Prospective oversight and approval of assisted dying cases in Victoria, Australia: a qualitative study of doctors’ perspectives

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ABSTRACT

Background Assisted dying (AD) is increasingly becoming lawful internationally. While all AD models have oversight mechanisms, Victoria, Australia is rare in requiring formal approval before AD is permitted. Other jurisdictions are now enacting or implementing prospective approval models yet little is known about their operation. This paper reports the first empirical research internationally analysing the operation of a prospective approval model.

Methods This qualitative study recruited doctors involved in providing lawful AD during the first year of the Victorian AD system. Recruitment occurred through the mandatory training doctors providing AD must undertake. Semistructured interviews were undertaken predominantly through Zoom conferencing, transcribed and thematically analysed.

Results 32 doctors from diverse specialties (including general practice) and diverse AD experiences were interviewed. Six themes were identified: (1) The primary gatekeeping to AD in practice was by the administrative Secretariat of the oversight body, the Voluntary Assisted Dying Review Board, and not the government department who issues the final ‘permit’; this may not have been intended by parliament. (2) The prospective oversight and approval process was bureaucratic and (3) the mandatory online system to manage AD was a barrier. (4) These factors caused unnecessary delays which (5) impeded AD for very sick patients. (6) However, this prospective process protected doctors and ensured system safety.

Conclusions Potential barriers to accessing AD posed by prospective approval should be evaluated carefully by jurisdictions implementing or considering such a model. Attention is needed not only to law but to system design and how AD is implemented in practice.

INTRODUCTION

There is an international trend to legalise assisted dying (AD), with further reform...
proposals in England and Wales, Ireland and various European countries and US states. Effective oversight is needed to ensure the AD (also known as euthanasia or physician assisted suicide) system provides timely access to AD but only for those who are eligible.12

Traditionally, most systems rely on retrospective oversight. For example, in the Netherlands, Belgium, Canada and permissive US states,3 bodies such as review committees retrospectively examine cases of AD, with the possibility of referral for sanction if concerns are raised.

The position is different under the new AD system in Victoria, Australia (commenced operation on 19 June 2019, see box 1 for overview).4 In addition to the usual retrospective oversight, the Victorian model includes two aspects of external prospective oversight and approval. The first is undertaken by an administrative Secretariat which supports the oversight body, the Voluntary Assisted Dying Review Board (VADRB). The VADRB Secretariat receives the legislatively-mandated forms at three key stages in the AD process including when patient eligibility is assessed by two doctors. The Secretariat manages the online Voluntary Assisted Dying Portal (Portal) which is the ‘only avenue’ to submit these forms to the VADRB.5 This is the process is represented above the dotted line in figure 1.

The second aspect is represented by the process below the dotted line (figure 1). Once a person is assessed as eligible by two doctors, the doctor coordinating the process must apply to a civil servant in Victoria’s Department of Health and Human Services (DHHS) for a government permit. There are two types of permits: one that permits self-administration by the patient and another which permits practitioner administration by the doctor. The DHHS is required to approve or decline a permit within three business days.6 Only once a permit has been obtained may a doctor prescribe the medication.

External prospective approval mechanisms are very rare internationally, only existing in Victoria and Colombia. Canada briefly had a preapproval process through the courts, but only as a stop-gap measure, while awaiting its legislation.3 Laws in Western Australia (based broadly on Victoria, although not requiring a permit)7 and New Zealand8 also incorporate requirements of prospective oversight, but are yet to come into operation.

Although unusual, some have argued that AD should be subject to some form of external prospective approval.9–11 For example, Lewis considers that in England and Wales, there is a parliamentary consensus that prospective approval from a High Court Judge is needed,9 as reflected in Assisted Dying Bill (HL) 2019–2021. Yet, as she notes in raising concerns about this, there is very little evidence about how prospective approval might operate.3

This article reports on the first empirical study of a prospective oversight and approval model internationally, drawing on interviews with doctors who have provided AD in Victoria. It sheds light on the operation of that system and has implications for design of AD systems internationally.

