

Māori Relevant Themes in the Enhancing Clinical Trials Project

iNZight Analytics

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Background and Approach

We were provided with a range of documents from the Enhancing Clinical Trials research project. All documents were read by a Māori mixed-methods researcher with an eye to extracting the common themes, including the issues/barriers and the solutions or suggestions from participants at various phases of the research. Some of the types of data and documents lend themselves more to an issue and suggestion format, whereas others lead to just simple themes. The process varied depending on the types of the data i.e. the interview and World Café notes were richer data sources than the survey.

The themes, divided into issues and suggestions are summarised in the table below. This report is divided into two sections: (1) Māori Researchers' Views and (2) Māori Themes in the Overall Project. Within these sections there are subsections for the different data and documents that fall under these broader streams. At all phases of the description, we have quoted material directly with quotation marks and attempted to credit the original report/source so readers can see where the ideas were drawn from. Both of the report sections start with a summary of the findings. At the final draft stage, we reported the findings to the Māori rōpu, who provided comments (reported on at the end of [section 1.1.2](#)).

Table 1 (below) provides a high-level overview of the themes that appear in the different data, and [sections 1.1.1](#) and [1.2.1](#) provide a summary for readers of the themes from Māori researchers' data and the overall project, respectively.

Part 2 presents additional deep dive analyses. The task was re-reading and revisiting data on the following two points:

- Workforce needs: Recruitment and retention
- Māori view of clinical trials: Outlining where clinical trials fit in with the broader Māori health view, including a rongoā perspective.

Part 2 of the report starts with summaries of both areas and then moves on to data-source specific notes on each topic area.

Table 1. An overview of the Māori-relevant themes and the recommendations from the Enhancing Clinical Trials project, including feedback from the Māori advisory rōpū (third column).

Prioritised Theme	Prioritised Recommendations	Feedback
<p>Māori Workforce Related</p> <ul style="list-style-type: none"> • Substantial Māori workforce development (investment) is needed • There are only a few highly-skilled (in terms of general research skills <i>and</i> Te Ao Māori) and overcommitted Māori researchers • There are barriers for Māori students, postgraduate students, and early career researchers to join the workforce (there is a pipeline problem) • Other Māori, supportive work arrangements, collaborations, and close allies help Māori researchers 	<ul style="list-style-type: none"> • Proper, sustained funding for Māori early career researchers (that has competitive-enough pay rates) • Māori cultural advisor roles, paid, and resourced help current researchers resist the “cultural double shift” • Mentoring programmes are needed, but there is a need to balance this with the time constraints for busy researchers • Consider pathways at all stages from secondary education onwards through to research • Māori researchers need cultural development; workforce development needs to recognise Māori are diverse • Networks consistently mentioned; a Māori-specific network could help, but needs proper resourcing (not another responsibility for those currently overworked) 	<ul style="list-style-type: none"> • Network of Māori researchers would be quick win • I decided the prioritisation of cultural advisors makes sense, that’s the cadre from which the workforce follows. • Avoid “maybe” words like consideration – prefer definite action words – in this case, “creation of pathways” would work better. • Re mentoring programmes, although there are time constraints on busy researchers, the balance should not be made at the expense of the mentoring programmes – the time constrains should be balanced against something else. E.g. there should be admin support for the busy researchers. • I’d be more definite and say that a Māori-specific network will help. • I’d universalise and say all Māori researchers need cultural development. I see learning for life as normalised within Te Ao Māori. • Māori health workforce has been on the Māori health agenda for over 50 years. It is time for action!! • A multifaceted intersectoral approach would be useful, health, education, MBIE • I originally gave this (theme) a ‘1’ but whanau/hapū/iwi safety is more important to me

