

## Background

**Digital innovation** is transforming health care with opportunities to increase care accuracy, efficiency, and accessibility.<sup>1,2</sup> Digital innovation in hearing health includes apps, sensors, and wearable devices to capture patient data; data integration comparing individual level data with large datasets; and use of AI-based tools.<sup>1</sup>

With innovation comes opportunity and risk. It is the role of regulation to limit potential risks that might arise from a healthcare service or product. This requires in-depth understanding and careful balancing of the perspectives of consumers, product developers, service providers, as well as policy-makers.

## Aims & Objectives

This **qualitative study** explored stakeholders' perceptions and understanding of the ways in which innovation and regulation are reshaping services in the hearing healthcare sector.

## Methods & Materials

- 29 participants from Australia (n = 16) and the UK (n = 13): adults with HL, their family members, healthcare professionals (HCP), academics/researchers, representatives of hearing device manufacturers, regulators and policymakers.
- Two online workshops (Australia and UK).
- Verbatim transcripts and online discussion boards were analysed in NVivo using **reflexive thematic analysis**.<sup>4,5</sup>

<sup>1</sup>Zahid, A., et al., *A systematic review of emerging information technologies for sustainable data-centric health-care*. Int J Med Inform, 2021. 149: p. 104420.

<sup>2</sup>Bidoli, C., et al., *Virtual hospitals: The future of the healthcare system? An expert consensus*. J Telemed Telecare, 2023: p. 1357633X231173006.

<sup>3</sup>Boisvert, I., et al., *Disruptions to the hearing health sector*. Nat Med, 2023. 29(1): p. 19-21.

<sup>4</sup>Braun V, Clarke V. *Using thematic analysis in psychology*. Qual Res Psychol 2006; 3(2):77-101

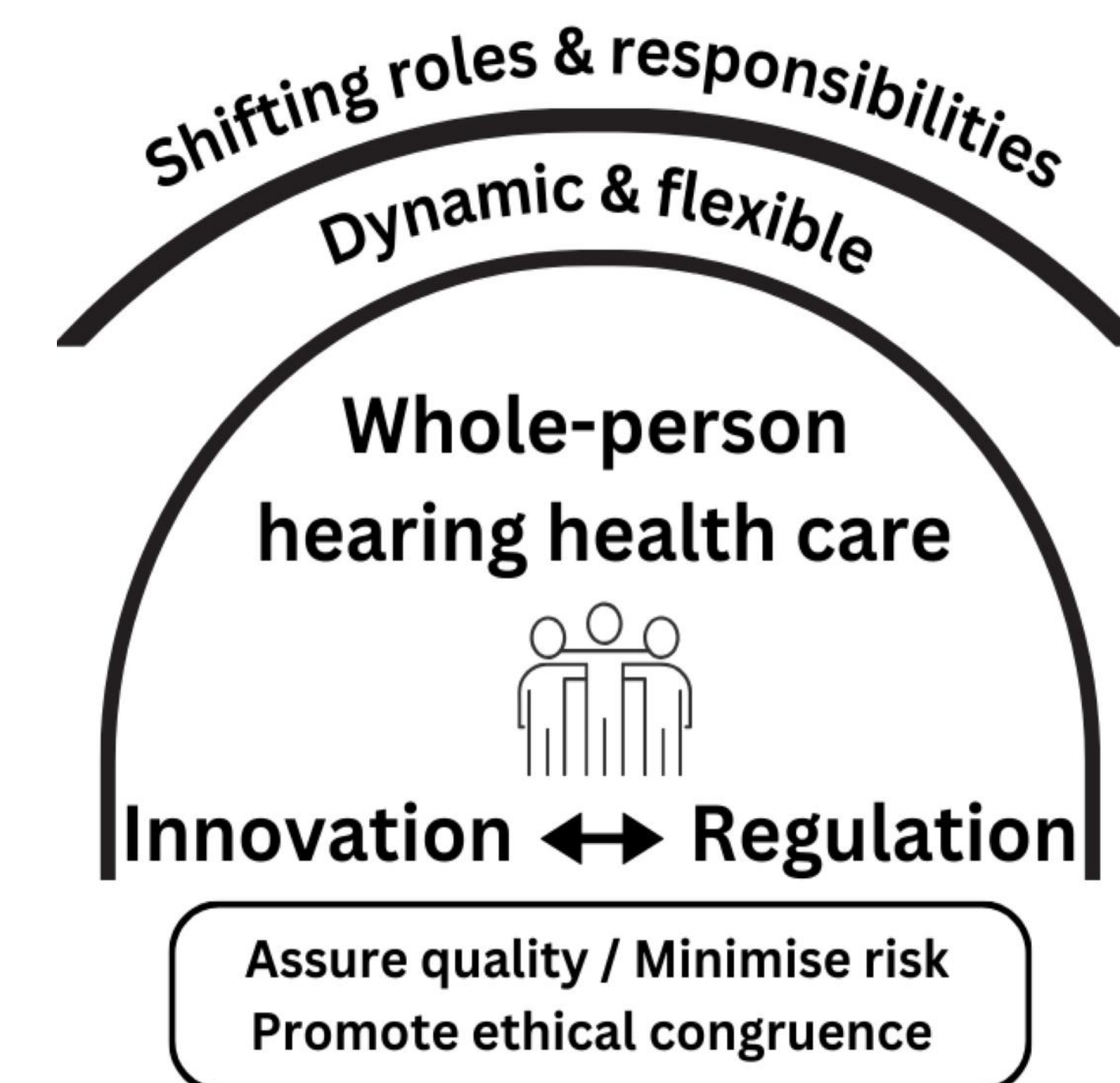
<sup>5</sup>Braun V, Clarke V. *Reflecting on reflexive thematic analysis*. Qual Res Sport Exerc Health 2019; 11(4):589-597.

## Results

We identified **three broad themes** in the data (Table 1). Participant discussions provided a **holistic conceptualisation** of innovation and regulation in the hearing health sector. Across the themes was an emphasis on the importance of **person-centred hearing care** (Table 1 and Figure 1).

**Table 1:** Themes and subthemes describing stakeholder perspectives of innovation and regulation in hearing health care.

Theme:	Subthemes:
<b>Conceptualising regulation &amp; innovation</b>	Innovation and regulation is about more than technology
	Quality and risk: drivers of innovation and regulation
	Perception of regulation as context dependent
<b>Ethical congruence between innovation, regulation &amp; societal values</b>	A desire for:
	consumer involvement at every stage of innovation and regulation
	innovation and regulation to tackle perceptions of stigma
	inclusive, accessible, and ethical hearing health care
<b>Shifting roles &amp; responsibilities</b>	fair and trustworthy business practices
	Shifting the responsibility to consumers
	Shifting the responsibility to product manufacturers
	Navigating the dominance of hearing health manufacturers



**Figure 1:** Summary of findings showing key themes relating to stakeholders' perceptions of innovation and regulation in the hearing health sector

## Conclusion & Recommendations

- Participants viewed regulation and innovation as essential vehicles for **minimising risk** and **ensuring quality** of hearing technology, services, and information.
- To be considered successful, both regulation and innovation require **active involvement from consumers**; be **ethical, equitable and inclusive**; and promote **holistic, fair and trustworthy practices**.
- Further considerations are required to ensure transparent and safe data management and sharing practices, as well as the accessibility of impartial, complete, and evidence-based information about emerging and new innovations.
- These findings serve as a guide for policymakers, regulators, and the industry to create a **more responsive and patient-centred hearing health sector**.