22. Holistic approaches to regulation of voluntary assisted dying

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INTRODUCTION

Jurisdictions that allow voluntary assisted dying (VAD) generally have specific regulation that permits the practice and then creates varying methods for supervising how it occurs. Effective regulation is seen to enhance the safety and quality of VAD and promote compliance with the law and other system requirements.[2] This chapter proposes that VAD regulation is more likely to be effective when it is designed in a holistic way. Research into, and evaluations of, VAD regulation should also adopt holistic approaches.

Holistic approaches are those which consider how all relevant regulatory instruments and actors may guide the behaviour of individuals and institutions in the context of VAD. To illustrate, historically much of the research on VAD has tended to focus on only a single instrument, such as only law or only policy or only training. Yet such a siloed approach fails to understand the reality that how VAD regulation operates in practice will depend on how all of these regulatory instruments, and more, operate together.[3]

This chapter begins by defining 'regulation' and why it is seen as important for VAD. It then outlines how taking a holistic approach will lead to better understanding of how these regulatory systems work and can be improved. A particular theoretical framework for designing and studying regulation is regulatory space theory. This chapter explores an example of a research project aiming to use this theory to implement a holistic approach. The chapter concludes that while such approaches involve a more complete understanding of the regulatory context and will lead to more effective regulation and evaluation of it, there are practical considerations in undertaking such work which must be addressed.

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[2] White, Willmott and Close (n 1); Sean Riley, 'Watching the watchmen: changing tides in the oversight of medical assistance in dying' (2023) 49(7) J Med Ethics 453–57.

[3] White, Willmott and Close (n 1).

A final point to note is that this examination of VAD regulation is, to some extent, agnostic about the specific content of the regulation. For instance, eligibility criteria and processes for assessing them can vary significantly across jurisdictions and models, as the chapters in this book show. But these differences in the content of VAD regulation are not particularly significant for the purposes of this discussion. The focus instead is on how each system of VAD regulation can operate most effectively according to its own goals and design, with the argument being that this is more likely to occur when it is understood how the different parts of a particular regulatory system collectively guide behaviour.

THE NEED FOR EFFECTIVE REGULATION OF VOLUNTARY ASSISTED DYING

What is Regulation?

This section explains why effective regulation of VAD is needed. A threshold issue is to explain what is meant by 'regulation'. This is a contested concept[4] with definitions of regulation varying depending on the perspective of the author and the purpose for which the term is being used. Historically, regulation has been perceived as primarily involving the formal coercive regulatory instruments issued by the State, and typically this has been the instrument of law.[5] This top-down 'command and control' model views regulation as something which is only created by the State and is then applied to its subjects.

Modern approaches to understanding regulation increasingly view it as a broader concept.[6] Such approaches recognise that regulation can occur through a range of instruments beyond law, including policies, guidelines, ethical codes, training, funding programmes and system design. They also recognise that regulation is not only done by the State. Many of these instruments listed above can be created and overseen by entities who are outside the State, and hence there is a broad group of actors who may regulate.

This chapter adopts this broader conception of regulation and will use Black's widely-used definition: 'regulation is the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification'.[7]

Regulation of Voluntary Assisted Dying

Black's definition of regulation can be used to reflect on the breadth of different regulatory instruments and actors in the field of VAD. A classic example of VAD regulation is that

[4] Julia Black, 'Critical Reflections on Regulation' (2002) 27 AJLP 1, 26; Christel Koop and Martin Lodge, 'What Is Regulation? An Interdisciplinary Concept Analysis' (2017) 11 Regul Gov 95.

[5] Black, 'Critical Reflections on Regulation' (n 4).

[6] ibid; Koop and Lodge (n 4); Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (CUP 2012).

[7] Black, 'Critical Reflections on Regulation' (n 4) 26.

done by VAD-specific oversight bodies, which exist in almost all jurisdictions to scrutinise individual cases of VAD provision. Reflecting the first part of Black's definition, a critical function of such bodies is to guide the behaviour of VAD providers towards a set of outcomes, namely compliance with the relevant legal and system requirements.

Oversight bodies also generally utilise all three types of regulatory mechanisms Black describes in the second part of her definition (noting that Black does not require all to be present to constitute regulation). Most prominent are the *information-gathering* and *behaviour modification* roles as oversight bodies generally collect or receive information about cases of VAD, and in instances of non-compliance, have behaviour modification options available to them. Such options can be viewed as being on a scale. At one end of the scale are 'persuasion' approaches including educative measures such as communicating with providers about the changes required in their practice for compliance. At the other end of the scale are 'punishment' or 'sanction' responses such as recommending criminal prosecution to the police or other authorities.[8]

Many oversight bodies also undertake *standard-setting* activities, which often draw on their data collection and reporting roles. One example of this standard-setting is the Euthanasia Code of Practice produced by the Dutch Regional Euthanasia Review Committees.[9] The Code's objectives are described as follows:

> The main aim of this Code is to maintain and, where possible, improve the practice of euthanasia in the Netherlands, which is based on many years of experience and involves very careful implementation. To this end, the Code provides physicians who are involved in the practice of euthanasia prior insight into the way in which the RTEs [Regional Euthanasia Review Committees] interpret the statutory due care criteria. The RTEs base their interpretation on the Act, the standards that have been distilled from the RTEs' review findings on individual notifications over the past 20 years and on case law.[10]

Oversight bodies can also undertake standard setting through feedback or statements about appropriate VAD practice in their annual reports or other publications.[11]

VAD is also regulated by other entities, including those which are not part of the State. An example that meets Black's definition of regulation is national medical associations (generally membership-based organisations) issuing position statements or policy guidance

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[8] This range of possible responses reflects broader regulatory theory on responsive regulation: John Braithwaite, 'The Essence of Responsive Regulation' (2011) 44(3) University of British Columbia Law Review 475; Ian Ayres and John Braithwaite, 'The Benign Big Gun' in Ian Ayres and John Braithwaite (eds), *Responsive Regulation: Transcending the Deregulation Debate* (OUP 1992) 19–53. For a discussion of these different approaches to regulation in the context of VAD, see: Ben P. White, Casey M. Haining and Lindy Willmott, 'How best to regulate voluntary assisted dying: A qualitative study of perceptions of Australian doctors and regulators' (2025) 33(1) Medical Law Review (early online).

[9] Regional Euthanasia Review Committees (RTE), 'Euthanasia Code 2022' (English version, 2022) <https://english.euthanasiecommissie.nl/the-committees/euthanasia-code-2022>.

