painaustralia

Submission to the Health Technology Assessment Policy and Methods Review

June 2023

Painaustralia—submission

Submission—Independent Health Technology Assessment Policy and Methods Review

About Painaustralia

Painaustralia is the national peak body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain. Our members include pain and other specialists, health practitioners, health groups, consumer organisations, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue.

Our aim is to have the voice of people living with pain, their families and carers represented in all aspects of health policy and decision making.

Recommendations

Formal Health Technology Assessment approaches in the context of pain treatment and management must consider:

- The use of new and emerging technologies—including the identification and accommodation of therapeutic advances for the treatment and management of pain that may enter the regulatory or reimbursement systems (or both).
- Continuous process improvement to facilitate earlier patient access to therapeutic innovations in a timely, equitable, safe and affordable way.
- The complexity of pain and the need to utilise cost assessments for base economic evaluations that adopt societal cost based perspectives to fully account for the costs and benefits of interventions.
- Strengthening the patient and consumer voice in assessing therapies at an early stage in review processes.

Executive summary

Globally, chronic pain has been estimated to be the leading cause of years lived with disability.[1]

In Australia, chronic pain affects the quality of life of over 3.4 million individuals and carries a significant economic burden—with the direct (medical) and indirect (productivity, carer costs, lost taxes, and extra welfare payments) cost of chronic pain estimated in 2018 to be > $73 billion while the estimated reduction in quality of life is valued at $66.1 billion.[2]

[1] Vos, T., et al. (2013) 'Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: A systematic analysis for the Global Burden of Disease Study', *Lancet,* 386 (9995), pp. 743–800; Dahlhamer, J., et al. (2018) 'Prevalence of chronic pain and high-impact chronic pain among adults—United States, *Morbidity and Mortality Weekly Report,* 67(36), pp. 1001–1006; Global Burden of Disease.(2017) 'Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study', *Lancet*. (2018), 392, pp. 1789–1858.

[2] Chowdhury, A.R., et al. (2022) 'Cost-effectiveness of Multidisciplinary Interventions for Chronic Low Back Pain: A Narrative Review', *Clin J Pain*, Nov 22, 38(3), pp. 197-207; Painaustralia and Deloitte Access Economics. (2019) *The cost of pain in Australia*, Report commissioned by Painaustralia.

Painaustralia welcomes the establishment of an independent review of Australia's Health Technology Assessment (HTA) policy and methods. Given it has been almost 30 years since Australia's HTA has undergone a review of this kind, it is vital that the outcome of such a review future-proofs formal HTA approaches for the next 30 years.

Importantly, for Australian's suffering from chronic pain—any subsequent reform to HTA policy and methods must consider: (i) advancements in therapeutic innovations available for treating and managing pain; (ii) the nature and complexity of pain; (iii) current and emerging models of care for people living with chronic pain; (iv) the use of current and emerging technologies to support access, self-management and care processes; (v) economic evaluation of the cost-effectiveness of multidisciplinary chronic pain management interventions; (vi) reduce disparities in access to pain treatment and management; and (vii) prioritise the perspectives from individuals living with pain.

It is Painaustralia's view that consideration of these important factors in a consistent way will strengthen formal HTA processes now and into the future for Australians affected by chronic pain.

Introduction

Treating pain is different from managing pain…Individual pain treatments target nociception, while pain management addresses multiple layers.[3]

…A single treatment would almost certainly be insufficient to deal with the fatigue, pain, cognitive and emotional problems, and many other symptoms reported by patients…[4]

Formal HTA approaches must accommodate interventions for the treatment and management of pain from a holistic perspective. Such an approach moves from 'a focus on managing pain itself' [to] 'managing the person who has pain'.[5]

Painaustralia welcomes the opportunity to have input into this first round of public consultation focusing on the key objectives of the HTA Review as set out in the Review Terms of Reference.

Our submission provides comment that incorporates the three overarching review terms of reference[6] while encompassing consideration of the Review's five objectives as to which aspects of the current HTA policy and methods: (i) are working effectively; (ii) may act as current or future barriers to earliest possible access; (iii) may act as current or future barriers to equitable access; (iv) detract from person-centeredness; and (v) may be creating perverse incentives.

