials between researchers and patients and the public, 2. Priority setting frameworks, which involve patients and the public in setting research priorities, 3. Study focused frameworks which present methods for involving patients and the public in the design and conduct of research studies, 4. Report-focused frameworks that offer guidance for reporting how PPIE was approached in a research study and 5. Partnership-focused frameworks, that emphasise support measures in place to facilitate effective partnership with patients and the public.

There is no single mechanism by which patients or lay-people can be involved in research. As Hoens et al. share, [7] effective PPIE requires careful, creative and collaborative planning and effective resourcing. Patient and public involvement and engagement exists on a spectrum. At one end, patients and the public are simply informed or consulted. At the other end, patients and the public are involved more extensively, such as when research is collaboratively co-designed and co-produced between researchers and patient/ public partners. Different levels of involvement may be appropriate at different stages of a research project. The International Association for Public Participation propose a spectrum of participation from "inform" to "empower" [107]. Figure 2 illustrates those levels. It is also important to note that PPIE is both useful and feasible for preclinical research as well as clinical research [101]. Significantly, both the breadth (e.g., in what aspects of the study is PPIE included) and the depth (e.g., are patients and community partners empowered to receive meaningful value from their involvement?) should be considered.

Figure 2. Levels of participation. (Adapted with permission from IAP2 Spectrum of Public Participation)



It is important to recognise common challenges of patient and public engagement. Richards et [108] outline some key barriers to PPIE that include tokenism, that is inclusion in order to "tick a box" that is not meaningful, unconscious bias towards patient partners, lack of attention to the vulnerabilities of patient partners and lack of support (financial, physical, procedural and resource-based). Many of these may be avoided if PPIE is underpinned by appropriate values. The Canadian Institutes for Health Research strategy for patient-oriented research presents a vision where "patients are active partners in health research that will lead to improved health outcomes and an enhanced health care system" [109]. They propose that PPIE should follow the guiding principles of Inclusiveness, Support, Mutual Respect and Co-building. To enable successful and collaborative engagement it is critical that researchers are transparent with potential partners from the beginning and consistently communicate with them what is planned, expectations, levels of involvement, types of contributions partners can make and the support and recognition that they can expect. In their review of PPIE in preclinical laboratory research Fox et al. [105] identify benefits of PPIE as well as specific but solvable challenges presented by the often highly technical nature of these studies and potential skills gaps arising from a lack of training and experience that preclinical researchers may have in communicating with patient partners.

Beyond the fundamental ethical imperative to create knowledge with and for all communities, PPIE is fundamentally a mechanism for improving equity and inclusivity in research. As such, careful thought must be given to who it is important to involve and to ensure that PPIE is diverse. There is a need to employ proactive strategies to engage with and involve members of less reached communities. This is true of all research, but particular considerations may be needed where research questions address issues that specifically impact some of those communities. The goal of involvement is not to achieve an unrealistic goal of broad generalisability, as it may be for the research itself, but to ensure that diverse voices are meaningfully represented from inception and throughout the process. There is limited literature describing PPIE in health research conducted in LMICs [110] but the need for PPIE is universal. Fox et al. [105] argue that PPIE can help to navigate the specific complexities of conducting research in LMICs by facilitating engagement with communities and enabling cultural adaptation of interventions.

Inclusive and diverse PPIE can help us to ask more relevant and rigorous questions that serve the needs of people with pain and the pain community and to develop dissemination strategies that allow all stakeholders to access and potentially benefit from research. The diversity of perspectives that PPIE can

bring to the research process may reduce imbalances of power, guard against the exclusion of specific groups, thus promoting equity, prevent potential failures of ethical practice and the hijacking of the research agenda by specific interests (for example, professional or commercial interests). There is a need for continued recognition and vigilance that patient groups themselves can be targeted by such interests, though the extent and nature of those relationships is frequently not transparent [111–115]. To mitigate potential conflicts of interest, researchers can consider and seek opportunities to work with independent patient and public partners are not recruited from or affiliated with such groups.

While PPIE has increased in frequency, it remains a feature of only a minority of published health research, is often not meaningful, and is largely only incorporated in human participant studies with PPIE partners who inadequately reflect the diversity of the relevant populations [116–119]. While there is a responsibility for researchers to engage meaningfully with PPIE, it is important to consider how the wider research ecosystem can promote, incentivise and normalise PPIE. We see examples of this in PPIE requirements of many key funding organisations for funding applications, and some journals require a clear statement as to how patients and the public were (or were not) included in the research process. Beyond these specific examples, the normalisation of engagement will require the inclusion of patients and the public and the sharing of power across the levels of decision-making structures in the ecosystem, including professional bodies and governance, ethical and funding arbiters. Given the significant benefits of PPIE outlined, it is also important that researchers and PPIE advocates, charities, and organisations promote inclusion and work to increase the number of minoritised and marginalised people in their groups. Although this is slowly changing, PPIE is limited in scope to who is involved, and activity does not always mirror the diversity of the population. Transparency and prioritising compensation and recognition for contributions are potential ways to increase representation. Compensation does not always have to be monetary and can include arrangements such as institutional library access, skills training, conference attendance, and/or co-presentation or co-authorship opportunities. [120]

There is a range of resources and guidance available to support effective PPIE (see Supplementary Table 3. These include wide ranging toolkits for engagement, co-production, guidance on compensation and reimbursement for patient partners, the evaluation of PPIE, knowledge translation and a reporting checklist (GRIPP2) for patient and public involvement in health and social care research [121]. In 2024 the ACTTION and IMMPACT groups published detailed consensus recommendations for PPIE in clinical studies [120].

Enhancing Trust: Patient and Public Involvement and Engagement
Core Value: Research should be undertaken in partnership with the public and people with lived experience. Universal Actions and Behaviours: • Commit to embedding Patient and Public Involvement and Engagement throughout the research process. • Value PPIE practices as a key quality indicator for research.

The network considered that the research community should embed PPIE throughout the research process. The network proposed the following specific actions that can be taken immediately:

Research Institutions, Funders and Editors

- Establish and adopt guidance and recommendations and appropriate support for researchers for embedding PPIE in research.
- Value and incentivise good practice in equity and inclusivity by making them key quality indicators of research and academic practice.

- Consider best ways to involve patient and public partners throughout decision-making structures.
- Ensure PPIE in the prioritisation and development of funding calls.

Regulators and Policymakers

- Review, ensure and rigorously implement policies and processes that incentivise and safeguard Patient and Public involvement and engagement in pain research.
- Ensure that Patient and Public Involvement and engagement in pain research are key criteria for regulatory approval or the adoption of research into policy.
- Ensure representation of patient and public partners throughout their decision-making structures.

Research Institutions and Funders

- Establish infrastructure, guidance, and support to facilitate and support PPIE throughout the research cycle.
- Offer sustainable funding and to adequately resource and support PPIE activity across the research process, including policies and funding to meaningfully and fairly reimburse patient and public partners for their involvement.

Editors and Publishers

- Require all submissions to transparently state what PPIE was incorporated in submitted research, and what was not with reasons presented.
- Require that PPIE is reported in alignment with reporting guidelines (e.g. GRIPP2). [121]
- Allow and facilitate patient and public partner authorship and remove barriers to such authorship (for example by removing need for institutional affiliations and their related email addresses for authors).
- Consider best ways to involve patient and public partners in editorial decision-making structures. Examples include ensuring patient and public partner membership on editorial boards, funding panels, advisory boards, ethics committees and as peer reviewers.

Peer-reviewers

- Consider PPIE as an important quality indicator when reviewing research.
- Request information about PPIE where it is not present or clear.

Researchers

- Plan PPIE at the very start (conception and planning) of the research process and engage potential partners before the project begins.
- For existing/ ongoing projects, consider how patients and public partners can be meaningfully involved if not currently doing so.
- Comprehensively report PPIE in alignment with reporting guidelines (e.g. GRIPP2) [121].

Consumers of Research

- Reflect on whether and how patients and/or the public were involved in the research process.

The medium to long term vision is for PPIE practices to be normalised and fully embedded in the design and reporting of all research.

Methodological Rigour

"We need less research, better research, and research done for the right reasons". These were the conclusions of Professor Doug Altman almost 30 years ago in his landmark commentary "The scandal of poor medical research"[19]. Professor Altman asked the question:

"What, then, should we think about researchers who use the wrong techniques (either wilfully or in ignorance), use the right techniques wrongly, misinterpret their results, report their results selectively, cite the literature selectively, and draw unjustified conclusions? We should be appalled. Yet numerous studies of the medical literature, in both general and specialist journals, have shown that all of the above phenomena are common." [19]

It is interesting to consider what progress has since been made to address this challenge. In 2022 Pirosca et al. [122] reviewed a sample of 49 Cochrane systematic reviews across a wide range of clinical disciplines. Of 1640 included clinical trials 62% were rated at high risk of bias and only 8% were rated as at low risk of bias. They estimated that 220,000 participants had been recruited into "bad trials" and those trials were estimated to have costed at least £726 million. While legitimate challenges of achieving blinding in some trials may have overestimated the degree of "bad trials", this remains a striking example of the problem of research waste.[20] Van Calster et al. [123] propose that poor quality research can result from poor design, conduct or reporting and propose the paradox that while methodology is undeniably the backbone of high-quality and responsible research, science consistently undervalues it.

In pain research similar examples are common. The recent International Association for the Study of Pain Taskforce on Cannabinoids conducted a series of reviews of the literature that offer a striking contemporary example of the problem. These reviews found that 86% of systematic reviews of the efficacy of cannabinoids were rated at low or critically low confidence [15], that all 36 clinical trials included in their own review were at unclear or high risk of bias [14] and that in pre-clinical (animal) studies, reporting of markers of methodological quality was very poor leading to judgements of unclear risk of bias in all 374 included studies.[12] Reviews of observational clinical studies frequently identify issues of quality or risk of bias in the included literature [124,125] and a meta-epidemiological study of observational studies in spinal pain and osteoarthritis found misalignments between study aims, methods and interpretations were common [126]. These examples illustrate clearly the dangers of a lack of attention to appropriate design choice, methodological rigour and transparency around that process.

Research waste is a substantial issue across the spectrum of biomedical clinical research. Research waste occurs where the wrong research questions are asked, where methods applied are sub-optimal, where research is not reported adequately and where research is inaccessible [21–25]. In a 2014 special series on increasing value and reducing waste in research the case was made for more careful prioritisation that is inclusive of all important stakeholders, which includes patients and the public, for systematic evidence synthesis to ensure that new research addresses important uncertainties and to reduce unhelpful duplication of effort and for greater rigour and transparency of methods and reporting [21–24].

Questionable research practices (QRPs) have been defined as "design, analytic, or reporting practices that have been questioned because of the potential for the practice to be employed with the purpose of presenting biased evidence in favour of an assertion"[127]. Although there is no accepted universal taxonomy of QRPs, frequently cited examples of QRPs include p-hacking (where researchers run multiple analyses or modify data eligibility to achieve statistically significant results) [128], inappropriate data redaction (e.g. arbitrary removal of "outliers") [129] hypothesising after the results are known (HARKing) [125] and the presentation of post hoc exploratory analyses as the primary analysis. [122] The drivers of QRPs are likely to be diverse and to range from naivety and a lack of relevant statistical and methodological expertise through to a desire (conscious or otherwise) to achieve a specific finding (usually in favour of the hypothesis). These in turn may be variously incentivised by a well-intentioned confidence in the veracity of the hypothesis being tested, a desire to achieve a novel finding, achieve a publication, or to

produce evidence to support a professional or commercial interest. Each represents a distortion of the scientific process. While these examples focus on quantitative methods, it is reasonable to assume that in qualitative research similar motivators are likely to encourage researchers to distort or selectively interpret and represent data. As Margry [131] suggests, questions for qualitative researchers such as "was my perception or interpretation of these words, facts, or phenomena fully correct? Was I as unbiased as I could have been in my interpretations and analysis? Did I see all the things relevant to my research and did I clarify what I did not consult? Did I leave something out which did not fit my theories? Can I justify my sources, have I cited correctly and sufficiently, or does this verge on plagiarism?" all speak to avoiding possible QRPs in social sciences.