[10] ibid 5.

[11] While oversight bodies normally publish regular reports, generally on an annual basis, some also issue specific guidelines or feedback documents on issues they would like to see addressed. For an example of this, see the Western Australian 'Practitioner Quality Practice Series', available at: Department of Health, 'Voluntary Assisted Dying Board' (Government of Western Australia) <https://www.health.wa.gov.au/voluntaryassisteddyingboard>.

on VAD. Such documents exist in many countries such as the United States,[12] Canada,[13] the United Kingdom[14] and Australia.[15] These are standard-setting statements that aim, in taking a position on VAD, to inform and guide the views of the medical profession about its permissibility.[16]

VAD policies of individual health facilities may also be seen as regulation because facilities can use such policies to guide the behaviour of clinicians, patients, family members, and others in the facility. Policies can set standards about what is permitted and create mechanisms for modifying behaviour to enforce those standards. There is a range of international research that demonstrates the significant impact that health service provider and facility policies can have on access to VAD.[17] Perhaps the most potent example is where institutional policies ban or limit access to VAD, on the basis of 'institutional objection'.[18]

A final example is that regulation, as defined by Black, may also come from interest groups such as dying with dignity advocacy organisations.[19] Although such organisations often

[12] See, e.g., American Medical Association, 'Opinion 5.7 Physician-Assisted Suicide' in American Medical Association, 'AMA Code of Medical Ethics' <https://code-medical-ethics.ama-assn.org/ethics-opinions/physician-assisted-suicide>.

[13] See, e.g., Canadian Medical Association, 'CMA Policy: Medical Assistance in Dying' (2017) <https://policybase.cma.ca/viewer?file=%2Fmedia%2FPolicyPDF%2FPD17-03.pdf#page=1&search=&phrase=false>.

[14] See, e.g., British Medical Association, 'Physician-assisted dying' <https://www.bma.org.uk/advice-and-support/ethics/end-of-life/physician-assisted-dying>.

[15] See, e.g., Australian Medical Association, 'Euthanasia and Physician Assisted Suicide 2016' (Position Statement, 24 November 2016) <https://www.ama.com.au/position-statement/euthanasia-and-physician-assisted-suicide-2016>.

[16] White, Haining and Willmott (n 8). It is noted that such documents are likely to serve multiple purposes including attempting to reflect the views (or breadth of views) of members of such associations.

[17] For an example from Belgium, see: Joke Lemiengre and others, 'Impact of Written Ethics Policy on Euthanasia from the Perspective of Physicians and Nurses: A Multiple Case Study in Hospitals' (2010) 1 AJOB Primary Research 49. For an example from the United States, see: Cindy L. Cain and others, 'Hospital and Health System Policies Concerning the California End of Life Option Act' (2020) 23 Journal of Palliative Medicine 60. For examples from Canada, see: James L Silvius, Ameera Memon and Mubashir Arain, 'Medical Assistance in Dying: Alberta Approach and Policy Analysis' (2019) 38 Canadian Journal on Aging/La Revue Canadienne du Vieillissement 397; Robyn Thomas and others, 'Medical Assistance in Dying: A Review of Canadian Health Authority Policy Documents' (2023) 10 Global Qualitative Nursing Research.

[18] Eliana Close and others, 'Institutional Objection to Voluntary Assisted Dying in Victoria, Australia: An Analysis of Publicly Available Policies' (2023) 20(3) Journal of Bioethical Inquiry 467–84. For a detailed discussion of institutional objection, see Chapter 28: L.W. Sumner, 'Institutional refusal to permit assisted dying'. See also Ben P. White and others, 'The impact on patients of objections by institutions to assisted dying: A qualitative study of family caregivers' perceptions' (2023) 24(1) BMC Medical Ethics (article number: 22); Eliana Close and others, 'A qualitative study of experiences of institutional objection to medical assistance in dying in Canada: Ongoing challenges and catalysts for change' (2023) 24(1) BMC Medical Ethics (article number: 71).

[19] Beyond organisations, there are also arguments that some patients seeking VAD and their families are capable of being regulatory actors and that their conduct can constitute regulation.

focus on law reform advocacy, many also gather information and undertake monitoring roles about how laws are operating in practice and the conduct of actors in the VAD field with the intention of trying to influence behaviour. An example is one dying with dignity organisation that collected data and published a map of residential aged care facilities that were willing to provide or permit VAD on their premises.[20] Its intent was to support consumer choice but also prompt reflection by facilities about their position, including the recognition that they may lose market share if they refuse to permit VAD onsite.

Why is Effective Regulation of Voluntary Assisted Dying Needed?

Having defined regulation and identified some examples showing the breadth of current regulation of VAD, this section concludes by explaining why effective regulation of this practice is needed. A threshold claim is that if VAD is seen as part of healthcare (which it is acknowledged that some contest), then VAD should be subject to regulation because healthcare generally is regulated. As noted above, regulation aims to alter behaviour towards intended outcomes. In healthcare, this is often about ensuring health practitioners and the healthcare system provide safe and high-quality care.[21] Hence if VAD is conceptualised as part of healthcare then, as with all healthcare, effective regulation of VAD is needed to ensure that its provision is safe and of a high quality.

A further claim can be made that there is a particular need for effective regulation of VAD as it is an end-of-life decision. Decisions involving a person's death are serious and grave; hence, specific societal control through regulation is needed.[22] Some go further and single out VAD as being different, even from other end-of-life decisions. It is seen as requiring special and specific regulation, hence advancing an even stronger case for the need for effective regulation.[23] One basis advanced to justify greater regulation of VAD compared to other end-of-life decisions is that VAD involves the intentional causation of a person's death. This view is reflected in an empirical study of doctors and regulators in two Australian states about

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See in particular: Ruthie Jeanneret and others, '"My Advocacy is Not About Me, My Advocacy is About Canadians": A Qualitative Study of how Caregivers and Patients Influence Regulation of Medical Assistance in Dying in Canada' (2024) 32(3) Medical Law Review 301; Ruthie Jeanneret and others, '"Regulatory Action" by Patients and Family Caregivers to Overcome Barriers to Accessing Voluntary Assisted Dying: A Qualitative Study in Victoria, Australia' (2024) 47(3) University of New South Wales Law Journal 705; Ruthie Jeanneret and others, 'Patients' and Caregivers' Suggestions for Improving Assisted Dying Regulation: A Qualitative Study in Australia and Canada' (2024) 27(3) Health Expectations (article number: e14107); Ruthie Jeanneret and others, 'Patients and caregivers as "regulatory actors" in assisted dying systems: Assisted dying as a case study' (2024) 24(3) Medical Law International 164.

