

6. Which 2016–2018 MRFF Priorities do you think need further focus (maximum of three priorities)

- **MRFF infrastructure and evaluation**
- **Targeted translation topics**

7. How can the 2016–2018 MRFF Priorities you identified in Question 6 be extended or re-emphasised in the 2018–2020 MRFF Priorities?

In the *Australian Medical Research and Innovation Strategy 2016-2021*, the Medical Research Futures Funds recognises the need to engage health consumers through co-design and creation earlier in the research pipeline (p.6) and the potential of consumer engagement to ‘maximise opportunities for research translation (p.1). The Patient Voice Initiative shares these views and suggests that effective consumer engagement is essential to achieving the MRFF’s key indicator of ‘better patient outcomes’ (p. 11) and vision of ‘a health system fully informed by quality health and medical research’ (p. 1). A fully informed health system needs to learn from the experience-based expertise of health consumers and know what matters most to health consumers. To reap the rewards of consumer engagement, Australian researchers need (a) assurance that efforts to work with health consumers will be valued by funding bodies and (b) clear and efficient training and guidance in good practice in consumer engagement in research.

Therefore, the Patient Voice Initiative recommends that MRFF:

- explicitly require consumer engagement in all research projects
- supports projects seeking to build a robust evidence base about health consumers’ needs, preferences, perspectives and experiences
- adopts a broad view when considering the need to develop medical research skills and capacity by nurturing and developing social science and health economic researchers alongside traditional health researchers.

MRFF infrastructure and evaluation: Explicitly require meaningful health consumer engagement in all research projects

The Australian Medical Research and Innovation Strategy 2016-2021, recognises the need to engage health consumers through co-design and creation earlier in the research pipeline (p.6) and the potential of consumer engagement to ‘maximise opportunities for research translation’ (p.1). The Patient Voice Initiative (PVI) shares these views and suggests that effective consumer engagement is essential to achieving the MRFF’s key indicator of ‘better patient outcomes’ (p. 11) and vision of ‘a health system fully informed by quality health and medical research’ (p. 1). A fully informed health system needs to learn from the experience-based expertise of health consumers and know what matters most to them. To reap the rewards of consumer engagement, researchers need (a) assurance that efforts to work with health consumers will be valued by funding bodies and (b) clear and efficient training and guidance in good practice in consumer engagement in research.

PVI recommends that the MRFF explicitly require consumer engagement in all research projects. Australian health consumers have repeatedly identified their willingness and need to be engaged earlier in the research pipeline (1, 2). Engagement is essential when scoping research to ensure researchers understand what matters most to patients in terms of outcomes, quality of daily life and addressing unmet needs (3). Being able to demonstrate this real-world value is also essential for

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uptake, not least when health technologies are being assessed by the Pharmaceutical Benefits Advisory Committee, the Medical Services Advisory Committee and the Prostheses List Advisory Committee. By the time such technologies are reviewed by these bodies valuable research dollars may have been wasted developing inappropriate technologies or conducting trials measuring outcomes less important to health consumers. As the PVI Chair, Jessica Bean, explains: 'The generation of medicines currently coming to market are breakthrough therapies that patients (like myself) have been waiting for our entire lives. The only thing more heartbreaking than not being able to treat disease is knowing there is a treatment that works in ways that matter to patients, but not being able to access it because those who don't live with a disease have become the gatekeepers of what defines value.' (1) The PVI recommends that the MRFF supports patient-centred research by making consumer engagement a key criterion when assessing grant applications. To ensure it is not tokenistic, the MRFF should adopt or adapt a recognised evaluation tool, e.g the Patient Centred Outcomes Research Institute (USA)'s Engagement Rubric. Such tools improve awareness of effective engagement, increase transparency in decision making and promote good practice.

Further, we recommend that the MRFF publishes guidance about how health consumers are engaged, such as that published by the US Food and Drug Administration (<https://www.fda.gov/downloads/Drugs/NewsEvents/UCM586195.pdf>). The MRFF should also ensure consumer engagement training is provided to researchers so they benefit from good practice.

The MRFF needs to work with health consumers throughout its processes. For example, the MRFF is to be congratulated for consulting on its priorities, but needs to make consultation documents and templates more user friendly and increase public awareness of its role.

Targeted translation topics – building a robust evidence base about health consumers' needs, preferences and experiences

While two-way communication with health consumers is critical for learning from health consumers and solving problems, there is also a need for robust evidence about health consumers' needs, preferences and experiences. Such 'patient-based evidence', from primary and secondary research not only offers the advantage of being suitable for critical review, it can reduce the burden that engagement places on health consumers and avoid duplication (2). For example, developing a solid foundation of patient-based evidence about people with a particular condition or disease, could inform a wide variety of research projects in the area. Building this evidence base needs to be prioritised as part of the research pipeline rather than being tackled as a piecemeal afterthought.

Just as with other aspects of clinical research, careful planning and appropriate methodological rigour is essential in building this evidence base (3). Patient-based evidence stems from approaches including patient-reported outcomes, discrete choice experiments, analytical hierarchy processes, ethnographic fieldwork, deliberative inclusive methods and synthesis of qualitative research (4). It is worth noting that the FDA now requires a section on patient-based evidence with each submission (5).

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Finally as part of building this evidence base, we also need to invest in and nurture social science and health economics researchers and view their expertise as critical to delivering better outcomes for patients.

- (1) Single A, Bean J 2018 Recommendations to improve the patient voice in health technology assessment in Australia. Patient Voice Initiative Incorporated. <weblink>
- (2) Research Australia, Australia Speaks! 2016 Opinion Poll, Darlinghurst, 2016.
- (3) Facey KM, Bedlington N, Bertelsen N, Single ANV, Thomas V 2018. Putting patients at the centre of healthcare: progress and challenges for health technology assessments. The Patient – Patient Centered Outcomes Research, doi.org/10.1007/s40271-018-0325-5.
- (4) Staniszewska S, Werkö S. Patient-based evidence. In: Facey KM, Hansen HP, Single ANV, editors. Patient involvement in health technology assessment. Singapore: Springer Nature; 2017. p. 43–50.
- (5) 35. FDA. Patient-focused drug development public workshop on guidance 1. Collecting comprehensive and representative input – Discussion document. 2017a. <https://www.fda.gov/downloads/Drugs/NewsEvents/UCM586195.pdf>

What Strategic Platforms (identified in the MRFF Strategy document) would the Priority/ies you identified in Question 8 fall under?

- (Required) Strategic and international horizons Data and infrastructure Health services and systems Capacity and collaboration Trials and translation Commercialisation

11. How can current research capacity, production and use within the health system be further strengthened through the MRFF? (max 500 words)

The above recommendations are intended to add value to the MRFF.

12. Do you have any additional comments on the Discussion Paper? (max 250 words)

No

Do you consent to this submission being made public on the MRFF website?

Yes

The Patient Voice Initiative is an Incorporated Association which advocates for the inclusion of the patient perspective in the structure and operation of:

- Australia’s health system;

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- all aspects of patient care in Australia; and
- the development, approval and funding of medical technologies

by:

- seeking input from stakeholders including patients, healthcare consumer organisations (patient groups), academics, government departments and officials, healthcare professionals, and healthcare, medical technology and pharmaceutical companies;
- undertaking capacity building of patient and healthcare consumer organisations;
- doing anything incidental, convenient or conducive to the attainment of those objects.