		<ul style="list-style-type: none"> • First equal with partnership with Māori. Unless you have trusted, skilled, Māori research leaders the engagement with communities is not optimal. • Support and sustain existing Māori researchers, including emerging researchers. Then develop pathways, mentoring programmes and networks.
<p>Partnership with Māori</p> <ul style="list-style-type: none"> • Any new infrastructure and the Independent Māori Health Authority provide an opportunity for partnership with Māori and to embed Te Tiriti o Waitangi • Māori control needs to be central to the research questions, methodology, and data • Māori participant recruitment is often not accounted for; Māori are less likely to participate in clinical trials • Tensions in the framing and scope of any work: is it a case of how Māori fit within clinical trials <i>or</i> about how clinical trials best meet the needs of Māori? • Researchers are developing the abilities to alter their methods/methodologies to be more responsive to Māori; they need to keep working on this • Greater Māori leadership and governance is needed to ensure “Māori responsiveness” 	<ul style="list-style-type: none"> • Need Māori roles within governance structures or Māori governance structures • Attend to workforce issues, mentioned above to ensure there are sufficient Māori kaimahi and leaders • Consider Māori rights and needs (partnership) at every step of project formation • More resources (financial, people) are needed to ensure sufficient recruitment for reasonable numbers of Māori participants in clinical trials; need to oversample Māori • Researchers are engaging in measures at a level that could seem tokenistic e.g., translating cover letters, offering karakia, but these are good steps and appreciated by some; more of this • Researchers need to plan for sufficient explanatory power for Māori participants 	<ul style="list-style-type: none"> • These are critical but likely to take longer to establish • I’d go further and say 50:50 Māori in governance structures, for consistency with Te Tiriti o Waitangi. • I’d remove the text about tokenistic – it’s an editorial comment. • The “Consider Māori rights and needs (partnership) at every step of project formation” begs the question of who is doing the considering – it needs to be the 50:50 Governance structure, ideally including strong community representation. • Māori governance models exist in the clinical trial setting. We need to fund and grow these. • Compliance with Tiriti o Waitangi is number one consideration. All others flow from this. If this isn’t number one, then there is the risk that other objectives will be met in a way that is leading to Māori being seen to be enablers only of the process, and not leading it. I don’t have a preferred priority for the others as they are all important if Tiriti compliance is to be achieved, alongside a range of others eg ensuring Māori tinorangatiratanga and mana motuhake, belief, values and tikanga are upheld – these are not options or priorities, they are a ‘must do’ thus can’t be seen to be less than another priority.

		<ul style="list-style-type: none"> • It is imperative that research is authentic to enable ownership by Māori. This ensures a win-win for all -meaningful and transformative research. • High importance on governance structures, workforce issues, then project issues (rights and needs), Māori participants, researcher activities
<p>Research Methods/Methodologies</p> <ul style="list-style-type: none"> • The data talked about where clinical trials may engage in culturally inappropriate practices for Māori, but also places where methods were developing (i.e., there are specific needs for Māori samples) • Better physical spaces are needed within communities, that are more culturally suitable • The measures and tools used in trials are not appropriate or accurate for Māori 	<ul style="list-style-type: none"> • More Māori-led research work on making clinical trials (and research generally), responsive to Māori • Need to design work that Māori want to participate in (seek Māori input, design, and feedback) • Develop resources across areas of need and make them standard, and a standard requirement across the workforce • Co-locate researchers in communities; develop spaces where Māori participants and whānau are comfortable 	<ul style="list-style-type: none"> • Co-location is not just for the researchers, but also for the Governance. • I have scored this (theme) a ‘1’ because it is an ethical and whanau/hapū/iwi safety issue. • Clinical trials focus, co-locate researchers, design, dev resources
<p>Data Systems</p> <ul style="list-style-type: none"> • There were multiple suggestions in the data around how to build a system • Concerns were raised about open-access data, data being stored overseas, and other areas where there may be data sovereignty issues • The tikanga for storing Māori samples and data is different to tauwi norms 	<ul style="list-style-type: none"> • In building infrastructure there is a need to embed Māori data sovereignty; systems and processes need to be developed • Create a national code for data sovereignty and guidelines around tikanga 	<ul style="list-style-type: none"> • Te Mana Rauranga is the Māori Data Sovereignty framework I know of. https://www.temanararaunga.maori.nz/ • We are moving slowly toward this. However, there are many gaps and lack of consistency within existing ministerial ethical systems that need addressing. These need to be fixed. Māori tissue and data portals are required that enable iwi/Māori researcher access.