A recent critical review addressing the challenge of producing reproducible and replicable pain research [132] identified a number of key factors driving non-reproducible research. These included a lack of transparency in the reporting of research, the high prevalence of underpowered studies, and the issue of researcher degrees of freedom, referring to the decisions available to researchers during the research process that can shift the outcome of the project. These might include, but are not limited to the removal of supposed outliers, selective changes in analytical approach or the selective reporting of outcomes. Lee et al. [132] recommended a number of potential solutions including widespread preregistration across the range of study designs, the adoption of registered reports to reduce elective publication issues, more open research practices such as sharing code, data and reproducible workflows and better adherence to reporting guidelines. Jamieson et al. propose that clear and transparent processes of reflexivity [59], in which the various "forking paths" that researchers navigate during a research project are acknowledged and resolved can help bring clarity to how researchers navigate degrees of freedom throughout the research processes, thereby enhancing trustworthiness.

It is vital to note that rigour is not at odds with the need for early stage, pilot and exploratory research. At all stages of the research cycle we should consider the optimal design to meet the goals of the research. Transparency is critical and we should be transparent and consistent about its exploratory or confirmatory nature and objectives, and what the limits of reasonable inference may be in that context. We should consider carefully where rigour can be reasonably introduced and what avoidable biases can be controlled for or managed, which outcome domains should be measured and how, the properties and limitations of those measures (clinical or otherwise) and the assumptions and the certainty of the evidence that underpins them. As MacLeod et al. suggest *"In essence, we need to value the quality of the research process more than we do the results of that research."* [43] (page 3).

In qualitative research, notions of rigour and optimal methodology are less homogenous. In terms of biases, qualitative approaches recognise that the researcher cannot be a blank slate and that researcher positionality should rather be recognised, understood and managed in a transparent and reflective fashion [133]. How researchers approach the complex concepts of bias and subjectivity should depend on what kind of qualitative research they are doing. For example, Braun and Clarke [134] argue that if researchers are working within a "Big Q" paradigm, which is qualitative research that is ontologically, epistemologically and methodologically fully aligned with qualitative values and philosophy (e.g. [135–137]), then instead of thinking about "researcher bias" from a positivistic perspective to be managed and controlled, we should welcome "researcher subjectivity" as a critical resource. Indeed, Braun and Clarke [138] argue that researcher subjectivity is fundamental for reflexive thematic analysis (TA), a particular type of TA which places a subjective, situated, questioning researcher at its heart. Braun and Clarke [134] give an example that instead of using code-recoding methods to arrive at a putative coding consensus, researcher subjectivity can be used as part of collaborative coding to strengthen the quality of interpretation.

Other kinds of qualitative research may be aligned to what "Big Q" proponents see as more positivistic perspectives of managing researcher bias as part of quality in qualitative research. There are many methodological writings available on strategies such as discussing interpretations and analyses until teams reach consensus (e.g. [139]) and code-recoding (including the possibility of quantifying agreement

between researchers, which may be seen as another step along a positivistic "small Q" continuum [135]. These strategies may be appropriate for more positivist-orientated qualitative research.

Various methods have been used to enhance the rigour of qualitative research including, but not limited to, reflexive practices, triangulation, peer debriefing, member checking and negative case analyses. However, the concept of universal criteria for rigour has been criticised [141]. Harley and Cornelissen [142] propose that rigour in qualitative research is established in and through a researcher's reasoning processes as opposed to being an intrinsic quality of a certain protocol, arguing that methodological templates or checklists may impede the reasoning required to truly achieve rigour and that what counts for a study will vary according to the epistemology and ontology in play [142]. In their model, rigour is underpinned by "coherence" and "inference to the best explanation". Coherence is demonstrated where the ontology, epistemology, methodology, methods/ data and theoretical claims of a study are clearly aligned and there are explicitly stated and logical links between the data and theoretical claims. Inference to the best explanation requires researchers to considered several possible interpretations of the data, display contrastive reasoning to justify the preferred interpretation and clearly indicate why that interpretation possesses the most explanatory power. But, as with quantitative research, transparency is critical to establish trust.

Methods guidance

There are a range of methodological guidance resources available to researchers to help plan and implement more rigorous and reproducible study methodology across a range of research areas. Supplementary Table 4 summarises a selection of these. Key examples include the new Enhancing Quality in Preclinical Data (EQUIPD) framework [143], which promotes aspects of good practice such as pre-defining clear hypotheses, clear planning and reporting of all methods and analytic approaches, pre-specification of a statistical analysis plan, appropriate use of randomisation and blinding and complete reporting. The PROGRESS framework [144–147] affords a clear structure and guidance for the design of prognostic research. In the field of clinical trials the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [148], the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) [149] groups have produced a range of guidance and resources on the development of high quality trials in pain and the UK Medical Research Council have developed a framework for developing and evaluating complex interventions [150]. For systematic reviews the Cochrane Handbook [151] has long been a trusted guide on best methods for evidence synthesis. Core outcomes sets have been developed for pain research which offer guidance for researchers on outcome domains of importance that should be measured and reported across studies (e.g. [152–154]) The INTEGRATE-pain project has produced recommendations for overarching COSs to be assessed in acute pain, the transition from acute to chronic pain, recurrent/ episodic pain and chronic pain [152]. The Core-OPPP group has produced a COS for paediatric persistent pain [153]. All these included PPIE as an essential part of the process. For each disease (and/or intervention related to pain), there may be additional COS to be considered (e.g. [154].Thoughtful engagement with these resources at the inception of a research project should allow researchers to minimise avoidable sources of bias, error and waste and to enhance the quality of their work, though methodological guidance does not obviate the need for methodological expertise in the research team.

Reporting Standards

Choosing and implementing appropriate and robust methods is critical, and it is equally vital to ensure that those methods are reported, transparently, honestly and in full. Users and reviewers of research can only make judgements based on what is (and is not) actually reported. Although there is a fair argument that the quality of reporting is likely an imperfect but reasonable surrogate measure of the quality of research conduct, discarding informative research based on an inability to recognise it is a potentially serious source of research waste.

The EQUATOR network [155] was established in 2008 [156] and has led the way in the development and curation of reporting guidelines for health research. It is important to recognise that reporting guidelines are broadly distinct from methodological guidance. While many of the items on a reporting guideline reflect good methodological practice, their goal is to provide a framework, often in the form of a checklist, that ensures a minimum list for the full and transparent reporting of research [157]. This common misunderstanding can often be seen where authors state incorrectly, for example, that their systematic reviews was conducted to PRISMA standards.

EQUATOR have published reporting guidelines for an inclusive range of study types including systematic reviews, clinical trials, observational studies, mediation analyses, diagnostic and prognostic studies, case reports, clinical practice guidelines, qualitative research, animal/ pre-clinical studies, quality improvement studies and economic evaluations, many with extensions for specific purposes and all freely available on their website. Reporting checklists continue to evolve with new tools being published regularly. As an example, a recent extension of the CONSORT statement (CONSORT-Outcomes) facilitates more comprehensive reporting of outcomes in clinical trial reports, and includes the requirement for clear reporting where switching of (primary) outcomes occurs and the reasons for doing this [158] Supplementary Table 5 outlines key EQUATOR reporting guidelines.

Reporting guidelines are not a new initiative and yet their application is piecemeal at best. Indeed, a recent review of meta-epidemiological studies that explored guideline adherence found 84 out of 90 studies concluded that adherence was inadequate [159], though, perhaps ironically, that the majority of those studies failed to report a clear reproducible methodology. It is the responsibility of researchers to ensure their reporting meets high standards and these checklists provide a mechanism for that. However, there is a major role for editor and peer reviewers to encourage and evaluate this behaviour. This can be done through mandating their inclusion in manuscript submissions, signposting to them in the submission process and indicating where they have not been met during review but it is essential that editors and reviewers scrutinise the quality of the checklist reporting. There may be potential to create automated checks for compliance in the future. Funders can also mandate their use as a requirement of successful funding. There is also a role for senior researchers to model these behaviours and make clear to their mentees the expectation that reporting standards are met.

Emerging and Future Methods

Research methods and methodologies are constantly evolving. Currently, we are seeing growth in and advocacy for the use of machine learning (MI), for big data research, “real world evidence” and artificial intelligence (AI). All may add value though there is a need to proceed with caution and be mindful of the potential for innovation bias, in which novelty and/or technical complexity (or marketing to that effect) are valued in place of rigour and transparency. As an example, any MI approach or AI whose code, underpinning data and the assumptions therein are not available to scrutiny lack the necessary transparency for trustworthiness. Regardless of method or technology, rigour and transparency are key.

Enhancing Trust: Methodological Rigour
Core Value: Research should be designed and conducted to optimise methodological rigour (appropriate to the question) and be reported completely and transparently. Universal Actions and Behaviours: • Value, conduct and promote methodologically rigorous research (the process). • Avoid and call attention to Questionable Research Practices. • Value and promote transparency of methods and compliance with accepted best standards of reporting.

The network considered that methodological rigour and transparency is a critical feature of trustworthy research and proposed the following specific actions that can be taken immediately to enhance trust.

Institutions

- Provide meaningful training to promote the values of Research Integrity.
- Offer sustainable training and infrastructure to support open research practices for research staff at all career levels.
- Sustainably invest in developing methodological and statistical expertise in academic staff.

Research Funders, Editors, Publishers and Peer Reviewers

- Prioritise methodological rigour and transparency as an important indicator in funding, reviewing and editorial decisions.
- Require that authors report research according to established reporting guidelines/ checklists at the point of submission and carefully audit that.

Regulators and Policymakers

- Prioritise methodological rigour and transparency as key criteria for regulatory approval and the adoption of research into policy.

All stakeholders

- Be aware of common QRPs, avoid them in their own practice and call attention to them and not tolerate them when encountered.

Senior Researchers

- Support early career researchers to feel able and safe to raise legitimate concerns about QRPs.

Researchers

- Seek or consider conducting a high-quality evidence synthesis prior to embarking on any new primary study.
- Ensure the aims and questions of research are clearly conceptualised and communicated.
- Give careful thought to the choice of design in light of the question.
- Consider avoidable biases at the design stage and choose methods to reduce or manage these.
- Consider the best suited outcome domains/ measures with consideration of established core outcome sets.
- Define primary and secondary outcomes (and times to be assessed) a priori
- Ensure adequate statistical/ methodological expertise at the point of study design and in the conduct of the study.
- Develop a detailed protocol for the design and conduct of the study prior to data collection where-ever possible.
- Make the protocol publicly available and accessible prior to data collection where possible.
- Ensure pre-registration of all research, regardless of design. Keep registrations up to date and cite them in associated publications.
- Report research in detail, in accordance with relevant reporting guidelines.

Consumers of Research

- Reflect on the reported design and methods of the study. Are they appropriate to the aims and research question(s)? Is there enough information to judge?

Openness and Transparency

For researchers to demonstrate the trustworthiness of their research requires transparency, both of process and of data. Transparency of process allows us to know the critical information about what was planned, what actually happened, what decisions were made and when in the research process. Across science globally, we have seen community-driven initiatives to drive the agenda towards more open and reproducible research. Key examples include 19 Global Reproducibility Networks [160] and the Centre for Open Science (COS) [161]. Sharing of research materials, tools and data allows us to check the veracity of a study's conclusions for ourselves and to evaluate the replicability or reproducibility of those findings. Critically, this transparency relieves us from the need for assumptions or acts of faith that research is trustworthy, and affords researchers the mechanism to demonstrate the veracity of their work.

Haven et al. [162] argue that transparency and open science are critically intertwined with research integrity. Open science has been be defined as "the practice of science in such a way that others can collaborate and contribute, where research data, lab notes and other research processes are freely available, under terms that enable reuse, redistribution and reproduction of the research and its underlying data and methods." [163]. It extends beyond simply publishing in an open access format.

In their critical review of reproducibility in the pain literature, Lee et al. [132] outline 3 key solutions to the challenges of irreproducibility, all of which relate to more open practices in research: 1. More universal study reregistration (across diverse study types), 2. More widespread adoption of Registered Reports, 3. The routine sharing of analysis code, data and reproducible workflows and 4. Consistent use of reporting guidelines.

