2018

Response to TGA Consultation paper

Chronic Pain
AUSTRALIA

Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

CHRONIC PAIN AUSTRALIA | **PO Box 425 Baulkham Hills NSW 2150**

Contents

Executive Summary

Thank you for the opportunity to respond to this comprehensive document which aims to explore regulatory options in response to opioid use in Australia.

We believe it is crucial that people who will be affected by any changes in the current availability of pain medicines should be at the centre of discussion about those changes.

We highlight several principles which inform our views on this consultation paper. In particular, principles of patient-centred care and consumer participation in the development of 'solutions' are central and internationally accepted as best practice in healthcare. Indeed, the Australian Commission for Safety and Quality in Healthcare insists that 'Partnering with Consumers' should underpin the way we design, implement, monitor and evaluate models of healthcare across our public health systems (Australian Commission on Safety and Quality in Health Care, 2014).

We are very concerned that thousands of Chronic Pain Australia members, supporters and users confirm that opioid analgesics are often used when pain is refractory to other treatments. Judicious prescribing for some patients with chronic non-cancer pain is an appropriate option that allows people to remain in paid employment and participate in family and social life. This needs to be reflected in any decisions made about opioid regulations that will affect Australians in chronic pain.

Healthcare in Australia has become increasingly restricted for people living with chronic pain. In recent times we have heard through our membership that prescribers are increasingly reluctant to continue patients on opioid medicines, notwithstanding this approach has enabled people to participate in work, family and leisure activities. Through the considerable networks of Chronic Pain Australia, as this reluctance has become more intense, we have seen an increase in suicide and predict this trend will continue. Continued pain and increasing social isolation are major contributors to considerations of suicide (Joiner, 2007).

In this response we will firstly detail guiding principles before going on to provide commentary on the consultation paper. We review the eight suggested options for change and draw our conclusions. Finally, we share four poignant stories illustrating the reality of living with chronic pain where restricted access to opioid medicines is creating distress and unnecessary suffering.

About Chronic Pain Australia

Our mission is to reduce the unnecessary suffering and isolation caused by chronic pain in the Australian community. We believe that no Australian living with persistent pain should suffer alone or without access to resources and information which help them effectively manage their pain. This should occur in a manner promoting dignity and self-respect, regardless of age, gender, sexual and identity preference, culture, belief, socio-economic or compensation status.

Since 2006 we have been ***the Voice*** for tens of thousands of Australians living with chronic pain. We have undertaken annual research to understand the experiences of people living with chronic pain in Australia, including how they manage it. We engage through social media, having built a community of 9,500 people. We run a 24/7 online forum with over 2700 users. We reduce stigma and increase awareness through our National Pain Week campaign each year in July.

More information about the Board of Chronic Pain Australia can be found here: http://chronicpainaustralia.org.au/about-us/our-people/board

Guiding principles

We agree that there is a crucial role for the Therapeutic Goods Administration (TGA) in regulating medicines used to control pain. However, we urge caution in excluding the voices of Australians who live with disabling chronic pain and for whom solutions to assist them manage their pain are often scarce, inaccessible and unaffordable.

We make initial and overarching comments.

1. 'Nothing about me without me'

In this consultation paper there is no mention of consumer participation in the development of 'solutions' that would reduce the problems likely to be experienced by people living with pain no matter what option or combination of options are chosen. There is a need to find systematic pathways for consumers to participate in planning, implementing, monitoring, and evaluating interventions aiming to reduce suffering and disability due to chronic pain. Such pathways are developing in other areas of healthcare. A good illustration can be found in the development of a framework for conceptualising and implementing consumer participation in drug treatment services. http://health.gov.au/internet/publications/publishing.nsf/Content/illicit-pubs-needle-tsu2-toc~illicit-pubs-needle-tsu2-2. This shows how systems can support consumer participation in healthcare, consistent with the Australian Commission on Safety and Quality in Health Care Standard #2: Partnering with Consumers.

2. Inflammatory language is stigmatising

We caution all parties to take care with the language used in relation to this topic. Our members, supporters, users and respondents are vocal in their response to inflammatory language including 'crisis', 'addict', 'epidemic' and the like. Australians living with chronic pain are highly stigmatised already, many are vulnerable and impoverished. The recent up-scheduling of codeine and the push for further limitation of other opioid medicines is creating a sense of despair, hopelessness and social isolation that is unprecedented in recent times. Our concern is that we are already seeing an increase in suicidality as a result.