	<ul style="list-style-type: none"> • Researchers need training on Māori data sovereignty; including through consistent, standardised resources, case studies, and examples in clinical trials research 	<ul style="list-style-type: none"> • Again, whilst it is essential data is used/stored/translated appropriately, if highly skilled Māori researchers and suitably resourced communities are co-creating research, data sovereignty should not be an issue. This would be covered. • Agreed prioritisation
<p>Knowledge Translation and Implementation</p> <ul style="list-style-type: none"> • There is insufficient researcher and funder engagement in knowledge translation. This is a particular issue for Māori, given the extractive nature of research, the need to tailor results for Māori providers, and a need to show participants reasons to participate 	<ul style="list-style-type: none"> • Include knowledge translation specific roles in the infrastructure, but these roles need to be Māori-specific too • Incentivise. Build in the need for researchers to have to consider the implications of their results for Māori communities (and base this at the output level, rather than just the grant/initial level) • Knowledge translation needs to be planned at the start of the research with end-users 	<ul style="list-style-type: none"> • Knowledge transfer relates to the number of studies that exist that have already provided evidence for changes in the health sector that would improve Māori health. Implementing the findings from earlier studies could save millions of health and research dollars. Not doing so is an example of health system procrastination. • Agreed prioritisation
<p>Funding and Timelines</p> <ul style="list-style-type: none"> • The funding available is not sufficient – it does not cover a long enough period to allow for job security for (Māori) researchers or for sustained engagement with Māori communities. • Meaning, the workforce misses out on talented Māori researchers and there are 	<ul style="list-style-type: none"> • Longer term funding is needed to ensure timelines align with Māori community needs/rights/researcher obligations to people • Researchers within institutions (e.g., universities) need to be trusted with their own budgets and timelines • Practically, there needs to be a budget for miscellaneous expenses 	<ul style="list-style-type: none"> • I agree with this comment. However, I think it is funding in general. • Agreed prioritisation

<p>issues where the needs of communities are not met (Māori engagement, community awareness of participation)</p> <ul style="list-style-type: none"> • A focus on longer time periods and resourcing is needed to engage Māori communities 	<p>that does not cause administrative barriers for Māori researchers (e.g., tyres for a research assistant were mentioned, bringing kai easily)</p>	
<p>Taiwi Workforce Related</p> <ul style="list-style-type: none"> • While there is some engagement, taiwi would like more training and support around Kaupapa Māori methodologies, data sovereignty and other cultural upskilling • Racism is <i>still</i> a problem for Māori researchers, participants, and communities 	<ul style="list-style-type: none"> • The system needs to incentivise being a good treaty partner, and help to develop good allies • The two highest rated areas where (all) survey participants wanted more support was in Kaupapa Māori methodologies and in Māori data sovereignty; training is needed • Consider how to operationalise cultural safety; there was a suggestion of micro-credentials or certifying people as safe to work with Māori (and Pasifika) 	<ul style="list-style-type: none"> • Micro-credentialling would be a good quick win • Just say “The system” • Just say “Need to operationalise cultural safety”. Consideration of how to do this is a first step in doing this. • Regarding micro-credentials, I’d re-frame this as what are the tohu from a Māori perspective. Whanaungatanga is a good start. Especially if there is a marae. • I think addressing racism will go a long way in addressing most if not all of the health limitations that exist for Māori. I scored it ‘7’ because I view it as a Pākehā responsibility • Whilst it is critical that non-Māori are ‘good’ te Tiriti partners, if Māori researchers and Māori communities/participants are given the appropriate tools and prominence, they will collaborate with Taiwi as necessary/suitable to achieve the best outcomes for all. • Impact taiwi in higher numbers first to be culturally safe

1 Māori Researchers' Views

1.1.1 Summary of Māori Researcher Related Themes

The following section provides a brief introduction and summary of the following sections and data. All of the theme names (featured in later sections) are in **bold**.

Themes from the April minutes of the Māori Rōpu suggest that it is important to distinguish between the levels of scope and the framing or problem definition phase of projects, for instance, **is this project a case of how Māori fit within clinical trials or about how clinical trials best meet the needs of Māori?** While there are issues at both levels, it is important to keep this in mind throughout. The Māori Rōpu also suggest that **Māori workforce development is needed** and that there are **inequities in funding**. The Māori Rōpu met again in September with issues and recommendations in mind, and suggested that **better physical spaces are needed for clinical trials, substantial investment in the workforce is needed, greater Māori leadership and governance are needed to ensure “Māori responsiveness”, Māori data sovereignty systems and processes need to be developed, alongside a focus on longer time periods and resourcing which is needed to engage Māori communities.**

The survey of Māori researchers (n=9) suggested that **Māori researchers undertake a broad range of duties** including everything from Māori cultural kaupapa through to general design and analysis. Their responses suggested that **other Māori, supportive work arrangements, and close allies help Māori researchers**, and that generally their comments suggest that **time, resources, and racism are barriers to effective clinical trials**.