Preregistration

Pre-registration is an established expectation for clinical trials and systematic review, but the benefits of pre-registration extend beyond those particular study types [44,164]. Open and detailed pre-registration of protocols for studies of any type can bring clarity to the research question and objectives, make clear the critical distinction between confirmatory hypothesis testing and exploratory analyses [165], reduce the risk of questionable research practices such as p-hacking, "motivated" protocol deviations, outcome switching, HARKing and selective non-publication of "negative results" [164]. Platforms such as trials registers, PROSPERO and the Open science Framework afford researchers to openly pre-register their studies [164,166]. Registries can also post the results of studies, allowing data to be publicly available regardless of publication status.

Due to the often exploratory nature of qualitative research, it would rarely claim to test pre-specified hypotheses. However, pre-registration still offers an opportunity to enhance the transparency of this research [29]. The OSF templates for qualitative research currently allow researchers to document reflexivity processes and positionality and allow for clear reporting of updates to methods when the research is underway, and to make public materials that are often not accommodated within published papers [29]. In this way, pre-registration should not stifle or restrict the research process but allows that process to become more visible, and as a result, more trustworthy.

Pre-registration does not necessarily guarantee clarity, complete reporting of results or abolish outcome switching. Speich et al. [167] identified common inconsistencies in the characteristics of trials that had been registered in multiple registries. The EU Commission require that all trials in the EU clinical trials register to post results to the registry within 12 months of trial completion. In a 2018 review of compliance using

their "EU Trials Tracker, Goldacre et al. [168] found 49.5% compliance with that requirement with non-commercially sponsored trials and older trials more likely to be non-compliant. At the time of writing the Trials Tracker reports that 84.1% have now reported results.[169] In a sample of 400 trials in the field of pain, registered in ClinicalTrials.gov, 39% had not made results available in the register or in PubMED indexed publications within 3 years of completion. Industry sponsored trials had then lowest availability of results (50%) [170]. Dufka et al. [171] found that across almost 1000 trials and a broad range of painful conditions and interventions, less than 60% of registered studies had made results available. Comparing trial registrations with published studies Smith et al, [3] found that registered primary outcome specifications never perfectly matched reported outcomes in published papers, with clear discrepancies found in 79% of registry-publication pairs. 30% were unambiguous discrepancies in that a registered primary outcome was not reported, or was "demoted" to a secondary outcome. A recent systematic review [172] across the medical literature found discrepancies in the primary outcome between registrations and published papers in 29% to 37% of studies and in secondary outcomes in 50 to 75%. Registries are evidently not a panacea but they at least afford a mechanism to be able to identify this practice [44] and there is evidence from the field of psychology [173] and clinical trials in cardiovascular disease [174] that studies with pre-registration return smaller effect sizes that studies without pre-registration, though causal inference regarding pre-registration cannot be made with confidence.

Registered Reports

Starting from the premise "If the research question is important and the methodology is rigorous, then the answer matters", Registered reports (RR) are a form of publication in which researchers submit their proposed research question, methodology and analysis plan to a journal prior to undertaking the research. That proposal is peer-reviewed and the journal undertakes a commitment to publish the completed research report, regardless of the results of the research, so long as it was conducted satisfactorily. Like pre-registration this practice reduces the risk of the same questionable research practices, creates a mechanism to improve methods and design through peer review [165] and offers a practical solution to the problem of publication bias.[165,166] Testing the assumption that RR would better reflect null findings Allen and Mehler [165] found that 60.5% of hypotheses tested in a sample of 127 RRs were not supported, contrasting starkly with estimates of 5 to 20% in the wider literature.

Pre-prints

Preprints are a version of a research paper that has not necessarily undergone peer-review or been accepted for publication [175]. These can be hosted on preprint servers (e.g. bioRxiv.org) that are usually open access. Pre-prints are citable, can be indexed in Google Scholar and growing numbers of journals will now accept papers that have been published as preprints [176].

The COVID-19 pandemic saw a surge in the use of preprints and raised concerns about their scientific integrity [177] in the absence of peer review, editorial oversight and internationally recognised standards. However, as discussed earlier, formal publication is not itself a guarantee of scientific integrity, rigour or data authenticity. Preprints offer the opportunity for pre-publication peer review, and are potentially a tool to accelerate dissemination and to mitigate publication and reporting biases (150). They offer a possible route to diminishing the role of publishers as gatekeepers of knowledge, though the scale of any lasting impact remains to be seen.

Sharing of study materials and data

DeVito et al. (2022) [178] define sharing as the making of materials relevant to understanding the conduct and analysis of a study available to interested parties to the extent that it is ethically and legally possible. This can involve protocols, analysis plans, data and analysis code. The FAIR principles for scientific data management and stewardship [179] posit that research data should be Findable, Accessible, Interoperable

and Reusable. At the heart of these principles is openness and transparency. The open sharing of study materials is a key step on the journey to a more transparent and trustworthy evidence base.

The sharing of data presents logistic, ethical and regulatory challenges and requires careful planning, resource oversight and infrastructure [180]. Health data are sensitive and there are numerous legitimate reasons why sharing all data will not always be possible or advisable. The British Psychological Society propose the principle "As open as possible, as closed as necessary" [29,30], recognising the need for maintaining confidentiality, protecting privacy and consent and managing security. Recognising these challenges Pellen et al. [181] offer a set of rules for clinical trial data-sharing to be implemented at different stages of the life cycle of a trial that incorporate anticipating and carefully planning data sharing from the conception of the project, transparency around those plans at all stages, the involvement of research participants in decisions around sharing, adherence to relevant regulatory and legal requirements, good data management practices and careful risk management. There is a role for funders and regulators to facilitate this. The US-based NIH Helping to End Addiction Long-term (HEAL) platform offers an example of an initiative to increase the openness and use-ability of data from NIH-funded research relating to the opioid crisis [182].

Qualitative research data poses some unique considerations for data sharing. In a recent study of the perspectives of qualitative researchers around open data, Branney et al. [183] identified that key themes related to the issue of context (in which inadequate description and explanation of the context in which data were collected risked misinterpretation of the data, and participant consent for future use of data beyond the initial project. They propose that researchers 1) deposit data in an archive that provides infrastructure for long-term sustainability and data protection whilst ensuring potential users can discover and access it, 2) provide enough information about the context of data collection so others can use it meaningfully and 3) engage in careful and transparent negotiated consent processes with participants. Campbell et al, [184] offer a framework for de-identifying and sharing sensitive qualitative data that involved 1) consulting with diverse stakeholders and sources to understand risks, 2) an iterative process for recognising potentially identifiable information and constructing strategies to remediate that, and 3) implementing strategies to assess the validity of deidentification. Reflecting on the challenges for sharing data from their research on sexual violence, they cite the wishes of their research participants – that they wanted others to learn from their experiences and for their experiences to change policy – as a powerful reason for proceeding with data sharing.

It is fair to say that open research and data sharing in clinical science is work in progress. The common practice of data sharing agreements that are essentially discretionary, upon request to authors, results in inconsistent transparency at best. To illustrate this, Gabelica et al. [185] found that in a sample of 3556 published papers from a single open access publisher, 96% contained data availability statements (DAS). Of these, 42% stated that data sets were available on reasonable request. When data were requested, 93% of authors did not respond or declined to share their data. A review of studies that investigated the prevalence of data or code sharing found that data availability was declared in 8% of studies and actually available in just 2%. Code was publicly available in less than 0.5% [186]. On that basis it is argued that there remains a need to embrace a culture where materials and data are shared, where possible, as the default [173].

There are numerous benefits to researchers adopting open practices. Allen and Mehler [165] illustrate how open research is a marker of research and researcher integrity that carries potential reputational benefits, may increase the chances of successful publication (of both "positive" and "negative results") and allow researchers to make their work visible, and as a result citable independent of the traditional publishing system. There should also be the satisfaction that by engaging in open practices researchers are personally contributing to the improvement of science as a discipline.

Although researchers can choose to adopt practices that enhance the openness and transparency of their work, other stakeholders have a crucial role in facilitating and encouraging these practices. In a recent audit of medical journal policies Gardener et al. [187] found that in a sample of 19 medical journals,

using the Transparency and Openness Promotion (TOP) guideline [63], journals scored a median 5 out of a possible 24 points on open sciences standards in 2020, increasing to 7 in 2021. A similar audit of 10 pain journals in 2020 [9] used an adapted score with a maximum score of 29. Of these 3 journals were signatories to TOP. The median score for pain journals 3.5/29, with the best performing journals scoring in 7. While pre-registration was required for clinical trials and 7/10 encouraged the use of some reporting guidelines, no journal's policy mentioned registered reports, only half mentioned data sharing, half of the journals did not mention a data sharing agreement and of those that did, only one made such an agreement a requirement. Four of ten journals mentioned or encouraged code sharing. This suggests that there is a substantial opportunity to improve journal policy on this issue in a way that supports, rewards and encourages the move to more open research in pain. The TOP Guidelines offer editors tools and guidance on how to promote and support better, more transparent research.[63] However journal policy changes may not be sufficient. In journals with strong policies for data sharing a review of RCTs found that data availability was not optimal in the majority of studies. [188]

The World Health Organisation (WHO) issued a joint statement in 2017 on the public disclosure of clinical trial results [189] that included ensuring prospective trial registration, timely posting of protocols, trial results and updating of the registry record, publication of results in an open access journal with clear links to the trial ID, funder monitoring of compliance with these safeguards and finally that funders consider the Principle Investigator's past reporting record when deciding on future funding. In 2023 the TranspariMED collaboration [190] reviewed the world's top 39 Medical Research Funders and found that adoption was inconsistent across funders, with only the UK NIHR adopting all safeguards.

Enhancing Trust: Openness and Transparency
Core Value: Research should be as open and transparent as possible. Universal Actions and Behaviours: • Value and promote transparency of methods and compliance with accepted best standards of reporting. • Commit to and promote the adoption of Open Research practices as the norm. "As open as possible, as closed as necessary." (29,30)

The network considered that transparency and accessibility is a critical feature of trustworthy research and propose the following specific actions that can be taken immediately to enhance trust:

Institutions and Research Funders

- Offer sustainable training and infrastructure to support open research practices for research staff at all career levels.
- Make open research practices a key quality indicator in evaluating grant proposals and or academic performance.

Regulators and Policymakers

- Require data accessibility and sharing of materials for all studies as key criteria for regulatory approval or the adoption of research into policy, unless there are specific and valid reasons.

Editors and Publishers

- Review existing journal policies against the TOP guidelines and develop an actionable and sustainable strategy with clear time-sensitive targets to maximise alignment.

- Recommend open pre-registration and publicly available protocols for all submitted research.
- Make open research practice a key quality indicator in reviewing submitted research.
- Be open to publishing research submissions that have been made available as pre-prints.
- Develop a policy to allow for the acceptance of registered reports.
- Require all submissions to include a statement on what materials and data are shared and how to access them, and to provide reasons behind non-sharing of materials and data.

Peer reviewers

- Make open research practice a key quality indicator in reviewing submitted research.
- Review study registrations and comment on inconsistencies with submitted research.

Researchers

- Ensure pre-registration of all new research. Keep registrations up to date.
- At the design stage of new research consider carefully which materials and data can be shared and create a plan for this.
- For ongoing studies consider what materials and data can be reasonably shared.
- Make detailed protocols publicly available and accessible prior to data collection where possible (including Statistical Analysis Plan).
- Make study materials, workflows, analysis code and data (IPD wherever possible), publicly available.
- Ensure available data meet the FAIR principles [179].
- Clearly report any deviations from protocol with justifications.
- Make research findings publicly available regardless of the outcome.
- Adopt and advocate for more open research practices for all research.
- Consider using pre-prints and registered reports to make your research public.
- Academic leaders and senior mentors can encourage, nurture and model open research practices and values and make them a key element in developing early career researchers.

The network proposed the following medium-term targets:

Editors and Publishers

- Require pre-registration of research and publicly available protocols as a prerequisite to publication, for all research designs.
- Require a declaration of open research practices as a mandatory item for all submissions.
- Implement and offer registered reports as a submission type.
- Modify journal policy to achieve closer alignment with the TOP guidelines.