3. Providing non-pharmaceutical, affordable and effective options for people in pain no matter where they live

We call for funding for local, accessible, person-centred, multi-disciplinary approaches within a public health framework for people no matter where they live. An example is found in the Nepean Blue Mountain Local Health District (NBMLHD) – Wagga Wagga NSW outreach program. With a total budget of $100K per year, the tertiary hospital pain team has upskilled local allied health professionals as well as medical and nursing professionals with both face-to-face in-service and telehealth pathways to improve pain management options for people in Wagga Wagga. The outcome is reported as highly beneficial for local people living with chronic pain. This model has demonstrated benefits at low cost to deliver accessible, affordable and effective non-pharmaceutical options for people living with chronic pain. This group would otherwise be offered very little apart from pharmaceutical approaches to manage their pain.

4. Who are the populations affected and to be included in this consultation paper?

There are two broad consumer groups to be considered:

a. People who are newly experiencing chronic pain and have not been prescribed opioids. For this group of people, resourced and accessible pain management needs to be available.

b. People with chronic pain who, through no fault of their own, have been prescribed and use opioids. This group of people need health and social care, not further stigmatisation. They require support to try different, effective and affordable pain management techniques, if appropriate and/or assessed as to whether opioids are indeed appropriate for them as part of their pain management plan.

5. Chronic pain suffering is bigger than the person in pain

The societal, vocational and local context in which people in pain live, that is, the individual's relationship to social determinants of health (Ferrer, 2018; Rubin, 2016), is crucial to how they access helpful treatments and strategies to manage chronic pain. Furthermore, WorkCover and other injury compensation insurers are frequently identified as part of the context for people living with pain, and can negatively affect their health outcomes. According to the Productivity Commission's Supporting Paper No. 5 'Integrated Care (Productivity Commission, 2017):

> *'… there is a strong prima facie rationale for a greater emphasis on public health and prevention in an integrated system, and in particular, an extension to community engagement and purchasing services that may have public health benefits and advocacy' (p40).*

For people in pain, identification of the broader context including housing, family, work (and work injury), poverty, nutrition, social support and education is a logical application of a philosophy of Integrated Care. We believe that healthcare cannot exclude social care agencies and services to address the health inequities that continue to deliver poor outcomes for people living with disadvantage.

We call for there to be a central focus on supporting people living with pain with broader social supports than are currently considered.

Introduction – purpose and scope

Please note this response will comment on the paper as it is written, in the order that content has been presented by the authors of the TGA Consultation paper.

1. When referring to the widespread inappropriate use of prescribed opioids it is important to note that evidence supports the contention that there is inappropriate behaviour by *prescribers* of opioid medicines. Levelling accusatory statements about the behaviour of people living with chronic pain perpetuates the stigma associated with this widespread challenge (Holloway, Sofaer-Bennett, & Walker, 2007).
2. In describing inappropriate use of the drugs named in this paper, it will also be important to take into account the likelihood that the Gabapentinoid and non-steroidal anti-inflammatory drugs (NSAID eg Ibuprofen) will be inappropriately used as a result of any restriction in access to drugs that are reported by people with chronic pain as useful for them. There is some evidence from USA of an increase in prescribing of Gabapentin related to restrictions around opioid prescribing legislation, with some noted inappropriate use. Many Australians in chronic pain currently use opioids, Gabapentinoids, anti-depressants and benzodiazepines. In the absence of useful opioids, these others are likely to be the replacement especially in an environment where other options are not available or affordable. People in chronic pain tell us that they have side-effects from Gabapentinoids and other drugs which preclude their use as a pain management strategy. It is worth noting that Gabapentinoids are only covered under PBS authority for 'refractory neuropathic pain' that has not responded to other analgesia. For many chronic pain sufferers, neuropathic pain is not necessarily their main pain type so the Doctor would either have to write a private script for this (not covered under PBS) or prescribe this medicine inappropriately - not a great scenario for doctor or patient. Patients may end up wearing an increase in cost as well as the unknown potential side effects of this new analgesia.
3. Thousands of Chronic Pain Australia members, supporters and users confirm that opioid analgesics are often used when pain is refractory to other treatments. Judicious prescribing for some patients with chronic non-cancer pain is an appropriate option that allows people to remain in paid employment and participate in family and social life. This needs to be reflected in any decisions made about opioid regulations that will affect Australians in chronic pain.
4. While there is ‘concern that patients with chronic pain are inappropriately being moved up the ‘WHO analgesic ladder’… without considering alternatives to medication’, unless these alternatives are affordable and accessible, what do we expect patients to do? There seems to be an assumption that there are well-resourced alternatives available across Australia that are affordable and that work. However, our work since 2006 listening to people living with pain informs us that this is not the case. This is one of the problems of dealing with discrete issues rather than looking at the pain management landscape as a whole. We note