[3] National Academies of Sciences, Engineering, and Medicine. (2019) *The Role of Nonpharmacological Approaches to Pain Management: Proceedings of a Workshop,* Washington, DC: The National Academies Press, p. 10, <https://doi.org/10.17226/25406>.
[4] Ibid., p. 11.
[5] Ibid., p. 10.
[6] (1) Health technologies; (2) Policies and methods; and (3) Funding and approval pathways.

Painaustralia acknowledges that: (i) the HTA Review also seeks to align with the objectives of the National Medicines Policy to 'ensure that Australia's subsidy schemes and funding programs continue to deliver the best possible access for Australians to the treatments they need'[7]; and (ii) there are other HTA reform processes taking place concurrently to the HTA Review.[8] The Reference Committee will consider the learnings from these processes to ensure consistency with the recommendations of the HTA Review.

Therapeutic innovations available for treating and managing pain

Formal HTA approaches must identify and accommodate major therapeutic advances for the treatment and management of chronic pain that may enter the regulatory or reimbursement systems (or both).[9]

The contemporary evidence base underpinning therapeutic innovations for pain management supports the use of therapies that include consideration of the pain experience from a biomedical and biopsychosocial perspective. This includes both pharmacological and nonpharmacological therapies.

Therapeutic innovations for the treatment and management of chronic pain have developed over the last 30 years. These have included: opiates; a range of alternatives to opiates, including neuroactive medications[10], counter stimulation methods[11] and cognitive-behavioural methods. While behavioural conditioning or modification programs have proven helpful to many individuals—they are considered expensive and time intensive. To help address this, multidisciplinary pain programs with an emphasis on cognitive behavioural methods have been designed and introduced.[12]

Importantly, effective pain management requires understanding and treating the multidimensional, including biopsychosocial, aspects of pain—not just the biomedical perspectives.

More recently, developments in understanding chronic pain from a biopsychosocial perspective together with limitations regarding the effectiveness and capacity for harm from some pharmacological therapies has resulted in a shift in treatment emphasis toward nonpharmacological therapies.

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[7] Australian Government—Department of Health and Aged Care—Health Technology Assessment Policy and Methods Review homepage, accessed 20 May 2023, <https://www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review#terms-of-reference-for-the-hta-review>

[8] Processes for patient and consumer engagement—improving the way that patients, consumers and carers are engaged and included in HTA; Expertise, role, and remit of advisory committees—membership of the Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee. The HTA Review will consider matters of committee organisation and processes that relate to the efficiency and timeliness of HTA considerations and subsequent decision making; International Collaboration Arrangement between the Department of Health and Aged Care and other Health Technology Assessment bodies; and other HTA reform commitments under the Strategic Agreement between the Department of Health and Aged Care and Medicines Australia.

[9] Australian Government—Department of Health. (2023) Strategic Agreement in relation to reimbursement, health technology assessment and other matters between the Commonwealth and Medicines Australia, p. 12.

[10] Neuroactive medications include tricyclic antidepressants—which increase the available levels of norepinephrine in the nervous system and can be effective in relieving chronic pain [National Academies of Sciences, Engineering, and Medicine op. cit.; Meldrum, M. (2003) 'A Capsule History of Pain Management', *JAMA*, 290:2470–2475].

[11] Counter stimulation methods are based on neural mechanisms and pathways include the traditional use of touch and electricity with more contemporary methods including neuromodulation (surgical and non-surgical) [National Academies of Sciences, Engineering, and Medicine op. cit.; Meldrum op. cit.].

[12] Meldrum op. cit., p. 2473.

