

Briefing

Implementing the governance mechanism for the immunisation system

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To:	Hon Dr Ayesha Verrall, Minister of Health		
Copy to:	Hon Willow-Jean Prime, Associate Minister of Health		
Consulted:	Te Whatu Ora: <input checked="" type="checkbox"/> Te Aka Whai Ora: <input checked="" type="checkbox"/>		

Contact for telephone discussion

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Minister's office to complete:

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|---|------------------------------------|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Decline | <input type="checkbox"/> Noted |
| <input type="checkbox"/> Needs change | <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn | |

Comment:

Implementing the governance mechanism for the immunisation system

Security level: IN CONFIDENCE **Date:** 9 June 2023

To: Hon Dr Ayesha Verrall, Minister of Health

Purpose of report

1. This briefing provides an update on the indicative immunisation governance structure endorsed by Cabinet and seeks your approval to an updated structure before its establishment.
2. This report discloses all relevant information and implications.

Summary

3. Cabinet has approved an indicative governance structure for immunisation that includes a strategic oversight group (the Immunisation Oversight Board), an operational governance group (the Immunisation Outcomes Collective) and a National Immunisation Technical Advisory Group [SWC-22-MIN-0227 refers].
4. Officials propose some amendments to the structure to enable governance that is responsive to public health needs as we shift back towards a business-as-usual approach to immunisation, including COVID-19 vaccines. The amendments include incorporating the functions of the proposed Vaccine Supply and Distribution subcommittee into the Immunisation Outcomes Collective, and shifting the membership of the Oversight Board from Chief Executives to Deputy Chief Executives.
5. The amended structure resolves some ambiguity in the original proposal and clarifies that responsibility for vaccine funding, eligibility and distribution remains with Pharmac, with support and advice from the Outcomes Collective.
6. These changes clarify the Minister's line of sight of the immunisation system.

Recommendations

We recommend you:

- a) **Note** that Cabinet approved an indicative model for immunisation governance in November 2022 [SWC-22-MIN-0227 refers]. **Noted**
- b) **Note** that the Public Health Agency, with the support of Te Whatu Ora, Te Aka Whai Ora, Whaikaha, Medsafe and Pharmac, propose amendments to the indicative model to enable responsive decision-making about immunisation. **Noted**

- c) **Note** that the governance structure will continue to evolve as the system embeds its operating model and will prioritise work that embeds and reflects partnership with Māori and enables greater collaboration, co-design and shared ownership across our communities. **Noted**
- d) **Agree** to the establishment of the Immunisation Oversight Board. **Yes/No**
- e) **Agree** to the establishment of the Immunisation Outcomes Collective. **Yes/No**
- f) **Note** that responsibility for National Immunisation Schedule vaccine funding and eligibility remains with Pharmac, with the support and advice of the Immunisation Outcomes Collective. **Noted**
- g) **Note** that agencies will update the 2012 MOU to reflect the changes to health agencies and their roles as a result of the health reforms. **Noted**
- h) **Note** that advice on future eligibility decisions and funding for COVID-19 vaccine purchases has been provided separately [H2023024109 refers]. **Noted**



Dr Diana Sarfati

Director-General of Health

Te Tumu Whakarae mō te Hauora

Manatū Hauora

Date: 09 June 2023



Dr Andrew Old

Deputy Director-General

Public Health Agency

Te Pou Hauora Tūmatanui

Manatū Hauora

Date: 12 June 2023



Sarah Fitt

Chief Executive

Pharmac

Date: 7 June 2023



Ben O'Meara

Deputy Chief Executive, Policy Strategy and Partnership

Whaikaha

Hon Dr Ayesha Verrall

Minister of Health

Date:



Dr Nick Chamberlain

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Te Whatu Ora – Health New Zealand

Date: 6 June 2023



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Date: 13 June 2023

Implementing the governance mechanism for the immunisation system

Context

There is an existing MoU between the Ministry of Health and Pharmac

1. In 2011 Cabinet agreed that, from 1 July 2012, responsibility for the prioritisation, purchasing and determining eligibility for funded vaccines would be transferred from Manatū Hauora (the Ministry of Health) to Pharmac [SOC Min (12) 10.4 refers]. The Ministry retained responsibility for the implementation of the National Immunisation Programme (the Programme) and District Health Boards (DHBs) were responsible for delivery of vaccination services and managing and funding local outbreaks.
2. Pharmac, DHBs and the Ministry signed a Memorandum of Understanding (the 2012 MOU)¹ to record and agree the different parties' roles and responsibilities.