[20] Dying with Dignity Victoria, 'Our Services' <https://www.dwdv.org.au/our-services/vad-and-aged-care-facilities/>.

[21] Charles Vincent and others, 'Redesigning safety regulation in the NHS' (2020) 368 British Medical Journal m760; Judith Healy and John Braithwaite, 'Designing Safer Health Care through Responsive Regulation' (2006) 184(S10) Medical Journal of Australia S56.

[22] White, Willmott and Close (n 1).

[23] Debates about whether VAD should be regulated differently from other end-of-life decisions are considered further in Chapter 36: Ben P. White, 'The future of voluntary assisted dying'.

how best to regulate VAD.[24] For some of these participants, the newness of the practice in Australia also contributed to VAD warranting additional regulatory scrutiny.[25]

This VAD exceptionalism, namely that VAD is the subject of special regulation which is different from that which governs other healthcare and end-of-life decisions, is reflected in international practice. In many places, this additional regulation is significant. An example is Australia, where VAD is tightly regulated by detailed legislation which controls each step of the process and outlines a suite of safeguards to ensure the law is followed.[26] But even in countries with longer practice of VAD, it is still the subject of additional and specific regulation. For example, after over 20 years of legalised VAD in the Netherlands, each death is still the subject of specific reporting to, and review by, Regional Euthanasia Review Committees.[27]

In making the case that effective regulation of VAD is needed, this chapter does not have to resolve whether VAD should be specially regulated. Effective regulation is needed even if VAD is not seen as exceptional, as all end-of-life decisions (and healthcare generally) should be properly regulated. However, if VAD is seen as exceptional, and this appears to be the case in international practice, then the case for effective VAD regulation is even stronger.

APPROACHES TO REGULATION OF VOLUNTARY ASSISTED DYING SHOULD BE HOLISTIC

What are Holistic Approaches to Regulation?

This section makes the case for why holistic approaches to regulating VAD are needed. But first, some more detail is needed on what such holistic approaches entail. Some of this has already been hinted at above, but it is worth explicitly setting out some of the key elements of holistic approaches to regulation.

There are a range of theories within regulatory scholarship that are based on holistic approaches.[28] Although there is variation across theories, there are three common features that holistic approaches share. The first is that they step beyond just the role of law in guiding behaviour. Historically, law has been a major focus of regulation[29] but holistic approaches explicitly recognise that law is just one of a range of regulatory instruments that can guide behaviour. Other regulatory tools or instruments that 'attempt to alter the behaviour of others according to defined standards or purposes'[30] include policy, guidelines, ethical codes,

[24] White, Haining and Willmott (n 8).

[25] ibid.

[26] Katherine Waller and others, 'Voluntary Assisted Dying in Australia: A Comparative and Critical Analysis of State Laws' (2023) 46(4) UNSWLJ 1421–70. See also Chapter 12: Ben P. White and others, 'Voluntary assisted dying in Australia'.

[27] Agnes van de Heide and others, 'Fourth evaluation of the Dutch Euthanasia law' (ZonMw, 30 May 2023) <www.rijksoverheid.nl/documenten/rapporten/2023/05/30/pg-1048101-b-vierde-evaluatie-wet-toetsing-levensbeeindiging-op-verzoek-en-hulp-bij-zelfdoding> accessed 5 April 2024.

[28] Black, 'Critical Reflections on Regulation' (n 4).

[29] ibid.

[30] ibid.

training, funding programmes and system design. Holistic approaches to regulation recognise that all of these instruments (and others) must be examined.

The second feature of holistic approaches is that they view regulation as not being the sole province of the State: non-State actors can and do regulate.[31] In the discussion above, examples were given of how non-State entities such as medical associations, healthcare institutions, and dying with dignity advocacy organisations can exert regulatory force on VAD and guide how it occurs (or does not occur) in practice. Indeed, in some instances, there is explicit recognition that non-State actors may be more significant in regulating some aspects of VAD than the government. A holistic mapping study of Belgian VAD regulation concluded that a 'hands-off' governmental approach led to a body of 'bottom-up' regulation generated by others.[32] In some domains of Belgian VAD practice, it was this guidance developed by non-State actors which was the primary form of regulation as those actors 'moved to fill these regulatory vacuums and address otherwise unregulated issues'.[33]

The third feature of holistic approaches to regulation is that they recognise the interaction between regulatory actors and instruments and that this shapes how regulation actually functions. This means that each regulatory actor and instrument does not have its own quarantined domain where their regulatory influence is the only force that guides behaviour. Instead, there are often overlapping zones of regulation so that, for example, law, policy and training may all potentially be aiming to regulate a specific issue, such as how a particular eligibility criterion is interpreted.[34] A related point is that this co-regulation of a particular aspect of VAD practice by multiple instruments may be aligned and give consistent guidance on desired behaviour. However, this is often not the case. Instead, different instruments may be giving inconsistent or conflicting regulatory guidance.

Why are Holistic Approaches to Regulation Needed?

These three features of holistic approaches show that understanding regulation in this way can be complex. However, the principal benefit of holistic approaches is that they enable a more complete understanding of how VAD is actually regulated. Such approaches better reflect the reality being examined and are more able to capture the complex influences that guide behaviour in practice. By contrast, an approach that focuses only on law, does not recognise the role of non-State actors, or fails to account for the interconnected nature of regulation, will provide only a limited and incomplete understanding of how VAD is governed.

One illustration of why this matters is the Swiss model of VAD. This is sometimes presented as a simple deregulated approach in which the criminal law will not punish assisting another to die, provided it is not done for selfish motives. However, there is other important non-legal

[31] ibid 5–8, 16–19.

[32] Madeleine Archer and others, 'Mapping Sources of Assisted Dying Regulation in Belgium: A Scoping Review of the Literature' (2023) Omega: Journal of Death and Dying (early online).

[33] Madeleine Archer and others, 'What Domains of Belgian Euthanasia Practice are Governed and by Which Sources of Regulation: A Scoping Review' (2024) Omega: Journal of Death and Dying (early online).

