



Response to Tasmanian Opioid Pharmacotherapy Policy and Clinical Standards Draft 2011 (TOPP)

November 2011

Introduction

Advocacy Tasmania Inc (ATI) is pleased to have an opportunity to comment on the TOPP draft document. It is clear that the authors of the document have devoted significant amounts of time and effort. The resulting document is impressive in its coverage of a wide range of issues relating to the delivery of pharmacotherapy services. In addition, the clinical/technical information provided constitutes an important resource for all who work in the ATOD sector.

What follows is a combination of two sources of response to issues raised by the TOPP draft. The first of these sources is the experiences of ATI advocates in working with pharmacotherapy clients since April 2010 when our ATOD advocacy work commenced. The second source is the collated views of eighteen (18) current pharmacotherapy clients who responded to ATI invitations to comment on their experiences with the pharmacotherapy program.

While different emphases arising from these two sources will be identified below, the high degree of overlap led us to the decision to offer a single, integrated response. In summary, the key points raised are:

- Concern in relation to the apparent inflexibility expressed in the TOPP draft with respect to dosing – in particular the determination to further restrict the availability of take-away dosing without consideration of individual circumstances/risk assessments.
- The difficulties faced by consumers in seeking and obtaining clinical reviews of their treatment plans (especially the dosing arrangements involved).
- The significant disparities across Tasmanian regions with respect to the availability of authorised prescribers generally and especially of addiction and pain-management specialists.
- The failure of the TOPP draft to identify, in its approach to clinical standards, appropriate outcome goals for the program;
- Instances where TOPP as a health intervention blurs with criminal justice interventions (especially with respect to the grounds for withdrawal of services);
- Issues surrounding the sharing of patient records across the shared-care network of service providers.

Advocacy Tasmania Inc – ATOD advocacy services

In April 2010, ADS-funded advocacy services commenced in all three regions. Service provision focused on consumers of government and non-government ATOD treatment services. From the outset, the pattern of self-referrals and referrals (from ADS, non-government ATOD service providers and from service providers in other sectors) exhibited a consistent focus on the operation of the pharmacotherapy program. In all three regions, ATI clients in our ATOD work were dominated by individuals expressing concern about various aspects of their interaction with the program. These included:

- Concerns about what was perceived as overly-restrictive dosing regimens;
- Referrals to ADS when restrictions were imposed on the continued prescribing of opioid analgesics (for consumers managing post-acute or chronic pain conditions);
- An apparent reluctance on the part of prescribers (ADS and community) to recognise the specific challenges facing consumers who live some distance from dosing outlets;
- Consumers being provided with inadequate information about proposed/enforced medication transitions;
- Consumers experiencing disrespectful/discriminatory attitudes from prescribers, pharmacists and other health professionals;
- Related to this last point, difficulties – especially in rural and regional Tasmania – in identifying and accessing alternative prescribers and dosing outlets where the relationship with available clinicians/pharmacists was problematic;
- Consumers struggling to access independent reviews of their treatment plans / prescribing, and in some instances being accused of “doctor shopping” because of their attempts to have their cases reviewed;

Consultation with pharmacotherapy consumers

Advocacy Tasmania was asked, prior to the release of the draft document, to assist with coordinating consumer feedback on key issues raised. This approach was readily agreed to – it is a core component of ATI’s funded consumer engagement work to facilitate consumer input when significant system-level changes are proposed.

Initially, it was envisaged that the consultation methodology would be based on conversations with pharmacotherapy clients who are part of existing treatment *group* contexts, especially in NGO service providers. Second, it was envisaged that the consultation process would revolve around a short, accessible document that summarised any important changes proposed by the new TOPP framework. Third, it was expected that the request for consumer input signalled a preparedness on the part of ADS to incorporate elements of such feedback into revised approaches.

It became apparent that too few current (or recent) pharmacotherapy clients could be accessed by “piggy-backing” on existing group contexts in service providing organisations. It also became clear that the scale of the TOPP (a main 298-page document followed by a 76-page summary) presented major difficulties for a consultation exercise. Further, ATI was informed at an early stage that some important issues (including take-away dosing) were not really “on the table” for consideration.

ATI responded to these challenges by circulating a broad invitation to past and current TOPP clients to contact ATI to discuss their experiences with the program. Flyers were distributed by pharmacotherapy clinics, prescribers, dosing pharmacists and a number of NGOs. Advocacy Tasmania is grateful for the support of those who distributed the flyers and who encouraged clients to make contact with ATI.