Recognise the complexity of pain

Formal HTA approaches must recognise the nature and complexity of pain. Chronic pain is considered to be 'one of the most difficult conditions to treat'.[13] Contributing factors for this include that it is challenging 'to assess the short-term and long-term effects of any particular treatment that you use. Pain is very individual'.[14]

While pain research over the last 30 years has generated various findings and developments in therapies for the treatment and management of pain—what has not changed is that, 'no one treatment works for every patient, even for pain of the same type and etiology. … [T]he meanings of pain—cognitive, affective, behavioural—are different for each individual and shape the pain experience and response to therapy.'[15]

Current and emerging models of care for people living with chronic pain

Pain research over the last 30 years supports the complexity of the pain experience and the need for pain management approaches to encompass multidisciplinary or integrated care models.[16]

A multidisciplinary approach may include medical interventions and medication (which may or may not be required), but it primarily focuses on non-invasive and non-pharmacological treatments. Pharmacological treatments can be effective in reducing symptoms but are not always necessary and may not be sufficient alone to improve an individual's ability to function.

Doubling Australians' access to multidisciplinary care to treat chronic pain could be achieved with a$70 million per year investment. Greater access to multidisciplinary care could deliver $3.7 million in savings to the health system (net of intervention costs) while reducing absenteeism ($65 million) and improving wellbeing ($203 million in QALYs gained). Overall, the benefit to cost ratio was estimated to be 4.9 to 1.[17]

There is consistent evidence that multidisciplinary care models are cost effective. Evidence-based research estimates a saving of $8,100 per patient, and savings of $356,288 per person over a patient's lifetime compared to conventional medical treatment.[18]

[13] Marcia Meldrum (associate researcher in the department of psychiatry and biobehavioral sciences at the University of California, Los Angeles) quoted in Collier, R. (2018) 'A short history of pain management', *CMAJ*, Jan 8, 190(1), pp. E26–E27.
[14] Ibid.
[15] Meldrum op. cit., p. 2474.
[16] National Academies of Sciences, Engineering, and Medicine op. cit., p. 1.
[17] Painaustralia and Deloitte Access Economics. (2019) *The cost of pain in Australia*, Report commissioned by Painaustralia, p. 67.
[18] Ibid., pp. 67–68.

An emerging model of care gaining support is that of First Contact Care. This model reorders the delivery of care—so that first-line treatments offered for conditions such as chronic low back pain are grounded in a biopsychosocial framework that supports and encourages self-management.[19] Further, in this model—a pain patient's first point of contact will be with a non-physician such as a nurse, physical therapist, or acupuncturist. Research has shown that where the first point of contact is with a non-physician—it lowers the risk of opioids being either prescribed or used in the long term.[20]

Using current and emerging technologies to support access, self-management and care processes

Formal HTA approaches must consider the use of current and emerging technologies to support access, self-management and care processes. Current technologies include text messaging and other mobile applications; virtual reality and artificial intelligence—including wearable devices, interactive voice response systems; and telemedicine. These technologies have the 'capacity to collect high-intensity, longitudinal data, which …has been shown to be valid and reliable and less vulnerable to recall bias than data collected farther from the time the pain occurred'. Further, some of these technologies have tailored theory- and evidence-based interventions to support approaches such as cognitive behavioural therapy and mindfulness. Other technologies have been used to deliver and support 'modular treatments'—where 'multiple approaches are combined to promote self-monitoring, goal setting, skill acquisition, education, assessment, patient–provider communication, and social support'.[21]

Importantly, while the use of technology has potential to support pain treatment and management access, self-management and care processes—more evidence regarding the effectiveness of these interventions and emerging technologies compared to 'in-person care'; 'which technologies are best or which components are most important or effective'; and 'to what extent clinician contact increases engagement and improves outcomes and the necessary frequency of that contact' is needed.[22]

[19] Foster, N. E. et al. (2018) 'Prevention and treatment of low back pain: Evidence, challenges, and promising directions', *Lancet,* 391(10137), pp. 2368–2383; op. cit. National Academies of Sciences, Engineering, and Medicine.