[34] For an example (using Belgian regulation) of how particular domains in VAD can be governed by different regulatory instruments, see: Archer and others, 'What Domains of Belgian Euthanasia Practice are Governed and by Which Sources of Regulation: A Scoping Review' (n 33).

regulation which has a significant impact on the scope and availability of VAD in Switzerland, which not adopting a holistic approach would miss.[35] For example, medical-ethical guidelines from the Swiss Academy of Medical Sciences and the Association of Swiss Physicians' Code of Conduct establish specific and additional requirements for doctors to participate in VAD, including requirements in relation to the person having a medical condition and experiencing suffering.[36]

In addition to providing a better understanding of how existing VAD systems work, holistic approaches are also well-suited to proposing reforms to those systems and designing new VAD systems that will be more effective. To illustrate, in terms of reforms, changing the law to address barriers to access may not have the desired effect if there are remaining deficits in training supports and system design, which mean that barriers remain.

Similar issues arise in designing new VAD systems. An example in the early Australian experience has been insufficient consideration of the regulatory domain of funding VAD provision. While the introduction of VAD was supported by high-quality implementation efforts in all Australian states, there was initially no specific remuneration programme for VAD practitioners to provide this service, and indeed the federal programme for healthcare funding specifically excludes funding for some aspects of the process.[37] This regulatory omission has created access barriers and challenges for VAD workforce sustainability. By contrast, New Zealand established a specific funding programme which has been reported to support VAD access.[38]

A final global observation about the benefit of holistic approaches (which is linked to the above arguments) is that they recognise that different regulatory actors and instruments have different roles and capabilities which can be harnessed to best bring about effective change.[39]

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[35] See Chapter 4: Brigitte Tag, 'Assisted suicide in Switzerland'.

[36] ibid.

[37] Casey Haining and others, 'Access to voluntary assisted dying in Australia requires fair remuneration for medical practitioners' (2023) 218(1) Medical Journal of Australia 8–10. It is acknowledged that there are some specific funding schemes to support regional and remote access to VAD, such as the Western Australian Voluntary Assisted Dying Regional Access Support Scheme (WA RASS). See Casey Haining, Lindy Willmott and Ben P. White, 'Comparing Voluntary Assisted Dying Laws in Victoria and Western Australia: Western Australian Stakeholders' Perspectives' 30(3) Journal of Law and Medicine 716–44; Casey Haining, Lindy Willmott and Ben P. White, 'Accessing voluntary assisted dying in regional Western Australia: Early reflections from key stakeholders' (2023) 23(4) Rural and Remote Health (article number: 8024); Lindy Willmott, Casey Haining, and Ben P. White, 'Facilitating regional and remote access to voluntary assisted dying in Western Australia: Targeted initiatives during the law-making and implementation stages of reform' (2023) 23(1) Rural and Remote Health (article number: 7522). It is also acknowledged that the state of Western Australia has more recently established its own programme to remunerate VAD practitioners to support access to VAD: WA VAD Board, 'Quality Practice Series #8' (Western Australian Government: Department of Health, May 2024) <https://www.enudge.com.au/email-share-link.php?ca=llQd3fP9Q2sVSvNMK1OnkQ%3D%3D&cl=PzzsVLE3SKY9iDbfoMJRoQ%3D%3D#remuneration> (Quality Practice Series #8).

[38] See Chapter 13: Jeanne Snelling and Jessica Young, 'Assisted dying in New Zealand'; Jeanne Snelling and others, 'Health care providers' early experiences of assisted dying in Aotearoa New Zealand: an evolving clinical service' (2023) 22 BMC Palliative Care (article number: 101).

[39] White, Haining and Willmott (n 8).

For instance, law can be a powerful regulatory instrument because it can compel particular action, backed by the coercive force of the State. This value of law's regulatory force has been identified in calls for duties to prevent institutions from blocking access to VAD to be enshrined in law, particularly because those institutions possess greater power than patients and may need to be compelled to permit access.[40] But the general and abstract nature of law may mean it is highly ineffective in other regulatory settings. An example is in supporting best practice at the clinical bedside, where instead, the use of local policies and clinical guidelines is likely to be more effective in guiding behaviour.[41]

Similar observations can be made about regulatory actors. Governments can be effective in bringing about change through their universal reach to the public and private sectors and across the full spectrum of healthcare settings. But directions or mandates from governments can lack clinical credibility and may not be accepted by health professions. By contrast, VAD communities of practice (groups of VAD practitioners who share experience and support each other)[42] are often highly credible for clinicians and can be influential in shaping practice.[43] But their impact tends to be local so they lack reach, and normative guidance can be weaker or less clear where there is disagreement in such groups about what constitutes appropriate VAD practice. In short, regulatory instruments and actors have a sweet spot for their effective regulation, and holistic approaches are better able to engage those strengths, and also use them in combination with each other, for better overall effect.[44]

CASE STUDY: A HOLISTIC STUDY OF VOLUNTARY ASSISTED DYING REGULATION

This section describes a case study research project that illustrates how a holistic approach may be used to examine the regulation of VAD. The project, entitled 'Optimal Regulation of Voluntary Assisted Dying',[45] draws on regulatory space theory (see below) with the goal of comprehensively mapping existing regulation of VAD. The project also aims to identify improvements to existing regulation and develop proposals for how best to regulate VAD. The focus is on the regulation of VAD in Australia, but the project includes case studies of VAD regulation in Canada and Belgium. Given the purpose of the chapter is to advance the case for holistic approaches to regulation, this section focuses on theoretical aspects, with only limited

[40] Ben P. White and others, 'Legislative Options to Address Institutional Objections to Voluntary Assisted Dying in Australia' (2021) UNSWLJ Forum 1–19 (article number: 3).

[41] White, Haining and Willmott (n 8); White, Willmott and Close (n 1).

[42] See, e.g., for Victoria: Voluntary Assisted Dying Review Board (Vic), 'Annual report, July 2022 to June 2023' (*Safer Care Victoria*, June 2023) 13 <https://www.safercare.vic.gov.au/sites/default/files/2023-08/VADRB%20Annual%20Report%202022-23.pdf>. For Western Australia, see: Voluntary Assisted Dying Board Western Australia, 'Annual Report 2022–23' (*Government of Western Australia,* 8 November 2023) 46 <https://www.health.wa.gov.au/~/media/Corp/Documents/Health-for/Voluntary-assisted-dying/VAD-Board-Annual-Report-2022-23.pdf>.

[43] White, Haining and Willmott (n 8).

[44] ibid.

[45] Queensland University of Technology (QUT), 'Optimal Regulation of Voluntary Assisted Dying' <https://research.qut.edu.au/voluntary-assisted-dying-regulation/>.

treatment of the research itself (some of which is published elsewhere and some of which is still in progress).