Health reforms

3. The Pae Ora (Healthy Futures) Act 2022 made significant changes to New Zealand's health system, replacing and supplementing many of the agencies involved in delivering immunisation services from 1 July 2022.
4. Te Whatu Ora, Te Aka Whai Ora and Pharmac as Crown entities have a degree of independence from Ministers in how they deliver a range of government services. Any new arrangement established for supporting cross agency decision-making for immunisation is subject to the statutory responsibilities of each member agency.

Immunisation

5. In 2022 Cabinet agreed to establish a cross-agency governance mechanism for the immunisation system to support the Programme in Te Whatu Ora to achieve its strategic priorities [SWC-22-MIN-0227 refers].
6. Cabinet further noted that the governance mechanism would need to evolve as the system embeds its operating model and to prioritise work that embeds and reflects partnership with Māori and enable greater collaboration, codesign and shared ownership across our communities.
7. Cabinet also agreed to transfer responsibility for COVID-19 vaccine purchasing and management advice to Pharmac [SWC-22-MIN-0092 refers]. It agreed that Pharmac would work collectively with other health agencies in undertaking its COVID-19 responsibilities.

¹ <https://pharmac.govt.nz/assets/2014-09-12-FINAL-Vaccines-MOU-between-PHARMAC-DHBs-and-the-MoH.pdf>

There is a need for clear governance and accountability for the immunisation system

8. To support the Programme in Te Whatu Ora to achieve the strategic priorities for COVID-19 (as well as wider immunisation goals) within a new health system, Cabinet agreed to establish a governance mechanism for immunisation.
9. The proposed governance mechanism endorsed by Cabinet included:
 - a. an Immunisation Oversight Board of Chief Executives,
 - b. a subcommittee of the Immunisation Oversight Board (focused on vaccine supply and distribution),
 - c. an Immunisation Outcomes Collective that directs activities and manages implementation, and
 - d. an Immunisation Technical Advisory Group that provides cohesive and robust advice across all aspects of immunisation.
10. Figure 1 below provides an overview of the indicative governance mechanism as initially considered by Cabinet.