The network proposed the following long-term targets:

Institutions, Funders, Editors and publishers

- Require full data accessibility and sharing of materials for all studies unless there are specific reasons.

Researchers

- Normalise open research practices in their work.

Consumers of Research

- Reflect on how open and transparent the research is. Was the study pre-registered? Was a protocol made publicly available? Are the materials and data made available?

There is a range of resources available to support researchers to adopt open science practices. These include support and guidance, platforms for pre-registration of research projects, preprint servers and a range of sharing platforms. Supplementary Table 6 presents some key examples of these resources.

Balanced Communication

While the preceding core values underpin best practices in the planning and conduct of research, it is important to consider the process of reporting and communication of research findings. The communication of research findings should be done in such a way that accurately reflects the results of the research without selectivity or distortion.

Fundamentally this process requires the publication of study results, regardless of the outcome, the avoidance of selective reporting or questionable statistical methods and the drawing and presentation of conclusions that fairly reflect both the initial research question and the data. Frequently, published research falls short of that standard.

"Spin" in research publications has been variously defined as "a specific reporting that fails to faithfully reflect the nature and range of findings and that could affect the impression that the results produce in readers, a way to distort science reporting without actually lying" [191,192] or in the context of clinical trials, "a misrepresentation of study results, regardless of motive (intentional or unintentional) that overemphasizes the beneficial effects of the intervention and overstates safety compared with that shown by the results" [193].

Spin can manifest as a range of reporting practices. In their ground-breaking study Boutron et al. [191] explored a range of possible markers of spin in the title, results, discussion and conclusions of a sample of clinical trials with statistically non-significant results. Spin markers included a range of reporting behaviours characterised by a selective focus on positive results from secondary analyses or inappropriate comparisons, inappropriate interpretations of null results and inappropriate claims of safety in the face of equivocal evidence. In 72 trials more than 40% of trials had spin in at least 2 sections of the text. Gewandter et al. [10] conducted a similar study in analgesic trials and found evidence of moderate to high levels of spin in 33% of abstract conclusions and 30% of main text conclusions. A meta-review of studies of spin in the biomedical literature found a median prevalence of spin in 67% (Range 10%-84%) of trial abstracts. The only consistent factor associated with the presence of spin was the presence of statistically non-significant results.[194]

Moore et al. [195] suggest the alternative term "narrative bias" for this phenomenon, which they define as "a tendency to interpret information as part of a larger story or pattern, regardless of whether the facts support the full narrative". They looked for evidence of narrative bias that included the domains "title overreach", outcome switching, selective reporting, "going beyond the data" and "singularisation". Table 3 describes each domain. In a sample of trials and reviews of cannabinoids and cannabis-based medicines for pain they detected moderate to severe narrative bias in 24% of RCTs and 17% of systematic reviews.

Table 3. Descriptors of narrative bias in the Narrative Bias Tool (Moore et al.[190]).

Domain	Description
Title overreach	Does the title extend beyond the study methods and findings to judgement, opinion, or narrative?
Outcome Switching	Does the abstract fail to present the outcomes in the order in which they appear based in the study registration or method section of paper (that is, the outcomes have been switched)?
Selective Reporting	Does the abstract present the outcomes selectively (e.g., only the significant results, or non-significant, depending on the position argued)?
Going beyond the data	Going beyond the data: Does the abstract discuss null findings to be important (e.g., "marginal", "promising", etc) and/or make claims about safety based on adverse event data?
Singularisation	Does the abstract conclude results in a singular direction, without acknowledging contestation, complexity or quality?

There is evidence that narrative bias can have important impacts on how research is understood by consumers. In an RCT where clinicians were presented with abstracts of RCTs in cancer with and without spin [196], the presence of spin resulted in clinicians interpreting the experimental treatment as more beneficial, though less rigorous, and were more likely to be interested to read the full article. Similar results were seen in the physiotherapy field [197] and in low back pain [198].

Spin can extend beyond published research papers into the news stories that report research. Numerous studies have found evidence of spin, exaggeration or misrepresentation in the media reporting of research [199–202]. That the media drives hype, sensationalism and the minimisation of uncertainty in science communication is unsurprising and researchers have a role to try to resist that influence. However, a cohort study of 463 press releases issued by UK universities and their associated news stories found a strong association between exaggeration in the press release and in the subsequent media reports. It is easy to dismiss media exaggeration as inherent in news reporting, but these results suggest that researchers and their institutional press offices may also be drivers of this problem [203].

Such distortion may have important impacts. Boutron et al. [204] conducted three trials in which patients and caregivers were presented with news stories with and without spin based upon pre-clinical and clinical research studies. In the presence of spin participants were more likely to consider the treatment studies to be beneficial. The potential for spin to lead to misestimation of potential benefits and harms is clear and might result in actual patient harms. There is evidence that these behaviours might be resistant to change. A randomised trial [205] to compare an editorial intervention in which authors received additional short instructions to help avoid spin to usual editorial practice did not demonstrate that such an approach was effective.

Together these studies highlight that researchers may resist dispassionately accepting and engaging with so called "negative" results, and that there is, in sections of the health research community a bias towards finding "positive" conclusions from uncertain or negative results.

The network discussed whether there was ever a place for spin in science and opinion was divided. The discussion revolved around the distinction between spin, persuasion and speculation and their relative value in science. There was broad acknowledgement that speculation on the basis of results is a key part of creative scientific thinking and communication but that the distinction between reasonable interpretation of the data (including clear articulation of uncertainty and careful consideration of the limits of reasonable inference, in light of the research question, the design and the data) and speculation should be clearly articulated.

The first step towards confronting this issue is one of awareness, self-reflection and vigilance. As researchers, research leaders, reviewers and editors there is value in reflecting on the norms of how we practice, and the practice in our research communities. We might consider where we may have chosen to report or unwittingly reported research results with an element of narrative bias and what the potential drivers of that behaviour were. Supplementary Table 7 identifies available tools for identifying spin and narrative bias in study reports. By making the rigour of the research process the key factor in determining the successful publication of research we might also remove or reduce one key incentive that drives these behaviours.

Enhancing Trust: Balanced Communication
Core Value: Research should be communicated with balance and without narrative bias. Universal Actions and Behaviours: • Report all planned results regardless of the findings. • Make clear the distinction between exploratory and confirmatory research. • Make clear the distinction between reasonable interpretation of the data and speculation.

The network considered that balanced communication is a critical feature of trustworthy research and propose the following specific actions that can be taken immediately to enhance trust:

Funders, regulators, policymakers, editors and peer-reviewers

- Be alert to narrative bias in grant applications and research reports and consider it a negative quality indicator in decision making.
- Funders and editors should consider offering guidance to applicants and reviewers on identifying and avoiding narrative bias.
- All these stakeholders should value rigorous process and balanced, complete reporting of results over discovery and novelty.

Editors and publishers

- Screen papers for narrative bias in the editorial process, and encourage reviewers to do the same.

Institutions

- Offer training and support for research staff in high-quality research reporting and value and incentivise high quality reporting. Institutional media offices should ensure press releases around research are free of narrative bias.

Researchers

- Report all planned results regardless of the findings.
- Routinely reflect on your own and your team's positionality and biases and potential CoIs when planning, conducting and interpreting your research.
- Be aware of types of narrative bias ("spin") and take conscious steps to avoid them in your interpretation of results. Acknowledge and try to minimise "positivity" or "discovery" bias.
- Carefully consider and acknowledge the uncertainty in results across all relevant sections of a research paper.

- Make the distinction between interpretation of the data and speculation clear in your reporting.
- Ensure the behaviours above are reflected in all dissemination materials and activities.
- Call attention to and discourage narrative bias in your research group and community.

Consumers of Research

- Reflect on how the authors present and interpret their results. Do they comprehensively report all planned analyses regardless of the findings? Do they adequately reflect uncertainty in the results and study limitations? Are they presenting a narrative that exaggerates the importance or significance of the findings?

Data Authenticity

We routinely consider and evaluate the influence of bias and error in research and we often do so under the assumption of essentially honest practice on the part of the researchers. MacLeod et al. [43] propose a distinction between "research integrity" and "researcher integrity". While issues with the former may result from range of factors including error, suboptimal research design, incomplete reporting, publication biases or other questionable but common research practices (for example p-hacking, HARKing), the latter refers to deliberate research malfeasance such as fabrication and falsification. Bolland et al. [206] propose a continuum of compromised research integrity that ranges from unintentional minor errors and honest mistakes to deliberate attempts to mislead including plagiarism, data manipulation, falsification and fabrication.

The scale of research misconduct in any field of research is essentially unknown and there are no data specific to pain research. In a broad review of surveys of scientists [207], 2% admitted to modifying, falsifying or fabricating data themselves and up to 33.7% admitted to using questionable research practices. When asked about other colleagues, 14% reported having observed falsification, fabrication and modification and 72% questionable research practices. A recent review of retracted articles in the pain literature [208] found that 66% were retracted for reasons related to misconduct, a likely underestimate given that some misconduct would almost certainly be misclassified as error. Retrospective studies of predictors of retractions [209,210] found that misconduct was more likely in countries lacking research integrity policies, where publication is rewarded with cash incentives, in cultures where mutual criticism is hampered and in the early stages of researchers' careers. Although misconduct is a feature of individual "researcher integrity"[43], the emergence of the paper mills and predatory journals and generative artificial intelligence creates the potential for a rapid escalation of the issue.

Unlike many of the behaviours considered in this framework, deliberate misconduct is not something that guidance directed to researchers is likely to impact. This is because, in deliberate misconduct, researchers are not acting in good faith. However, it represents a clear threat to the trustworthiness of published research and it requires awareness, vigilance and action on the part of the entire research community.

The common use of mixed language such as "problematic", "fraudulent", "misconduct" and "integrity concerns" to describe concerns in the literature is an indicator of the challenge of assigning intent to bad practice. In doing so there is a risk of legal consequences, as well as causing potentially undeserved reputational damage and distress. In some cases, the evidence of misconduct has been overwhelming, as in the cases of anaesthesia researchers Yoshitaka Fujii [211,212], Joachim Boldt [211,213] and Scott Reuben [211,214,215]. In other cases, the overall patterns of data may put natural explanation out of reach, leaving reasonable doubt about investigator conduct. As a result, a shift to consider papers through the "trustworthiness" lens presented in this framework affords a potential solution. By establishing clear

standards for what features allow research to meet an acceptable threshold for trustworthiness, we place a burden of proof on researchers to meet that threshold, without the need to prove or speculate on possible malfeasance. This relieves the burden on readers and reviewers to compile evidence of misconduct and error and can then be used by gatekeepers (readers, reviewers, editors, systematic reviewers and clinical guideline developers) to reduce the proliferation and impact of untrustworthy evidence.

Identifying studies with concerns regarding potential misconduct can be challenging. In high profile cases, misconduct was identified due to a recognisable pattern of characteristics across multiple research publications [18,207], but detecting signs of potential misconduct in single papers can be more difficult. A 2021 scoping review of methods for assessing misconduct [216] identified 27 methods aiming to detect a diverse range of target behaviours including textual plagiarism and markers of data falsification/ manipulation but recognised the need for formal validation and further development.

A number of tools have recently been developed. These tools all have subtly different, though overlapping purposes. The REAPPRAISED checklist [217] is aimed at any reader or reviewer of any research paper with the goal of identifying flaws that call its integrity into question. Parker et al. propose a tool for spotting "early warning signs" of fraudulent research [218], Weibel at al. [219] have developed a tool for identifying "problematic" (in relation to whether they had been fabricated, data had been altered, or were not in accordance with good clinical practice) clinical trials and the Cochrane Pregnancy and Childbirth review group [220] and Mol et al. [221] have developed tools and processes for screening trials for concerns about trustworthiness These tools can be seen to share common features in that they are multidimensional and screen papers for indicators of concern related to research governance, author characteristics, methodology, data authenticity. Three [218,219,221] of them explicitly recommend searching for retraction notices for the paper under scrutiny and one [221] for other publications from the same author team. Supplementary Table 8. presents available tools for evaluating the trustworthiness or research integrity of research papers.