The transcripts or notes were provided from six interviews with Māori working in the space. Their kōrero suggested that **collaboration and networking helps** with their work, but that further **Māori workforce development is crucial**, and within that there is a need to **recognise that Māori are diverse**. Their experiences led them to suggestions around the idea that **Māori control needs to be central to the research questions, methodology, and data**. However, when Māori do lead projects they suggest that **Māori researchers need more funding, but also need to be trusted with their own budgets and timelines**. Other barriers include the fact that interviews say that **Māori researchers experience racism**. Generally, the Māori researchers reflected that **knowledge translation need to improve and researchers need to make research resources more culturally suitable**. Some had hope for the future as **the new health system structure presents opportunities**.

1.1.2 Māori Rōpu

Provided with the terms of reference, agendas, information packs, and hui minutes. This section includes relevant content from the April and September meeting minutes.

The terms of reference for the ropu (approx. 10 members):

“The Māori Advisory Team will validate and help support project work coming out of the Enhancing NZ Clinical Trials project. At regular intervals, the team will help review workstream outputs. Key activities of the team include:

- Providing advice and guidance on project workstreams outputs to ensure that recommendations align with principles of Te Tiriti o Waitangi, with final recommendations contributing to Māori health advancement
- Promoting and engaging support for the Enhancing New Zealand's Clinical Trials project within Iwi, hapū, Māori networks, and other relevant organisations; this may include initiating conversations between the respective organisation(s) and the project workstream(s)”

April Meeting Minutes

Is it a Case of how Māori fit within Clinical Trials or about how Clinical Trials Best Meet the Needs of Māori?

Issue: A number of points were made around Māori inclusion in clinical trials, from various gestures – such as use of te reo/tikanga through to involving Iwi more.

It was suggested in the minutes that the Māori perspective is broader than what is captured within the idea of clinical trials. This relates to broader ideas around health and well-being. The rōpu raised concerns that distinctions between e.g., drug trials and public health interventions does not fit well with Māori thinking.

The rōpu highlighted the following areas for investigation:

- “How involved are Māori participants in clinical trials?”
- Informed consent –it does not consider cultural perspective on risks and benefits
- Use of tikanga
- Research question prioritisation - looking at what is supported
- Kaitiaki around what happens with the data.”

The rōpu also discussed the use of te reo Māori in consent process for Māori participants.

Suggestion: Only so much is possible within the current project. The rōpu suggested future work more heavily involving Māori as i.e., Iwi engagement was not possible within the 15 months of the project. Further work is needed to move to a different, more Māori-centered scope, and be able to focus on deeper issues like helping Māori to fit within clinical trials versus how to redesign the idea of clinical trials to best meet the needs of Māori.

Māori Workforce Development is Needed

Issue: The meeting minutes highlight the need for workforce development for Māori.

Inequities in Funding

Issue: Concerns around funding were raised – i.e., people may choose to pursue clinical trials funding if they were better funded, rather than prevention type research which arguably impacts Māori more.

September Meeting Minutes

The September meeting minutes related to a specific aim/agenda: “The aim ... is to develop options for infrastructure to support Māori researchers and patients to participate in clinical trials in NZ.” This meant that the rōpu provided multiple practical suggestions.

Better Physical Spaces are Needed for Clinical Trials

Issue: The notes include this well-put quote: “Infrastructure includes both human relationships and physical objects (e.g., brick and mortar, civil engineers, architecture) – as both shape behaviour”. The current physical spaces are a barrier for scientists and clinicians to collaborate.

Suggestion: There needs to be better connections between scientists and the communities, including scientists being located within the community/the workforce being physically located there. More specific suggestions came through in the notes: “Need for more wharenui connection between scientists and the community. It is important to have a connection with the community, especially to be able to identify priorities and what works”; “Mara has been influential with the Iwi Māori Partnership Board, tribal governance, and setting up epi-centers”. Physical spaces are needed that are more inclusive and community based.

Substantial Investment in the Workforce is needed

Issues: The rōpu raised issues with Māori workforce development. At the meeting, they estimated that 4% of the workforce is Māori.

