

A Guide to Patient and Stakeholder Involvement (PSI) in Research

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Background and foundation

As a part of SHARE – Centre for Resilience in Healthcare’s overarching vision of reforming the understanding of quality and safety of current healthcare systems¹, patient and stakeholder involvement (PSI) in SHARE’s research activities is a key strategic priority. The aim of SHARE’s PSI strategy is to encourage and facilitate a broad spectrum of patient and stakeholder involvement across all of SHARE’s research activities, to increase the relevance and impact of our research.

In order to form a comprehensive, nuanced and accurate picture of the healthcare services, it is important to include the perspectives of those who rely on these services for their health, as well as the perspectives of those who provide, govern and regulate healthcare. Genuine involvement has the potential to improve the quality of research and the relevance of research topics and outcomes. Collaboration between researchers and patients and other healthcare stakeholders can, for example, contribute to research that better reflects user needs and priorities; improved research design; and increased recruitment and participation throughout a research study. Patients and other stakeholders may be involved throughout all phases of the research process, from prioritisation and planning, management and conduct, to the dissemination of findings and implementation of change based on results. Patient and stakeholder involvement in research can thus illuminate new knowledge and facilitate insights into a broad variety of user-centred, clinical, managerial, and governmental perspectives, while also ensuring that research findings are targeted for expedient implementation across multiple levels of the healthcare system, in aid of service development and improvement.

The purpose of this document is to provide a tangible guide for how to accomplish patient and stakeholder involvement in health research. The current SHARE PSI strategy and this guideline document have been developed by a working group consisting of SHARE researchers and Centre management representatives². Both of these documents are revisions of the previous SHARE PSI

¹ SHARE Research Strategy, 2023-2027

² Silje Sjøseth Askeland, Inger J. Bergerød, Stig Bjonness, Heidi Dombestein, Maren Sogstad, Veslemøy Guise, Lene Schibeavaag, Petter Viksveen, and Siri Wiig.

strategy (2020-2022)³. As part of the revision process, all SHARE affiliated researchers, PSI panel members, and SHARE board members have been invited to give input.

Definition of patient and stakeholder involvement (PSI)

Involvement refers to the *active* involvement in research from people who use healthcare services, their carers, and other healthcare system stakeholders, rather than people contributing only as research subjects. In essence, PSI in healthcare services research is when research is done *with* the people who use or provide services, rather than research that is done *to*, *about* or *for* them by others.⁴ ‘Involvement’ is distinct from both ‘participation’, where patients and stakeholders are recruited as participants in research, and ‘engagement’, where researchers share knowledge and information with the public or otherwise engage in dialogue with healthcare stakeholders at the end of the research process. Thus, the use of the term ‘PSI’ implies that patients and stakeholders are actively involved in research, often across several or all stages of the research process and for the entire duration of a project as members of the research team.

From the inception of SHARE, we have used the term ‘PSI’ instead of the term ‘PPI’ (Patient and Public Involvement). This is because ‘PSI’ is a term more suited to the research conducted within SHARE, which is primarily focused on health services research from a quality and safety perspective. An expanded range of stakeholders than are typically considered as part of the ‘PPI’ term (usually restricted to patients, carers, user organisations and the public) are relevant as key partners in our research. Notably, healthcare system workers such as healthcare professionals, managers and regulatory representatives are crucially important stakeholders for the health services research conducted within SHARE.

Who are we going to involve and how?

Who

The stakeholder groups most relevant to the research that SHARE conducts are defined in the table below, based on original work by the Patient-Centered Outcomes Research Institute⁵.

