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Clinical governance in changing times: balancing risk, regulation and duty of care in aged care

Dr Melanie Tan *RUSSELL KENNEDY LAWYERS*

"When the facts change, I change my mind." (John Maynard Keynes)

Introduction

Clinical governance provides systemic management, oversight and accountability over clinical care in a risk environment.[1] However, risk changes with time, as we have seen with COVID-19 — both in its emergence and in epidemiology.

How can clinical governance be effectively implemented when facts, and evidence relating to those facts, keep changing? Only rarely can risk be eliminated, and the Aged Care Quality and Safety Commission (ACQSC) recognises that safety and quality have multiple influences in clinical care.[2] Regulatory obligations and a common law duty of care operate *in tandem* to require that reasonable steps are taken to mitigate risk.

Regulation in aged care sets out expected standards of care. Clinical governance, in itself a regulatory requirement,[3] should provide a framework to support such standards. It should also support the underlying common law duty of care owed by providers to their consumers, staff and other third parties.

What is the interplay of risk, regulation and duty of care in aged care within a constantly changing and dynamic risk environment? These factors must diverge in a single and clear framework for clinical governance, but there is no "one size fits all". Not only must clinical governance address current, emerging and potential risks, but it must also be able to accommodate changes, and *potential* changes, to these risks. Clinical governance is to be evidence-based, so information should be closely monitored as it emerges.

Although it is important to keep abreast of regulatory developments,[4] the underlying requirements of the Aged Care Quality Standards (Standards) do not change. Similarly, our duty of care does not change, although it may also evolve according to the circumstances at hand (including the regulatory and risk landscape). So how do we manage clinical governance in changing times? This paper proposes five key principles for a suggested approach to clinical governance in aged care to manage these challenges.[5]

Clinical governance in aged care

Clinical governance processes must *actively* consider risks and balance these against other obligations in the Standards. Simultaneously, they must also balance risks and regulation with their duty of care to residents, staff and families. So first and foremost, any "blanket" approach to governance should be treated with caution, especially where policies are reactive to the risk environment, without more.[6]

Secondly, there has been little bespoke guidance for aged care in the current risk environment. This was subject to criticism in the Aged Care Royal Commission's Special Report on Aged Care (Special Report), who noted there had been no federal pandemic plan specifically directed at aged care.[7] Clearly, clinical governance for hospitals cannot simply be transposed to aged care.[8] The Royal Commission heard evidence that "best practice" in the health care sector may not translate into "best practice" in aged care.[9]

However, that is not to say that policies cannot be *appropriately* adapted, and it is the author's view that the ability to adapt is key to effective clinical governance in changing times, where little evidence is settled. For instance, recommendations regarding CPR in acute hospital settings might be appropriately adapted for residential aged care facilities.[10] However, in adapting such policies, expert input is imperative. Indeed, it was noted in the Special Report that the key national advisory body on infection control (CDNA[11]) did not include any members with aged care experience.[12]

Further, the operation of protocols must be flexible, or their content should be. What is crucial is that they are specific to the needs of the aged care provider, and not generic in nature. The Royal Commission commented that there is no "one size fits all" approach (referring to transfer of COVID-19-positive residents to hospital).[13]

The ACQSC has also noted, in relation to spot checks during this pandemic, that many "outbreak management plans" did not contain "service-specific information".[14]

Policies and procedures should also allow for some exercise of discretion within them. Just as there is no "one size fits all" policy across providers, there is also no "one size fits all" policy across consumers. Rigid adherences to policies have been known to attract criticism.[15] Courts have supported the exercise of judgment and discretion when applying (often imprecise) policy guidelines, whose function is to assist decision-making — not to prescribe the decisions.[16]

This paper proposes five key principles to clinical governance, purposefully designed to be adaptable and flexible. In accordance with the Standards, they pivot around consumer-centred care.[17] An approach to resuscitation policies will be used to illustrate each of these principles. Given the potential for chest compressions to generate aerosols and associated impossibility to physically distance, the issue of cardiopulmonary resuscitation (CPR) has been a vexed one for some providers.

A five-step approach to clinical governance in aged care

1. Actively plan for risks by considering facts, evidence and consumer preferences as they evolve

Aged care providers should consider the facts at hand, and the evidence around those facts, to anticipate potential issues in clinical governance. For example, the emergence of the COVID-19 pandemic at the beginning presented an opportunity to consider its potential impact on their consumers, having the benefit of other countries' experiences before us.