METHODS

Approach

Regulatory space theory12 was the guiding theoretical framework for this article. It proposes a ‘space’ occupied by a series of regulatory actors and their tools of regulation all interacting to influence behaviour. For doctors supporting patients seeking AD, this space includes the legal framework governing AD, the key State actors who oversee AD, and the wider system established to regulate access (eg, technological infrastructure). This theory does not assume that systems operate as intended; it aims to discover how regulation works in practice to guide behaviour. It is particularly apposite to analyse new fields of regulation where very little is known, as is the case here. Using regulatory space theory to study AD is also appropriate given how highly regulated this field is (very unusual for medicine). A qualitative research design was adopted, drawing from grounded theory principles, including theoretical sampling and constant comparison.13

Study design and participants

Participants were recruited using purposive sampling. Eligibility criteria were a Victorian doctor involved in the AD process since it became legal. ‘Involvement’ meant the doctor had been a coordinating doctor (who has carriage of the process) or consulting doctor (who provides an independent opinion on eligibility). Participants were recruited through the training programme doctors are required to complete before they can assess eligibility. All doctors who consented to be on the ‘participation in research’ list compiled through the training as at 18 June 2020, 1 year after the Victorian system began, were invited to participate. Snowballing sampling also occurred. Variation in years of work experience, specialty, number of patients assisted and regionality were considered to capture breadth and depth of experience.
Informed consent was obtained before each interview. Study reporting is based on the Consolidated Criteria for Reporting Qualitative Health Research.  

**Procedures**

Semistructured, in-depth interviews were conducted by MS from April to July 2020 using the video conferencing platform, Zoom or by telephone (n=2). Participants’ age, gender, location, role, specialty and years of work experience were collected. All interviews were audiorecorded. The interview guide is available in the online supplemental appendix 1.

The audiorecordings were transcribed verbatim by a transcription company and reviewed by the interviewer for accuracy and to remove potentially identifying information. Participants were offered the opportunity to amend their interview transcript (member checking).

**Data analysis**

Transcripts were entered into NVivo Plus (V.12; QSR International). Using thematic analysis, MS (a trained qualitative health researcher) independently coded the transcripts line-by-line, and inductively identified concepts about participants’ experiences and perspectives about how the system was operating in practice. Similar concepts were grouped together into themes. With the assistance of BPW and LW, a coding
framework was developed capturing all concepts about participants’ experiences and perspectives of the regulatory framework.

MS undertook a second round of coding, developed with BPW and LW based on their previous research, using a framework that mapped each key domain of the regulatory framework. These two rounds of coding permitted analysis both in relation to wider thematic trends and specific aspects of the regulatory framework.

Following this, MS extracted all data potentially relevant to prospective oversight and approval for BPW who reviewed it iteratively and thematically coded (manually). The themes were tested by MS and LW, and key interviews reviewed in full to ensure data was understood in context. Interpretation of data and preliminary themes were discussed iteratively among the research team throughout all stages of the analysis.

RESULTS

After excluding doctors who replied to say they were not involved in AD, 89 doctors remained on the research list. Of those 89, 32 participants were interviewed comprising 12 vocationally registered general practitioners and 20 medical specialists (see table 1). Interview duration ranged from 33 to 90 min (mean 63 min).

Six themes were identified regarding participants’ perspectives on prospective oversight and approval for AD under the Victorian system:

- The Secretariat of the VADRB was the primary—but possibly unintended—gatekeeper through its Portal.
- The prospective oversight and approval process was bureaucratic.
- Design of the mandatory online system was a barrier.
- The prospective oversight and approval process caused unnecessary delays.
- But the prospective oversight and approval process protected doctors and ensured safety.

