PATIENT AND PUBLIC INVOLVEMENT IN THE MANAGEMENT AND PREVENTION OF CARDIOVASCULAR DISEASE. A STATEMENT OF THE ASSOCIATION OF CARDIOVASCULAR NURSING & ALLIED PROFESSIONS OF THE ESC AND THE ESC PATIENT FORUM

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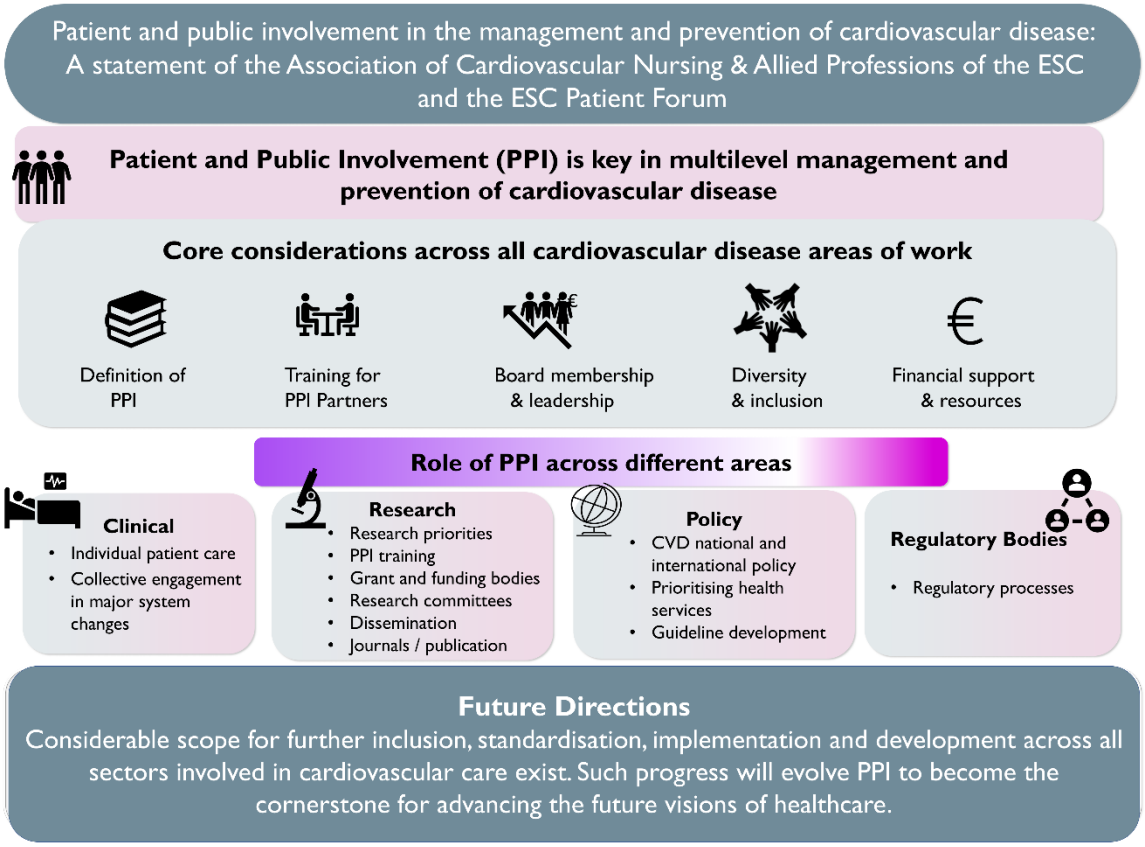
ABSTRACT

Patient and Public Involvement (PPI) plays a pivotal role in enhancing the management and prevention of cardiovascular disease (CVD), at multiple levels. The partnership with patients and the public, those who are directly affected by CVD, is central to delivering personalised care, and may contribute to decreasing the burden of CVD and reducing health inequalities. This statement describes the concept of PPI and highlights the role of PPI across different settings including: clinical practice, research, regulatory processes, and policy and clinical guideline development. Recognition of the value of PPI and how to create environments and infrastructure to embed PPI into these areas requires further attention, specifically for underrepresented communities. Therefore, considerations for good practice as well as future directions for improvement are provided. Whilst the content of this paper focusses on CVD, the insights provided can be applied to other conditions.