Eighteen (18) consumers contacted ATI and discussed their experiences in phone interviews. Of this group, fourteen were males, and the ages were all in the range from late-30s to early-50s with the exception of one respondent in the 20s. Nine of the participants had experience of pharmacotherapy programs operating in other jurisdictions. Only three of the participants had traversed a pain-medication “pathway” to the program, with the remaining fourteen participants having a history of injecting drug use. The regional split of respondents was seven from the south, nine from the north and two from the north-west. Ten of the respondents currently have community prescribers, with the balance being clients of ADS. Consumers were not asked to identify themselves and were reassured that no information that might conceivably identify them would be included in our report or otherwise communicated to other parties.

Interviews were largely unstructured, with participants invited to talk freely about what had worked well, or not so well, in their contact with the program. No issues were raised with participants other than generic “what changes would you like to see?” prompts. Participants were not encouraged to expect that their views would necessarily influence policy or practice. The only undertaking given was that their views would be accurately communicated and that a summary report would be lodged on the ATI website in December so that participants could (a) check that their views had been appropriately represented and (b) read about the views of other participants.

Eighteen participants is fewer than ATI would have liked. We are not in a position to claim that any level of “data saturation” was reached and that we have identified all the major issues of concern to consumers. Nevertheless, there was considerable consistency of responses across the respondent cohort and we are confident that the views expressed can be taken as broadly representative of the larger consumer cohort. Advocacy Tasmania is grateful for the trust placed in us by those who did participate.

Program inflexibility

The most common of the themes recurring in the comments of consultation participants, reinforced by the experiences of our ATI advocates, concerns the allegation that pharmacotherapy clients are too often treated as a homogeneous cohort rather than as individuals with different risk factors, different protective factors and – more importantly – different aspirations.

ATOD consumers – especially those in the illicit/injecting component of the ATOD spectrum – face barriers in the form of community attitudes about substance misuse and the ‘character’ of those who are seeking treatment. Those attitudes are sometimes evident in the approaches taken by service providing organisations, including in the ATOD sector. Consultation participants consistently spoke of a “one size fits all” approach to pharmacotherapy that was at odds with their expectations as health consumers.

The TOPP draft is clear in its intention to make more uniform the supervised dosing regimens that will apply to program participants. Consumers told us that they believe *less* uniformity – more attention to the specific needs and capacities of program participants – is the most important change required in the program.

The example most commonly offered in this respect was, of course, the issue of take away dosing. Consumers are aware that the TOPP draft proposes a further restriction on take aways to just two, other than in exceptional circumstances that are inadequately specified in the document. This is perceived as a significant threat by consumers who currently receive more than two take aways and it is unfortunate that neither the TOPP document nor recent consultation forums have clarified the process or timetable proposed for changes to current prescribing patterns.

Consumers told us – both in the recent consultation process and over the course of our advocacy work – that any attempt by them to make a case for more flexibility in dosing (i.e., access to occasional or regular additional take aways) was interpreted as “typical drug-seeking behaviour”. One consumer, with well over a decade of unproblematic participation in the program, reported that their (community) prescriber was still unwilling to consider even temporary variations in access to take aways (in this case, for the purposes of travel to have contact with family members). Here we have an example of a consumer who “ticks all the boxes” in terms of risk and protective factors – stable employment, stable accommodation as a home-owner, no contact with illicit drug users, no breaches of program requirements whatsoever – who is still viewed as someone without self-regulation capacities. Advocacy Tasmania supports the adoption of a “least restrictive” approach to service provision – across all sectors and programs. It is clear that the TOPP as described in the draft document fails to embrace that approach.¹

Missing from the TOPP draft is any indication of a typical, let alone optimal, patient trajectory through the program. That is, there is no attempt to map any form of timeline with key milestones relating to changes in prescribing patterns and/or exit from the program (i.e., where consumers can safely and successfully no longer require any form of replacement therapy). In this respect, the TOPP varies from other health and human services policy frameworks. Accountability – the requirement that the program demonstrate appropriate achievement of desired outcomes – appears to be framed only in terms of stable patient participation in the program itself, not in terms of social inclusion (made possible by a relaxation of dosing constraints) or successful exit from the program itself.

For consumers, this translates as a bleak, unchanging future where their own movements and activities are circumscribed by their particular dosing regimen (ironically, not unlike the lifestyle patterns of those in daily search of illicit substances). They are not currently encouraged to believe that by demonstrating clearly-understood forms of behavioural self-regulation that they will be granted more freedom. There is no ladder to climb.

Consultation participants, when they raised these issues, were asked to nominate the “indicators” that should be used in assessing the scope for greater dosing flexibility. The responses were consistent: adherence to program guidelines and reasonable stability in their

¹ We note, however, that the actual practice of clinicians often incorporates a greater degree of flexibility in response to different consumer characteristics than is suggested by the TOPP draft. What is unclear to us is whether this signals that clinical practices will now be obliged to conform with the policy guidelines or whether actual clinical practice will continue to vary from those guidelines.

accommodation and employment and social arrangements. It should be noted that there was considerable variation in participants' views about the timelines that should apply to any relaxation of dosing restrictions. Some – especially those who had been in the program for a relatively short period – were of the view that flexible dosing arrangements could at least be trialled early (i.e., within the first twelve months of participation). Those who had been involved in the program for longer periods were more conservative in their estimates of when such flexibility should be offered.