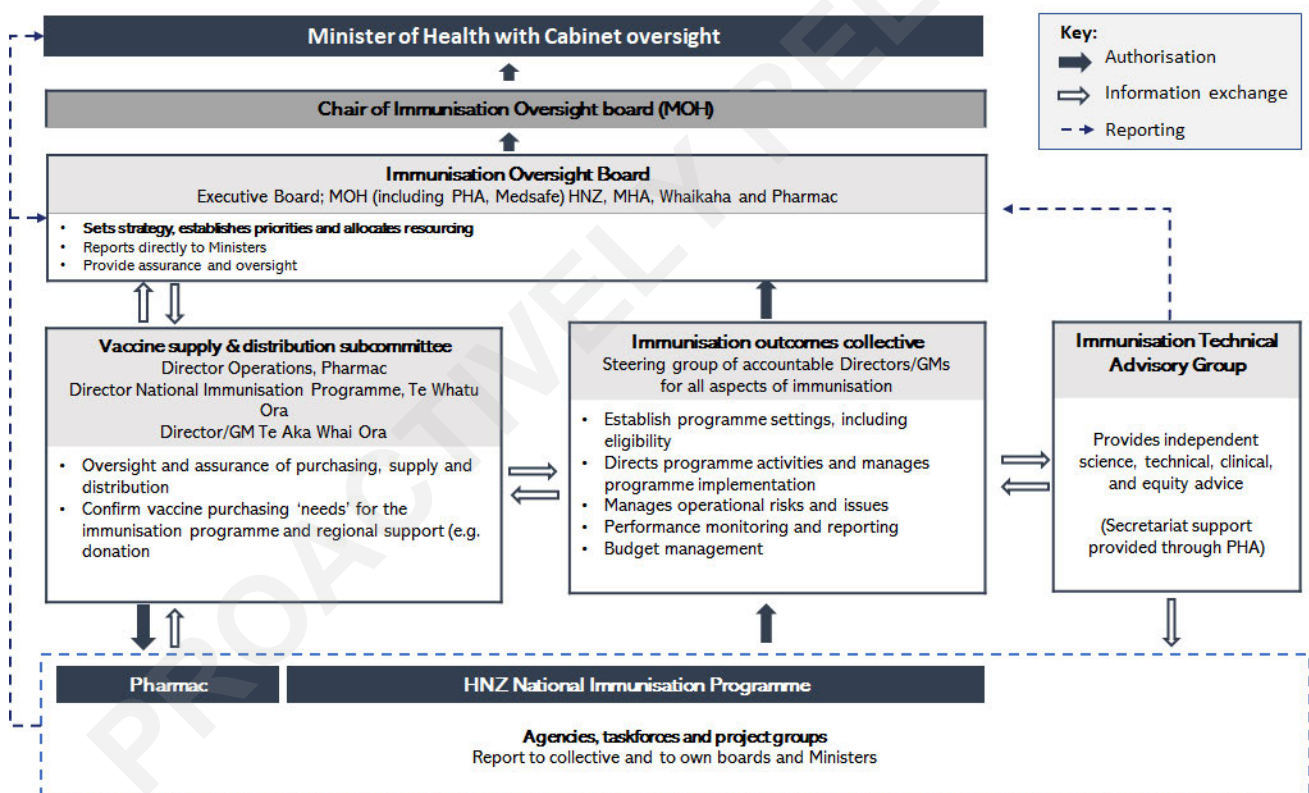


Figure 1. Governance and accountability for immunisation

11. The indicative governance structure outlined in Figure 1 aims to involve various parts of the health sector in decision-making processes relevant to the successful implementation of the Programme. It further aims to improve visibility and communications between officials and Ministers.
12. The Public Health Agency Te Pou Hauora Tūmatanui (the PHA) has worked with Te Whatu Ora, Te Aka Whai Ora, Pharmac, Whaikaha and Medsafe to determine how best

to implement a final immunisation governance structure that supports Cabinet's decision.

Opportunities to revise and improve the immunisation governance structure for final implementation

13. Following consultations with Te Whatu Ora, Te Aka Whai Ora, Pharmac, Whaikaha and Medsafe, and informed by decision-making processes over recent months regarding bivalent COVID-19 and mpox vaccines, we have identified opportunities to revise and improve the indicative structure in line with its original objectives. These amendments will enable governance that is responsive to our public health needs as we shift back towards a business-as-usual approach to immunisation.
14. The revised structure is presented in Figure 2 below. The changes are:
 - a. the Immunisation Governance Board is now at Deputy Chief Executive level;
 - b. the Immunisation Outcomes Collective has merged with the Vaccine Supply and Distribution subcommittee.
15. The revised structure maintains Ministerial oversight over the strategic direction of the immunisation system Programme and reduces the need for direct Ministerial involvement in operational decisions.