KEYWORDS

Patient and Public; Consumer Involvement; Cardiovascular Disease; Decision Making

GRAPHICAL ABSTRACT



INTRODUCTION

'Nothing for us, without us' (1) reinforces the principle that people with lived experience should be meaningfully engaged in defining approaches that affect their health and wellbeing (2). The impact of cardiovascular disease (CVD) remains globally devastating. CVD persists as the leading cause of death (3) and is the source of considerable burden for the 253 million people globally affected by it, with years living with CVD associated disability doubling to 34.4 million from 17.7 million since 1990 (4). Furthermore, health inequalities, including sex, ethnicity and socioeconomic status, significantly contribute to CVD burden, exist both between and within countries (5), with low-middle income countries (LMICs) being particularly affected (6) The inclusion of patients and the public, those who are directly affected by CVD, in the development and implementation of CVD healthcare services, research and associated policy is central to delivering personalised care, decreasing CVD burden and reducing health inequalities. Such involvement has been reported to support prioritising health services based on need (7), improve the quality and trust of regulatory decisions (8), increase the relevance, cultural appropriateness and overall quality of research (9), and reduce research waste (10).

The principle of patient and health user involvement is not new. In the United Kingdom (UK) community health councils were formed by the government in the mid-1970's to give healthcare users an opportunity to contribute to health service design and operation (11). At the end of the same decade The World Health Organization (WHO) reported the 'right and duty' for people 'individually and collectively' to participate in the 'planning and implementation of their health' (12). Similarly, the European Union faced a change in the traditional relationship between healthcare professionals and patients during the HIV pandemic, while in the mid-1990's the European Medicines Agency (EMA) inspired adaptation of European legislation and lay the groundwork for involving patients in all its processes and decision-making (13). Over subsequent years the level and breadth of patient and public involvement (PPI) has grown to include policy development, regulatory activity, healthcare service delivery and research although country-specific strategies remain limited. Notable differences include the UK which has frameworks for PPI in public health commissioning (14), quality guidance and standards (15), research priority setting (16) and standards for UK public involvement in research (17). Similarly, the Patient Centre Outcomes Research Institute (PCORI) in the USA, the Canadian Institute for Health Research Strategy for Patient-Orientated Research (SPOR) and the Consumer and Community Advisory Group (CCAG) associated with the National Health and Medical Research Council (NHMRC) in Australia promote and advise on proactive patient and health consumer partnership in health and research. While PPI in high-income countries (HIC) is continuously evolving, such engagement in LMICs can be tokenistic due to time and financial challenges, gaps in health

infrastructure (opportunity and access), cultural and social stigmas, and uncertainty in the patient role in involvement (9, 18).

This statement has been developed in collaboration with representatives of the ESC Patient Forum, and in accordance with ICJME criteria, they have been included in the authorship team. It aims to explore PPI in CVD clinical practice, research, regulation and policy, including enablers and considerations to its use. Given the importance, and current variability in the application of PPI in CVD, areas of good practice and reflections for current and future development will be indicated. Despite the focus on CVD, the content of this paper will provide useful insights that can be translated and applied to other conditions and specialities.

DEFINING PATIENT AND PUBLIC ENGAGEMENT AND INVOLVEMENT

There are a myriad of terms and approaches to the inclusion of patients and the public working in partnership with clinicians, researchers, regulatory authorities and policy-makers. Key definitions include PPI and patient engagement, sometimes with different definitions within different contexts (Table 1) while other discipline-specific definitions, for example, community-based participation research (CBPR), participatory action research and co-design in research (supplement table 1) also exist. Despite subtle differences in the definition of engagement and involvement (Table 1), these are often used interchangeably with the intention of recognising the importance of the active involvement of patients, carers, families and the public contributing across all domains of CVD activity – namely that PPI includes actions *with* or *by* patients or the public, and not *to*, *about,* or *for* them, engagement refers to e.g. raising awareness and sharing knowledge *by* and *for* patients and the public (19). The 2023 publication by the WHO provides the first framework for non-communicable disease specialities, including CVD, to transition from 'intent to action' to 'meaningfully engage' (the transition of power through respectful, dignified and equitable inclusion) those with lived experience in all health processes (2).

Table 1: Key definitions relating to patient and public involvement in clinical practice, research, regulation and policy development

TERMS USED	DEFINITION/DESCRIPTION
Clinical care/service	
Patient and public involvement	'Ways in which patients can draw on their experience and members of the public can apply

	their priorities to the evaluation, development, organisation and delivery of health services'(20)
Engagement in practice transformation efforts	'Raising awareness, and sharing knowledge by and for patients or the public' (19)
Research	
Patient and public involvement (PPI)	'Research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. It is an active partnership between patients, carers and members of the public with researchers that influences and shapes research' (21)
Patient and public engagement (PPE)	'A range of methods of involving members of the public in research'(22)
Regulatory authorities	
Patient engagement	'The effective and active collaboration of patients, patient advocates, patient representatives and/or carers in the processes and decisions within the medicines lifecycle, along with all other relevant stakeholders when appropriate' (23)
Policy	
Meaningful engagement	'Respectful, dignified and equitable inclusion of individuals with lived experience in a range of processes and activities within an enabling environment where power is transferred to people; valuing lived experience as a form of expertise and applying it to improve health outcomes' (2)