Reviewing data for signs of inauthenticity also presents substantial challenges. There are a range of potential indicators of inauthenticity including, but not limited to, impossible or implausible values for a given measurement in a given population, improbable or impossible variances, duplicated or highly similar data across independent measure, timepoints or studies, extreme results compared to the wider field, and in the context of randomised studies, distributions of baseline data that are inconsistent with random allocation. Tools for identifying inauthentic data in reports of clinical trials and in individual patient data are in development currently. The NIHR funded INSPECT-SR and INSPECT-IPD projects aim to produce such tool [222] .

Identifying inauthentic data in qualitative research has received substantially less attention. Where data are narrative and analysis is, to varying degrees, interpretive, notions of authenticity are harder to delineate. Reflecting on an example of research misconduct from the field of cultural anthropology, Margry [131] points out that sometimes necessary steps such as the anonymisation of fieldwork locations and participants can reduce our capacity to trace and check the veracity of data. In our own field of pain, we ask participants to share their narratives of lived experience, in a condition that is frequently stigmatised and where people with pain often experience invalidation of those experiences. On that basis it is critical that researchers start from a position of trust and take great care not to contribute to that stigmatisation or invalidation; that they accept that pain and its associated experiences are what people with pain tell us they are. However, the risk that researchers will not report or represent data authentically remains. An emerging threat to the authenticity of qualitative data, particularly in the advent of online and non-synchronous data collection processes is that of the "impostor participant", in which bad actors present fake identifies or fake experiences often as a result of financial incentives to participate [223,225]. Jones et al. [2] recommend a range of techniques for minimising these risks.

Studies with concerns around authenticity can have a substantial impact on the literature [226,227]. In a cohort of trials of Cognitive Behavioural Therapy (CBT) for back pain, from a single lead author, for which concerns about authenticity were identified [228], 8 trials had been included in 32 systematic reviews and 10 clinical guidelines and had substantial impact on estimates of effectiveness and their conclusions and recommendations [228].

As a result, there is a need to consider what actions and behaviour might reduce the scale and impact of untrustworthy research in our evidence base. We argue that all actions start from adopting a position of vigilance. While an uncomfortable possibility, we know that research misconduct exists, that it can mislead and do harm, and that all stakeholders need to be prepared to confront it. Making research misconduct part of the community conversation and routinely considering the authenticity of data may itself have a preventative effect. Where researchers or consumers have concerns regarding data authenticity they should contact authors for clarification and information. Where responses are not received or do not satisfactorily resolve those concerns then concerns should be raised through correspondence with the journal editors. The website PubPeer (www.pubpeer.com) also offers a public forum for raising concerns and questions about published research. Researchers who receive such concerns should respond in a timely and transparent fashion. Where legitimate errors have occurred these should be acknowledged and appropriate action taken.

Where concerns are raised regarding published articles journals should have clear policies for investigating and responding to those concerns; where concerns are confirmed on investigation those articles should be retracted in a timely manner [229]. The ICMJE and COPE offer guidance for this process [61,62]. These include correspondence with those raising the concerns, the author(s), the author's institutions to request an investigation, and/or the relevant regulatory body or equivalent. Where the investigation funds evidence of misconduct the editors should publish a retraction. Where there is no satisfactory response from authors and institutions the editors should publish an expression of concern. These should be clearly and consistently labelled for readers.

However, in practice this process is often slow and inconsistent, with untrustworthy data remaining uncorrected and concerns/ retractions not clearly labelled [206,229–232]. Even where articles are retracted they are often still cited by authors or included in systematic reviews [233–236]. This is, at least in part, the result of inconsistent and often insufficient practice in the clear labelling of retracted papers [233,237,238]. Network discussions raised limited resources as one barrier to journal editors ensuring timely action in response to expressions of concerns. Academic publishing is a highly profitable enterprise with estimated sales amounting to over 19 billion USD and the profit margins of industry leaders approaching 40% [239,240]. Such profits clearly raise the possibility for publishers to invest in resource to support editorial teams, for instance by funding specific research integrity editorial positions or for publishers to appoint independent teams of scientists available to review allegations of misconduct.

Investigations are usually conducted by the institution where the research was conducted, though in practice the speed and quality of institutional practice is inconsistent [241]. This highlights the need for institutions to adopt clear policies and procedures for allegations of research misconduct, to enact them transparently and to ensure that they maintain the resource to support those. To protect both science and scientists it is critical that these processes are robust, timely and transparent, with clear communication between editors and institutions. The Cooperation & Liaison between Universities and Editors (CLUE) recommendations [242] offer guidance for improving that communication. Finally, research funders have a role in driving best practice through the development and enforcement of clear policies that require high-quality institutional investigatory processes into allegations of research misconduct.

Enhancing Trust: Data Authenticity
Core Value: Inauthentic data should be identified and excluded from the scientific literature. Universal Actions and Behaviours: • Be vigilant to markers of potential inauthentic data and research misconduct, call attention to them and take action. • Commit to timely action to remove inauthentic data from the literature. • Commit to timely correction of errors in the published literature.

The network considered that data authenticity is a critical issue for trustworthy research and propose the following specific actions that can be taken immediately to enhance trust:

All stakeholders

- Be aware of and vigilant to markers of potential data inauthenticity or research misconduct throughout the research process and commit to take timely action appropriate to their role where there are concerns. This might entail raising concerns with and seeking clarification from the authors of research, raising concerns with editors/ publishers and/ or institutions and funders.

Research Funders, Regulators, Policymakers and Institutions

- Maintain and rigorously enforce clear policies to handle allegations of research misconduct.

Research Funders

- Prioritise funding for both the development of tools to better detect inauthentic data and/or research misconduct and inauthentic data and meta-science to examine the burden of research misconduct and the threat and evolution of questionable or suboptimal research practices.
- Require funded researchers to confirm that they have screened all cited sources in applications and reports for retractions or expressions of concern.
- Funders should consider making evidence of prior misconduct or unresolved expressions of concern a barrier to future research funding.

Regulators and policymakers

- Review research for expressions of concern and retractions before including them in regulatory approval processes or allowing them to inform policy.

Institutions

- Provide meaningful training and promote the values of Research Integrity (RI) for all research and research-adjacent. Embed RI principles into all academic training.
- Assess and incentivise research in line with the Hong Kong principles. [48]
- Conduct timely, robust and transparent investigations of researchers where expressions of concern are raised and demonstrate appropriate actions and accountability.
- Implement policies that require authors to correct or update publications if found to include retracted articles

Editors and publishers

- Publishers must invest to ensure that journal editors are afforded the resources to process allegations of misconduct in a robust and timely manner in accordance with accepted best practice.
- Consistently take swift action to investigate expressions of concern, consistent with COPE/ ICMJE guidance and act upon the findings of those investigations, with a willingness to retract where appropriate.
- Ensure expressions of concern and retraction notices are indicated clearly on journal website and indicated with high visibility on papers themselves to reduce the risk of further citation.
- Consider implementing a screening process for submissions to identify markers of inauthenticity. This would be enhanced by routinely requesting underlying data during the review process.
- Require authors confirm that they have checked all cited sources for retractions and EoCs.
- Consider developing systems for implementing local checks for retractions and EoCs

Researchers

Senior Researchers

- Support early career researchers to feel able and safe to raise legitimate concerns about potential misconduct or inauthentic data.

Systematic reviewers and Clinical Guideline developers

- Consider formalising an approach to screening potentially included studies for Trustworthiness. It is possible to set a predetermined and clear threshold of requirements for studies to meet in order to be considered trustworthy to be included in analyses. Where studies do not meet this threshold authors might exclude them from analyses and/or undertake sensitivity analyses of their potential impact on the results. There would be a value in transparently reporting such studies and the reasons for concern.
- Ensure that search strategies capture expressions of concerns and retractions

Authors of all research papers

- Routinely review all citations in their manuscripts on submission to check to see if any have been retracted or have EoCs. The Retraction Watch Database [168] offers an excellent resource for this and some reference management software now automatically flag retracted papers. This is important for all papers but become particularly critical for systematic reviews where these articles may impact directly on the results and conclusions. On that basis we recommend systematic reviewers build these processes into their protocol and clearly report them. Retracted articles should be excluded from any analyses or synthesis of results.
- Avoid being the focus of concerns regarding data authenticity and/or potential misconduct by consistently embracing the core values presented here, particularly in relation to rigour and transparency.
- Respond quickly to concerns received about their work and where error has occurred be prepared to take timely and transparent action to correct the record.

Consumers of research

- Check to see if the paper has been retracted or has an expression of concern.
- Be alert to markers of potential data inauthenticity or research misconduct and raise concerns where you have them.

The network proposed the following medium to long term targets:

Medium term:

Editors and publishers

- Ensure there is a dedicated editor(s) for Research Integrity to sustain capacity for rapid action.

Long Term:

Editors and Publishers

- Consider making full data accessibility an expectation for all submissions unless there are legitimate reasons preventing this.

Discussion: Integrating trust into the research ecosystem: an integrated framework and call to action.

Trustworthy research is undertaken with integrity, is equitable and inclusive, rigorous, accessible, transparent, and authentic, and is communicated with balance. We propose that trustworthy evidence is necessarily underpinned by each of these values and that action across the pain research community has the potential to radically improve our science, and ultimately the lives of people with pain. Untrustworthy research is inequitable, exclusionary, done or applied to people rather than with them, is not rigorous, transparent, accessible nor authentic, is not fully communicated or is communicated with bias and spin. Only one of these things need be present to make research less trustworthy. Research is, in essence, the application of formal process to observation and inquiry. It then follows that the integrity, fairness, quality, accessibility and transparency of that process should be our primary concern. Although there are many influences and incentives that might divert us from that end, the challenge is that we collectively commit and act to maintain that focus.

The challenges to trustworthy evidence are complex. They are not simply a function of individual researcher choices but rather seem to result from a research ecosystem that can incentivise suboptimal practice by failing to recognise or confront it and prioritises quantity over quality and headlines over rigour. In such a competitive, frequently insecure and highly-incentivised environment it is easy, though not inevitable, to deviate from the ideals and values of best practice and why we do research. It is also clear that all key stakeholders, and researchers in all of their roles will be important in steering us toward a culture of trustworthiness. The framework and its recommendations are clearly applicable beyond the realm of pain and broadly address the challenge of simply doing any research in health to a high standard. Our goal in the ENTRUST-PE project was to highlight these critical challenges and offer a framework to specifically support change for the pain research community.

Figure 3 depicts a visualisation of the ENTRUST-PE framework that incorporates the core values presented here, with key actions and behaviours to support those, placed within a research ecosystem with multiple stakeholders and roles that can all drive improvement.

Figure 3. The ENTRUST-PE framework

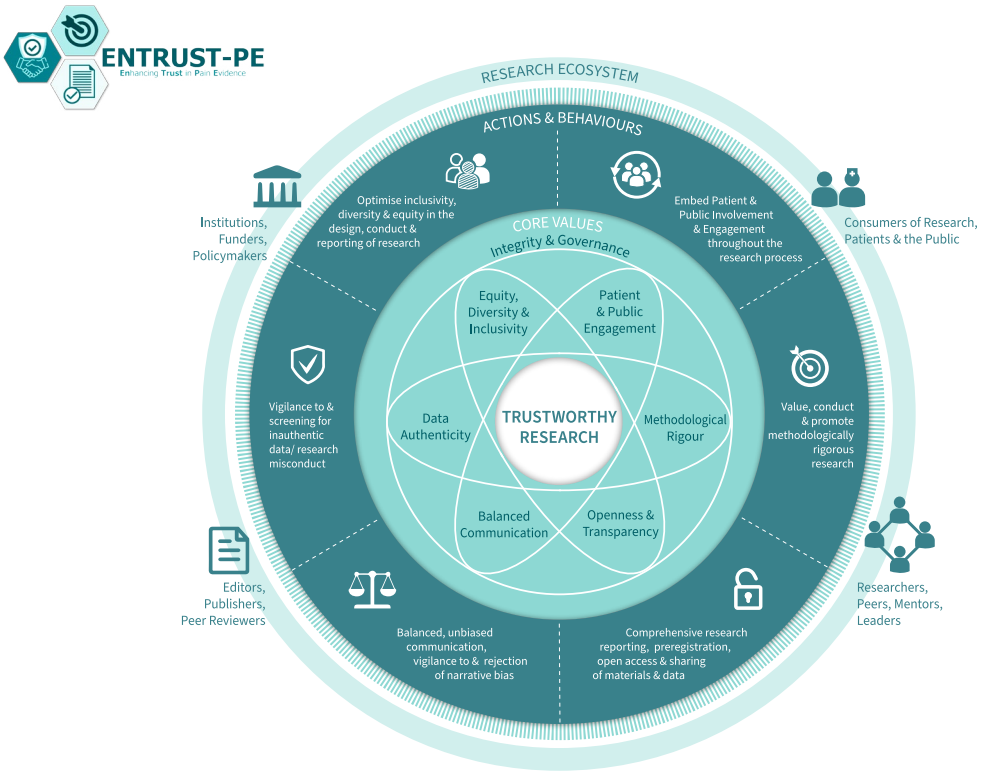


Figure 4. Illustrates the specific actions and behaviours of key stakeholders in the research process that can enhance the trustworthiness of research at each stage across the life of a research project, from inception, through to post-peer review.