[20] Kosloff, T. M. et al., (2013) 'Conservative spine care: Opportunities to improve the quality and value of care'., *Population Health Management,* 16(6), pp. 390–396; Weeks, W. B. and Goertz, C.M. (2016) 'Cross-sectional analysis of per capita supply of doctors of chiropractic and opioid use in younger Medicare beneficiaries', *Journal of Manipulative and Physiological Therapeutics*, 39(4, pp. 263–266; Wheldon, J. M., et al. (2018) 'Association between utilization of chiropractic services for treatment of low-back pain and use of prescription opioids', *Journal of Alternative and Complementary Medicine,* 24(6), pp. 552–556; op. cit. , National Academies of Sciences, Engineering, and Medicine, p. 31.

[21] National Academies of Sciences, Engineering, and Medicine op. cit., p. 34.

[22] McGuire, B. E., et al. (2017) 'Translating e-pain research into patient care', *Pain*, 158(2), pp. 190–193; National Academies of Sciences, Engineering, and Medicine, op. cit., p. 35.

HTA cost assessment perspective

The cost assessment perspective framing a HTA process determines the foundation for the economic evaluation underpinning the assessment of an intervention. A health care cost assessment process 'generally includes consideration of the costs and benefits relating to the patient and the healthcare sector should the new intervention be adopted'.[23] Alternatively, a societal cost assessment perspective encompasses a broader consideration of costs and benefits beyond the patient and the health care system—such as whether an intervention 'may reduce costs in the welfare system or reduce the demands placed on caregivers'.[24]

Painaustralia understands that the PBAC[25] cost assessment process adopts a health care cost perspective. As noted earlier, Painaustralia is of the view that HTA assessment processes must consider the complexity of pain. To effectively do this, cost assessments must adopt societal cost based perspectives that include evaluation of: (i) direct costs and outcomes—including direct costs borne by the health care system (for example, drug costs, costs of hospitalisation) and direct outcomes (quality of life impact) on the patient; and (ii) indirect costs, outcomes and effects—including productivity loss of patients due to illness and gains due to participation in the workforce due treatment interventions; and indirect outcomes (quality of life impact) on those affected by caring for an ill patient (for example, carers, parents).[26]

Economic evaluation of the cost-effectiveness of multidisciplinary chronic pain management interventions—that consider both the direct and indirect costs and health outcomes

Formal HTA approaches must consider economic evaluations of the cost-effectiveness and cost savings of multidisciplinary chronic pain management interventions from health care and societal perspectives.

Painaustralia understands that the research corporation RAND[27] has been developing a fit-for-purpose economic model to evaluate therapeutic interventions for chronic low back pain that incorporates actual patient data on health care costs, productivity costs, and health-related quality of life for four health states: no pain, low-impact chronic pain, moderate-impact chronic pain, and high-impact chronic pain. This model enables researchers to separate out data from patients with different pain states to assess how costs in each of the chronic pain groups are affected by different treatments. It supports the evaluation of which treatments provide the greatest cost savings and benefits from a societal perspective and health care perspective.[28]

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[23] Hanley, R., Manton, A. and Trace-MacLaren, K. (2019) *The Value of Vaccines Ensuring Australia keeps pace with community values and international practice*, GlaxoSmithKline Australia Pty Ltd and Hears Pty Ltd, accessed 28 May 2023,p. 20 <gsk-value-of-vaccines-advance-copy.pdf>.

[24] Hanley et al., op. cit.

[25] PBAC—Pharmaceutical Benefits Advisory Committee.

[26] op.cit. Hanley et al.,p. 20; GlaxoSmithKline Australia and ViiV Healthcare. (2018) *The Pharmaceutical Benefits Scheme in Australia—An explainer on system components*, February, report prepared by GlaxoSmithKline Australia Pty Ltd and ViiV Healthcare Pty Ltd with the assistance of Deloitte Access Economics Pty Ltd, accessed 28 May 2023, <https://au.gsk.com/media/6259/gsk-viiv-the-pbs-in-australia-feb-2018.pdf>.

[27] The RAND Corporation is a research organization that develops solutions to public policy challenges.

[28] National Academies of Sciences, Engineering, and Medicine op. cit., p. 23.