Conceptual Framework: Regulatory Space Theory

As noted above, there are a range of theoretical approaches to studying regulation holistically. The conceptual framework used in this project is regulatory space theory. It is outlined here both to explain its role in the project and to illustrate how a holistic approach may be used to study VAD regulation more generally.

Regulatory space theory was first developed by Hancher and Moran in the context of business regulation.[46] It has since been employed in a range of settings, including in health, such as to study the regulation of patient safety,[47] biobanks,[48] precision medicine,[49] research ethics,[50] drug control,[51] domestic abuse disclosure schemes,[52] and health policy decision-making.[53] As part of this project, the case has been made for applying regulatory space theory to the end-of-life care setting,[54] and it has been applied in the VAD field.[55] A strength of the theory is its ability to account for a complex regulatory framework comprised of a multiplicity of intersecting regulatory actors and instruments, which makes it apposite for the VAD context.

Regulatory space theory is based on the concept or metaphor of a 'regulatory space' in which regulation occurs. Therefore, the first stage, as part of determining the regulatory space being analysed, is to define the concept of VAD and then identify what issues or domains of VAD exist and are subject to regulation.

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[46] Leigh Hancher and Michael Moran, 'Organizing Regulatory Space' in Leigh Hancher and Michael Moran (eds), *Capitalism, culture and economic regulation* (Oxford, Clarendon Press 1989) 148–72.

[47] Eirini Oikonomou and others, 'Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare' (2019) 9(7) BMJ Open e028663; Vincent and others (n 21).

[48] Jane Kaye and others, *Governing biobanks: understanding the interplay between law and practice* (Oxford, Hart Publishing 2012).

[49] Dianne Nicol and others, 'Precision medicine: drowning in a regulatory soup?' (2016) 3(2) Journal of Law and the Biosciences 281–303.

[50] Scott Burris, 'Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals' (2008) 2(1) Regulation & Governance 65–84; Graeme Laurie, 'Liminality and the limits of law in health research regulation: What are we missing in the spaces in-between?' (2017) 25(1) Medical Law Review 47–72; Samuel Taylor-Alexander and others, 'Beyond regulatory compression: Confronting the liminal spaces of health research regulation' (2016) 8(2) Law, Innovation and Technology 149–76.

[51] Toby Seddon, 'Markets, Regulation and Drug Law Reform: Towards a Constitutive Approach' (2019) 29(3) Social & Legal Studies 313.

[52] Jamie Grace, *Domestic Abuse Disclosure Schemes* (Palgrave Macmillan Cham, 2022).

[53] Corinna Klingler and others, 'Regulatory space and the contextual mediation of common functional pressures: Analysing the facts that led to the German Efficiency Frontier Approach' (2013) 109(3) Health Policy 270–80.

[54] White, Willmott and Close (n 1).

[55] See, e.g.: Ben P. White and others, 'Prospective oversight and approval of assisted dying cases in Victoria, Australia: A qualitative study of doctors' perspectives' (2024) 14(e1) BMJ Supportive and Palliative Care e1462-e1471.

The second stage is to map the relevant regulatory actors and instruments which occupy that space. To show how this mapping exercise may be conducted, an illustrative table of possible actors and their common instruments in a VAD 'regulatory space' is outlined in Table 22.1. This is an incomplete list as the actors within a specific regulatory space will depend on the jurisdiction and its context, and they may change over time. To illustrate, how a country's healthcare system is organised will have a significant impact on which regulatory actors are present. So too will other wider factors such as political systems and culture; an example is that the roles advocacy groups are permitted or encouraged to have in any given society will vary. It is also acknowledged that regulatory instruments in Table 22.1 may intersect; for example, funding programmes may be established by legislation or policy, and training for health practitioners may include information about their legal duties.

The final stage of mapping the regulatory space involves identifying the power and influence that actors and instruments possess, and then exercise, to guide the behaviour of others. A critical part of this exercise is to examine how and where in the regulatory space these influences compete with each other. Regulatory space theory acknowledges, and indeed expects, that there will be competition and conflict in terms of the regulatory objectives of actors and how their instruments reflect those objectives. The conclusion of this stage is to identify, after these competing influences have been weighed against each other, what conduct is prohibited, permitted, or encouraged.

This exercise produces a comprehensive map of the regulatory space that addresses: what issues are regulated; by which (overlapping) actors and instruments; how power and influence are exerted and by whom; and how competing influence from actors and instruments is resolved to guide behaviour?[56] Part of constructing this map also includes careful scrutiny for actors or instruments that might be expected to have regulatory influence but appear to be missing. This could suggest an actor or instrument lacks influence, but it may just be that their power is hidden.

This regulatory space analysis can then answer practical questions such as:

- Which sources of regulation are most important in guiding the conduct of doctors and other health practitioners who are providing VAD? How is conflicting or inconsistent guidance navigated?
- Which domains of VAD practice are heavily regulated and controlled, and in which domains are health practitioners and institutions permitted to exercise a high degree of discretion?
- When are health practitioners and institutions able to disregard legal, policy or ethical duties (such as providing VAD or information about it), and how do they do this?

In addition to regulatory space theory enabling a comprehensive understanding of existing frameworks, it can also be used to improve current VAD regulation or design new regulation.[57] In settings where VAD is already regulated, this could involve evaluating how existing actors and instruments could function together better to promote safe and high-quality

[56] Kaye and others (n 48).

[57] C Scott, 'Analysing regulatory space: fragmented resources and institutional design' (2001) Public Law (Summer) 329–53; Oikonomou and others (n 47).

Table 22.1 Illustrative regulatory actors and instruments in a voluntary assisted dying regulatory space

Actors/Instruments	Law	Policies/ Guidelines	Training and Education	Funding Programmes	System Design
Parliaments, Courts and Tribunals e.g., federal, state/ provincial and/or local (depending on a country's system of government)	Yes Legislation and court decisions	-	-	Yes	Yes
Governments and their departments e.g., federal, state/ provincial and/or local governments and departments (particularly health departments) (depending on a country's system of government and how their healthcare system is administered)	Yes Generally secondary legislation	Yes	Yes	Yes	Yes
Statutory agencies and bodies e.g., VAD oversight bodies; local health authorities; safety and quality commissions; clinical excellence bodies; health and medical licensing and complaints boards; therapeutic goods and pharmaceutical regulators; clinical ethics advisory bodies; directors of public prosecutions; coroners	Yes Some via secondary legislation or enforcement of law	Yes	Yes	Yes	Yes

Actors/Instruments	Law	Policies/ Guidelines	Training and Education	Funding Programmes	System Design
Health service organisations (public and private) e.g., hospitals; residential aged and/or disability care providers; hospices and community care providers	-	Yes	Yes	Yes	Yes
Non-government organisations e.g., health and medical colleges and societies; health and medical associations and unions; patient support and advocacy groups; private health insurers; universities and other training and education providers	-	Yes	Yes	Yes	-

Source: Adapted from White, Willmott and Close (n 1), which discussed regulatory space theory in the context of end-of-life care generally.