Stakeholder Group	Description	Example
Patients / Service users	People with current or past experience of illness or injury; people at risk for health problems or who use healthcare services	A person who has Type I diabetes
Carers	Family members, friends, or other persons who provide informal care and support to patients / healthcare service users	The wife of a man receiving homecare, or the parents of a child with mental health issues
Patient and User Organisations; Stakeholder Organisations	Representatives for organisations who advocate for the interests of patients, carers, healthcare professionals, or other stakeholder	An employee of an organisation representing stroke survivors
Healthcare Professionals	Healthcare practitioners, including doctors, nurses, paramedics, and other allied health professionals	A general practitioner in primary care services
Clinical or Organisational Managers	People (with or without a healthcare background) in managerial roles with varying degrees of responsibility for the governance of healthcare organisations, such as hospitals and community health centres	A hospital ward manager or primary care clinic administrator
Industry	Representatives of companies that design or produce diagnostics, devices, technologies, pharmaceuticals, and other similar industries	The chief medical officer of a device manufacturer
Learning Institutions	People who deliver healthcare training and professional education, including trade or professional associations representing these institutions	Nursing students or teachers at a nursing school
Policy Makers	People who help craft public policy at any level of government	A policy adviser in a local government body
Regulatory Authorities	Representatives of a government agency that monitors and regulates the performance of healthcare organisations	Regulators from national health supervision boards
The Public	Members of the public who have an interest in improving healthcare services	An older citizen consulting on homecare service development
Other	Other healthcare stakeholders not covered by the categories above	An ombudsperson who handles complaints about care quality

⁵ www.pcori.org/engagement/engagement-health-research-literature-explorer/engagement-health-research-literature

Patient and stakeholder involvement may occur directly through individual patients, carers, professionals and other stakeholders, or indirectly through representation and participation from e.g. user organisations or staff associations. Relevant patient and stakeholder representatives or group representatives can be sought according to the research topics and settings in question in a given research project. In this process, it may be important to consider who the stakeholders are for the research project, based on characteristics such as gender, age, ethnicity, or knowledge and experience of using or working in a particular service. Clearly defined selection criteria to ensure the right user in the right place may be necessary in some contexts. Furthermore, all SHARE research projects, including PhD projects, should aim to identify those stakeholders most relevant to their project and at which stages of the research process to involve them, how, and for which purpose.

How

Involvement in research can be conceptualized according to three different approaches on the following continuum: consultation, collaboration, and user led. These are defined below:

- Consultation: researchers consult with stakeholders to seek knowledge and advice on any aspect of the research and apply responses to guide decision-making in the project;
- Collaboration: stakeholders are active and on-going partners in a research project, e.g. as research team members holding co-researcher positions; and
- User led: stakeholders set the research agenda, make decisions on research design, and/or lead the research management process.

Involvement can take place in different ways at different stages of a research project or in a broader sense with stakeholders serving on ethics committees, advisory boards, review panels, etc.

SHARE researchers are responsible for their own projects and the decisions made within them but are expected to familiarise themselves with the PSI strategy and reflect on how they can best implement the aims of the strategy in their work. All new projects should develop specific measures for how to implement the strategy. SHARE researchers are urged to strive for active collaboration with patients and stakeholders in relevant research activities, and to do this as early

as possible in the research process. If possible, it is encouraged to recruit relevant stakeholders as paid co-researchers and/or formal members of the research team, to encourage greater ownership of the project and its outcomes. Larger research projects should also involve stakeholders as members of Expert Advisory Boards and should establish user panels / resource groups with key stakeholders and actively involve the panels/groups as is relevant throughout the project period.

Researchers should engage all involved stakeholders in a formal clarification and alignment of expectations early on in the project, to ensure that the stakeholders and researchers both have a common understanding of their respective contributions and responsibilities, and the purpose and forms of involvement and support in the project. A clarification of expectations should also work to ensure fair and equal participation among different stakeholders in a research project, despite their differing degrees of research expertise and experience, and thus different prerequisites for participation. Such an orientation may be especially important for stakeholders who have no previous research experience. It is also encouraged to seek formal agreements on such aspects as ethical guidelines such as confidentiality, ownership of project materials, the sharing of results, etc. Such agreements should preferably be developed with the input of relevant stakeholders.

Activities that may include PSI

Patients and stakeholders can be involved in a range of activities at all stages of the research process, including during the planning, conduct, and dissemination of research. The research process, or research cycle, is here divided into the following stages: Identifying and prioritising topics; Designing and managing; Undertaking; Disseminating; Implementing; and Evaluating impact. The stages of the research cycle are illustrated in Figure 1. Inspired by important work on PPI in research by INVOLVE⁶, examples of involvement in each of the stages are described below, with some suggestions for how to achieve active involvement at each stage.