The Secretariat of the VADRB was the primary—but possibly unintended—gatekeeper through its Portal

Participants identified the VADRB as the primary gatekeeper to AD. However, although framed as the ‘VADRB’ or ‘Board’, it was clear that participants were commenting on the processes of its Secretariat. This gatekeeping occurred through the Secretariat’s management of the Portal which controls the process of accessing VAD. Although the final ‘permit’ to access AD is from the DHHS, participants reported the most significant source of prospective oversight occurred earlier from the Secretariat. Indeed, for participants, the DHHS was largely invisible; even for the DHHS permit, participants’ interface was through the Portal.

Participants described the Secretariat undertaking a prospective approval process at each of the three points when doctors uploaded a form (and other documentation) into the Portal. Participants reported this as a gatekeeping function because no further steps could be taken until the Secretariat approved and returned the relevant form to the doctor. Portal design meant that the next required form did not become

| Table 1 Participant characteristics |
|------------------------------------|
| Demographic characteristics         | No of participants |
| Sex                                 |                  |
| Men                                 | 18               |
| Women                               | 14               |
| Age (years)                         |                  |
| 30–39                               | 5                |
| 40–49                               | 8                |
| 50–59                               | 7                |
| 60–69                               | 10               |
| 70–75                               | 2                |
| Location (region)                   |                  |
| Major city                          | 19               |
| Inner regional                      | 12               |
| Outer regional                      | 1                |
| Clinical qualifications             |                  |
| Specialty                           |                  |
| Anaesthetics                        | 1                |
| General medicine                    | 3                |
| General practice                    | 12               |
| Haematology                         | 1                |
| Medical oncology                    | 10               |
| Nephrology                          | 1                |
| Radiation oncology                  | 2                |
| Palliative care                     | 1                |
| Surgery                             | 1                |
| Years of experience as either vocationally registered GP or medical specialist* | |
| 1–5                                 | 5                |
| 6–10                                | 4                |
| >10                                 | 23               |
| Participation in assisted dying     |                  |
| Assisted dying role                 |                  |
| Consulting doctor only              | 2                |
| Coordinating doctor only            | 14               |
| Both consulting and coordinating doctor | 16            |
| No of assisted dying cases acting in either role since becoming legal (mean 10.5, range 1–60) |
| 1–5                                 | 14               |
| 6–10                                | 8                |
| 11–15                               | 4                |
| 16–20                               | 2                |
| 21–25                               | –                |
| 26–30                               | 3                |
| >30                                 | 1                |

*These are the clinical qualifications required for doctors to be able to assess eligibility for assisted dying.

GP, general practitioner.
Some participants queried whether this additional Secretariat oversight was intended by the legislation (box 2). Not all objected, however: a few participants observed that this controlled and staged process ensured correct procedure was followed.

**Prospective oversight and approval process was bureaucratic**

Overwhelmingly doctors described the Victorian prospective oversight and approval process as bureaucratic—a ‘byzantine bureaucratic process’—or ‘highly legalistic’ (box 3). Many reported ‘frustration’. Participants described forms returned for typographical errors or minor corrections, particularly in relation to medication names, dates of birth or person’s names (eg, full name vs shortened name). Doctors often considered the form submitted was very clear (especially if errors related to names or medication correctly stated elsewhere in the form) so returning the form for recompletion was ‘pedantic’.

Other concerns about bureaucracy extended to more substantive matters, which participants considered were applied inflexibly. This included required evidence about eligibility criteria of residency and citizenship. Some participants considered they had provided sufficient information, and that requests for further detail were ‘unrealistic and unreasonable’.

The Secretariat was perceived by some to be disconnected from clinical realities. Participants pointed to a lack of clinical understanding; having to explain ‘as I would to a medical student’. Further, the Secretariat was ‘working 9:00 to 17:00 hours, Monday to Friday’ but medicine is not office hours.

However, some participants disagreed, endorsing this detailed approach to reviewing forms as ‘reasonable’ and ‘necessary’, even if ‘annoying’ (box 3). Errors in forms (even minor ones similar to those complained about above) were appropriate to correct—necessary ‘checks and balances’—given the gravity of these decisions and they did not want to make mistakes.