VAD. Such an analysis may also point to creating a new regulatory actor or instrument to address identified deficits.[58] Alternatively, a critical evaluation of particular regulatory actors and instruments may reveal they are not enhancing the system and should be removed.[59] A 'clean slate' approach could be taken, which involves learning from how past VAD regulation operated but putting aside existing structures to consider anew how best to regulate VAD.

Mapping the Regulatory Space of Voluntary Assisted Dying

Using regulatory space theory, this project has mapped existing VAD regulation in key Australian states to identify, as comprehensively as possible, all the regulatory actors and instruments that guide behaviour in this field. Methods used have included legal doctrinal analysis, policy analysis, document analysis (e.g., reports of VAD oversight bodies), and semi-structured qualitative interviews. At the time of writing, over 150 interviews across three Australian states (Victoria, Western Australia and Queensland) have been conducted with all

[58] Julia Black, 'Enrolling actors in regulatory systems: examples from UK financial services regulation' (2003) Public Law (Spring) 63–91.

[59] Oikonomou and others (n 47).

key stakeholders: terminally ill patients seeking VAD and their families, health practitioners (e.g., doctors, nurses, pharmacists and social workers), and regulators both from the State VAD infrastructure and non-State regulators such as health and medical organisations, health administrators and patient support and advocacy groups.[60]

The regulatory space has been progressively constructed, initially drawing on the preliminary framework outlined in Table 22.1 above which was developed as a starting point for this project. The focus was to develop a provisional map for each known category of regulatory instrument and then examine which actors produce such instruments or engage with them, and the role of the instruments in regulating VAD. Work began on regulation that was publicly available, such as law and published policies, as well as regulation that was discussed in public documents, such as the reports of VAD oversight bodies. This was supplemented by interviews, which enabled deeper understanding of how these instruments work in practice, and also provided access to non-public regulatory instruments, such as institutional policies requested from interviewees. The interviews also identified new regulatory instruments and new regulatory actors, which were explored further.

[60] More details about the interview samples for this project are available in the publications reporting on the views of the different cohorts. See, e.g.: Lindy Willmott and others, 'Participating doctors' perspectives on the regulation of voluntary assisted dying in Victoria: A qualitative study' (2021) 215(3) Medical Journal of Australia 125–9; Ben P. White and others, 'Access to voluntary assisted dying in Victoria: A qualitative study of family caregivers' perceptions of barriers and facilitators' (2023) 219(5) Medical Journal of Australia 211–7; White, Haining and Willmott (n 8); Haining, Willmott and White, 'Comparing Voluntary Assisted Dying Laws in Victoria and Western Australia: Western Australian Stakeholders'Perspectives' (n 37); Ben P. White and others, 'Models of care for voluntary assisted dying: A qualitative study of Queensland's approach in its first year of operation' (2024) 48(6) Australian Health Review 693.

This preliminary research produced a series of research outputs about each category of instrument – law,[61] policy and guidelines,[62] training and education,[63] funding programmes[64] and system design[65] – as well as outputs that examined how one or more of these instruments operate together.[66] The intent was that individually charting each of these categories of regulatory instruments in detail would facilitate building an understanding of the wider regulatory space as a whole. A final set of outputs in progress is integrating findings across this body of research to articulate the VAD regulatory map at an overall level.

High-level findings in relation to the Australian regulatory map to date include that VAD is highly regulated, particularly by the prescriptive legislation which outlines in detail how

[61] See, e.g.: Waller and others (n 26); Ben P. White and others, 'Mapping the legal regulation of voluntary assisted dying in Victoria: The coherence of a new practice within the wider legal system' (2022) 29(3) Journal of Law and Medicine 783–810; Ben P. White and others, 'Does the Voluntary Assisted Dying Act 2017 (Vic) Reflect Its Stated Policy Goals?' (2020) 43(2) University of New South Wales Law Journal 417–51; Katrine Del Villar, Lindy Willmott and Ben P. White, 'The Exclusion of Long-term Australian Residents from Access to Voluntary Assisted Dying: A Critique of the "Permanent Resident" Eligibility Criterion' (2023) 49(2) Monash University Law Review 1–44; Lindy Willmott and others, 'Restricting conversations about voluntary assisted dying: Implications for clinical practice' (2020) 10(1) BMJ Supportive and Palliative Care 105–10; Katrine Del Villar and others, 'Voluntary assisted dying and the legality of using a telephone or internet service: The impact of Commonwealth "Carriage Service" offences' (2022) 47(1) Monash University Law Review 125–73; White and others, 'Legislative Options to Address Institutional Objections to Voluntary Assisted Dying in Australia' (n 40).

[62] See, e.g.: Close and others, 'Institutional Objection to Voluntary Assisted Dying in Victoria, Australia: An Analysis of Publicly Available Policies' (n 18); White and others, 'The impact on patients of objections by institutions to assisted dying: A qualitative study of family caregivers'perceptions' (n 18); Eliana Close, Lindy Willmott and Ben P. White, 'Regulating voluntary assisted dying practice: A policy analysis from Victoria, Australia' (2021) 125(11) Health Policy 1455–74; Eliana Close, Lindy Willmott and Ben P. White, 'Voluntary assisted dying: peak bodies must provide practical guidance' (2022) 52(6) Internal Medicine Journal 926–31; Willmott, Haining and White (n 37).

[63] See, e.g.: Lindy Willmott and others, 'A cross-sectional study of the first two years of mandatory training for doctors participating in voluntary assisted dying' (2024) 22(4) Palliative and Supportive Care 674; Ben P. White and others, 'Development of voluntary assisted dying training in Victoria, Australia: A model for consideration' (2021) 36(3) Journal of Palliative Care 162–67.

[64] See Haining and others (n 37).

[65] See, e.g.: Ben P. White, Ruthie Jeanneret and Lindy Willmott, 'Barriers to connecting with the voluntary assisted dying system in Victoria, Australia: A qualitative mixed method study' (2023) 26(6) Health Expectations 2695–708; White and others, 'Prospective oversight and approval of assisted dying cases in Victoria, Australia: A qualitative study of doctors' perspectives' (n 55); Haining, Willmott and White, 'Comparing Voluntary Assisted Dying Laws in Victoria and Western Australia: Western Australian Stakeholders' Perspectives' (n 37).

