# Practical guidance for patient-centred health research

To support the development, approval, and reimbursement of medical interventions that best meet patients' needs, there is an increasing emphasis on patient-centred research. This type of research engages patients in identifying unmet needs[1] and refining the design and conduct of clinical studies,[2] as well as advising on subsequent regulatory assessments[3] and post-marketing vigilance. However, despite many ongoing pilot projects, at present there is little evidence-based, practical guidance on how effective patient engagement can be facilitated.

To this end, an expert group representing a wide range of stakeholders and disciplines was convened by WHO and the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases in June, 2017. The group generated a set of practical recommendations for patient engagement in drug development, clinical research, and regulatory decision making (panel). These principles are based on lessons learned within longitudinal research initiatives, such as Outcome Measures in Rheumatology,[2] and active patient engagement in regulatory processes by the European Medicines Agency[4] and the US Food and Drug Administration.[5] The nine principles outlined here were developed after an extensive dialogue among the expert participants and an iterative consensus process, and they form a starting point that can be tailored to suit different chronic diseases and other health-care contexts.

Engaging with patients helps bridge the gap between health research, policy, and patient-centred practice, increases transparency, and leads to more meaningful outcomes. Patient engagement should be initiated in a stepwise approach through which all parties can learn together and identify the format that works best for all involved. At all stages of engagement, researchers must aim to provide support, define roles, manage expectations, and give feedback to ensure that engagement is mutually beneficial. In this way, everyone can benefit from knowledge sharing. Overarching principles for engaging patients include recognition that the patients' perspective is pivotal, that early involvement of patients is always best, and that involvement at all stages is necessary. Patients should be offered the opportunity to consult each other on experience-based views, and to ensure proper representation, inviting at least two patient research partners is recommended.[6] Lastly, acknowledgement of the input of patients and provision of feedback is essential, and integrated knowledge translation is desirable.[7]

Patient engagement is an evolving concept. We acknowledge that there are different levels of patient engagement, which are all equally valuable and complementary. The degree of patient participation, and the level of power or authority gained through participation, should not be fixed but should instead be tailored to suit the individual research purpose.

The research agenda for future refinement of the process will include the development of new methods to assess the impact of patient engagement on both research processes and outcomes, and novel ways to enhance the effectiveness of existing methods of engagement. The impact of patient engagement, not only in terms of added value but also in terms of cost and potential drawbacks, is poorly understood. There is a lack of consensus on a validated method or tool to demonstrate impact and on which outcomes of patient engagement should be measured. Various stakeholder groups have different expectations and objectives regarding patient engagement and thus need different methods and outcomes for evaluation. Another challenge is that we, as an expert group, all agree that principal investigators and stakeholders should invest in support, information, education, and feedback to patient experts; however, there is a growing awareness that it

**_Panel:_ Best practice principles for engaging patients in health research, treatment guidelines, and regulatory processes**

- The perspective of patients is pivotal in health research, treatment guidelines, and the authorisation of medicines
- Capturing patient perspectives requires multiple forms of engagement that are complementary; the strategy should be tailored to suit different chronic diseases and contexts
- Transparency for all stakeholders about the role of patients in the process facilitates participation and manages expectations from all perspectives
- Broad representativeness of patient perspectives in terms of demography, geography, disease severity, and sample size must be ensured
- Involvement of at least two patient experts throughout the research, assessment, and deliberation processes ensures that the patient perspective is preserved and increases the validity of the outcomes
- Providing adequate information, support, and feedback to patient representatives is key to effective engagement
- Teaching researchers the knowledge and skills required to support public engagement should always be considered
- Productive participation always requires resources to be allocated to the process, with extra effort in terms of time, money, and energy
- Continuous monitoring and measuring of interactions will be vital for refining procedures according to feedback.

does not make sense to train patients in the medicine development cycle without simultaneously preparing researchers for their role in engaging patients in that process. There is therefore a need to explore both the benefits and drawbacks of educating patient experts as well as exploring the needs of researchers in terms of guidance, coaching, and training.[8]

Ultimately, we hope that adoption of our best practice principles and other initiatives will allow for increased patient engagement that is optimised to meet the needs and expectations of all stakeholders, including researchers, clinicians, regulatory bodies, and patients, with clear, measurable outcomes.

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# Unpaid doctors in Japanese university hospitals

The Abe Administration has promoted a so-called workstyle reform as part of its agenda. Consequently, legislation that sets an upper limit for overtime at 80 h per month has been introduced. Health care is no exception. A committee organised by the Ministry of Health, Labour and Welfare (MHLW) is discussing the new legislation for doctors, which will be implemented in 2024. According to a survey by the MHLW, doctors outwork any other profession.[1] 40% of doctors exceed the criterion for workers in other sectors.[1] More than 10% of doctors, most of whom work at university hospitals and tertiary hospitals with emergency services, do more than 155 h of overtime per month.[1]

On Feb 20, 2019, the MHLW controversially proposed that overtime should be limited to 155 h per month.[1] An outcry from doctors ensued, with the argument that if human rights and health impacts are the same across all sectors, then the limit of overtime should be too. Those in support of the MHLW's proposal believe that a stricter limit on overtime worked will negatively affect patient care. Attaining balance between the health of doctors and the sustainability of health services remains technically and politically challenging.

The Japanese health system is at a crossroads. The transformation of health-care provision for a rapidly ageing population remains a big challenge. Facilities and beds are in oversupply,[2] and, as a doctor is required at each facility, most of which are small to medium sized private clinics and hospitals, care remains fragmented. University hospitals are also struggling because of the limited number of paid doctors set by the Ministry of Education, Culture, Sports, Science, and Technology (MEXT) and the fee schedule set by the MHLW, which is biased toward general practitioners.[3]

To fill the gap in doctor supply, young doctors (mostly registered as graduate students) unofficially work full-time at university hospitals. In the evenings and weekends, these young doctors have part-time jobs at private clinics and hospitals. According to a recent internet survey,[3] 46% of doctors younger than 50 years reported having worked without pay. Until recently, MEXT, which supervises medical schools, denied the existence of unpaid doctors.

Burnout is a major population health problem[4] that affects both doctors and patients. Setting an upper limit on