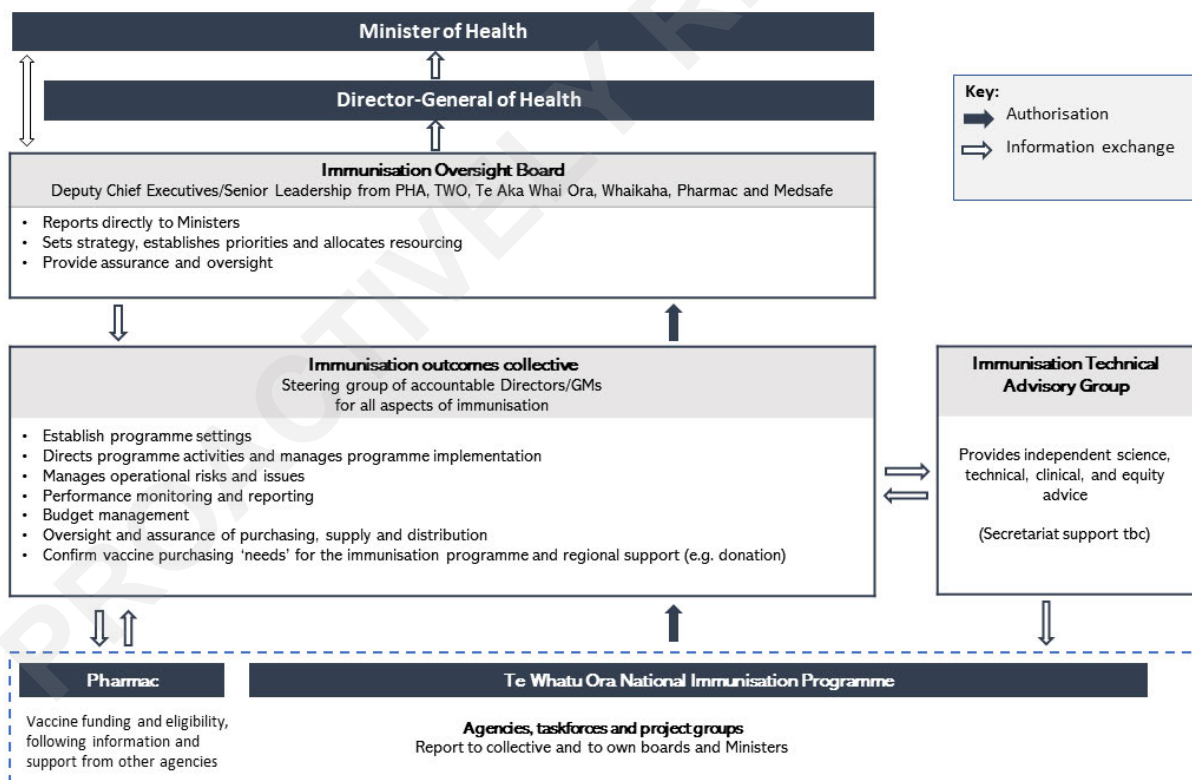


Figure 2: Revised governance structure

Strategic governance will remain under the Immunisation Oversight Board

16. The Immunisation Oversight Board (the Board) will be responsible for strategic governance.

17. The Chair of the Board will be the Deputy Director-General (DDG) of the PHA and will be the principal point of contact between Ministers and officials on immunisation issues. The Board will consist of the PHA, Te Whatu Ora, Te Aka Whai Ora, Whaikaha, Pharmac and Medsafe, mainly at the DDG (or equivalent Tier 2 staff) level.
18. Medsafe and Pharmac should be represented at this level as the regulatory system and procurement and funding functions can be pivotal to strategic decisions.
19. **Appendix 1** sets out the proposed roles and responsibilities of the various health agencies and new governance bodies. The Terms of Reference will set out the Board's purpose and functions in detail, which will include approval and accountability of the immunisation strategy that is currently in development, and setting priorities.

The Immunisation Outcomes Collective will focus on operational governance including oversight of supply and distribution

20. The Immunisation Outcomes Collective (the "Outcomes Collective") will exercise operational governance over the immunisation Programme. It will also be able to co-ordinate health agency advice to Pharmac to support Pharmac's decision-making on vaccine funding and eligibility, implement recommendations of the Immunisation Taskforce report and ensure whānau voice is incorporated into decisions.
21. The Outcomes Collective will primarily consist of senior managers involved across the immunisation system from the PHA, Te Whatu Ora, Te Aka Whai Ora, Whaikaha, Pharmac and Medsafe.
22. Forecasting demand and managing supply of COVID-19 and mpox vaccines has strengthened the working relationships between Pharmac, Te Whatu Ora and other health agencies. Based on our experiences working together, we consider governance over vaccine supply and distribution will be better managed through the Outcomes Collective instead of creating a separate subcommittee relating to vaccine supply. This reinforces the intention to maintain oversight of the immunisation system and ensures a more efficient and streamlined process.

Pharmac will continue with vaccine funding and eligibility (including COVID-19)

23. Pharmac currently makes decisions on the funding and eligibility for almost all vaccines, as it does with other publicly funded medicines, independent of Ministers, and vaccines are funded out of the Combined Pharmaceutical Budget. The exception to this is COVID-19 vaccines and some other vaccines purchased in response to national outbreaks.
24. Manatū Hauora has developed separate advice [H2023024109 refers] on changes to funding streams and decisions for future COVID-19 vaccine purchasing by Pharmac. The changes to the governance structure will complement that proposal.