ACNAP's definition of PPI

PPI is essential for delivering cardiovascular care that is patient-centred, equitable , and responsive to the needs and priorities of those it serves. Despite the array of definitions the concept of meaningful engagement of patients, members of the public and communities, at all stages of clinical practice, research, regulation and policy processes is consistently recognised, they often lack specificity for cardiovascular care. To address this, ACNAP has developed a definition of PPI that aligns with its vision and the principles of the ESC Patient Forum, drawing on the framework proposed by Tritter (20) and adapting it to reflect their shared values and priorities in cardiovascular care.

The ACNAP definition is: *patient and public involvement (PPI) in cardiovascular care refers to the active and meaningful ways in which patients, carers, and members of the public equitably contribute their lived experience and articulate their priorities to shape the development, organisation, delivery, implementation and evaluation of services for the prevention and treatment of cardiovascular disease across clinical care, research, regulation, and policy. PPI should be equitable, inclusive, transparent, and a core activity of all aspects of cardiovascular care.*

By establishing this definition, ACNAP provides a shared understanding of PPI, supports meaningful and inclusive involvement of patients and the public, guides implementation in clinical, research, regulatory, and policy settings, and ensures alignment with the ESC Patient Forum's commitment to patient-centred care and collaborative decision-making.

METHODS

This statement is informed by literature retrieved from searching Ovid Medline and PubMed databases from inception to 21st July 2025.

The following search strategy that combines key terms was used: ((patient or public or consumer or community or "person centered") [adj3] (involvement or engagement or participant* or Advocacy or co-design)) [ti] OR ("patient-led" or "shared decision making") [ti] OR ("own care" or "self care" or selfcare) [ti] OR cardiovascular diseases/ or myocardial infarction/ or coronary disease/ or stroke/ or brain ischemia/ or death, sudden, cardiac/ or heart diseases/ OR ("cardiovascular disease" or CVD or stroke or "heart disease" or "heart failure" or "cerebrovascular disease" or "peripheral arterial disease" or "deep vein thrombosis" or DVT or "pulmonary embolism") [ti] OR (prevention or management or administration) [ti,ab] OR Primary Prevention/ or Secondary Prevention/ or Disease Management/

The search was restricted to English language articles. The reference list of articles retrieved was searched, and publications that were part of personal databases or familiar to the authors of this work, were included when appropriate.

PPI IN CLINICAL PRACTICE, RESEARCH, REGULATION AND POLICY DEVELOPMENT

Common attributes of PPI across clinical practice, research, regulation and policy is that there is inclusive, respectful, meaningful, active partnership with those with lived experience to inform health, research, regulation and policy from priority setting to dissemination. To achieve this, core considerations relevant for all settings, as described in Box xx, should be actioned.

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BOX 1: Core considerations for PPI

1. Establish a standardised global definition and framework for PPI in cardiovascular disease encompassing clinical, research, policy and regulatory activities.
2. Demystify PPI so that those from underrepresented groups feel able to partner and to contribute.
3. Identify the training and support needs of PPI members before their involvement and develop training and support materials for those engaging in PPI activities.
4. Include PPI in Board membership and leadership committees in all settings, including professional organisations.
5. Ensure PPI partnership is inclusive and diverse, involving partners from underrepresented communities.
6. Secure financial support to establish meaningful PPI participation, to sustain long-term involvement, and encourage impactful input; provide reimbursement of participants in terms of time and resources; ensure equity of financial compensation and support in LMIC.

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PPI IN CLINICAL PRACTICE

PPI in clinical practice is based on the expectation that it will improve the outcomes and quality of decisions related to care and treatment. It can provide valuable insights into the needs, values and preferences of those living with a certain health condition at the individual patient level. Collaboration between patients, and health care professionals may lead to valuable relationships including informed or shared decision making. However, collective PPI as part of major system change goes considerably beyond the individual patient level and can influence the development of organisational, policy and

guidelines changes to transform models of care delivery to improve outcomes and reduce health inequalities.