the more holistic approach provided by the National Pain Strategy, which the federal government has not acknowledged, endorsed nor resourced to date.

5. We raise a query about the categories and criteria used to deem a death is 'intentional'. Chronic Pain Australia is concerned that the number of suicides due to social isolation, stigma and desperation is under-reported in these statistics. According to the Australian Parliament:

   > *'Determining the true number of suicide deaths in Australia is not straightforward. There is an ongoing debate on whether the number of suicides is accurate or whether it is seriously under-reported and therefore hiding the severity of the problem' (Simon-Davies, 2011).*

   This highlights a fundamental problem from our point of view. We believe, based on feedback from family members of people who were unable to live with chronic pain, that there is indeed an under-reporting of suicide. Therefore, we assert there is a need to examine the role of system failures to de-stigmatise the reality of living with chronic pain in an environment where lack of access to affordable and effective alternatives across Australia is the norm. This is particularly a problem where people living with pain have to deal with a widespread societal attitude that living with chronic pain is somehow linked to human weakness or that the person in pain is somehow to blame.
6. Another example of inflammatory language that does not help ease the burden on people living with chronic pain: 'The opioid *crisis* is the latest self-inflicted wound in public health'

National Pharmaceutical Drug Misuse Framework for Action (2012 – 2015)

1. We agree with goal number two of this framework: 'to enhance the quality use of pharmaceutical drugs without stigmatization or limiting their accessibility for therapeutic use'. However, we question whether this is what actually occurs in practice. Without a system and/or policy for enabling de-stigmatisation of living with chronic pain it cannot occur.
2. If changes to regulations are to occur, they must not limit access for therapeutic use. One approach may be that when opioids are prescribed longer than 3-6mths a review via pain specialist or review in tertiary pain clinic occurs. Currently such reviews are hard to achieve and extended waitlists are experienced. We suggest more comprehensive access and support for telehealth options to ensure that people in rural, regional and remote Australia are receiving equitable healthcare. This could help prevent long term opioid prescribing and promote early risk identification of potentially other issues e.g.) yellow flags and depression etc. or developing ongoing chronic non-cancer pain.
3. We submit that it is not only prescribing patterns and patient expectations that need to be changed. The wider social view of pain and pain management needs to change over time. This requires a long-term public health awareness campaign within a philosophy of Integrated Care.
4. We agree that real time prescription monitoring is important. However, this should be consistent across all Australian States and Territories, and not isolated from other person-centred strategies.

5. We agree that exploring opportunities to improve access to non-opioid adjuvant medications for pain conditions is important. However, this needs to be done in a context of exploring affordable, accessible and person-centred approaches both drug and non-drug related.
6. With reference to the list on page 8:
    a. We agree that psychosocial factors should be assessed at every presentation but question who will do this. GPs are already overstretched and MBS item numbers do not reflect the complexity of consultation required.
    b. ‘Patients should be managed’: the language here is contrary to an inclusive person-centred philosophy of *‘nothing about me without me’.* Language promoting a partnership approach would be more appropriate.
    c. *‘Better system pathways and linkages’* require systems adopting an individualised case management model. In this approach individuals are able to establish a therapeutic connection to a health professional who is aware of available health and broader social supports. Appropriate referrals and connections where all parties include the person living with chronic pain are effective and a recommendation in Supporting Paper No. 5 of the Productivity Commission review paper ‘Shifting the Dial’ (Productivity Commission, 2017). This was also one of the recommendations in the National Pain Strategy 2011 (Australian and New Zealand College of Anaesthetists, Faculty of Pain Medicine, Australian Pain Society, & Chronic Pain Australia, 2010).
    d. We agree that a trial period is helpful, however we note that currently ‘trials’ may not be actively followed up leading to people falling through cracks in the health and social care system. Quality of Life measures and improved function should be fundamental criteria for assessing any trial.
    e. The problem with ‘evidence-based’ treatments is that not all individuals conform to what is called a ‘significant’ result. We voice the concerns of a large number of people living with pain who report taking low dose opioids who are functional in society. We suggest looking at other ‘evidence’ e.g. n=1 studies in addition and suggest that there are a significant number of outliers who will suffer if their experience is not included as ‘evidence’.
    f. While relaxation of regulatory control should not support misuse of opioids, we suggest it should also not make it harder or more expensive for those whose functionality and reduction in disability require access to opioids.
    g. Online authority systems should be integrated with other online systems to identify and support people living with a range of social, educational, vocational and health disadvantage, as recommended in Supporting Paper No. 5 of the Productivity Commission (Chapter 9, Productivity Commission, 2017)
    h. While we agree that prescribers need more education and training about opioids, we would add that health professionals need more training about person-centred approaches to partnering with people living with chronic pain. Such training would include consumers in the development, implementation and evaluation of same.