The importance of having clinicians on board with relevant experience to consider the evidence cannot be over-emphasised. This pandemic has shown that we cannot always rely on adequate, timely guidance from the government.[18] While (generic) external guidelines should be followed (with discretion), their absence in any given situation does not preclude providers from formulating their own, on the basis of information available.[19] Issues in clinical governance may be anticipated, and appropriate steps considered, independent of external guidelines or legal mandates.[20]

Like all other Standards, clinical governance under Standard 8 should be centred on the consumer. Consumers' feedback and wishes must be sought and considered when designing any clinical governance framework. To that extent, clinical governance requires a multi-dimensional approach. The importance of this was highlighted by the Aged Care Royal Commission (ACRC), which observed that the "understandable" restriction on visits to aged care homes had "tragic, irreparable and lasting effects".[21] Care must be taken not to manage risk such as to cause another harm. For instance, the Special Report concluded that maintaining the quality of life of residents is just as important as preparing for and responding to outbreaks.[22]

Planning should involve active anticipation of emerging issues, active identification of gaps in protocols and potential "calls to action" or trigger points. Providers should be prepared for a range of possible situations, assessed on the basis of facts, evidence, and the individuality of consumers. Finally, clear lines of decision making must be identified from the outset. Confusion does not support good governance.[23] Indeed, the ACRC was critical of the "confused and consistent messaging" that had emerged during this pandemic, and the lack of clear lines of accountability. It observed that "*clear leadership, direction and lines of communication are essential*".[24] This should be the backbone of any robust governance system.

1.1 Planning: CPR as a case study

CPR has the potential to generate aerosols, risking the transmission of viral particles through propulsion of infected droplets from a person's airway. The risk associated with CPR has not been confirmed,[25] and further evidence might emerge in due course. In the meantime there remains at least a theoretical risk of aerosol exposure from chest compressions. This poses a risk of infection to staff involved, and therefore other consumers. It may be reasonable to assume, when planning, that the risk of viral inoculation through CPR will be subject to fluctuating levels of local community transmission (as this in turn would impact the likelihood of the person in need of CPR carrying the virus).[26]

Adopting the precautionary principle,[27] the level of community transmission within the provider's demographic should be considered when policies and procedures for resuscitation are considered. Policies might also be "graded" according to level of community transmission at any given time. Consumer preferences are also central to making plans around resuscitation. Do consumers have an advance care directive in place in relation to CPR (and they do not have capacity to make one if not)? Has this issue been addressed in their Care Plan, taking into account any known preferences and associated co-morbidities?

2. Review and assess: actively review and assess the risks against consumer well-being

Risks will continue to evolve, as will the impact such risks have on consumer well-being — as consumer well-being will also evolve. As such, planning alone will not suffice — ongoing assessment and review is essential. Aged care providers should therefore *actively assess*

risk as an ongoing process, in the context of their individual circumstances, and on the basis of clinical and consumer input. The Special Report stated, in relation to visitation restrictions as an infection control measure:

> Providers must continually review and revise their position on visitation, recognising the particular circumstances of their facility and the level of community transmission in their location.[28]

Active assessment and management of risk should monitor the impact of any proposed measure on the well-being, preferences and rights of consumers, and protocols must be specific and relevant to them. As pointed out in the Special Report:

> Systems and plans are, of course, important, but they should always be linked to the object of protection. The aim of providing real, tangible and meaningful assistance to people must be our primary, overriding and constant focus.[29]

2.1 Reviewing and assessing — CPR as a case study

Policies on resuscitation should consider the many variables impacting the effectiveness of CPR (eg underlying patient condition/co-morbidities, whether there may be a reversible cause),[30] as well as consumer goals of care. The risks of CPR should be assessed against its likely benefit to particular consumers and risk of harm to them, such as neurological injury.

3. Actively respond to risks and consumer preferences

Risk must be approached in a balanced and considered manner, and caution be exercised in adopting a reactive approach to emerging issues. From the outset of the pandemic, the ACQSC has supported a proportionate risk-based regulatory response.[31] This approach is consistent with ethical decision-making in public health, which support appropriate planning.[32] Again, turning to the issue of visitations addressed in the Special Report:

> . . . visitations should be humane and proportionate to risk, even during periods of community transmission.[33]

As always, consumer preferences should also be sought and considered when responding to risks.