Pain research contains a multitude of different study methods, settings and disciplines, from pre-clinical to clinical, from exploratory to confirmatory. Thus, we propose that the core features of good practice apply regardless, though may manifest somewhat differently in some circumstances. For example, for evidence synthesis (including both systematic review and clinical practice guidelines) there is a recommendation that some form of trustworthiness/ integrity screening be considered for deciding which studies to include. For editorial and publishing processes the same is recommended as are clear policies to mandate and incentivise good research governance, and responsive processes to expressions of concern.

Inherent to the universal actions and behaviours and some specific elements of the framework is the need for education. Education and awareness raising across the community about the core values of research integrity and each element of the framework is vital to success. All researchers in all roles can make a meaningful contribution to that effort. We also need to reach beyond the community and help consumers of evidence to understand and value these.

As part of the pain research community, we believe lasting change comes from within. There are examples of excellent practice in pain science for each of the core values, but they are not consistent across the community, and excellence in addressing one core value is not necessarily reflected across all. Neither do we consider ourselves to be outside or mere observers of current practice. We are all at varying stages of engaging with many of the values and actions presented here; none of us are perfect and humility and reflection in relation to where our own practice can improve is essential. The framework

is offered as a lever for quality improvement for all. We hope that readers use this resource as an opportunity to reflect on their own practice and where it might be improved. We have endeavoured to approach this framework in a spirit of "idealistic realism". To meaningfully improve the trustworthiness of pain research requires both systems-level change and for us to collectively develop our research culture(s) to truly embrace research integrity. Across the whole research ecosystem and all of our roles there is a need to take collective responsibility to foster positive change. Although that might appear ambitious or perhaps overwhelming it is worth noting that most of the framework simply reflects examples of contemporary good practice and correction to where we, or our systems, have fallen short. The need and responsibility for senior researchers to show leadership across their many roles in the ecosystem is critical. This includes advocating for changes to policy and systems, making those changes with a sense of the urgency of the mission, to model the behaviours recommended in the framework and to create cultures, incentives and environments that allow early career researchers to safely adopt them.

The long-term vision is that the pain research community moves to normalise each of the elements of the framework, embedded throughout the research ecosystem and pipeline. If such practices were widespread and normalised then all research would transparently meet a higher burden of proof that it is trustworthy. The resultant improvement in certainty and reduction in research waste could be enormous with benefits for all. However, creating systemic change in complex and stressed multi-level systems is notoriously challenging. We acknowledge that in the current research ecosystem some of the proposals may threaten specific commercial and other interests within the structures, at least in the short to medium term. However, there is a need to monitor progress in research practices and it is that need that drives our recommendation for research funders to prioritise high-quality meta-research to monitor behaviours across all elements of the framework. Perhaps most importantly, we recognise that, at face value, the recommendations here may seem overwhelming, both in terms of burden of work and resource requirements but also in terms of researchers feeling confident and competent to engage with them.

On that first point we argue that research and editorial processes must be adequately resourced to be conducted to the highest standards, and publishers, funders and institutions should recognise the need for investment to allow research to meet those standards and also that quality in research should, in most cases, supersede efficiency. On the second point we would suggest that quality improvement is a journey that needs to begin somewhere. For the individual researcher considering how to start on that journey of creating more trustworthy research, for each of the elements in the framework we would suggest that "commit to making one change" may be more realistic than "do everything now". We have attempted to offer clear and specific short-term actions for each element of the framework but in addition the network considered "What one thing can I do now?" for suggestions for a practical first step for any researcher to take to move towards each of the values in the framework (see table 3).

Table 3. What one change can I make immediately?

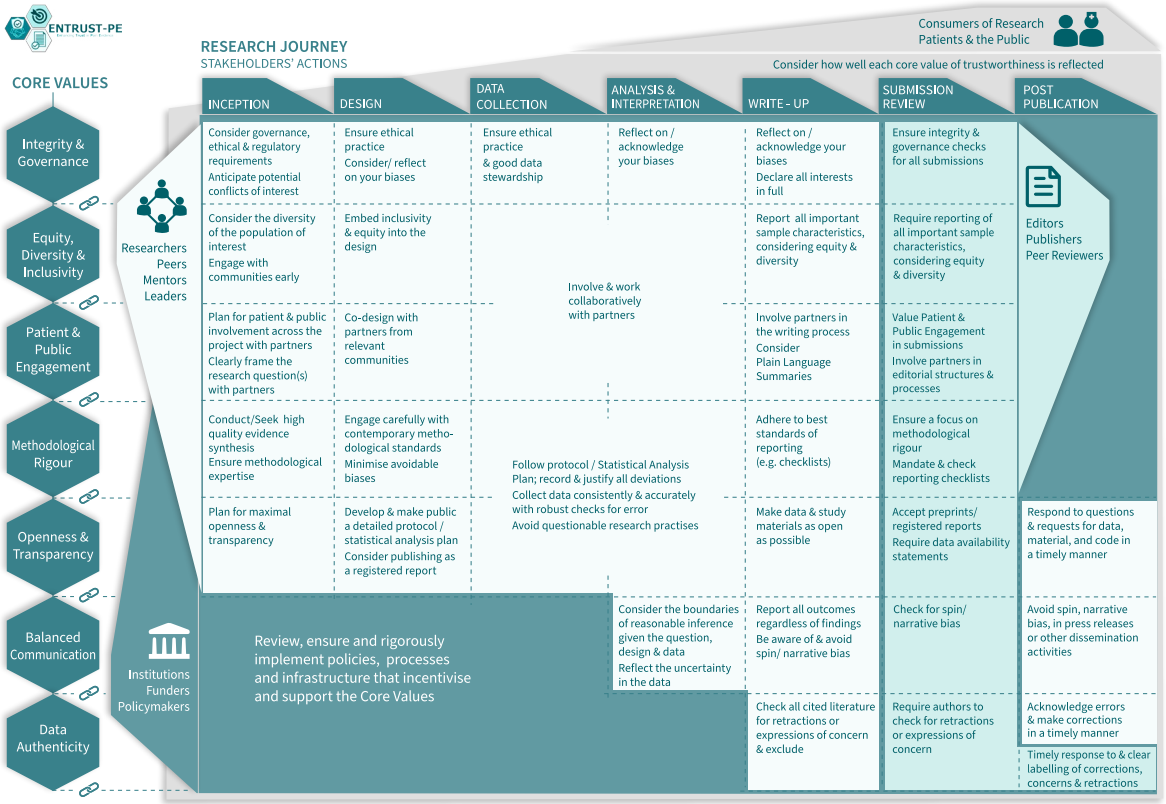
Research Integrity and Governance	Act consistently in alignment with the principles and values of research integrity. Be aware of local and wider research integrity and governance policies and act in alignment with those.
Senior investigators: lead by example.	Does the abstract fail to present the outcomes in the order in which they appear based in the study registration or method section of paper (that is, the outcomes have been switched)?
Equity and Inclusivity	When reporting research: • adopt inclusive language, • use accurate interpretations of constructs of race, ethnicity, sex and gender • clearly make and report efforts to promote diversity and inclusion of study samples • comprehensively report sample characteristics
Patient and Public Involvement and Engagement (PPIE)	Plan PPIE at the very start (conception and planning) of the research process. Engage diverse potential patient and public partners before the project begins and involve them throughout the process. Clearly report PPIE.
Methodological Rigour	Ensure the aims and questions of research are clearly conceptualised and communicated, choose appropriate research designs in light of the research question, provide adequate detail to reproduce study methodology.
Transparency and Openness	Pre-register all your research, regardless of design. Keep registrations up to date.
Balanced Communication	Report all planned results regardless of the findings. Consider a range of alternatives as well as study limitations in your interpretation of study findings.
Data Authenticity	Draw attention to any errors in your work and issue corrections in a full, transparent and timely fashion.

Each of these actions has the potential to improve the trustworthiness of your research and each action should make the next improvement easier. We have also curated some key resources to assist you in that goal.

This project has strengths and limitations. We have involved an international interdisciplinary group from across the pain research and methodological spectrum, including people with lived experience of pain and researchers across the different career stages. We have also included editors and past editors from some of the leading pain journals. Our approach has been discursive and non-hierarchical to share expertise and explore the challenges and practical solutions. However, we acknowledge that despite our diverse expertise our team would benefit from additional diverse perspectives across a range of characteristics; nevertheless, we aim to foster dialogue and collaboration and are committed to providing platforms for underrepresented voices to ensure the relevance and applicability of our framework on a global scale. In pursuing this central goal, we recognise the need for continual reflection, questioning our assumptions, biases, and blind spots. We are open to and welcome feedback and collaboration from voices within and outside our network, acknowledging that true progress in pain research requires inclusivity, transparency, and humility. We did not apply a more formal methodology to create consensus through our meetings nor were we able to conduct formal systematic evidence syntheses to inform the various elements of the framework.

In conclusion, the ENTRUST-PE framework offers an integrated framework for creating more trustworthy evidence. It conceptualises trustworthiness to be underpinned by multiple features, each of which should be met to optimise trust. It also emphasises that action to consistently and meaningfully improve trust will be needed at all levels and across all roles and proposes specific actions to that end. The risk of not acting to ensure and enhance trust in our evidence results in a failure to improve understanding of chronic pain, to develop better solutions and to expose people with pain to avoidable harm. We present the framework as a “Call to Action” for the pain research community to act together to put the trustworthiness of our research first.

Figure 4. The journey of a trustworthy research paper, including actions and behaviours for key stakeholders across the life of a research project that enhance trustworthiness.



Declarations of interest

NOC is a member of the Cochrane Central Editorial Board. Between 2020 and 2023 Neil was Co-ordinating Editor of the Cochrane Pain, Palliative and Supportive Care group, whose activities were funded by an infrastructure grant from the UK National Institute of Health and Care Research (NIHR). He is the Chair of the International Association for the Study of Pain (IASP) Methodology, Evidence Synthesis and Implementation special interest group.

JB is co-chair of IASP Global Alliance of Partners for Pain Advocacy Task Force, a voluntary role; is Patient & Public Partnerships Editor at the Journal of Orthopaedic & Sports Physical Therapy; member PAINSTORM Advisory Council, receives travel support to attend annual meetings received an honorarium and travel support for the 2023 Canadian Pain Society annual meeting and 2024 San Diego Pain Summit; received travel support for the 2024 New Zealand Pain Society Annual Meeting; is a co-researcher on MRFF Grant 2022802 “Our Recovery – A consumer-led, evidence-based online program to optimise pain self management in the community”.

GC has been awarded research grants of the Research Foundation Flanders (FWO) and Ghent University for research on the psychological aspects related to pain, distress and disability, and for research on the promotion of physical activity in diverse populations. He is currently involved in the UK Advanced Pain Discovery Platform (APDP) PAINSTORM (as co-PI), in the APDP Consortium to Research Individual, Interpersonal & Social Influences in Pain (CRISSP, as member of advisory board), and in the APDP projects CHIPP and Forecast (as affiliated researcher). He receives consultancy for advising a company

MoveUP in developing a digital intervention to promote a healthy lifestyle in bariatric patients. Geert Crombez is currently editor in chief of Health Psychology Review. He is also member of the steering committee of the Behavioural and Social Sciences Ontology (BSSO) Foundry. He is also member of the international advisory board of GALENOS (Global Alliance for Living Evidence on aNxiety, depressiOn and pSychosis), which aims to develop an ontology in the domain of mental health.