Can some of the problems with opioids potentially be addressed – at least in part – through regulatory measures?

1. We suggest two additional drivers of opioid overuse:
    a. Cultural expectations/understanding of pain - requiring public health awareness campaigns including at primary and secondary school level; and
    b. Limited effective and/or available pain management alternatives
2. With respect to addiction, we note that addiction can occur even with prescribed and monitored doses. Medical professionals should prescribe appropriately and with support for appropriate broad review mechanisms (please see 12d above)
3. Particular indications for opioid products should also include acute pain, cancer, palliative care and End of Life.
4. Product information, particularly Consumer Medicines Information should be health literate. Currently information is not at appropriate levels and misses the aim of informing consumers.
5. We have contact with consumers from particular states who are more distressed as a group than others due to highly restrictive practices resulting from the state and territory's discretionary powers in relation to opioid prescribing regulation. This gives rise to an increase in stigma as people living with chronic pain are asked to jump through more hoops, some in the context of being seen as 'an addict' in a pharmacy. However, such state and territory discretion is also an opportunity to engage with this group to better understand and co-design approaches that work for people in pain.
6. Real time reporting and alerts may limit the few who are deliberately misusing, however there are more opportunities to stigmatise patients at the point of dispensing. Those patients travelling interstate are already adversely affected by pharmacists' accusations of addiction and refusal to supply. People living with chronic pain describe their public humiliation in front of other consumers in pharmacies around Australia.
7. We also highlight the lack of traceability of 'private scripts' – real time monitoring needs to be a national system that includes such scripts. Again, this needs to be mindful of the far reaching consequences of increasing the stigma and further social isolation of people living with chronic pain.
8. We ask how ERCCD will protect people living with chronic pain from stigmatisation and restriction of pain management that works for them?
9. We recommend that 'active intervention' should include extensions to the Enhanced Primary Care plan program so that people in pain can access ongoing allied health within the public system.
10. Although it will be necessary to involve health professionals in the effective implementation of real-time prescription monitoring, we strongly recommend that consumers should be advisers to this process. Again, *'Nothing about me without me'* should be the underpinning philosophy, consistent with the Australian Commission on Safety and Quality in Health Care Standard #2: Partnering with Consumers.

11. Although greater vigilance and attention should be expected of clinicians to prevent inappropriate prescriptions, we are very concerned that people on low dose opioids and functioning well in the life of the community should not be caught in the cross fire.

Regulatory options for consideration

1. We emphasise that it is not only prescriber behaviour and changes in expectations of community about the prescription of opioids that will have impact on the current situation. What we believe will have a greater impact is the availability of affordable, accessible *person-centred* pain management options that have been *locally* co-designed with people living with chronic pain and *centrally* funded and supported.
2. Care needs to be taken when referring to 'lack of evidence'. The statement made in paragraph 2 on page 11 infers that using opioids is bluntly ineffective. Chronic Pain Australia research indicates that for many, low dose opioids DO work in increasing function and decreasing disability and suffering. These people may well be the 'outliers' within the study cohort that contributes to the 'evidence base'.
3. Furthermore, we query whether applying a diagnosis such as Osteoarthritis (OA) is a mechanism to legitimise chronic pain which may be broader than a simple degenerative process e.g., in the presence of Central Nervous System sensitization or immune processes more difficult to apprehend and label. Legitimising pain with a diagnosis means that people can access Enhanced Primary Care programs for example. This would then give new meaning to whether particular pain management approaches are effective for people who have a diagnosis of OA.
4. 'Inappropriate prescribing' by medical practitioners needs to be emphasised and managed by government. Much of this document reports that patients are misusing medications however the importance of prescriber behaviour needs to be acknowledged, highlighted and appropriately managed.
5. Although the clinical and regulatory burden of any additional measures will need to be monitored, surely the impact of any changes on the lives of people living with pain will need to be carefully monitored. This is particularly important for those who are already using opioids. Alternatives will need to be provided. This problem was created by some in the medical profession, not people with pain, yet it is this group that are being stigmatised and disadvantaged.