3.1 Actively responding — CPR as a case study

An example of a *reactive* approach (rather than a responsive one) might be a policy requiring CPR to be withheld for all residents, without further consideration. A *responsive* approach might be guiding how decisions on resuscitation should be made for individual residents, and how the risk can be managed (if at all).

Providers might consider relevant industry recommendations or consensus, even their application to aged care must be adapted — which can be done with specific clinician input.[34] Emerging literature or evidence should be factored in if relevant, with clinician guidance. For example, providers may consider implementing modifications to CPR such as the following (extrapolated from recommendations for acute care):[35]

- palpating for chest movements to assess for breathing, rather than listening or feeling for it; and
- covering the patient's mouth and nose, with a towel, cloth or mask during chest compressions (while regularly checking the airway for secretions).

4. Consider your regulatory obligations

Policies and procedures within clinical governance frameworks support other obligations in the Standards — the core of which is consumer centred care.[36] Consider regulatory obligations as an "anchor" to clinical governance. Other standards and requirements, such as dignity of risk, should be incorporated within your clinical governance framework.[37] Similarly, aged care providers and staff should understand what their duty of care is, and how this sits alongside the Standards and other regulatory obligations — therefore training and education is also essential to good governance.

Consumer choice must remain central to clinical governance. The Special Report pointed out, "[r]esidents' entitlement to quality of life does not change in an emergency, although how this can be achieved does".[38] Clinical governance protocols are by no means mutually exclusive to supporting consumer preferences or consumer rights, however must operate in tandem.

4.1 CPR — regulatory obligations

In the context of a CPR policy, the eight Standards may be applied as follows:

Standard 1 — consumer dignity and choice. Consumer's wishes must be understood from the outset.

Standard 2 — ongoing assessment and planning with consumers. Advance care planning is a component of this standard which should guide appropriate resuscitation protocols.

Standard 3 — personal and clinical care. This standard requires the provision of care that is "safe, best practice, tailored to the needs of consumers and optimises their health and wellbeing".[39] This includes responding to a deterioration in physical health — and therefore identifying when CPR should (or should not) be given for a particular consumer, having taken into account their individual circumstances.

Standard 4 (services and supports for daily living) and *Standard 5* (service environment) should always be considered in a clinical governance framework. However, in the context of resuscitation policies they do not have any direct relevance — other than to consider

whether premises are adequately designed for effective resuscitation and managing the risks.

Standard 6 — feedback and complaints. A resuscitation policy might consider how complaints and open disclosure[40] might be managed in the event of unsuccessful resuscitation, or decisions not to resuscitate.

Standard 7 — human resources. Roles and responsibilities of staff should be clearly delineated, in the event a consumer needs to be resuscitated. Examples of appropriate protocols might include:[41]

- properly training staff in donning/doffing PPE;
- training staff to not commence chest compressions, or permit anyone in the room, without appropriate PPE;
- designating one person as responsible to ensure all staff involved in resuscitation are using PPE safely;
- keeping to a minimum the number of staff who intervene.

Standard 8 — organizational governance. This is the overarching standard, of which clinical governance is a component.

5. Understand your duty of care

Duty of care is not always about eliminating risk, especially when such avoidance will lead to another harm. Duty of care involves taking reasonable steps to manage risk, and applying reasonable care and skill in doing so. To refuse CPR solely on the basis of a theoretical risk of inoculation to staff might be considered a breach in a provider's duty of care to the consumer. Where providing care that is associated with risks to others, duty of care requires these risks to be appropriately balanced, and managed.

The content of duty of care will be considered in the context of the circumstances, and characteristics of the person carrying out that duty. For example, the standard of care expected of a personal care assistant is that of the ordinary skilled personal care assistant in aged care.[42] This is a different standard of care to that expected of a registered nurse. Aged care providers also themselves have a duty of care to ensure adequate policies and procedures are in place, and that staff (including employees and visiting/casual staff) are adequately trained in these.[43]

Finally, as always, clinical governance in aged care should be evidence based. It is therefore important that providers actively stay up to date with contemporaneous best practice and evidence as it evolves, and seek appropriate clinical input. This should also be carefully documented.

5.1 CPR — duty of care

It is likely aged care providers will be considered to have a duty of care to resuscitate a consumer who is found to be non-responsive (unless the consumer has previously refused consent[44]). The Coroner in the Reimers inquest found that staff had failed to recognise the deceased's deterioration, or did not have the "necessary competencies" to apply basic first aid or assess the deceased.[45] The Coroner in this inquest recommended that all personal care assistants be adequately trained in first aid/CPR, suggesting she considered this to be well within the scope of a provider's duty of care.