The other dimension of inflexibility noted by consumers relates to the different levels of access to dosing, and to a lesser extent to contact with prescribers. Some consumers are obliged to travel considerable distances to access dosing. In some rural and regional areas of Tasmania, this can represent a major challenge, given the inadequacy of public transport services. Even in larger centres such as Hobart, there are often significant access problems for consumers. Consumers consistently said that they felt these difficulties should be factored into assessments of appropriate dosing – that participation in the program was made too hard for those consumers who were locationally disadvantaged.

Adapting TOPP to the pain medication 'pathway' to pharmacotherapy

It is clear that a significant, and growing, proportion of TOPP clients are seeking to address dependencies that have developed after they were prescribed opioid analgesics in response to acute or chronic pain. These consumers have no history of risky substance use and generally have done no more than accept the clinical advice of a GP or specialist. It is a significant challenge to the self-identity of such consumers to be referred to Alcohol and Drug Services for an assessment, followed by a referral to a pharmacotherapy program.

Advocacy Tasmania contends that inadequate recognition of this identity-challenge is consistent with the one-size-fits-all approach referred to in the previous section. That is, consumers are primarily classified according to whether they are neuro-adapted to opioids or not, with treatment responses flowing from that assessment. Other characteristics, including indicators of whether the consumer is likely to be capable of self-regulated behaviour, appear to be viewed as less important. In the case of consumers who have a dependence arising from the use of opioid analgesics, an argument can be made that the only failure of self-regulation occurred on the part of the analgesic prescriber, not the consumer.

Advocacy Tasmania acknowledges that Tasmania is experiencing a serious shortage of pain-management specialists – a shortage that looks likely to continue into the foreseeable future. Accompanying that specific deficiency is a more general lack of understanding of pain management approaches in Tasmania's (indeed, Australia's) general practice field. ADS and the TOPP are accordingly shouldering a burden that should properly be addressed elsewhere in the health system. Nevertheless, it is important that consumers are treated in a respectful manner and provided with every opportunity to demonstrate that they can self-regulate with respect to opioid replacement medication.

Consumer rights: communication and participation

The Australian Charter of Healthcare Rights², which the Tasmanian Government signed on to in 2008, provided for seven overlapping categories of rights:

1. access
2. safety
3. respect
4. communication
5. participation
6. privacy, and
7. comment

Consumers have expressed concerns about the ways in which TOPP guarantees, or fails to guarantee, all seven of these rights. Two in particular, communication and participation, featured regularly in consultation participants' comments and in the case records of our ATOD advocacy work.

The Charter describes the right to communication in simple terms: "I have a right to be informed about services, treatment, options and costs in a clear and open way. I receive open, timely and appropriate communication about my health care in a way I can understand." Consumers consistently told us that they did not receive the information they needed – especially about the options available. Many claim to have been told that there was only one option appropriate (usually buprenorphine) and only one approach to dosing. Consumers claim also to have been provided with inadequate information about the psycho-social supports that may be available to assist them in their treatment.

The Charter describes participation as follows: "I have a right to be included in decisions and choices about my care." In the accompanying *Roles in realising the Australian Charter of Healthcare Rights* document, the key elements of this right are spelled out and include the right to "seek a second opinion if you have any uncertainty"³.

All Tasmanian Government healthcare services are also obliged to abide by the *Tasmanian Charter of Healthcare Rights and Responsibilities*,⁴ enshrined in the Health Complaints Act 2005. That Charter, too, stresses the right of the consumer to "take an active role in his/her own health care in being consulted about options and by participating in decisions" (p3)

Consumers tell us that there are significant impediments to their right to seek a second opinion in relation to prescribing decisions involved in their pharmacotherapy. The first impediment is lack of readily-available information about other authorised prescribers. Second, many authorised prescribers are unwilling to accept new patients, even for the purposes of a one-off assessment. Third, many regional and rural areas of Tasmania simply don't have multiple prescribers available, irrespective of whether they are accepting patient referrals. Fourth, consumers are unconvinced that community prescribers will offer a genuinely independent assessment if it means contradicting the views of a nearby colleague.