Option 1: Consider the pack sizes for Schedule 8 opioids

1. For those people who are discharged from hospital with prescription codeine and other opioid products, we support smaller pack sizes as proposed in acute settings with health literate conversations with patients on discharge. There should also be pre-operative discussions about what the patient should expect of their medicines, with a 'teach-back' approach to ensure the patient understands and is clear on how to use the medicines and for how long. After major surgery or trauma, people should be provided with larger packs e.g. 2-4 weeks supply with GP follow up review appointment to pick up early issues/complications. These larger pack sizes should also be provided to patients being actively treated for cancer or receiving palliative care.

However it is important to include in this group people living with chronic non-cancer pain who have been assessed as effectively using a low dose opioid medicine which enables them to remain socially and vocationally functional in their community. While there is discussion about there not being 'good evidence' for opioid use in this context, we argue that good evidence should include n=1 studies and the qualitative literature that shows the reality for many. We also note that neither is there good evidence to cease their use. We recommend that when the dosage is higher than for example 40mg per day, careful partnership and availability of other options must be the focus.

2. Excessive pack sizes may make opioids more available on a black market. However special consideration needs to be given to those who live in remote locations where travel to GP is difficult and access sometimes restricted and bulk billing does not apply. Large pack sizes may be appropriate in some circumstances. This would be a good opportunity for telehealth options in a country like Australia.
3. Page 12 paragraph 3: this is already the case and people in pain report stigmatisation / refusal and consequent distress, unmanaged pain, and having no options available to manage their pain.

Option 2: Consider a review of the indications for strong opioids

1. Review of Cochrane and other meta-analyses is unlikely to produce evidence for the efficacy of any treatment for chronic pain. Restricting 'evidence' to high level studies and randomized controlled trials eliminates most research. We recommend a broader conceptual framework for reviewing what works and doesn't work for people in pain. N=1 studies and qualitative research are suggested as legitimate and vital when seeking 'evidence'.
2. Page 13 Paragraph 3. This is once again further isolating people who cannot afford or access other options. Chronic Pain Australia predicts an upswing in suicidality as a result. There is an urgent need for resourced and accessible alternatives to be available, not just de-prescribing. Feedback from consumers provides evidence of reluctance to prescribe is already happening in a context where no useful alternatives are being provided. This is leading to unnecessary suffering.
3. In addition to considering pediatric indications, the needs of the very frail elderly who are treated with multiple medications and have multiple comorbidities should be considered. For many frail elderly people there is a higher risk of falls and other threats to their health which require consideration.

Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist / authority prescribing

1. We agree that it will be necessary under this option to have exclusions based on individual clinical response to higher doses (>100mg per day) when community participation in family life, employment and social activity are considered.

Option 4: Strengthening Risk Management Plans for opioid products

1. Page 15 Paragraph 1: We strongly recommend that any educational activities MUST be in partnership with consumers. This ensures the training is grounded in lived experience, and gives a face to the recipient which has the potential to reduce stigma unwittingly applied by health professionals.
2. Paragraph 3: In the delivery of any patient education initiative, an essential additional topic is the inclusion of 'Patient Centred approaches to delivering pain care'. This would teach health professionals about the unintentional attachment of stigma to people living with chronic pain, the effect of language in the therapeutic encounter, and the meaning of person-centred care.

Option 5: Review of label warnings and revision to the Consumer Medicines Information

1. Consumers would have no problem with better, more health literate information on and in the packages of S8 medicines. However, care needs to be taken not to perpetuate stigmatising and blaming language that further isolates people in pain who appropriately and effectively use these medicines to remain functional within society
2. Consumer warnings in the Consumer Medical Information (CMI) could certainly give better information. Apart from medication options, other non-drug options should be outlined.

Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

1. We tend to agree that there should be priority review of any new chemical entities to provide viable alternatives to opioids for pain relief. This may be applied to biological agents such as being developed by the Institute of Molecular Bioscience in Queensland https://imb.uq.edu.au/pain-pathways who are working with a venom-derived compound that targets a particular protein on a nerve whose role is to signal pain. This may also apply to cannabinoid products with further research into usefulness for chronic non-cancer pain.
2. We tend to agree with the list on page 18. It seems sensible to reduce the harms associated with pathways to deliberate misuse.

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids

1. Given the low levels of health literacy (4th grade equivalent most common) many people may be unaware of the safety issues. Any patient information needs to be developed using readability guidelines and health literacy principles.
2. GPs in remote areas require ongoing support from Pain Specialists to ensure that prescribing is consumer-appropriate and person-centred, and that the person in pain is not left isolated and experiencing extreme disability due to pain.

Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain

1. We agree with this recommendation. We additionally call for funding for local, accessible, multi-disciplinary approaches within a public health framework such as the Nepean Blue Mountain Local Health District (NBMLHD) – Wagga Wagga NSW outreach program. See earlier comment about this program (page 4 point 3).
2. When referring to health practitioners this should include nurses and allied health practitioners and their related colleagues. For example, there are many nurses, Occupational Therapists, physiotherapists and exercise physiologists working in the community with people who have chronic pain, but who are not necessarily in a specialist pain clinic. Unless they have a special interest in pain management, they may not necessarily identify opioid misuse among their clients, which is a missed opportunity for optimising pain management.
3. When considering reducing dosage for people who have been on long term opioid therapy, there is a need to only include those individuals for whom opioid therapy has provided limited improvement in quality of life or functionality.
4. Resources available but not visible to practitioners: importantly, in the current context these resources are mostly inaccessible and unaffordable for people living with long term pain.
5. We agree that a National Prescribing Curriculum including the use of opioid analgesics in chronic non-cancer pain would be essential at undergraduate medical training. However, this needs to be done in partnership with people living with the problem to avoid further stigmatising people who are managing chronic pain.
6. Focus on safe/sensible opioid prescribing in the acute pain setting is a key area of intervention as it can impact whether or not a person transitions into persistent pain. It should also include screening for yellow flags (psychosocial stressors) at the acute pain stage to better define these clinical pathways and better support those at risk of overuse.
7. Page 21 paragraph 2: Discussion of other pain management options usually occurs in primary care with the GP. However current MBS remuneration for the time required for complex consultation needs to be reviewed for uptake and development of a plan developed in partnership with the person in pain.

Conclusion

In conclusion we wish to emphasise the urgent need for clinicians, administrators and regulators to develop a partnership with consumers who are affected by potential changes. We assert that without such partnerships, the consequences of regulation of opioid medicines will lead to inappropriate use of other more available medicines and an upswing in suicide.

It is also essential to acknowledge that chronic pain suffering is bigger than the person in pain. The inflammatory language that is frequently used during this debate is highly damaging and stigmatising.

We note that regulating opioids while there is a dearth of available, affordable and effective alternatives leads to desperation and isolation for people who are already suffering and disabled by chronic pain. Any restriction in availability of opioids must ensure that exclusions are built in for people living with chronic pain who are able to participate in the life of the community on a stable regime of opioids. Navigating these exclusions must be person-centred and not add to the burden of living with chronic pain.

We understand that the scope of the TGA is to regulate medicines. However, there is a wider landscape for people in pain and the Australian Government would do well to consider this. Identification of the broader context including housing, family, work (and work injury), poverty, nutrition, social support and education is a logical application of a philosophy of Integrated Care. Integrated Care is strongly recommended by the Australian Productivity Commission if we are to optimise and get better value from our health care system (Productivity Commission, 2017) . We believe that healthcare cannot exclude social care agencies and services to address the health inequities that continue to deliver poor outcomes for people living with disadvantage due to chronic pain. We call for there to be a central focus on supporting people living with pain with broader social supports than are currently considered.

Chronic Pain Australia would like to thank the thousands of consumers who have contacted us to share their stories of how regulation of opioid medicines will affect them.