However, any potential risks to staff or other consumers should be appropriately managed, such as ensuring the air way is covered to prevent expulsion of infective particles where there is a risk of viral transmission.[46] Not only do providers have a duty of care to their consumers, but they also have a duty of care to their staff, other consumers, and potentially third parties.

Conclusion

A key to successful clinical governance in changing times is to adopt a robust and flexible approach to current, emerging, and potential risks. Training on clinical governance policies and procedures is also crucial, and staff should understand how to apply such protocols and how to manage risks — as well as their regulatory obligations and duty of care.

Good clinical governance should be embedded in an organisation's foundation, but kept under review in accordance with changing facts, evidence and consumer preferences. Contemporaneous clinical input can ensure governance systems are sufficiently tailored, responsive, and in accordance with best practice.

Clear lines of accountability enable us to identify where things went wrong, and how they can be improved. Therefore, while it is important to adopt a malleable approach to clinical governance, such approach must be tethered around robust leadership. Effective leadership offers some certainty in an uncertain world.

Dr Melanie Tan
Senior Associate
Russell Kennedy Lawyers

Footnotes

1. Specifically, the ACQSC defines it as "an integrated set of leadership behaviours, policies, procedures, responsibilities, relationships, planning, monitoring and improvement mechanisms that are implemented to support safe, quality clinical care and good clinical outcomes for each consumer". See www.agedcarequality.gov.au/providers/quality-care-resources/clinical-governance.

2. Aged Care Quality and Safety Commission Regulatory Strategy, 1 January 2020.
3. Standard 8(3)(e), Aged Care Quality Standards.
4. For example, the "Industry Code for Visiting Residential Aged Care Homes During COVID-19" (which is voluntary, reviewed three times). There may also be public health directions which come into play from to time.
5. Presented as an e-poster at the LASA Ten Days of Congress, 12–23 October 2020.
6. See for example the Aged Care Royal Commission's Special Report on COVID-19 which stated at p 9: "In all but extreme cases, blanket bans on visitation are unacceptable and should be both explained and justified."
7. *Aged care and COVID-19: a special report*, 30 September 2020, Royal Commission into Aged Care Quality and Safety.
8. M Scopetti et al, "Expanding frontiers of risk management: care safety in nursing home during COVID-19 pandemic", published online 28 August 2020, *International Journal for Quality in Health Care*, 1–4, doi: 10.1093/intghc/mzaa085.
9. Special Report, p 6 — referring to transcript, Sydney Hearing 2, Erica Roy, 11 August 2020 at T8482.36-31.
10. See M Tan et al, "Clinical governance, risk and duty of care for aged care providers in times of COVID-19: a look at CPR", published online 1 September 2020 at www.russellkennedy.com.au/insights-events/insights/clinical-governance-risk-and-duty-of-care-for-aged-care-providers-in-times-of-covid-19-a-look-at-cpr — citing S Craig et al, "Management of adult cardiac arrest in the COVID-19 era: consensus statement from the Australasian College for Emergency Medicine" (2020) 213(3) *Medical Journal of Australia,* published 3 August 2020: doi:10.5694/mja2.50699.
11. Communicable Diseases Network Australia, overseen by the AHPPC (Australian Health Protection Principle Committee).
12. Special Report, p 12.
13. Special Report, p 21.
14. See "What could be improved" at www.agedcarequality.gov.au/providers/infection-control-spot-checks#:~:text=The%20Aged%20Care%20Quality%20and%20Safety%20Commission%20has%20recently%20started,arrangements%2C%20including%20safe%20PPE%20protocols. Note that the Commission has also said that the "content, format and presentation of a clinical governance framework will vary depending on the specific characteristics of each aged care service". See "Fact sheet 1: Introduction to clinical governance", July 2019, Aged Care Quality and Safety Commission.
15. See for example, Inquest into the death of John Frederick Reimers, 23 August 2019, COR 2016 5983 (Reimers).
16. See for example, High Court decision in *Queensland v Masson* (2020) 381 ALR 560; [2020] HCA 28; BC202007601.
17. See "Fact sheet 1: Introduction to clinical governance", July 2019, Aged Care Quality and Safety Commission: "The purpose of clinical governance is to support the workforce and visiting practitioners in your service to provide safe, quality clinical care as part of an holistic, person-centred approach to aged care that is based on their needs, goals and preferences of consumers."
18. Special Report, p 4.
19. For example, the Royal Commission noted the absence of government recommendations in relation to mask-wearing, despite being a "very cheap and effective method" of infection prevention control — see p 16 of the Special Report, referring to evidence of Professor McLaws — Transcript, Sydney Hearing 2, Mary-Louis McLaws, 10 August 2020 at T8399.30-31.
20. See relevant sections in A Courtney et al, "Aged care and the COVID-19 pandemic: 10 legal tips for residential aged care providers", published online at 12 March 2020 at www.russellkennedy.com.au/insights-events/insights/aged-care-and-the-covid-19-pandemic-10-legal-tips-for-residential-aged-care-providers.
21. Special Report, p 6.
22. Special Report, p 8.
23. M Sheean and M Fox "Early Warnings: The Lessons of COVID-19 for Public Health Climate Preparedness" (2020) 50(3) *International Journal of Health Services* 264–270. See also Special Report, p 14: "A lack of clarity of roles during the Newmarch House outbreak added to the complexity of the response".
24. Special Report, p 11. See also p 12, evidence of Professor Gilbert AO and Adjunct Professor Lilly, with which the Commissioners agreed: "there must be a clear operating protocol in place, outlining the relevant stakeholders, their respective riles and the hierarchy of decision making" (Exhibit 18-1. Sydney Hearing 2, Newmarch House tender bundle, tab 21, CTH.1000.0005.8876 at 9996).
25. K Cooper et al "COVID-19 in cardiac arrest and infection risk to rescuers: A systematic review" (2020) 151 *Resuscitation* at 59–66, https://doi.org/10.1016/j.resuscitation.2020.04.022.
26. S Craig et al "Management of adult cardiac arrest in the COVID-19 era: consensus statement from the Australasian College for Emergency Medicine" (2020) 213(3) *Medical Journal of Australia* (published 3 August 2020): doi:10.5694/mja2.50699.
27. Described in the Special Report (p 18), in accordance with the Public Health and Wellbeing Act 2018 (Vic) as follows: "if a public health risk poses a serious threat, lack of full scientific certainty should not be used as a reason for postponing measures to prevent or control the public health risk".
28. Special Report, p 9
29. Special Report, p 6.
30. In Reimers, the Coroner considered that there should be a distinction between "natural and unnatural events" which may require resuscitation.
31. Commissioner's letter to providers, 12 March 2020.
32. J Chase "Caring for Frail Older Adults During COVID-19: Integrating Public Health Ethics into Clinical Practice" (2020) 68(8) *J Am Geriatr Soc* 1666–70.