Partnering with patients in clinical practice is regarded as a marker of high-quality care and is considered an important pillar of person-centred care which calls for a whole of systems approach (24, 25). There is increased consensus that such practices contribute to improved safety, quality of care, patient outcomes and experiences, and improve the performance of healthcare services (26). Effective partnerships between clinicians and patients should be embedded into institutional and organisational practice and culture and based on the principles of meaningful engagement – namely dignity and respect, power and equity (such as neutralisation of power imbalances and elimination of discrimination), inclusiveness and intersectionality (by incorporating associations of the individuals' identity and social factors), and commitment and transparency from both parties (2). Such partnerships could be effective in the development and promotion of person-centred care, education and training for patients and healthcare professionals, tools and resources for communication and to support shared decision making, integrated care models, and measurement of success (e.g. patient experiences and patient reported outcomes) (27).

PPI at the individual patient level

PPI at the individual level concerns participation that relates to a patient's own care. One common example of this approach is the concept of shared decision making (SDM), defined as a communication process by which patients and clinicians collaborate to choose tests, treatments, and care plans that most align with an individual patient's preferences and values aligned with the best available evidence recommendations (28). SDM was conceived to diverge from the traditional paternalistic biomedical model of healthcare towards a more person-centred approach and represents a middle ground between paternalistic and a patient-autonomous approach; it is an equal partnership in which the clinician and patient share responsibility for the decisions (29). SDM tools have been designed to support patients and healthcare professionals in the decision-making process. Thoughtful design of such tools, incorporating patients as partners in the development as well at attention to crucial components to be included, are of vital importance, and may improve decision acceptance, increase patient engagement in the execution of the treatment and as a result improve outcomes (30).

A 2024 Cochrane review (31) reported that SDM improves communication between patients and their health care professionals, patient understanding, acceptance, satisfaction, and involvement in medical decisions. However, a systematic review of 28 studies of SDM in older people identified 149 barriers

and 67 facilitators which included challenges at patient (e.g. due to poor health, cognitive or physical impairments), clinician (e.g. suboptimal interpersonal skills), and system level (e.g. pressure for time and high turnover of patients) (32). This indicates that there are numerous variables that influence the SDM process which are equally evident within cardiovascular care. Mehawej and colleagues (2021) found that older patients with atrial fibrillation (AF) and those with cognitive impairment were less likely to engage in SDM for stroke prevention (33). Nevertheless, education and explaining the treatment options is crucial and nurses may be well placed to provide this (34). Another report showed that patients experiencing ST elevation myocardial infarction (MI) felt there was little choice other than to receive an invasive procedure while their cardiologists who were aware of the concept of SDM felt that the principle was more relevant in those with non-ST elevation MI suggesting that SDM is not considered as suitable or feasible in critical situations where early and acute decision making is required. However, conflicting values (e.g. on participation in care) of patients and clinicians may also impact the therapeutic process and potential for SDM: where patients might experience participation as being responsible and accepting responsibility, whilst healthcare professionals might interpret participation as the vehicle to provide information for patients to act on this (35).

Collective PPI as part of major system changes

Engaging patients on a collective level refers to patients participating in activities where the impact extends beyond their own care (36). This shift that places patients at the centre of healthcare (person-centred care) has occurred partly in recognition that they provide a unique insight into (their own) care delivery, and partly due to the findings of reports investigating serious failings in clinical care (37, 38). Engagement of PPI on a collective level is also varied but may include contributing to a review and redesign of services, providing expert input into resource allocation discussions, or leading patient safety and quality processes. Nevertheless, while the focus of an intervention may be strategic, the intrinsic value to patients of participating in a process of change is equally valuable (39). Consequently, the concept of value can be taken into account when evaluating the benefit of engagement (39). The intensity of this engagement can be measured along a continuum from consultation where feedback is given, to involvement where patients advice is sought, to partnership and shared leadership where patients are collaborating with clinicians as equals to deliver a project (40). Collective PPI is complex but five 'simple rules' have been defined to underpin successful initiatives and include: style of leadership; development of feedback loops; learning from past experience; engagement of physicians; and inclusion of patients and families (41). An example of a specific healthcare service design is the concept of nurse-led clinics. In such design it is crucial that the values of patients and healthcare professionals are covenant and non-conflicting for the engagement to be effective (35). It is therefore

essential that clinicians are clear of their goal for the PPI activity and the programme is subsequently designed in a way that makes achieving the goal realistic. Community engagement strategies (for example, home visits, engagement of churches, or local physicians) have been helpful in overcoming challenges to deliver care, but also demonstrated to be successful strategies for recruitment and retention, especially in underrepresented communities (42, 43). Notably, greater PPI may entail an improved merge of those parts of the populations that already benefit from good (access to) healthcare, due to economic and social status, and those already experiencing inequalities in healthcare (44).