We also thank The TGA for the opportunity to respond to this paper.

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Appendix A

This section will provide an insight into the reality of the lives of people who will be affected by regulation of opioid medicines. These stories are shared with the authors' consent and obtained through Chronic Pain Australia networks.

Stories from Australians living with chronic pain who are affected by restriction of opioid medicines.

1. [redacted]

Thank you for advocating for those who have to live with chronic pain. I suffer chronic pain following five surgeries on my hip after a workplace accident. Any new restrictions on the access of Endone/ panadeine forte will have a negative impact on my daily struggle. I was sacked after my fifth operation when my employer would not recognise my RTW certificate. I am now self-employed working around my physical limitations. With three young children and a mortgage I have no choice but to continue to work in a trade which causes ongoing pain. I manage my pain using the many different tools I got from the pain management centre I attended years ago. This includes physio, pressure point massage, heat, meditation etc. I use panadeine forte and then Endone when really sore. My use of these drugs has remained relatively low and constant for months. I take 20 panadeine forte and 5 endone a month on average. I cannot work while on these drugs so use at the end of the day as the pain increases. Having used Lyrica and Seroquel in the past I do not want to use them again. They are not as effective and the side effects are dangerous. It would be so easy to just give up work and slide back into depression. Having also been hospitalised for PTSD as a result of this injury maintaining employment is important to me and only possible with opioid medication.

Accessing this medication is already difficult enough as you are treated as a drug seeker. This along with my combative Workcover insurers who would rather film me while denying a surgeon's request for treatment on a legally accepted permanent injury have affected my whole family. Any further hurdles placed on a medication no one wants to use but have to so we can function is madness. Keep up your great work as you are a lone voice for the silent sufferers.

My whole family live with the consequences of my ex-employers documented negligence. I realise there a thousands of us suffering in silence and facing the same hidden struggles. Within a 12-month period I was hospitalised for PTSD, two surgeries (operation 4 and 5) and a subsequent dislocation. I worked very hard to get back to work as I had done previously, only to be sacked.

When I am not in strong pain I can function and have some quality of life. I have accepted it takes $30 of pain medication a month and other pain management tools to maintain an income and sanity. Why would anyone want to make access to this even harder? As usual the minority who abuse medication will spoil it for the majority who use their medication as prescribed and benefit from it.

2. [redacted]

Appropriate prescribing of opioid medicines saves lives. Severe chronic pain has a deleterious effect on both the body and the mind. Suicide is a very real risk when pain is left untreated. Not to mention the ongoing physical degeneration, which leads to more pain and increased disability for the patient, and higher health care costs for the country.

I suffer from a genetic connective tissue disorder - one that experts have described as being one of the most painful conditions known, surpassing cancer pain in some individuals. This condition is life-long, degenerative, with no cure and very few treatments.

Personally, I have tried hundreds of treatments spanning decades, and a wide range of medicines. I am currently taking prescribed opioids (+ Lyrica and Mobic) and have been for just over 2 years now. This is the only thing that keeps my severe daily pain at a somewhat manageable level. I am well informed about the risks of opioid medicines, and I follow my doctor’s instructions explicitly. My main pain medicine is extended release (safer for me, and less likely to be diverted), and I only have a minimal amount of immediate release (for break-through pain) which I use very judiciously. I have a long-term relationship with both my doctor and my pharmacist. I have never ‘been high' on my medicines, would never sell or give them to another person, and I do not fear addiction.

Already, I have to see my doctor monthly and he calls to get Authority for the maximum one months’ supply of my main pain medicine (Palexia). I am reviewed by a different doctor on a yearly basis. I have blood tests to keep an eye on liver function etc. I have seen pain specialists. My pharmacist always checks any changes or possible drug interactions, and answers any questions I have. I am always happy to conform to the rules and regulations, as I know they are there to protect me - but already they take a lot of time, energy and money - none of which I have much of as a disabled person.

Opioid medicines DO work for a large number of chronic pain patients. For some of them, it is the only thing that helps. When other options have been tried and failed, then trialing opioids is appropriate. Opioids should never be the first treatment, and non-drug treatments should be continued. In many cases, taking an opioid medication allows a person to engage in exercise – this combination may improve the persons health and lower their pain and disability long-term. But without the opioid, exercise would not be physically possible – and may even be harmful.