Valuation of prevention

Formal HTA processes must fully value preventative interventions in assessment processes. Current assessment processes generally restrict the scope of a review to the costs and benefits to the patient and health system excluding broader societal impacts (including productivity and socio-economic considerations).[29]

When the impact of interventions outside the scope of the health system are not factored into assessments—the full value of preventative interventions remain unaccounted. For example:

Survivors of vaccine-preventable diseases may face immediate impacts (for example, temporary inability to work) and/or life-long consequences (for example, need for ongoing disability support) that come with significant costs to families, communities and governments. If these impacts and costs are ignored, the full value of preventing these diseases is underestimated and inaccurate.[30]

Where evidence is available, Painaustralia considers that assessment processes must consider the costs and benefits for the impact of interventions outside the health system—from a societal perspective.

Reduce disparities in access to pain treatment and management

While research provides evidence to support the efficacy and effectiveness of multidisciplinary approaches to pain management—there are disparities in access for some population groups.

Patients with chronic pain can face long waiting times to access public services typically located in public hospitals, particularly in rural and remote areas. Among service providers, the provision and duration of allied-health pain management programs vary greatly. The level of service provision for children and rural patients is also notably lower than that reported for adults in urban areas.

Best practice multidisciplinary approach to pain management therefore remains inaccessible for most Australians. Nationwide, medications were used to manage chronic pain in an average 68.4 per cent of GP consultations involving someone attending for pain management. In terms of Medicare local regions, the highest rates were experienced in rural areas (72 per cent), followed by regional areas (68 per cent) and with the lowest rates recorded in metropolitan areas (65 per cent).

To address concerns regarding access—researchers and clinicians advocate a focus on the social determinants of health. This is because a focus on the social determinants of health considers the same groups of people who may encounter challenges in accessing quality pain treatment and management care. For example, the United States' Centers for Disease Control and Prevention (CDC) published a study that showed a higher than average prevalence of chronic pain and high-impact chronic pain including: among women; those previously but not currently employed; persons with low levels of education; and those living in or near poverty or in rural settings.[31]

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[29] GlaxoSmithKline Australia Pty Ltd and Hears Pty Ltd. (2019) *The Value of Vaccines Ensuring Australia keeps pace with community values and international practice*—Infographic, accessed 28 May 2023, <infographic-valueofvaccines-digital-final.pdf>; op. cit. Hanley et al.

[30] GlaxoSmithKline Australia Pty Ltd and Hears Pty Ltd. (2019) *The Value of Vaccines Ensuring Australia keeps pace with community values and international practice*—Infographic, accessed 28 May 2023, <infographic-valueofvaccines-digital-final.pdf>.

[31] National Academies of Sciences, Engineering, and Medicine op. cit., p. 27; Dahlhamer, J., Lucas, J., Zelaya, C., et al. (2018) 'Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States 2016', *CDC*, MMWR Morb Mortal Wkly Rep 2018; 67:1001–1006.

Further, it has been observed that that low socioeconomic populations can be excluded from clinical trials for various reasons. As a consequence, there may be challenges with the application of conclusions drawn from randomised clinical trials involving middle-income participants to the broader population. This calls for research focused on modifying treatments for individuals from low socioeconomic groups.

The perspectives from individuals living with pain must be prioritised

Pain is a complex clinical problem. Assessment depends on verbal report, and the patient's physical perceptions may be modified by cognitive and affective factors.[32]

The strengthening of the patient and consumer voice in assessing therapies must be supported.

Any co-design engagement process must support the capture of voices at an early stage in the review process to support decision making that has a full 'understanding of issues arising from new technologies, innovations and associated implications for consumers'.[33]

Further, approval processes should be consumer-centered. The involvement of consumers in the process of assessment varies across countries in terms of when and how consumers are involved. To improve patient and broader consumer involvement in the process, Painaustralia suggests that the values developed by the Health Technology Assessment International (HTAi) special interest group, for patient and citizen participation are instructive.

Adopting international best practice in this area for patient and citizen participation would provide more informed decision making that takes into account the important quality of life considerations for consumers who are the beneficiaries of these treatments.