Outbreak response vaccines

25. The 2012 MOU did not explicitly assign responsibility for national outbreak responses, noting that Pharmac would "discuss with the Ministry of Health and affected DHBs any proposed vaccine response to localised and national outbreaks of disease, and pre-pandemic preparedness". Such discussions have taken place to manage outbreak responses or late influenza season demand, for example measles and influenza in 2019.

26. Pharmac has indicated that as its funding model works best for long term investment decisions in vaccines, its preference is for significant outbreak responses to continue to be funded outside of the Combined Pharmaceutical Budget.
27. As the MOU will need to be updated to reflect the changes to health agencies as a result of the health reforms, we propose that its revision can clarify Te Whatu Ora's responsibilities for national and local outbreak responses. Pharmac's responsibilities under an updated MOU would be unchanged.

National Immunisation Technical Advisory Group (NITAG)

28. NITAGs are multidisciplinary bodies of national experts, recommended by the World Health Organization, that provide evidence-based recommendations to policy-makers and immunisation programme managers. Health agencies are working together to consider the Terms of Reference for a NITAG and in the interim, the PHA will continue to seek expert advice on issues as they emerge.

Te Tiriti o Waitangi

29. The new governance structure is an opportunity to enable Māori to exercise their rights and interests in regard to immunisation for Māori communities, and ensure that the immunisation programme can deliver its services in a Tiriti compliant and equitable way. It will be a priority for the new governance mechanism to partner and codesign with Māori at all levels of the immunisation system (including at a governance level) as work progresses towards a National Immunisation Strategy.

Equity

30. Equity is the core principle of the Pae Ora (Healthy Futures) Act 2022. Health inequities are unfair, avoidable, and remediable. To achieve health equity, health outcomes need to be consistent for all population groups in New Zealand. The proposed governance structure can support partnership by ensuring participation by Māori and Pacific peoples and other communities experiencing immunisation related health inequities in all decisions and be included at the decision-making table. Further specific details on the importance of the governance system for the different cohorts are provided in **Appendix 2** below.

Next steps

31. Following your consideration of this paper, officials will set up the Oversight Board and Outcomes Collective, and develop Terms of Reference for each group. The Terms of Reference will provide for the groups' continued evolution as the agencies settle into their roles and develop their strategic planning.

ENDS.

Appendix 1: Future roles and responsibilities

Role	Responsibility
Minister of Health	Approves targets for immunisation, overarching Health budget (in consultation with Cabinet). Kept informed on key immunisations matters.
Director-General of Health	Signs off on major decisions within Manatū Hauora's responsibility, including those needing Ministerial approval, kept informed of key immunisation matters.
Immunisation Oversight Board	Provides senior level leadership to allow for a clear steer on strategic issues and risks across the immunisation programme. Signs off on the National Immunisation Strategy, point of contact for Minister and Director-General of Health.
Immunisation Outcomes Collective	Signs off on advice to be presented to Oversight Board, co-ordinates decision-making on significant operational changes or matters that require a co-ordinated response across agencies. Provides advice to Pharmac to support Pharmac's decision-making on vaccine funding and eligibility.
Pharmac	Decides on funding, including setting the eligibility, for all publicly funded vaccines (excluding new vaccines, not already funded in New Zealand, needed to respond to an outbreak).
Public Health Agency	Provides systems leadership across the public health sector; and advises the Director-General on matters relating to public health, including (i) personal health matters relating to public health; and (ii) regulatory and strategic matters relating to public health. Includes the following units (among others): Pacific Health Hauora Māori Tūmatanui Office of the Director of Public Health Policy and Regulation Global health
Manatū Hauora –Te Pou Hauora Māori	As the chief steward for Māori health, Te Pou Hauora Māori will provide support to ensure that as a Ministry we are meeting our obligations under Te Tiriti o Waitangi.
Te Whatu Ora - National Public Health Service	Ensures effective and equitable operationalisation of immunisation programs through collaboration with Districts, providers, community organisations and relevant stakeholders. Engages in