Finally, considering facilitators and barriers in collective levels of meaningful patient participation in healthcare organisations is crucial. These may include, 1) preconditions for patient participation, 2) strategy for patient participation, 3) preparation for patients and staff for participation, 4) support for patients and staff during participation, and 5) evaluation of participation. The result of this review and earlier evidence highlights that while PPI can improve some healthcare metrics preparation and planning are key to delivering a meaningful programme of PPI activities (45).

Resources for PPI activities in clinical practice

The financing of PPI activities is a key enabler to support PPI activity (2), and in many healthcare systems PPI reimbursement is mandated (46-50). Other key enablers, as stated in the WHO Framework, include redistributing powers, eliminating stigma, capacity building, and institutionalising engagement. While in some countries governments have mandated that health authorities have a legal responsibility to engage patients and the public in the commissioning and delivery of services (14), there is concern that there is a risk that only high-income countries will adopt the framework, as PPI may still be seen as 'nice-to-have' rather than a fundamental part of healthcare provision (51).

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BOX 2: Clinical practice specific PPI considerations

Minimum Standards

1. Individual patient care: Collaborative partnerships should be established between healthcare professionals, patients, and potentially family members, to achieve informed or shared decision making and deliver personalized care.
2. System changes: Patients and the public should be partners in major system change plans and policy development from priority setting to dissemination. For example, this includes partners the redesign of healthcare services (such as specialised clinics) and quality improvement processes.

Considerations for Implementation

1. To achieve the full potential of PPI, it must be adopted as an integral part of healthcare policy and quality improvement. This requires a cultural shift and practice redesign with partnerships being a crucial aspect of high-quality, person-centred care.
2. PPI approaches should focus on the context, adapting to culture and local community, particularly in low-and middle-income countries, where PPI may be challenging due to structural and financial barriers.

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PPI IN RESEARCH

When considering PPI in research, most emphasis is placed on PPI in designing, delivering and disseminating research for individual projects (Graphical Abstract). Beyond this, PPI has a considerable contribution to make to the wider research system in defining research priorities, grant review and funding policies, ethics committees, co-authorship and editorial policies and procedures.

PPI in research studies

Patient involvement in research is typically termed PPI in the UK, community-based participatory research (CBPR) in the USA and Canada while co-design and consensus methods are also methodological designs that include patient and/or public involvement (Table 1). Whilst these concepts are similar in philosophy, differences do exist: PPI and co-design includes patient involvement from planning to dissemination, consensus methods are more likely to apply to individual aspects of the research while CBPR tends to engage communities in delivering the research rather than other aspects of the research process (52). Although the effectiveness of co-design is rarely evaluated (53) PPI improves the quality of the research design, recruitment, interpretation and communication of results (54)while CBPR enhances recruitment and outcomes (52, 55-57). Despite this, researchers often have limited awareness, knowledge and skills of PPI and have concerns regarding ethical considerations and oversight of PPI activities (58). Although the reporting of PPI is limited in LMIC, PPI mostly occurs in research planning contributing to improved study design and relevance to the community (9) An area where PPI would be particularly beneficial is in the contextualisation of international research for LMIC (18). However, PPI in research is not without challenges. Maintaining relationships over time, lack of resources to support effective engagement, the burden on patients dependent on their condition (59) and lack of training for both patients and researchers (60) are particular difficulties. Therefore, training, appropriate planning and resources in terms of e.g. time and finances, must be supported by funding bodies for effective PPI in research. There is a growing bank of tools to support PPI in research. Ethical frameworks for involving patients in research design (61)

payment frameworks (62) the establishment of core PPI organisational groups (for example, the International Core Outcome Measurement in Effectiveness Trials (COMET), People and Patient Participation Involvement and Engagement (PoPPIE) working group to support patient involvement in designing core outcome sets) and reporting guidelines for PPI in research (63) are all now available

Defining research priorities

Defining research priorities is important addressing health need gaps but also for focusing the use of limited resources (64) and reducing research waste (10). Strategies to address this include ensuring research is focused on patient-centredness and tackling patient-defined research priorities (10), where uncertainties in the evidence exist (16). This can be at research group, organizational, national or international level. In CVD examples of patient and public partnerships in setting national research priorities include advanced heart failure (65), congenital heart disease (66), heart surgery (67), cardiovascular prevention and rehabilitation (68) in the UK and aortic dissection in Sweden (69). However, the involvement of PPI in priority setting is not internationally applied and should become universally adopted.

Grants and funding bodies (panels and reviews)

As highlighted previously, while PPI has demonstrated to improve the quality of research and outcomes, effective PPI is commonly challenged by time and financial resource. Patient involvement should be financially supported equivalent to other included experts (2) and therefore, funding organisations have a responsibility to both recognise but also appropriately fund PPI. Certainly, some research funding bodies (for example, NIHR in UK, CHIR in Canada) mandate and fund PPI activity within grants, although others (for example NIH in USA) do not explicitly state this.