² [http://www.health.gov.au/internet/safety/publishing.nsf/content/com-pubs_ACHR-pdf-01-con/\\$File/17537-charter.pdf](http://www.health.gov.au/internet/safety/publishing.nsf/content/com-pubs_ACHR-pdf-01-con/$File/17537-charter.pdf)

³ [http://www.health.gov.au/internet/safety/publishing.nsf/content/com-pubs_ACHR-pdf-01-con/\\$File/17388-roles.pdf](http://www.health.gov.au/internet/safety/publishing.nsf/content/com-pubs_ACHR-pdf-01-con/$File/17388-roles.pdf)

⁴ http://www.healthcomplaints.tas.gov.au/_data/assets/pdf_file/0004/145318/CHARTER_July_2006.pdf

Two other issues arise to effectively deny consumers this basic right. First, it is apparent that some requests for a referral to an independent review are interpreted as complaints. It may be the case that a consumer is unhappy about not just the assessment outcome but the way in which the assessment was conducted. In that case, it is appropriate that a complaint be lodged so that the conduct can be scrutinised. However, in most cases the consumer is simply not yet ready to accept the ramifications of the initial assessment (e.g., a proposed transition from an analgesic such as oxycodone to an opioid replacement) and wants to be sure that there is no alternative. In that instance, the pursuit of a second opinion is an appropriate response – one that would be uncontroversial (even encouraged) in other health sectors.

Second, a consumer who seeks a second opinion because they want to continue with their existing medication runs a very real risk of being labelled as a “doctor shopper” who is then categorised as exhibiting “typical” drug-seeking behaviours. The TOPP draft fails to address these issues. The policy framework should acknowledge that the full participation of the consumer in their own health care – their right – is contingent on the consumer accepting that the proposed course of treatment is the most appropriate option. Encouraging consumers to reassure themselves about the appropriateness of proposed treatment should be a feature of TOPP.

Consumer rights: access

Included as first-mentioned rights in both the Australian and Tasmanian Healthcare Charters is the right to access. Given the resource constraints imposed on ADS, and the wider shortage of healthcare professionals, this will continue to be a difficult right to guarantee for prospective and actual TOPP clients. In these difficult circumstances, it is all the more important that access to those services that are funded and available be protected.

In this context, it is concerning to find that among the triggers for clients to be involuntarily excluded from the program (p145, on involuntary withdrawal) is the suggestion that “drug dealing on or near the treatment program premises or dosing location” would constitute grounds for exclusion. Advocacy Tasmania understands that such behaviour would create significant operational problems for the program. However, we are here talking about (alleged) criminal behaviour that should properly be referred to the police. It is not appropriate for a health service to wear a deputy sheriff’s badge, and even less appropriate that a health service impose an extra-judicial sentence (exclusion from treatment) that it knows would amount to a form of corporal punishment. There is ample scope in the other (quite reasonable) grounds listed for involuntary exclusion (e.g., violence, unacceptable disruption, etc) without including this particular provision.

Consumer rights: privacy

One important element of the Tasmanian shared-care approach to pharmacotherapy that receives too little attention in the TOPP draft is the ways in which patient information will be shared.⁵ Tasmania is trialling a web-based, real-time system of sharing patient information (DORA) that will not only provide early indicators of risk factors (e.g., drug seeking, missed doses, etc) but will provide an information portal that will support prescribers, pharmacists and other key elements of the treatment system. Advocacy Tasmania supports the

⁵ We acknowledge that a parallel review process focusing on opioid prescribing is addressing this issue, but is nevertheless an important component of the overall Tasmanian Government approach to pharmacotherapy.

development of well-designed e-records systems as an important component of a responsive health sector.

We note, however, that some consumers who participated in the TOPP consultation process indicated that they were very concerned about potential breaches of confidentiality with respect to their participation in TOPP. Some consumers go to considerable lengths to minimise the chances of their status as a TOPP client becoming known to other parties (e.g., employers). Some consumers acknowledged that their continued participation in TOPP was, at least in part, contingent on that confidentiality. A further concern expressed by consumers in relation to any real-time monitoring platform is the potential for an unwarranted “chilling” impact on prescribing where prescribers become over-reticent about *all* opioid prescribing decisions even when they are demonstrably appropriate.

The operation of DORA – or any other comparable mechanism for sharing health records or other related personal information – must recognise these sensitivities. The consumers who raised these issues with Advocacy Tasmania were not fully aware of the extent to which they may have provided formal consent for such information sharing. That is, they knew that they had consented to a sharing process, but were unclear about the extent of the network likely to have access to that information.

Advocacy Tasmania recommends that the TOPP policy framework and practice standards specify (a) whether the sharing of patient information is consent-based or is mandated by a specific legislative provision; and (b) the ways in which consumers will be appropriately informed about the full network of individuals, organisations and institutions that will have access to patient information. As well as the safeguards that are in place to ensure that such information is used appropriately.

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