⁶ Briefing notes for researchers: public involvement in NHS, public health and social care research (2012)

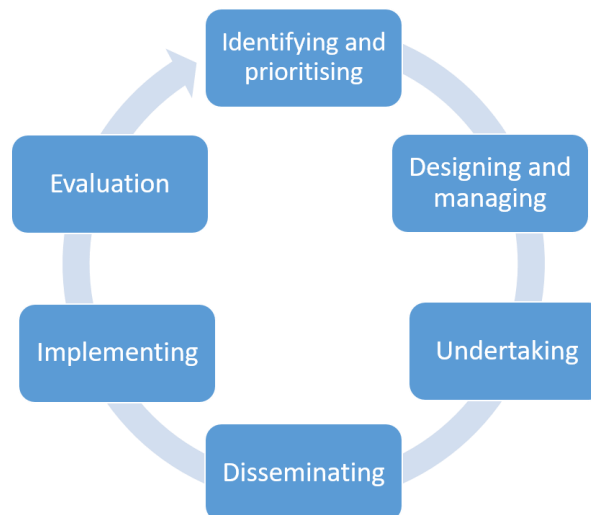


Figure 1: The research cycle

Identify and prioritise topics

During this initial phase, patients and stakeholders can influence what will be researched by

- identifying areas where healthcare quality and safety research is needed; and
- helping to set priorities for the type of research that SHARE will undertake and which populations to study.

PSI in the identification and prioritisation of research topics is fundamental to SHARE’s PSI strategy. By actively collaborating with patients and stakeholders at an early stage to identify pertinent areas of research, we can ensure that the research conducted by SHARE meets important needs of service users and providers across the healthcare system. Such partnerships can feature opportunities for mutual learning and shared decision-making regarding the relative importance of research topics, settings, and populations to study. This can be achieved through PSI in, for example, brainstorming workshops, user panels or resource/reference groups, research networks, and research project steering groups.

Design and manage

During this phase, patients and stakeholders can join in research design and management by e.g.

- contributing to the design of research projects and proposals;
- helping develop or review research grant proposals and study protocols;
- providing input to decisions on study aims, research questions, and outcomes of interest;

- providing input on selection of data collection methods and outcome measures, alongside design and development of research tools such as interview guides and questionnaires;
- identifying issues of ethical concern (including risk assessment) in projects and provide advice on how to handle these;
- identifying factors that can promote/inhibit study participation and assess the possible burdens for research participants;
- helping write or review information letters and consent forms for study participants; and
- leading, advising on, or assisting in participant recruitment and retention processes.

PSI in overall research design as well as the development of grant applications and/or research tools and information can ensure that research projects, processes, and intended outcomes remain relevant to the needs of patients and stakeholders (e.g. by appropriately framing research questions). PSI in the management of research projects may occur through active stakeholder membership in project steering groups or as collaborators in project management teams. Patients and stakeholders can also take or share the role of principal investigators in a study, in which case they are employed as paid members of the research team. Their contextual knowledge and insights may add significant value to the co-design of data collection and analysis processes.

Undertake

During this phase, patients and stakeholders can get involved in carrying out research, often as members of the research team, by e.g.

- collecting data, including gathering and reviewing documents, undertaking library-based searches, conducting interviews, and facilitating focus groups;
- assisting with the transcription and coding of data; and
- contributing to data analysis and interpretation of research results.

PSI in the undertaking of research can strengthen the rigour and quality of data collection and analysis processes. As a result, PSI can reveal new perspectives in the interpretation and understanding of research results. For example, co-researchers may identify or describe themes in ways that other researchers have missed. Patients and stakeholders who will be involved in data collection require appropriate training and support to carry out the required research roles.

Disseminate

During this phase, patients and stakeholders can be involved by e.g.