33. Special report, p 9.
34. For example, S Craig, above n 26.
35. S Craig et al "*Management of adult cardiac arrest in the COVID-19 era: consensus statement from the Australasian College for Emergency Medicine*" (2020) 213(3) *Medical Journal of Australia* (published 3 August 2020): doi:10.5694/mja2.50699.
36. See Standard 1.
37. The Commission has specifically stated that "there are links between each of the eight Quality Standards and clinical care that should be reflected in your clinical governance arrangements". See "Fact sheet 2: Clinical governance and the Aged Care Quality Standards", July 2019, Aged Care Quality and Safety Commission.
38. Special Report, p 8.
39. "Fact Sheet 2: Clinical governance and the Aged Care Quality Standards", July 2019. Aged Care Quality and Safety Commission, p 4.
40. Note that open disclosure is a specific requirement of clinical governance in Standard 8(3)(e)(iii).
41. Above n 26.
42. The Coroner in Reimers, recommended that personal care assistants should be mandated to hold a Senior First Aid/CPR Certificate Aid/CPR Certificate for Personal Care Assistants on its "Skills Gateway" webpage: www.skills.vic.gov.au/victorianskillsgateway/Students/Pages/OccupationSearchDescription.aspx?type=occupation&keyword=Personal%20Care%20Assistant&searchid=920&31=-1&32=0&ReturnUrl=%2fvictorianskillsgateway%2fStudents%2fPages%2fOccupationSearchResults.aspx%3ftype%3doccupation%26keyword%3dPersonal%2520Care%2520Assistant%2631%3d-1%2632%3d0%2633%3d.
43. The Coroner in Reimers also found that the aged care provider failed to ensure that a nurse "had the necessary induction, support and competencies" to manage a critical incident concerning a resident, which ultimately led to his death. See above n 15.
44. By an advance care directive or otherwise.
45. See Reimers, above n 15.
46. Above n 26.