Further, while the first experience with the AD process was frequently challenging, some participants reported becoming better at navigating the process with more experience: ‘you learn what the Board needs’. Some also reported the processes becoming more ‘streamlined’ and responsiveness improving over time, reflecting a new system that was evolving.

**Design of mandatory online system was a barrier**

The mandatory online system (Portal) design and useability was seen as a significant barrier in the prospective oversight and approval process (box 4). Described as ‘clunky’ and ‘not intuitive’, participants reported difficulties navigating this technology with next steps hidden from view or difficult to find. Reflecting bureaucracy concerns, participants were frustrated to enter the same data repeatedly (such as qualifications and relevant experience) and many found scanning and uploading large volumes of paperwork challenging and time consuming. Support for users was reported as lacking, whether it was training, a ‘help button’, or the ‘ability to talk to a human’. However, Secretariat staff were reported by many participants as helpful in navigating a difficult Portal.

In contrast, some participants considered the Portal functioned ‘really well’ and was ‘actually a pretty

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Box 2 The Secretariat of the Voluntary Assisted Dying Review Board was the primary—but possibly unintended—gatekeeper through its Portal (participant quote)

‘As soon as you submit your first assessment, it just says your process now finishes, it now stops until we have reviewed it. Once we are satisfied with it, then you can progress onto the next stage. They don’t have the power to do that. They only have the power to review it, and to give advice which I’m grateful for…. I think the Act is well intentioned and workable, but the Board at the moment have taken it on themselves to just stop the progression through the legislation at each point until they review’: Participant 15, General Practitioner

Box 3 Prospective oversight and approval process was bureaucratic (participant quotes)

‘Usually it’s something completely innocuous like you mis-transcribed the phone number or you mis-transcribed the date of birth.’: Participant 23, Medical Oncologist

‘So, there’s this incredible bureaucracy … I got a letter from a specialist written to another doctor but about the same patient, but because the letter wasn’t addressed to me, they didn’t accept it. But they accepted it a week later when it comes “To whom it may concern”. So, this obsessiveness which is adding days and weeks to the suffering of these people I find obscene.’: Participant 4, General Medicine Specialist

‘I thought on what grounds do you, as a bureaucrat, have to say that they’re medically not eligible? … There are two doctors that have said they’re medically eligible and you’re saying you don’t think that they’re eligible? So what I did was I added some extra detail about the pathophysiology and cardiac failure and then they made them eligible. I mean it was just bullshit, it was absolute bullshit. I basically explained cardiac failure as I would to be second or third-year medical students and that was enough to make them eligible.’: Participant 14, General Medicine Specialist

‘But I’d hate to think that there was maybe an error made if those checks and balances weren’t there. So I think I do appreciate that detail. I have misspelt, probably typographically, the first name. So you put in the patient’s name I think two or three times in a row, and I think I [substituted] an L and an E. That was picked up and sent back. Again, that’s annoying, but again it could make a big difference if that one letter actually changed the whole name.’: Participant 27, Medical Oncologist

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good system’. Again, participants reported that greater experience made the Portal easier to navigate.

Prospective oversight and approval process caused unnecessary delays
Participants repeatedly described what they considered to be unnecessary delays in the prospective oversight and approval process, especially in relation to the

Box 4 Design of mandatory online system was a barrier (participant quotes)

‘The website is appalling. It’s just so non-intuitive. It took me ages to work out how to get around the website. It’s really, really, really clunky.’: Participant 14, General Medicine Specialist
‘You go “I’ve put the date of birth in the damn thing 15 times, guys. Would it be possible that you could actually correct it yourselves when it’s clear?”’: Participant 23, Medical Oncologist

Box 5 Prospective oversight and approval process caused unnecessary delays (participant quotes)