[66] See, e.g.: White and others, 'Access to voluntary assisted dying in Victoria: A qualitative study of family caregivers' perceptions of barriers and facilitators' (n 60); Willmott and others, 'Participating doctors' perspectives on the regulation of voluntary assisted dying in Victoria: A Qualitative Study' (n 60); Jeanneret and others, '"Regulatory Action" by Patients and Family Caregivers to Overcome Barriers to Accessing Voluntary Assisted Dying: A Qualitative Study in Victoria, Australia' (n 19).

VAD may be provided. This legislation is supplemented by a broad spectrum of regulatory instruments with policy, training and system design playing a significant role in governing VAD. Of note is the unanticipated impact of VAD information technology systems, which most Australian jurisdictions use to process forms that VAD practitioners must submit throughout the process.[67] It was found to be influential in managing compliance by VAD practitioners in eligibility assessments, with reports of it having a gatekeeping function in at least one jurisdiction.[68] As mentioned above, the absence of funding mechanisms has had an adverse impact on the operation of the VAD system.[69]

In terms of regulatory actors, as anticipated, the regulatory map includes State actors that are both VAD-specific (e.g., VAD Boards (oversight bodies) and VAD care navigators) and health-specific (e.g., health departments and health and medical disciplinary bodies). Non-State actors also feature prominently, such as health and medical organisations and patient support and advocacy groups. One component of this project also makes the case that patients seeking VAD and their families may be considered regulators.[70]

The project also involves mapping the regulatory space of VAD in Canada and Belgium. In relation to Canada, this includes particular work on law[71] and policy[72] accompanied by a range of insights into how regulation is operating in practice via semi-structured interviews with key stakeholders, as outlined above.[73] In relation to Belgium, a scoping review of literature on VAD regulation has been used to construct a map that charts regulatory instruments and

[67] White, Haining and Willmott (n 8).

[68] ibid; White and others, 'Prospective oversight and approval of assisted dying cases in Victoria, Australia: A qualitative study of doctors' perspectives' (n 55).

[69] Haining and others (n 37).

[70] Jeanneret and others, '"Regulatory Action" by Patients and Family Caregivers to Overcome Barriers to Accessing Voluntary Assisted Dying: A Qualitative Study in Victoria, Australia' (n 19).

[71] See Chapter 11: Eliana Close and Jocelyn Downie, 'Medical assistance in dying in Canada'.

[72] Eliana Close and others, 'Medical Assistance in Dying in Canada: A Review of Regulatory Practice Standards and Guidance Documents for Physicians' (2025) Palliative Care and Social Practice (forthcoming).

[73] Eliana Close, Jocelyn Downie and Ben White, 'Practitioners' experiences with 2021 amendments to Canada's medical assistance in dying law: A qualitative analysis' (2023) 17 Palliative Care and Social Practice 1–23; Close and others, 'A qualitative study of experiences of institutional objection to medical assistance in dying in Canada: ongoing challenges and catalysts for change' (n 18); Jeanneret and others, 'Patients' and Caregivers' Suggestions for Improving Assisted Dying Regulation: A Qualitative Study in Australia and Canada' (n 19); Jeanneret and others, '"My Advocacy is Not About Me, My Advocacy is About Canadians": A Qualitative Study of how Caregivers and Patients Influence Regulation of Medical Assistance in Dying in Canada' (n 19); Eliana Close, Jocelyn Downie and Ben P. White, 'Oversight of Medical Assistance in Dying in Canada: Perspectives of Physicians, Nurse Practitioners, and Organisational "Regulatory Actors"' (under review); Eliana Close, Jocelyn Downie and Ben P. White, 'Monitoring of Medical Assistance in Dying: A Qualitative Analysis of Doctors', Nurse Practitioners', and Organisational Actors' perspectives' (under review).

actors and their functions,[74] as well as the domains or issues that they regulate.[75] Further work, drawing on interviews with Belgian VAD practitioners, examines how the system is operating in practice, including the impact of regulation on their decision-making.[76]

Improving Voluntary Assisted Dying Regulation

The project's final stage will reflect on how to improve approaches to regulating VAD. Initially drawing on regulatory space theory, as noted above, this includes critically analysing current VAD regulation and proposing how existing and new regulatory forces could function together effectively to support the provision of safe, high-quality, person-centred VAD. However, as noted above, this theory provides only limited normative guidance as to the optimal content of VAD regulation, such as in relation to appropriate eligibility criteria. Hence, other sources of reflection for this exercise include comparative analysis with the Canadian and Belgian experience and drawing on the principles of what constitutes high-quality end-of-life care, such as the literature on a 'good death'.[77] Some of this work is underway, including reflections from interviewed doctors and regulators about how best to regulate VAD.[78]

PRACTICAL OBSERVATIONS ABOUT IMPLEMENTING HOLISTIC APPROACHES TO VOLUNTARY ASSISTED DYING REGULATION AND ITS EVALUATION

The final section of this chapter makes some practical observations about holistic approaches to VAD regulation, beginning with reflections for researchers. Although this chapter has advocated for holistic approaches to researching VAD regulation, there are important practical constraints or considerations when doing such work. For example, research funding can

[74] Archer and others, 'Mapping Sources of Assisted Dying Regulation in Belgium: A Scoping Review of the Literature' (n 32).

[75] Archer and others, 'What Domains of Belgian Euthanasia Practice are Governed and by Which Sources of Regulation: A Scoping Review' (n 33).

[76] Madeleine Archer and others, 'Health Professionals' Perspectives on the First Belgian Euthanasia Criminal Trial: A Qualitative Study' (2025) Medical Law International (forthcoming); Madeleine Archer and others, 'Key Challenges in Providing Assisted Dying in Belgium: A Qualitative Analysis of Health Professionals' Experiences' (2025) 19 Palliative Care and Social Practice 1–19; Madeleine Archer and others, 'How Does Regulation Influence Euthanasia Practice in Belgium? A Qualitative Exploration of Involved Doctors' and Nurses' Perspectives' (2025) 33(1) Medical Law Review (early online).

[77] Emily Meier and others, 'Defining a Good Death (Successful Dying): Literature Review and a Call for Research and Public Dialogue' (2016) 24(4) American Journal of Geriatric Psychiatry 261–71; Mehreen Zaman and others, 'What would it take to die well? A systematic review of systematic reviews on the conditions for a good death' (2021) 9(2) The Lancet Healthy Longevity e593-e600.