Stakeholder involvement and participation

Further to approaches that prioritise perspectives from individuals living with pain in HTA approval processes—the involvement and participation of consumer advocacy and support organisations is also critically important.[34]

It is Painaustralia's view that there are some structural and practical considerations in current approval processes that present challenges to full participation in this regard. This is the case—in particular for smaller consumer organisations who lack the resources and relationships at government level that larger or industry groups may have. This includes:

(i) passive notification of calls for consultation. Painaustralia considers reliance on notification solely via an announcement on a website is not sufficient. It risks excluding many small organisations that may not be aware of the call for consultation. Notification must be proactive and could include, for example, a comprehensive proactive notification to all relevant industry groups and organisations of consultation calls; and

[32] Meldrum, M. (2003) 'A Capsule History of Pain Management', *JAMA*, 290:2470–2475, p. 2473.
[33] Australian Government—Department of Health. (2023) Strategic Agreement in relation to reimbursement, health technology assessment and other matters between the Commonwealth and Medicines Australia, p. 12.
[34] Haldane, V., Chuah, F.L.H., Srivastava A., Singh S.R., Koh, G.C.H., Seng, C.K., Legido-Quigley, H. (2019) 'Community participation in health services development, implementation, and evaluation: A systematic review of empowerment, health, community, and process outcomes', *PLoS One*, May14(5): e0216112 (online); WHO. (1978) Declaration of Alma-Ata in International Conference on Primary Health Care. Alma Ata, USSR: World Health Organisation; Parkhurst, J. (2017) *The politics of evidence*. London: Routledge.

(ii) an overreliance on the views of only a limited number of the same consumer group contributors that risks not hearing the views of all relevant stakeholders. It is our view that engagement must be broader. Painaustralia considers that mechanisms must be designed to ensure that all relevant organisations, irrespective of size, have the capacity and opportunity to be involved in and participate in consultations. For example, the establishment and funding of an industry group or peak body representing small consumer health advocacy and support organisations may assist in addressing the structural and practical inequities faced by small organisations to fully engage in consultations. An alternative may be the development of a compensatory policy acknowledging the impost in terms of time and resources that consultations place on small organisations together with an appropriate recompense regime.

Formal HTA processes must ensure engagement of all relevant or affected stakeholders and mitigate any potential for uneven influence or an overreliance on the views of some organisations or groups.

Conclusion

As to the cost of pain in Australia and why reforms to the HTA review process are needed to ensure Australians affected by chronic pain are able to access therapeutic advances for the treatment and management of pain in a timely, equitable, safe and affordable manner—for perspective, it is salient to consider the figures for Australians affected now and into the future.

In 2018, chronic pain affected 3.24 million Australians—of whom 53.8 per cent were women and 68.3 per cent were of working age.[35]

As to the future—it is estimated that by 2050, the prevalence of chronic pain will increase to 5.23 million (16.9 per cent)—with the chronic pain of 2.95 million of those Australians 'expected to limit the activities they can undertake.'[36]

Until we can provide consumers with access to affordable, best practice alternatives, medications will continue to play an important role in the management of chronic pain. It is important that our regulatory processes consider the needs for new and innovative therapeutic pathways for consumers. As many people living with chronic pain opt to self-medicate, it is vital that they continue to have access to new and emerging pharmacological and non-pharmacological technologies that are evidence-based. Importantly, it is vital that we consider more effective ways to ensure that consumer input is a crucial part of these approval processes.

A failure to treat and manage chronic pain not only has direct and indirect costs for those suffering from this debilitating condition, it also has been shown to lead to higher health costs but importantly from an economic and societal perspective it costs us all.

Thank you for the opportunity to provide input into this round of consultation. Painaustralia looks forward to participating in future consultations as detailed in the HTA Policy and Methods Review consultation plan.

[35] Painaustralia and Deloitte Access Economics. (2019) *The cost of pain in Australia*, Report commissioned by Painaustralia, p. 18.
[36] Ibid.