Patients and the public as grant reviewers are increasingly common (70). Pre-grant submission feedback leads to the adoption of almost 40% of the patient advice to improve proposals (71). In some instances post-submission patient reviews are incorporated into the overall review panel process while in others PPI review is considered separately. Roles include ranking on priority of shortlisted scientific reviews (72), although others are more detailed asking PPI reviewers to consider if the methods are appropriate for patients, if the PPI plans throughout the proposal are well defined and if the funding for related PPI activities is sufficient (73). However, overall, there is a lack of international best practice guidance on how best to attain meaningful patient involvement in grant reviewing and grant panels. Suggestions for improvement have included training and education for researchers and committees;

aligning perspectives of the funding bodies and patient perspectives on researcher expectations and making it mandatory for researchers to include how patient's advice was incorporated (71).

Editorial policies and co-authorship

There has been a considerable increase in patient authored and co-authored papers on PubMed in recent years, with a 9-fold increase observed from 2020 to 2021 (74). Most health journals comply with the International Committee of Medical Journal Editors (ICMJE) which provide standards for authorship, although guidelines for patient co-authors are not specifically defined. Such guidelines may describe the specific contributions of patient co-authors, their potential need of support, and the associated prerequisites for the authorship team. Within the ICMJE the responsibility rests collectively with the authorship team to ensure all authors meet the required criteria. In contrast, the recently updated Good Publication Practice (2022) for company sponsored biomedical research have added, that authorship criteria should be applied consistently to all contributors, including patients (75). At the medical journal level the majority (69.2%) of Editors-in-Chief believe it is acceptable for patients to be authors or co-authors, but a third did not (76) highlighting an inconsistency across journals. Furthermore, only 3.6% had a policy on how patient partners should be considered as co-authors (76). Additionally, the BMJ have included PPI in their peer-review process, as part of their commitment to co-produce content and enhance the relevance and patient centredness of their papers (77).

The adoption of the Guidance for Reporting Involvement of Patients and the Public in health and social care research (GRIPP and GRIPP-2) (63, 78), to improve PPI reporting in research has been slow. However, some journals, for example, The BMJ journals, have started to require all authors to include a PPI statement in the methods section. Editorial policies are also expanding to include patient-specific resources. From a cardiovascular perspective the European Society of Cardiology (ESC) produces guidelines for patients and The European Journal of Cardiovascular Nursing has patient representation on its editorial board and commissions patient perspective articles written by patients. This 'Science for Patient' section aims to describe and translate findings from reviews into plan English to support patients and the public to understand the research. An area of ongoing contention across all specialities is equity of access to published papers and open access policies, which often restrict patients without an academic affiliation from accessing papers.

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BOX 3: Research-specific PPI considerations

Minimum Standards

1. PPI must be embedded in the entire research system, from identification of priorities (local, national and international), the design and planning of research, the implementation (including data collection, analysis and interpretation, as appropriate) and the dissemination of findings. This includes the use of patient researchers, where appropriate.
2. Funding organisations should align funding calls to research priorities identified through PPI, mandate the inclusion of PPI in all grant applications (including how the PPI has informed the proposal) and patients and the public should be equal partners in grant review panels, Budget allowance, equitable with technical expertise, specific for PPI expertise and activities should be included.
3. All research committees, at all levels should include PPI partners across the entire research process.
4. Editorial boards of journals and publications should have PPI membership and should accept, and expect, patient co-authors in line with ICJME requirements. PPI partners should also be part of the peer review process.
5. Tailored training should be provided for PPI partners to build confidence and understanding of the research process, and at the same time researchers should be trained on how to conduct effective PPI as a core research competency.

Considerations for Implementation

1. For effective PPI establishing best practice frameworks, guides and policies for the inclusion of patient and public partners in research (including research development, funding organisations, and editorial boards and processes) should be established to aid practice and provide transparency.
2. Creating safe spaces for patient and public partners where respectful, inclusive and equitable engagement is key for PPI members to feel valued and listened to. Training for both PPI partners and staff should be developed and provided in all sectors of research regarding PPI policies and inclusion.
3. Opportunities for PPI activities should be generated from the appropriate PPI community. Such activities may include providing lay summaries, patient-led grant calls or publications, PPI perspectives suggested for all grant and paper submissions or patient-perspectives in journals, as potential examples.