[78] White, Haining and Willmott (n 8).

be limited, necessitating a more limited focus, and access to interdisciplinary perspectives to support holistic approaches may not be possible.[79]

One practical observation is that research about a single regulatory instrument or actor remains important. Such work has inherent value and can also generate the required knowledge base needed to support wider holistic research. This was the approach taken in the research project outlined above, where a programme of instrument-specific research provides the building blocks for a holistic evaluation of VAD regulation. When research focuses on a single regulatory instrument or actor, holistic thinking can still inform that research. For example, such research can evaluate that instrument or actor within the context of its wider regulatory space and also recognise that it is only one of a number of factors that guide behaviour.

Other practical observations can be directed to current or potential regulatory actors in relation to the design and implementation of VAD regulation. An initial observation is that holistic approaches mean those producing a regulatory instrument must take into account how it is likely to operate within the existing wider regulatory space. This means recognising that there may already be current regulation on the topic dealt with by the new instrument, which may or may not be consistent with its efforts to guide behaviour. To illustrate, if a medical college is producing a policy about how to discuss VAD with patients, they must take into account existing law, policy, guidelines and training that purport to deal with this issue. Efforts to encourage doctors to raise VAD with patients when this is appropriate may be thwarted if the law prevents this,[80] or facilitated if there are guidelines that align with this position.[81] Recognising the other regulatory actors and instruments in the regulatory space can help enhance the effectiveness of proposed regulation.

Taking a holistic approach, regulators should also consider which type of regulatory instrument should be employed to best guide behaviour towards desired outcomes. This may include consideration of how regulatory instruments could be used together, particularly by State regulators who generally have a wide suite of regulatory instruments to choose from. This involves recognition of the capabilities of different regulatory instruments and their

[79] It is noted, however, that at least part of the regulatory space mapping undertaken in the Belgian study (above) relied on a scoping review of the literature, which is a cost-effective method of engaging with holistic perspectives of regulation: Archer and others, 'Mapping Sources of Assisted Dying Regulation in Belgium: A Scoping Review of the Literature' (n 32); Archer and others, 'What Domains of Belgian Euthanasia Practice are Governed and by Which Sources of Regulation: A Scoping Review' (n 33).

[80] For example, VAD Acts in two Australian states – Victoria and South Australia – prohibit health practitioners from raising VAD with their patients: see Waller and others (n 26). This is also the position in New Zealand: Snelling and others (n 38).

[81] See, e.g., Canadian Association of MAiD Assessors and Providers (CAMAP) guidelines: CAMAP, 'CAMAP Publications and Guidelines' <https://camapcanada.ca/for_clinicians/publications/>. See also QUT and Advance Care Planning Australia, 'Navigating the topic of Voluntary Assisted Dying in Advance Care Planning Conversations: Guiding principles for health professionals' (2024) <https://research.qut.edu.au/voluntary-assisted-dying-regulation/wp-content/uploads/sites/292/2024/02/S1868_ACPA_GuidingPrinciples_QUT_FinalWEB.pdf>; QUT and Advance Care Planning Australia, 'Navigating the topic of Voluntary Assisted Dying in Advance Care Planning Conversations: Guiding principles for health and aged care organisations' (2024) <https://www.advancecareplanning.org.au/__data/assets/pdf_file/0027/234675/ACPA_QUT_FactSheet_HealthAndAgedCare_FinalWEB.pdf>.

usual function. As discussed above, law can be useful for establishing a broad framework for authorised conduct, but other instruments such as policies, guidelines and training are often more effective regulatory instruments to guide conduct in the clinical setting. There should also be efforts to ensure consistency in approach across regulatory instruments so that the guidance given about desired behaviour is coherent.

A final practical observation for regulators is to acknowledge the constraints in taking the proposed holistic approach when designing regulation. One challenge in developing coherently-designed VAD regulation is that the regulatory space is comprised of a range of regulatory actors with different interests and objectives. Coherence is particularly difficult to achieve where there are many influential non-State actors involved.

An illustration of this is Australia's experience of implementing VAD in its various states. Each state has had an extended implementation period (generally of 18 months) to enable governments to develop the necessary infrastructure, including an oversight board, guidelines for clinicians, health services policy guidance, training for medical practitioners, and community information.[82] Such an implementation exercise actually provides a good example of a generally coherent and planned design of VAD regulation that accords with the holistic approaches being advanced in this chapter. However, a challenge has been the response of non-State actors. Some developed regulation (e.g., policies) which was supportive and consistent with existing State approaches. However, others, particularly some private health providers and those with religious or ideological opposition to VAD, developed regulation which was inconsistent with, and had the effect of partially frustrating, the policy objectives of the State to permit and regulate VAD.[83]

Holistic approaches to VAD regulation also have practical implications for those who are the subject of this regulation, such as health practitioners and health administrators. Being aware that there is a wider regulatory space means they can account for multiple sources of regulatory guidance and know that these sources may not always give consistent direction. For instance, health practitioners and health administrators are better placed to navigate regulation if they are aware that it is possible that their local institution's VAD policies may not always be consistent with health department guidance or the law.

CONCLUSION

This chapter has argued that holistic approaches should be adopted when designing, reforming and researching VAD regulation. This means recognising that there is a range of regulatory actors and instruments exerting influence (which sometimes conflicts) to guide behaviour within VAD systems. While such approaches necessarily involve more complexity, they better reflect reality and are more informative in research and more effective when used to design or reform VAD regulation.

A concluding observation is to reflect on the very limited consideration of VAD by the broader discipline of regulation. This is surprising considering the amount of attention the

[82] Margaret O'Connor and others, 'Implementing voluntary assisted dying in Victoria, Australia' (2021) 36(3) Int J Health Plann Manage 602–609.

[83] See, Close and others, 'Institutional Objection to Voluntary Assisted Dying in Victoria, Australia: An Analysis of Publicly Available Policies' (n 18).

regulation of VAD has received in literature across other disciplines such as law, medicine and bioethics. Given how significant the concept of regulation is for the VAD field, more research that is explicitly regulatory in nature is needed. Further, it is suggested there is scope for regulatory research undertaken in relation to VAD to contribute to the broader discipline of regulation. The serious nature of VAD (including that it leads to a person's death) means that findings about how it is regulated may also be of relevance to the regulation of other fields, including those which involve life and death decisions.