	surveillance, outbreak response, education and health promotion; to provide a robust and efficient immunisation system.
Te Whatu Ora National Immunisation Programme/Prevention	Leads funding of vaccine administration and implementation of immunisation programs including sector and community engagement, service delivery, operations, quality, clinical, safety and major project delivery. Coordinates information technology, communications, and equity functions.
Te Whatu Ora Board	Decides on funding and eligibility for national and local outbreak response vaccination campaigns.
Te Aka Whai Ora	<p>Directs and guides the immunisation programme to understand and respond to needs of whānau Māori.</p> <p>When new services are commissioned or existing services are reviewed, Te Aka Whai Ora will partner with Te Whatu Ora to make sure service design and priorities reflect the diverse needs of the community, including for Māori.</p> <p>When services are not performing for Māori, Te Aka Whai Ora and Te Whatu Ora will ensure the issues are quickly identified, and drive service and system improvement.</p> <p>Te Aka Whai Ora will have a special role in partnering in the development of the strategy, advocating for tino rangatiratanga for Māori.</p>
Whaikaha	Ensures that the Immunisation Programme takes the rights and needs of disabled people/tāngata Whaikaha into account, and provides a strong voice across government to ensure that disabled people are front-of-mind in the development of the National Immunisation Strategy.
Medsafe	Regulates therapeutic products in New Zealand. Ensures that vaccines meet acceptable standards of safety, quality and efficacy. Gives pre-market approval and conducts post-market surveillance.
National Immunisation Technical Advisory Group (NITAG)	Provides technical expert advice to support decisions on immunisation.
Pharmac Immunisation Specialist Advisory Committee (ISAC)	Provides objective clinical advice and recommendations to Pharmac (on any matters referred to it by Pharmac) to support immunisation funding and eligibility decision-making, including category management for vaccines.

Appendix 2: Equity

Māori

32. Māori have the poorest health status of any ethnic group in Aotearoa New Zealand and also the lowest immunisation rates. Māori experience poorer health outcomes, exhibit lower life expectancy than other ethnic groups and are most affected by inequities. Māori experience significant barriers to accessing general practice and this is a major contribution to the ethnic inequalities in the immunisation system. Co-design has a strong track record for delivering good immunisation rates over the COVID-19 programme, and will be essential to redesigning an equitable immunisation system as part of our future discussions on strategy.

Pacific Peoples

33. Pacific peoples are most affected by inequities in the distribution of the socioeconomic determinants of health. Insights from the Pacific community indicate that many feel they do not have the information they need to make a fully informed decision about immunisation. This is not due to a lack of information, but rather an abundance of complex or conflicting information (particularly online) which can be overwhelming to decipher. Community elders and leaders are felt to have more legitimacy and authority to communicate information about immunisation and wellbeing.
34. The Pacific Health Directorate within the PHA will also be represented within the proposed governance system particularly in the Board, Outcomes Collective and also on NITAG.

Disabled people (tāngata whaikaha)

35. Disabled people represent almost a quarter of the population and remain worse off than non-disabled people across all social and economic outcomes. The current health system does not work for disabled people who experience many inequities when accessing health services, including poorer health outcomes compared with non-disabled people. Inequities in access to health care are particularly intensified for Māori disabled people, Pacific people with disabilities and disabled people who experience other forms of intersectional marginalisation.
36. There is a general lack of data about the health of disabled people that makes it difficult to evaluate the extent to which disabled New Zealanders, including disabled women, are currently experiencing poorer health than the rest of the population. Without any historic efforts to collect disability data, the voices, experiences and health outcomes of disabled people are not reflected in health system priorities, policies or accountabilities. The proposed governance structure aims to facilitate better representation and needs.
37. This historic ableism and “invisibility” of disabled people in the health system has caused significant inequities in timely and appropriate access to immunisations and other interventions, despite being named as a priority group. Emphasis in the immunisation system remains on non-disabling, removing barriers and ensuring a more meaningful ‘enabling’ system that help disabled people get around barriers
38. Whaikaha, as an agency, will play a key role in identifying opportunities to improve consultation and engagement with disabled people.