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PPI IN REGULATORY ORGANISATIONS

The inclusion of patients in all aspects of medicine regulation has come more into focus in recent years. It was in the early 1990s that the first patient representative served on an U.S Food and Drug Administration (FDA) advisory committee, with them receiving voting rights in 1996 (79). It is now more widely recognised that patients bring considerable benefit to the regulatory scientific process, that regulation bodies need to work in partnership with patients, that roles and contributions of patient partners should be defined, and that patients are appropriately financially supported for their work (80). Involvement activities are not standardised and include an array of undertakings - steering, advisory and review panels, operational committees, providing advice on outcomes important to patients (including patient reported outcomes), priority setting and patient-led collaborations, to name a few. Key regulatory authorities including the FDA (81), UK Medicines and Healthcare Products Regulatory Agency (MHRA) (82) and the European Medicines Agency (EMA)(8) now have established strategies or frameworks for patient involvement. Additionally, The European Patients' Academy on Therapeutic Innovation (EUPATI), a pan-European public-private partnership program of the European Patients' Forum (EPF), has published guidance for PPI in four regulatory areas: pharmaceutical industry-led medicine in research and development (R and D), ethics committee, regulatory authorities and health technology assessments (HTA)(83). Despite these advancements, many other regulatory bodies still undervalue PPI and are at different stages of strategy development (84).

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Box 4: Regulatory-specific PPI considerations

Minimum Standards:

1. Regulatory bodies must work in partnership with patients, ensuring that roles and responsibilities are clearly defined, contributions formally recognised, and participation supported through appropriate financial reimbursement. Involvement should extend the regulatory continuum, including steering and advisory committees, operational working groups, priority-setting, patient-led collaborations, and the co-development of patient-reported outcome measures.

Considerations for Implementation

1. Establishing best practice frameworks and training to support consistent, high-quality PPI across regulatory activities. Regulatory bodies have a role in setting the standard for research requirements and thus could influence and drive requirements for transparent and active PPI in research.
2. Allocate resources and develop evaluation mechanisms to embed PPI within routine practice and to assess its impact on regulatory decision-making.

3. Collaborate nationally and internationally to align standards, share learning, and set expectations for PPI across regulation settings.

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PPI IN POLICY AND CLINICAL GUIDELINE DEVELOPMENT

Given the consensus that PPI in policy-making is important, and that International standards do exist for the integration of PPI in policy and clinical practice guideline development (85), evidence of actionable patient involvement is sparse and underdeveloped. A review of 101 USA-based guideline developing organisations identified only 8% required patients on development groups, only 24% sought public comment on draft guidelines and only 20% created patient-specific guideline outputs (for example, patient summaries) (86). Conversely, Brazil has noted public consultation and increased patient participation in public health initiatives led to almost four times more initiatives being amended from their initial recommendation (87).

The National Institute for health and Care Excellence (NICE), which develops UK national clinical guidance, advice and standards, has a PPI policy (88) and details PPI roles such as direct involvement in guidance production and quality standards as formal members of committees and indirectly through reviewing scopes, draft recommendation and by submitting evidence (88). Likewise, NHS England, who lead the health service in England, highlight roles in governance (open Board meetings, open annual general meetings, and representatives on committees, working groups and programme boards), NHS Citizenship (dialogue to influence priorities and decision-making) and partnership working with different communities and the voluntary sector (7). Specifically in CVD, the European Society of Cardiology (ESC) has ESC Patient Forum members on every Guidelines Task Force, patient advocates are involved in guideline review, and patient-versions of the guidelines are produced. Overall, key areas for consideration as a lack of a standardised approach to PPI in clinical practice guideline development, varying terminology of 'PPI' is used which hinders understanding of their contribution and a lack of reporting of PPI involvement in some areas of clinical practice guideline development (89). Challenges have also been reported in producing patient versions notably working with volunteers, the lack of consultation, financial resources and difficulties in translating the recommendations into patient-level information with calls for greater transparency of methods, and consideration of appropriate dissemination of patient versions to reach the target audience (90).

While policy and clinical practice guideline organisations have tended to focus on the PPI role, some attention has been given to defining the expectations of international, national and regional senior

teams ensuring the adoption and execution of PPI in service and policy development. The WHO framework for meaningful engagement specifically targets World Health Organisation and Member States including senior management and programme directors, ministers of health and their advisors, health sector planning managers and resource and administrative advisors (2). Similarly, the NHS England (NHSE) Patient and Public Participation policy highlights the corporate responsibilities of the Board of NHSE, the chairman and non-executive directors, the chief nursing officer, regional directors, and all managers while also acknowledging that all staff are responsible for considering the need for PPI in their work (7). What is required is evaluation of these policies to ascertain the progress made in PPI becoming routinely embedded in policy development.