CE has received research funding from the UK Medical Research Council, The UK National Institute for Health Research, Versus Arthritis UK, and the MayDay Fund. He has also received consultancy income from Orion Pharma for advice on digital therapeutics and research ecosystems, and Reckitt (contracted by Oxford University Innovations) for advice on children's chronic pain, and on pain communication. CE is a practitioner psychologist and consults on the development of psychological and interdisciplinary rehabilitation, currently working for 50% release from the University of Bath at Great Ormond Street Hospital, London UK to establish a new clinical programme. He receives author royalties from Oxford University Press for three books.

MCF is funded by an Australian Government Research Training Program PhD scholarship and a Neuroscience Research Australia PhD Pearl supplementary scholarship. He is the Treasurer of the International Association for the Study of Pain (IASP) Methodology, Evidence Synthesis and Implementation special interest group, and the Early Career Researcher Representative of the IASP Complex Regional Pain Syndrome special interest group.

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EN is Local Network Lead for Brunel University London's UK Reproducibility Network, Co-Chair of European Health Psychology Society's Open Science Special Interest Group and Associate Editor for Health Psychology & Behavioural Medicine.

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(G-BA) and the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777500. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA. All money goes to the institutions (UKM) EPZ is working for. EPZ is council member of the International Association for the Study of Pain (IASP), board member of the German Pain Society, past chair of the Acute Pain SIG of the IASP, past chair of the subcommittee Acute and Chronic Pain and Palliative Medicine Pain Management of the European Society of Anaesthesiology and Intensive Care (ESAIC) and member of the research committee of the ESAIC. She is working member of the ESRA-prospect group (https://esraeurope.org/pain-management/) and vice chair of the PANDOS research group (https://www.esaic.org/research/research-groups/pandos/). She is scientific coordinator on the ERA-NET Neuron CO-Fund IT-Pain project (https://itpain.org/) and Co-Coordinator of the ENTRUST-PE and INCHILD-Pain projects. EPZ is Deputy Editor in Chief for the EJA and the EJAIC and section editor for the EJP.

ASCR declares the following interests: Employee Imperial College London; Hon Consultant Chelsea and Westminster Hospital NHS Foundation Trust (retired from direct clinical practice); Consultancy and advisory board work for Imperial College Consultants- in the last 36 months this has included remunerated work for: AsahiKasei Pharma, Lateral, Pharmnovo, Novartis, Mundipharma, Toray, Confo, Combigene, Orion, Shanghai SIMR Biotech, Vertex, & Science Practice (Wellcome Trust); ASCR is named as an inventor on patents: Rice A.S.C., Vandevoorde S. and Lambert D.M Methods using N-(2-propenyl) hexadecanamide and related amides to relieve pain. WO 2005/079771, Okuse K. et al Methods of treating pain by inhibition of vgf activity EP13702262.0/ WO2013 110945; Committee membership: International Association for Study of Pain- multiple activities related to President -elect position, and Federation liaison roles (SE and S Asia), Member Joint Committee on Vaccine and Immunisation- varicella sub-committee, Analgesic Clinical Trial Translation: Innovations, Opportunities, and Networks (ACTTION) steering committee member, Medicines and Healthcare products Regulatory Agency (MHRA), Commission on Human Medicines - Neurology, Pain & Psychiatry Expert Advisory Group; Grants and studentships - UKRI (Medical Research Council & BBSRC), Versus Arthritis, Alan and Sheila Diamond Trust, Royal British Legion, European Commission, Ministry of Defence, Dr Jennie Gwynn Bequests, The British Pain Society, Royal Society of Medicine, Royal College of Anaesthetists - Heritage and Archives Committee (2020 - date); Lecture honoraria: MD Cancer Cancer Center -2021, University California San Francisco. CSF12th Pediatric Pain Master Class (USA) Dec 2021, Bioevents – Controversies in Neuropathic pain – 2021, Royal Marsden Hospital 2019, Indonesian Neurological Association Pain Study Group International Lecture Series Donated to (Association of Southeast Asian Pain Societies (ASEAPS) –Oct 2022, Malaysian Society of Anaesthesiologists – July 2022, Siriraj Hospital Bangkok international relations programme- visiting Professorship Nov 2022 – used for expenses, Pain Association of Singapore- lecture honorarium March 2023; Author royalties: Amazon KDP- Dardanelles to Dunkirk – donated to Halo Trust, Royal Pharmaceutical Society- British National Formulary- finished 2023.

GR has paid casual contract at the University of Oxford to teach Evidence-Based Medicine (EBM) and supervise research .Her expenses have been reimbursed for speaking at conferences and events, and she has received fees for speaking to and training coroners by the Judicial College. She is an Associate Editor of BMJ Evidence Based Medicine for which she receives a small annual remuneration. She is the Director of a limited company that has been independently contracted to conduct research and work in the private sector, including for AstraZeneca and Field Fisher. She receives remuneration from subscriptions to her personal SubStack publication. Between September 2017 and March 2021, she was financially supported by the NHS National Institute of Health Research (NIHR) School for Primary Care Research (SPCR), the Naji Foundation, and the Rotary Foundation to study for a Doctor of Philosophy (DPhil) at the University of Oxford. She has received grants to conduct research from NIHR SPCR and the Primary Care Research Trust of Birmingham and Midlands Research Practices Consortium Grant.

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DT in the past 3 years has received research grants and contracts from the US Food and Drug Administration and the US National Institutes of Health, US Patient-Centered Outcome Research Institute, and US National Center for Occupational Health and Safety; received compensation for serving on advisory boards from Eli Lilly, GlaxoSmithKline, Novartis, and Pfizer, and Vertex Pharmaceuticals.

EW has received grant funding from charities and UKRI funding bodies.

AW received a 2022 consultancy from Reckitt for non-pharmacological advice on pain, contracted by Oxford University Innovations via UCL Consultancy, and paid to UCL discretionary account. She also had paid consultancies for a 2019 review of clinical programme for military veterans with chronic pain for King Edward VII Hospital London, UK, and in 2019-2020 a review of MSc in Pain for Sydney University, Australia. She is employed as section editor for psychology for PAIN.

JW declares funding from NIHR (NIHR203568) as PI on the INSPECT-SR project, which will produce a tool for assessing trustworthiness of RCTs. JW additionally declares Stats or Methodological Editor roles for BJOG, Fertility and Sterility, Reproduction and Fertility, Journal of Hypertension, and for Cochrane Gynaecology and Fertility.

AH, FK, DS, GS and JV have no declarations of interest.

Patient and Public Involvement and Engagement Statement

The ENTRUST-PE project included a patient partner (JB) as a full and equal network member from the inception to the completion of the project. JB is a co-author of ENTRUST-PE publications.

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Supplementary table 1: Examples of policies and tools to support and promote research governance and integrity.

Project/ Policy maker	Resources	Link/ Reference
World Conference on Research Integrity (WCRI)	The Singapore Statement on Research Integrity	https://www.wcrif.org/guidance/singapore-statement
	The Hong Kong Principles for Assessing Researchers	https://www.wcrif.org/guidance/hong-kong-principles
	Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations	https://www.wcrif.org/guidance/montreal-statement
Coalition for Advancing Research Assessment	The agreement on reforming Research Assessment	https://coara.eu/agreement/the-agreement-full-text/
Declaration on Research Assessment (DORA)	The Declaration	https://sfdora.org/read/
	Reformscape (online tool to explore responsible academic career assessment and drive positive change)	https://sfdora.org/2024/01/30/announcing-reformscape/
Ensuring Value in Research (EVIR)	International funders consensus principles on ensuring value in research.	https://evir.org/our-principles/
SOPS4RI Standard operating procedures for research integrity.	Guideline for research performing organisations. Toolbox for promoting RI in RPOs and for Research Funding organisations.	https://sops4ri.eu/
NIH	Understanding Research Integrity Resources	https://grants.nih.gov/policy/research_integrity/index.htm
ALLEA	The European Code of Conduct for Research Integrity	https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf
UKRI	UKRI Policy on governance of good research practice	www.ukri.org/wp-content/uploads/2022/03/UKRI-310322-GRP-Policy2022.pdf
NHMRC	The Australian Code for the Responsible Conduct of Research	https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#block-views-block-file-attachments-content-block-1
Universities UK	Concordat to support research integrity	https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity
COPE Core Practices	• Allegations of misconduct • Authorship and Contributions • Complaints and Appeals • CoI / Competing Interests • Data and Reproducibility • Ethical Oversight • IP • Journal Management • Peer review processes • Post-publication discussions and corrections	https://publicationethics.org/core-practices https://publicationethics.org/guidance/Guidelines
ICMJE	ICMJE recommendations	https://www.icmje.org/recommendations/
TOP guidelines	Guidelines for Transparency and Openness Promotion (TOP) in Journal Policies and Practices	https://osf.io/ud578
H2020 Integrity	Training tools and resources for research Integrity	https://h2020integrity.eu/
Think, Check, Submit	Tool/ checklists for choosing trusted journals and publishers for your research.	https://thinkchecksubmit.org/
European Commission	Living guidelines on the responsible use of generative AI in research	https://research-and-innovation.ec.europa.eu/document/2b6cf7e5-36ac-41cb-aab5-0d32050143dc_en
RIGHT-COI&F Checklist	Checklist providing guidance on how to report information on COIs and funding in guidelines and guideline policy documents	Reporting Conflicts of Interest and Funding in Health Care Guidelines: The RIGHT-COI&F Checklist. [1]

Supplementary Table 2. Key resources to support Equity and Inclusivity in Research

Project/ Policy maker	Description	Link/ Reference
Inclusion, Diversity, Equity, Antiracism, and Accessibility (IDEAA) Considerations for Journal Authors and Reviewers		Palermo. Editorial: Introducing New Reporting Guidelines to Address Inclusion, Diversity, Equity, Antiracism, and Accessibility: Implementation at The Journal of Pain. https://doi.org/10.1016/j.jpain.2022.11.001 [2]
Confronting Racism paper series in Journal of Pain Vol 23, No 6		Morais et al. Confronting Racism in Pain Research: A Call to Action. https://doi.org/10.1016/j.jpain.2022.01.009 [3] Letzen et al. Confronting Racism in All Forms of Pain Research: Reframing Study Designs. https://doi.org/10.1016/j.jpain.2022.01.010 [4] Hood et al. Confronting Racism in All Forms of Pain Research: A Shared Commitment for Engagement, Diversity, and Dissemination. https://doi.org/10.1016/j.jpain.2022.01.008 [5]
NIHR FOR EQUITY tool	Tools and resources to help make research evidence more relevant for action to reduce social and health inequalities	https://forequity.uk/
NIHR INCLUDE	Improving Inclusion in under-served groups in health and care research: Guidance	https://www.nihr.ac.uk/include/home/guidance
	Impaired capacity to consent framework	https://www.capacityconsentresearch.com/include-impaired-capacity-to-consent-framework.html
IASP	Factsheet: Global Inequities in Pain Treatment: How Future Research Can Address This Better	https://www.iasp-pain.org/resources/fact-sheets/global-inequities-in-pain-treatment-how-future-research-can-address-this-better/
PRO EDI	Tool for improving how equity, diversity and inclusion is handled in evidence synthesis.	PRO EDI participants characteristics table. https://www.trialforge.org/trial-diversity/pro-edi-improving-how-equity-diversity-and-inclusion-is-handled-in-evidence-synthesis/ [Accessed 13/5/24]
NC3Rs	Experimental Design Assistant (for animal experiments)	https://eda.nc3rs.org.uk/

Supplementary Table 3. Key resources to support Patient and Public Engagement in Research