‘So I work as a GP, I’ve got appointments all through the day, so I would then go through to the house on my way home, update him with what’s happened and so forth. And at that point he would make a second [request for assisted dying], you’ll be writing those requests up to the Board at night, and then have to go through the Board, which is another 24 hours. And then you’d be going through your day surgery and then on the way home again at night, and during this time the Board is working 9:00 to 17:00, Monday to Friday. And then we go to a weekend and there’s nothing until the Monday … it was very shortly after that point that the patient effectively lost consciousness, and so was not able to say to the pharmacist that they wished to have the medication. So we probably lost – I would say we lost three to four days of actual time because of the process. So I’m not saying that he would necessarily have taken the medication, but he could have had the option.’: Participant 30, General Practitioner

‘You go onto the application for the permit, that’s fine. So you apply for that online. Then the Secretariat is allowed up to 72 hours to authorise that. So that is 72 hours of business time. Now, that absolutely is completely outrageous as well. So if we’ve got somebody who’s pretty poorly, all these delays that are occurring at the Secretariat level are unacceptable.’: Participant 17, Palliative Care Specialist

‘Like it’s usually not a problem—the Board aren’t—in general, the holdups in this situation—like they usually take 24, at the most 36, 48 hours, to approve any step along the way. Given that you need a 9 day minimum anyway, that’s not a big problem. So you do your first bit, someone does the consulting. By the time the 9 days is up that’s all been approved. Then you can do your written declaration which gets approved pretty much—and then your permit which gets approved within 24 hours. So that’s all pretty quick.’: Participant 22, Medical Oncologist

Secretariat’s staged gatekeeping of forms (box 5). Most participants reported each review of a form took about 24 hours. This was particularly problematic if a form required resubmission, as each minor error requiring correction caused further delay. Other delays were attributed to poor Portal design, for example, applications not progressing because the button to click to submit to the Secretariat was not clear.

Some participants commented specifically that the final approval step in the process—the permit—was problematic. Issues raised included why a permit was needed (especially given the earlier significant scrutiny by the Secretariat), why different types of permits for self-administration and practitioner administration were required, and the three business days allowed to consider a permit: ‘72 hours of business time … completely outrageous’. Other participants were not concerned about delays (box 5). They could navigate the system and considered Secretariat responses were timely and did not impede access to AD, particularly given the required 9-day waiting period.

Prospective oversight and approval process was not apposite for very sick patients
Some participants considered the Victorian prospective oversight and approval process not apposite for very sick patients (box 6): ‘If you’re unwell and you really need it, it doesn’t work.’ It took too long and was too demanding for patients. While some delays occurred after prospective approval (eg, delays getting medication), participants identified specific instances where patients missed out due to oversight and approval ‘bureaucracy’; ‘you’ve got people dying going through this process…’.

Hence, some perceived this process ‘unfairly’ excluded some patients from AD. Some participants noted, however, Secretariat responsiveness to expedite its processes when a patient was expected to die.

But prospective oversight and approval process protected doctors and ensured safety
In contrast to challenges reported with Victoria’s prospective oversight and approval process, some participants valued this process (box 7). It protected them because decisions had been ‘okayed by the Board’ and this can ‘spread the blame out’ to the other doctor and the VAD system as a whole. Others looked
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Box 7 Prospective oversight and approval process protected doctors and ensured safety (participant quote)

‘The Board’s really good. I mean a lot of people see them as a speed bump or they’re just there to make—but I think they really are trying to help. Their function really is to protect us. If I do something wrong, then I’m quite vulnerable. This is pretty high stakes legislation that we’re playing with.Unless we’ve got a really good administrative Board that will not let anything through that is not within the legislation, then I would feel a little bit exposed.’: Participant 1, Medical Oncologist

beyond individual protection and considered prospective oversight and approval as systems level ‘checks and balances’ to ensure safe and appropriate decisions.