- contributing to the development of project dissemination plans;
- being included as co-authors in journal articles, co-presenters at conferences, or having their contributions acknowledged in journal articles and reports;
- contributing to teaching activities;
- producing progress reports or newsletters to keep stakeholders and the public informed throughout a project;
- helping to ensure project results are reported back to all those who were consulted, collaborated or participated, including patient organisations, support groups and service providers; and
- helping to ensure that research results and associated information are easily accessible to a public audience, e.g. by summarising research findings in clear, user-friendly language.

Active PSI in the dissemination of research results helps our findings reach a wider audience than without such involvement, as patients and stakeholders will often have access to social media networks, publicity channels, interest groups and forums that researchers may either not be aware of or have access to. Stakeholders who have been involved throughout the research process are more likely to fully participate in dissemination activities. SHARE researchers are therefore encouraged to involve patients and other stakeholders early in the research process, to support their contextual knowledge of the research and sense of project ownership.

Implement

PSI can contribute to the translation of new knowledge into real-world practice, leading to actual change and improvement in healthcare services. Those with a personal stake in research are more likely to put in extra effort to ensure that change happens as a result. They may even be better placed than researchers to establish relationships with key agencies and policy makers. Thus, PSI can influence and facilitate the implementation of research findings and outcomes into clinical or managerial practice, as well as contributing to policy development.

Evaluate impact

During this phase, patients and stakeholders can be involved by e.g.

- co-designing the evaluation protocol;
- evaluating the research process and PSI activities together with the research team;
- evaluating the implementation of research findings in real-world practice; and
- reflecting on their own role and experience in the project as a collaborative stakeholder and what they have learned.

All SHARE projects should seek to evaluate patient and stakeholder involvement as an intrinsic part of the research process, in cooperation with patient and stakeholder collaborators and co-researchers. Such evaluations will contribute toward developing and improving SHARE's PSI practices and associated activities. Letting others know about what worked well (or not), how, and why will contribute valuable knowledge to the evidence base on the drivers for PSI in research. This can be achieved by including information on experiences and outcomes of PSI in research reports and journal articles. This includes what was learned by involving stakeholders in the research team and its impact on the research process, such as PSI leading to changes in the research direction or to different study outcomes. Together with the stakeholder representatives concerned, all SHARE projects should strive to regularly evaluate, document and report activities, experiences and outcomes concerning PSI, focusing on research impact as well as the personal impact for those involved. SHARE will also encourage and facilitate the transfer of knowledge and experience of PSI between projects, for example as part of SHARE's monthly research meetings.

Organisational support of PSI and resources on involvement

- Further PSI guidance, information, and training resources for researchers, co-researchers and other collaborators (in Norwegian) are available online, for example in the form of an [e-course](#), a [video](#), and a [researcher guide](#) on PSI in the specialist health services.
- SHARE has an internal PSI resource group, working to further develop and facilitate research involvement within SHARE, that can provide support.⁷
- The SHARE PSI advisory panel was established in 2020 and features a broad group of patient and stakeholder representatives who meet at regular intervals. The main function

⁷ The Centre [management team](#) can be contacted for any related questions.

of this panel is to provide input and contribute advice on involvement to research projects and activities across SHARE. The primary intention is for the PSI panel to contribute their expertise at the *Identifying and Prioritising* and *Dissemination* stages of the research process, however, they can be contacted for consultation individually or as a group by SHARE researchers at any stage of the research process.

- SHARE has funding available to facilitate PSI in some research activities and projects, for example, to compensate for stakeholders' time used in the research activities, hire co-researchers, organise user panels or to fund seminars, and dissemination activities. SHARE researchers can access these funds by applying to the PSI recourse group.
- The Network for Carer Research ([Nettverk for pårørendeforskning](#)) is coordinated by SHARE. The Network consists of ca. 170 researchers, clinical practitioners, carers, and other stakeholder groups. It is open to SHARE researchers and can facilitate PSI in projects with a focus on carer research.
- Hosting PSI themed seminars and workshops at the University of Stavanger.
- Regular strategy evaluations, e.g., by the SHARE management team, the SHARE board, and/or the SHARE PSI panel will consider its relevance, outcomes, and impact.