Source	Resources	Link
Advocacy Groups		
Global Alliance of Partners for Pain Advocacy (GAPPA)	Links to resources for people with pain.	https://www.gappa-pain.org/about
Toolkits/ Wide-ranging Resources/ Recommendations		
Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)	Patient engagement in designing, conducting, and disseminating clinical pain research: IMMPACT recommended considerations.	Haroutounian et al. 2024 PAIN. In press. https://doi.org/10.1097/j.pain.0000000000003121 (6)
Association of medical research charities (AMRC)	Guidance, standards and tools for public involvement	https://www.amrc.org.uk/guidance-and-tools-for-public-involvement
Arthritis Research Canada	Workbook to guide the development of a Patient Engagement In Research (PEIR) Plan	https://www.arthritisresearch.ca/wp-content/uploads/2018/06/PEIR-Plan-Guide.pdf
Centre of Excellence on Partnership with Patients and the Public CEPPP (Canada)	Patient and Public Engagement Evaluation Toolkit: Centre of Excellence on Partnership with Patients and the Public;	https://ceppp.ca/en/evaluation-toolkit/
Cochrane (Global)	Involving People: A learning resource for systematic review authors	https://training.cochrane.org/involving-people
Collaboration 2.0 Sustainable Collaboration for Value and Innovation (Sweden)	Patient and next-of-kin	https://training.cochrane.org/involving-people
European Patients' Academy (EUPATI)	Guidance to support PPIE across the entire process of medicines research and development with regulatory agencies, health technology assessment(HTA) bodies, ethics committees and the pharmaceutical industry.	https://toolbox.eupati.eu/guidance/
National Institute of Health and Care Research (NIHR, UK)	UK Standards for Public Involvement in Research (now + community engagement)	https://nihr.ac.uk/pi-standards/home https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437 https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371
Patient Advisory Network (USA)	INSPIRE Research Portal	https://depts.washington.edu/panport/how-use-portal
Patient-Centered Outcomes Research Institute (PCORI, USA)	Engagement Resources	https://www.pcori.org/engagement/engagement-resources
Patient Focused Medicines Development (Europe)	The Patient Engagement Management Suite	https://pemsuite.org/
The Value+ Toolkit	European Patients' Forum (EPF) and the European Commission (EC) tool kit for patient involvement.	https://www.eu-patient.eu/globalassets/projects/valueplus/value-toolkit.pdf

Source	Resources	Link
Co-production Guidance		
National Institute of Health and Care Research INVOLVE (UK)	Guidance on co-producing a research project	https://www.invo.org.uk/wp-content/uploads/2019/04/Copro_Guidance_Feb19.pdf
Knowles et al. 2021	More than a method: trusting relationships, productive tensions, and two-way learning as mechanisms of authentic co-production. Research Involvement and Engagement. 2021; 7: 34	https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-021-00262-5
Ethics Guidance		
Centre for Disease Control (CDC, USA)	CDC Prevention Center's Partnerships Trust Tool	https://orphroadmap.org/docs/modernization/Partnership_Trust_Tool.pdf
Patients Active in Research and Dialogues for an Improved Generation of Medicines (PARADIGM, EU)	Patient Engagement Monitoring and Evaluation Framework	https://imi-paradigm.eu/petoolbox/monitoring-evaluation/?vgo_
Council of Medical Specialty Societies/ Patient-Led Research Collaborative (USA)	Patient-Led Research Scorecards	https://patientresearchcovid19.com/storage/2023/02/Patient-Led-Research-Scorecards.pdf
Hamilton et al. 2021	Patient Engagement In Research Scale (PEIRS). Health Expectations 2021; 24:3:863-879	https://onlinelibrary.wiley.com/doi/10.1111/hex.13227
Reimbursement/ Compensation Guidance		
National Health Council (USA)	Patient Engagement Compensation and Contracting Toolbox	https://nationalhealthcouncil.org/patient-engagement-compensation-and-contracting/
NationaL Institute of Health and Care Research (NIHR UK)	Payment guidance for researchers and professionals	https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392
Richards et al. (2020)	Patients as Partners in Research: How to Talk About Compensation With Patient Partners. JOSPT 2020; 50:8:413-414	https://www.jospt.org/doi/10.2519/jospt.2020.0106
Reimbursement/ Compensation Guidance		
International Association for the Study of Pain (IASP)	Factsheet: How to Translate Pain Research to Impact Practice	https://www.iasp-pain.org/resources/fact-sheets/how-to-translate-pain-research-to-impact-practice/
Reporting Standards		
GRIPP 2	Reporting standard for PPI	https://www.equator-network.org/reporting-guidelines/gripp2-reporting-checklists-tools-to-improve-reporting-of-patient-and-public-involvement-in-research/

Supplementary Table 4. Methodological Guidance Resources

Study Type	Resource	Link
Prognostic Research	PROGRESS framework and series	https://www.prognosisresearch.com/guidance
Observational Studies	Strengthening Analytical Thinking for Observational Studies. The STRATOS Initiative	https://stratos-initiative.org/
Systematic Reviews/ Evidence synthesis	Cochrane Handbook	hhttps://training.cochrane.org/handbook
	Cochrane: Optimal methods for acute post-op pain reviews	https://community.cochrane.org/news/optimal-methods-use-pain-outcome-systematic-reviews-postoperative-pain-management
	Joanna Briggs Institute Manual	https://jbi-global-wiki.refined.site/space/MANUAL
	Synthesis without meta-analysis SWiM	https://www.bmj.com/content/368/bmj.l6890
Pre-clinical	EQIPD framework	https://go-eqipd.org/
	NC3Rs Experimental Design Assistant	https://eda.nc3rs.org.uk/
Clinical mechanistic	EEG ARTEMIS-is	https://osf.io/pdx6y/
	f-MRI Guidelines for reporting an fMRI study. Poldrack et al. 2008	https://pubmed.ncbi.nlm.nih.gov/18191585/
Clinical trials	ACTTION guides	https://www.acttion.org/publications
	The Clinical Trials Toolkit (NIHR)	https://www.ct-toolkit.ac.uk/
	COPPS-2	https://www.equator-network.org/reporting-guidelines/recommendations-for-the-development-implementation-and-reporting-of-control-interventions-in-efficacy-and-mechanistic-trials-of-physical-psychological-and-self-management-therapies-the-copps-stat/
	Outcomes OMERACT IMMPACT INTEGRATE-PAIN	https://omeract.org/resources/ http://www.immpact.org/ https://www.painconsortium.nih.gov/resource-library/integrate-pain-initiative
	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	https://www.ich.org/page/efficacy-guidelines
Statistical Analysis plans (SAP)	Guidelines for the Content of Statistical Analysis Plans in Clinical Trials [7] DEBATE-statistical analysis plans for observational studies [8] Statistical Analysis Plan (SAP) Checklist (Word) (Trials)	https://jamanetwork.com/journals/jama/fullarticle/2666509 https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/s12874-019-0879-5#ref-CR7
COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN)	Tools for the selection, development and evaluation of health outcome measures.	https://www.cosmin.nl/cosmin-tools/

Supplementary Table 5. Core EQUATOR reporting guidelines: www.equator.network.org

Study Type	GUIDELINE	Extensions
RCT	CONSORT (Consolidated Standards of Reporting Trials)	Multiple, including: Checklist for the preparation and review of pain clinical trial publications: a pain-specific supplement to CONSORT.[9] Better reporting of interventions: template for intervention description and replication (TIDieR)checklist and guide. Consensus on Exercise Reporting Template (CERT)
Observational studies	STROBE (Strengthening the Reporting of Observational Studies in Epidemiology)	Multiple
Systematic Reviews	PRISMA 2020 (Preferred Reporting Items for Systematic reviews and Meta-Analyses)	Multiple
Study protocols	SPIRIT (trials) (Standard Protocol Items: Recommendations for Interventional Trials) PRISMA-P (reviews)	
Diagnostic/ Prognostic	STARD (Standards for Reporting Diagnostic Accuracy) / TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis)	TRIPOD+AI statement: updated guidance for reporting clinical prediction models that use regression or machine learning methods.
Case Reports	CARE (CAse REport) guidelines	Multiple
Clinical practice Guidelines	AGREE 2 (Appraisal of Guidelines, Research and Evaluation) RIGHT (Reporting Items for practice Guidelines in HealThcare)	Conflicts of Interest and Funding in Health Care Guidelines: RIGHT-COI&F
Qualitative Research	SRQR (Standards for Reporting Qualitative Research) COREQ (Consolidated criteria for reporting qualitative research)	
Animal pre-clinical	ARRIVE 2 (Animal Research: Reporting of In Vivo Experiments)	
Quality Improvement	SQUIRE (Standards for QUality Improvement Reporting Excellence)	SQUIRE-EDU
Economic Evaluations	CHEERS (Consolidated Health Economic Evaluation Reporting Standards)	
Patient and Public Involvement and Engagement	GRIPP2 (Guidance for Reporting Involvement of Patients and the Public)	

Supplementary Table 6. Key resources to support Open Research Practices

Support and Guidance	Pre-registration platforms	Pre-print servers	Sharing Platforms (from DeVito 2022(10))
FOSTER Open Science https://www.fosteropenscience.eu/	Clinical trials registers, various	MedRxiv	OSF
UK Reproducibility Network (UKRN) https://www.ukrn.org/	MedRxiv	OSF	
The UKRI Concordat on Open Research Data, https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf	OSF	arxiv	Zenodo
		Nature precedings	Dryad
		Psyarxiv	Octopus
			NHLBI data and specimen repository
			GitHub
			YODA
			Vivli

Supplementary Table 7. Tools/ Guidance for evaluating narrative bias ("spin")

Tool	Objective	Source
Narrative bias tool	Instrument to evaluate narrative bias in RCTs and Systematic reviews in pain.	Moore et al. PAIN 2024.[11]
Spin classification tool	Tool to identify and classify spin in reports of RCTs	Boutron et al. JAMA. 2010 [12]
SPIN-PM: A consensus framework to evaluate the presence of spin in studies on prediction models	A consensus framework to evaluate the presence of spin in studies on prediction models	Andaur Navarro al. J Clin Epidem 2024 [13]

Supplementary Table 8. Tools for evaluating Trustworthiness/ Research Integrity/ Data Authenticity Issues

Tool	Study type	Objective	Reference
INSPECT-SR	RCT IN SRs (in process)	Evaluate Data (in)authenticity	In development.
Parker et al. 2022	ANY	Identify markers of potentially fraudulent research	Parker et al. Journal of Clinical Epidemiology 2022 [15]
REAPPRAISED	ANY	Evaluate publication Integrity	Grey et al. Nature 2020 [16]
TRaCT	RCT	Evaluate Trustworthiness	Mol et al. Research Integrity and Peer Review 2023 [17]
Weibel et al. 2022	RCT	Evaluate Research integrity / identify problematic studies	Weibel S et al. Res Syn Meth 2022 [14]

Supplementary Table 9. Resources for improving publication integrity.

Study Type	Resource	Link
International Committee of Medical Journal Editors (ICMJE)	PROGRESS framework and series	https://www.prognosisresearch.com/guidance
Committee on Publishing Ethics (COPE).	Retraction guidelines	https://doi.org/10.24318/cope.2019.1.4
	Cooperation between research institutions and journals on research integrity and publication misconduct cases	https://doi.org/10.24318/cope.2018.1.3
	Sharing of information among editors-in-chief regarding possible misconduct	https://doi.org/10.24318/cope.2019.1.7
	Flowchart: Scientific rigour of published data: dealing with concerns	https://doi.org/10.5281/zenodo.7896759
	Flowchart: Fabricated data in a submitted manuscript	https://doi.org/10.24318/cope.2019.2.3
	Flowchart: When institutions are contacted by journals	https://doi.org/10.24318/GvV9U5HC
Cooperation & Liaison between Universities & Editors (CLUE) Working Group	Cooperation & Liaison between Universities & Editors (CLUE): recommendations on best practice	Wager et al. Research Integrity and Peer Review (2021) 6:6 https://doi.org/10.1186/s41073-021-00109-3
Responsibilities of Publishers, Agencies, Institutions, and Researchers (RePAIR)	Consensus Guidelines for in protecting the integrity of the research record	https://publicationethics.org/files/RePAIR%20Consensus%20Guidelines%20v2.pdf

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