Even some participants critical of the Victorian process acknowledged that a prospective system can play an important safeguarding function. Some considered prospective oversight and approval to be appropriate or at least did not object to it, but believed that current implementation was disproportionately focused on safety and unreasonably impeded access to AD. That said, there was also recognition that the VADRB and Secretariat were in a ‘no-win situation’: ‘if they stuff up in any way, if there is a glitch in the system, then opponents will jump on that and crucify them’.

DISCUSSION

Conceptualising themes in participants’ perspectives

The thematic schema illustrates relationships between the six themes (figure 2). The Secretariat was seen by participants as the primary gatekeeper, in practice, to AD through its Portal which controlled progress through each stage (theme 1). The Portal and this system design were significant because that shifted the focus of controlling access to AD both away from the final approval permit and away from the DHHS. Instead primary oversight rested with the Secretariat and scrutiny occurred progressively throughout the process. This process overall was described as bureaucratic (theme 2) and difficult Portal technology and system design was a barrier (theme 3). These latter two themes were connected; for example, repeatedly needing to enter the same data reflected both a bureaucratic approach and technology design issues.

This gatekeeping, bureaucracy and technology design all contributed to unnecessary delays (theme 4). The Portal’s staged process, the requests for more detail and responses to minor errors, and the technical challenges in using the Portal combined to mean the prospective oversight and approval process took too long. These delays, and demands of the system, posed challenges for the very sick cohort of patients it was designed to help (theme 5). Finally, across the top of the schema is the overarching and systemic safeguarding role of prospective oversight and approval (theme 6). Its link with bureaucracy recognised that formal processes were seen as necessary to support the system’s safety, but reflected concerns that processes were often regarded as disproportionate.

Victoria’s prospective oversight and approval process was perceived as presenting barriers to AD

Victoria’s prospective oversight and approval process was seen as challenging for many doctors navigating the system and presenting barriers for patient access to AD (particularly where they are close to death). Although there is not other literature against which to test these findings (this is the first empirical study

Figure 2 A thematic schema of participants’ perspectives on prospective oversight and approval process in Victoria’s assisted dying system. *The DHHS does not appear in this thematic schema because its role was not identified by participants as a theme. While it does grant the final permit for assisted dying, this occurs through the Portal operated by the Voluntary Assisted Dying Review Board’s Secretariat (as outlined in figure 1). DHHS, Department of Health and Human Services.
to specifically examine these prospective processes), the VADRB’s reports are consistent with issues participants raised about the VAD system’s first year of operation. For example, the VADRB’s report on the first 6 months of operation notes 83% of cases had forms returned to clarify or provide missing eligibility information. The VADRB later stated: ‘The Board has a very low threshold for errors or inconsistencies in applications. While some may view these errors or inconsistencies as minor or trivial, voluntary AD is a very serious matter.’

As reflected in the VADRB’s quote, evaluations of prospective oversight and approval processes are shaped by perceptions of what constitutes appropriate supervision and control of AD. Some participants did not consider these processes an undue barrier and others considered the system was working. Strikingly, sometimes very divergent views were expressed describing the same issue (eg, the time period for a permit was both ‘no issue’ and ‘outrageous’). Variation in participant views may also reflect different experiences. This includes differences in the number of cases (more experience meant better at navigating the system) and the nature of cases (eg, urgent cases highlighted timing concerns; complex eligibility cases made documentation difficult).

System design (not just law) is critical
While there is much examination of the legislation authorising AD, as important is the system design that regulates access. The Victorian model has two aspects to its prospective oversight and approval process: forms sent to the Secretariat during the process and a DHHS permit needed to authorise AD (see figure 1). One major finding of this research was that participants identified that the primary (and very detailed) scrutiny in this process was from the Secretariat. A second (linked) finding was that this scrutiny occurred robustly at each stage in the process, not just once at the end. This is significant in practice: as represented in figure 3 by the darker red arrows, participants described three additional reviews of forms, each of which must be approved by the Secretariat via the Portal, before the next stage of AD process could progress.