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BOX 5: Policy-specific PPI considerations

Minimum Standards

1. PPI is essential to ensure that health policies and clinical guidelines are patient-centred and relevant to patient needs. Certain principles can guide PPI herein: i) Standardised definition of PPI and approach to integrated into policy development at national and international level; ii) Follow national and international standards on PPI integration at all levels, in which roles, expectations, responsibilities and reimbursement have been outlined; (iii) Include the roles and responsibilities of PPI in the job descriptions of all senior team members (e.g. Chief Executives, Board chairs and members); iii) Include PPI in prioritising health services development and implementation as well as associated policies; iv) Consult PPI during policy and guideline development, and produce accessible patient versions of all policies, clinical guidelines, and standards; v) Establish best practice frameworks to provide guidance in PPI involvement and associated benefits.

Considerations for Implementation

1. Establish mechanisms for PPI within policy and guideline development, ensuring diverse representation, clear roles, arrangements for reimbursement, and accessible communication.
2. Provide training and support for both patients and professionals, embedding PPI from the earliest stages of development with structured feedback on contributions.
3. Establish long-term commitment to PPI by evaluating its impact and process to ensure inclusivity, effectiveness, and accountability.

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EQUITY, DIVERSITY AND INCLUSION IN PPI

The benefits of PPI in research have been demonstrated predominantly in high income countries. However, there is often an imbalance of patient participation in favour of white males (91). Thus, positive efforts to recruit women, members of Black, Asian and minority ethnic groups, those from lower socio-economic groups, and other under-represented communities is required. Efforts to address this have been made with the NIHR mandating the consideration of inclusion and reducing health inequalities a requirement for funding proposals, ensuring future research considers inclusion and equity (7).

Across low-to-middle income countries (LMIC) several challenges exist that serve to obstruct inclusion implementation (18). These challenges include gaps in health infrastructure, low socioeconomic status, cultural stigma, and uncertain roles. Strategies to enhance patient mobilization, leveraging existing partnerships for increase financial support, the use of peer-to-peer partnerships either locally, nationally, or internationally, and to increase education addressing the role of patients and public in research as strategies to address challenges with PPI in research in LMIC is needed (18).

Patient-led organisations have primarily been created for the sole purpose of patient advocacy. While varied in structure, scope and implementation methods, all have the same goal – to advocate and provide a voice for the lived experience in clinical service development, research, and health policy (92). In cardiovascular disease examples include the Global Heart Hub.

A very good example of involvement in cardiovascular disease prevention is the recently issued manifesto, advocating for cardiovascular health, by the Global Heart Hub, that outlines key actions on 8 areas: public information, early disease detection, efficient testing, digital access; health professionals training; research investment; policy guidance and equity access (Global Heart Hub, 2024). Each key action states a clear view of the need for that action with some tips on how to do it. This shows how patients can have a global impact on cardiovascular disease.

DISCUSSION AND FUTURE DIRECTIONS

The importance of meaningful PPI is evolving at pace, although cardiovascular care throughout Europe has been slower to respond. ACNAP and the ESC Patient Forum strongly advocate for the value and integration of PPI within clinical, research, regulation, and policy. This statement not only highlights examples of good practice in these settings and provides a definition of PPI tailored to the cardiovascular field, but also forms a foundation on which ACNAP and the ESC patient forum believe current and future activities should be built. As highlighted previously, much of the existing work is

from the UK which has been trailblazing on the integration of PPI partnerships, especially within research. However, while the UK provides the majority of the existing and implementation evidence, this leads to an inequity across Europe. Since patients are at the heart of the ESC's mission of reducing the burden of cardiovascular disease, ACNAP and the ESC patient forum are committed to addressing this equity-gap by proposing evidence-based opportunities for integrated, purposeful and meaningful PPI across all aspects of cardiovascular care, across all specialisms and professions, to be implemented across Europe and beyond. This will not only strengthen the quality, relevance and utility of work undertaken, but also strive for equity of patient partnerships, which are distinctly lacking in many countries. These opportunities not only allow for standardisation, but also support the advancement of future visions of healthcare, particularly in areas where public scepticism may exist. For example, the rapid growth of Artificial intelligence (AI) in healthcare highlights the importance of PPI both in building trust (93) and in the understanding the acceptability of it use (94). Therefore, this statement can be used to establish the core foundations in terms of recognising the value of PPI, embedding a PPI culture, defining principles for practice, while also creating environments that encourage and support PPI. These elements are key to impactful care delivery, research, regulation and policy in settings where growth is needed and that aims to address the global CVD burden.

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DISCLOSRE OF INTEREST

None declared

DATA AVAILABILITY STATEMENT

The data that support this paper are available in the paper.

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