Specialist waiting lists are already too long, and their fees are too high. With the current healthcare system, it is entirely inappropriate to suggest restricting opioid prescribing to specialists. Even if a patient could secure a monthly appointment for an authority S8 script, the cost would be exorbitant. This suggestion may be appropriate if it also includes a complete overhaul of the medical system, including employing tens of thousands of new specialists, and heavily subsidising their fees.

Appropriate care for both acute and chronic pain patients when ending or lowering dosage of opioid medications is lacking. Physical dependence (not to be confused with addiction) is a common issue – inappropriate cessation of opioids can lead to addiction or even criminal behaviours. I have heard many horror stories (especially in the current US climate) of patients being 'cut off' and having to deal with physical withdrawal symptoms alone. I have personally experienced a too-fast reduction of a different class of medication, and it was one of the worst experiences of my life. Sudden cessation of opioids is almost always contra-indicated, and can cause severe physical and mental issues, even death. As much thought and planning should go into appropriate cessation practices, as is going into the prescribing and use of opioids. Education for both health care professionals and patients is needed. Regulations for appropriate tapering down and to ensure no sudden cessation may be needed. Even cessation clinics or in-patient programs (without being grouped with addicts, or stigmatised as such).

I would love to see appropriate, effective and accessible alternatives to opioids for the treatment of chronic pain, but they are not currently available. Anecdotal evidence suggests that a large number of chronic pain patients would prefer an effective alternative to opioids, with lower risks and less side effects. Research into new treatments, and fast-tracking of emerging research and treatments would do more to reduce opioid prescriptions and misuse than further restrictions would.

Rather than further restricting what currently works for hundreds of thousands of chronic pain patients, I believe that better education for both health professionals and patients, plus further research into both opioids and alternatives will produce better results for everyone.

3. [redacted]

Opioids are an essential part of my pain management plan. Without opioids to reduce my pain levels, I could not function at all. I currently exercise, practice mindfulness, see a psychologist regularly, and I have completed courses in pain management (non-pharmacological approaches). Without daily opioid medication, however, none of this would be possible. I have severe Rheumatoid Arthritis (RA) that has never been controlled by the RA medications. My opioids are prescribed by my GP, who IS the most appropriate person to do the prescribing. The suggestion that only specialist pain management doctors should be able to prescribe opioids is terrible. Waiting lists are too long, specialists are inaccessible and extremely expensive, and they do not generally prescribe opioids anyway, even where it is entirely appropriate. GPs develop a long term relationship with patients, and understand ALL of the patient's diseases and co-morbidities, medical history, and any past substance abuse issues, and therefore are the best people to assess and prescribe opioid pain relief, if appropriate.

I take 10 or 20mg Targin (slow release oxycodone) each morning, depending on how severe pain is when I get up, I take 30-40mg of Oxynorm (Immediate release oxycodone, in 10mg doses) during the day for breakthrough, again depending on how severe the pain is and what I need to achieve that day, and 20mg of Targin at night. These doses have been stable for five years. When I was on a biological DMARD that was effective, I was able to reduce my opioid intake by almost half, for several months, with no adverse effects, no withdrawal, and no addiction problems, for me opioids are safe and effective.

4. [redacted]

My chronic pain struck 12 years ago and for the first 11 years I did not ask for opioids. Doctors did however have me on all sorts of medications that did not even touch my pain and caused long lasting withdrawal effects when I tried to reduce the dose or get off them.

As you can imagine life in constant pain whilst raising two small children was fairly miserable and socially my life ground to a halt or when I did 'have' to go out for children's events etc I would pretend I was fine when all the while I would be in enough pain to kill a brown dog!

These days I am kinder to myself. I am 50 now and I want to have a life again so once a month I have been taking a dose of Panadeine forte (60mg) and enjoying getting out with my hubby. Now because of this crazy crackdown I'm afraid that my Doctor will freak out because I take it once a month and won't prescribe it all and I'll be back to square one.

Is going out with my family and being in low pain once a month too much to ask?? On that note CBD (without THC) could be a viable alternative to opioids for many pain patients but the government in all its wisdom has decided to clamp down on that, so you can no longer buy it. Pain patients don't want to get high from ANYTHING! We just want to be free of pain. Why deny me taking something that helps once a month only or taking something else that has just been proven by WHO to do no harm at all. It's all very disappointing.

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