It is unclear whether the Victorian system as implemented, requiring each of these forms to be approved by the Secretariat, reflected what was intended (as some doctors noted in interviews). More recent evidence is that now the Secretariat does not approve or reject forms but instead conducts an administrative check to provide feedback to doctors about any compliance issues identified. Regardless, the broader implication of these findings is that jurisdictions proposing to implement AD must pay careful attention not only to the legal framework but also the design and implementation of the system that regulates access.

Wider implications for jurisdictions considering prospective approval
Prospective approval AD models are currently rare with the only such operative models in Victoria and Colombia. However, some jurisdictions will shortly implement them and others are considering them. This first empirical study to analyse how an AD prospective oversight and approval process operates in practice can inform those deliberations.

These findings about the Victorian system raise questions about whether its prospective oversight and approval process may be an unjustified barrier to AD. This may be due to the nature of the Victorian law, and perhaps particularly how it has been implemented, rather than prospective approval itself being problematic.

Nevertheless, the limited experience of judicial pre-approval in Canada and literature about when people receive AD points to the need for careful consideration before adopting prospective approval models. For example, Dutch research suggests that in its system (which is not limited to terminally-ill patients), 72% of patients who received AD had an estimated life expectancy of 4 weeks or less; for half of those patients, it was 1 week or less. If a requirement for prospective approval creates delays, this may preclude some sick patients with limited life expectancy accessing AD.

Given these potential barriers to AD, further research is needed to evaluate the effectiveness of prospective approval in ensuring only eligible patients can access AD. This should include, for example, whether it is any more effective than retrospective oversight as a process to safeguard compliance with substantive eligibility criteria (beyond correcting the more procedural matters identified by some participants).

Finally, if prospective approval models are adopted, deliberation is needed to ensure optimal implementation. Where possible, system design should address potential adverse implications for doctors and patients, such as those identified in Victoria’s model. Also important at a system level is determining the optimal nature and role of retrospective oversight: if each case of AD has already been prospectively approved, there may be scope for traditional approaches to any retrospective oversight to be different.

Strengths and limitations
This research is the first empirical study internationally that specifically examines a prospective oversight and approval process for AD. A study strength is interviews were undertaken with a large and diverse group of doctors all of whom had experience in AD. However, these findings represent their perspectives at a point in time, namely within the first year of Victoria’s AD system commencing. This means some concerns raised may no longer reflect practice (eg, the Secretariat’s approach to reviewing forms), and participants also noted improvements over time, which are

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likely to have continued. Further, doctors’ perspectives are shaped by their AD cases, acting only within a particular AD system, and their viewpoint on what constitutes appropriate regulation. This study does not capture the perspectives of patients and families or regulators.

Conclusion
At the heart of designing AD systems is striking the optimal balance between providing access to eligible patients and ensuring the system operates safely. Historically, oversight in AD systems has been retrospective but there appears to be increasing adoption of models that also include prospective oversight and approval. This examination of the novel Victorian system suggests, at least in its first year of operation, there may be costs to its approach. Careful evaluation of the strengths and weakness of prospective oversight and approval is needed, not only in relation to the legal framework but also how the AD system is designed and implemented.

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Contributors
LW, BPW and PY conceptualised the study design and obtained funding. BPW oversaw the literature search and analysis of literature. MS undertook data collection (interviews). MS did the initial coding and analysis of the data in consultation with BPW and LW. BPW undertook a further...
round of coding and analysis. BPW, LW and MS analysed the original data and participated in its interpretation. BPW wrote the first draft of the manuscript, including the figures, which was edited by LW and MS. PY critically reviewed and edited the manuscript. All authors approved the final manuscript.

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**Data availability statement** Data are available on reasonable request. All data requests should be submitted to the corresponding author for consideration. Access to the anonymised data for this study might be granted following review by the corresponding author (in consultation with the authorial team) and the Queensland University of Technology (QUT) Human Research Ethics Committee (UHREC).

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