Suggestions: Workforce development has to take a long-term approach: “Short-term: can point to best practice; need to move from “ticking” the Māori box exercise to doing best practice.” Although, micro credentials may be a short-term way forward. The rōpu noted the need for the universities “to get their act together around this,” as they are hard to work with.

There needs to be better pay and resourcing throughout, as people leave due to pay and workload. Scholarships along the way would help too and offering a salary supplement or salary to do a PhD. There has to be a clearer/mapped out career pathway for people and succession planning.

It may be that bringing in community workers helps with Māori workforce development, but this development needs resources too. The rōpu suggested the need for “An opportunity for Māori RN PhDs to continue working and studying with scholarships” They suggested that this would benefit the quality of the work and flow through to different questions and ways of doing things.

Greater Māori Leadership and Governance are Needed to Ensure “Māori Responsiveness”

Issue: Māori responsiveness is needed in data governance and in analysing the data. There needs to be greater iwi/Māori control over data and more authority in that space. There is not enough of a Māori focus in research and not enough Māori involved. The minutes point out that the number of Māori staff may even be decreasing. There are issues in knowledge translation and the ability for many trials to make concrete gains for Māori. Trials need to be designed to put emphasis on the whānau (Māori world view) versus the patient (Western world view).

Suggestion: Leadership and governance are critical for any infrastructure to be implemented appropriately. There also needs to be increased support for Māori organisations to partner/conduct clinical trials. More Māori in the workforce will make whānau Māori feel more accepted, more likely to participate and as they may feel their worldview will be respected.

Māori Data Sovereignty Systems and Processes need to be Developed

Issue: The current data governance models are not sufficient to meet Māori needs. There are also shortages in the workforce in these areas. This cannot be on a university-level as that would create 7 different systems, “creating a burden on governance relationships”.

Suggestions: This is aided by the new health system structure. Discussions around data governance need to be ongoing, especially around intergenerational research. Need iwi oversight on data sovereignty and descent information. The rōpu suggested a single clinical trial data repository for NZ, which would allow Indigenous data sovereignty to be overseen centrally, making it standardised and transparent. There is a need for some entity (the Māori Health Authority was suggested) to facilitate formative VM workshops that are paid for by the universities.

A Focus on Longer Time Periods and Resourcing is Needed to Engage Māori Communities

This issue: There is no awareness of the clinical trials that are happening, the criteria for trials exclude Māori patients, and there is not always sufficient support for them to participate (e.g., through GPs), sometimes “the Māori worldview is different than the scientific view”. The reliance on “key people” for “momentum” in this area is exacerbated by the workforce issues described above.

Suggestion: Funding was raised as an issue – costs are high, funding is not reliable and there is a “one-size-fits-all” model. The rōpu subsequently recommended longer (5 year) grants to support more extended workforce development. If any centralization process is developed it needs to be examined around how it would affect work in communities.

February Online Hui to Review the Draft Report

In February 2022, the Māori rōpu held an online hui to discuss the findings of this report and to add any final themes or recommendations needed for the final report. We presented the findings (largely based on Table 1 of this report to the rōpu; which was updated after the meeting). We took notes, including the following points:

- Presentation gives a lot of hope, positive aspects especially around Māori Health Authority. Research project proposed (what would Kaupapa Māori clinical trials look like?) extremely important to implement.
- Importance on funding, workforce & data systems which group agrees on.
- Creating sufficient data systems: emphasis on creating consistent codes and training which are shared (sharing knowledge; making a standard course of content).
- Engaging Māori in clinical trials is important. Furthermore, could this be extended to: developing kaupapa Māori clinical trials?
- There are a lot of recommendations and actions/resources needed; there is a need to prioritise Table 1 further.
- Not enough resources for Māori researchers, Māori participants, Māori communities.
- The ethics system as not sufficient, or building on precedent (but as Jennifer noted, this is outside of the scope of the initial project).

- The need for good practice to build towards best practice long term. There is a need for a spectrum for people to move towards better – but need to create this without undue burden on anyone. There is also a spectrum of Māori participation from Māori providing advice through to partnering.
- There is a need to reward those who do good things in this space.
- An inbuilt mechanism which protects Māori is needed as well: too easy to create an exercise of ticking the box. Could also be dangerous to incentivise, as this doesn't maintain the integrity needed for Māori responsiveness.
- Researchers seem to be better able to address tikanga and Te Tiriti, but more development is needed in data sovereignty. Māori data sovereignty needs to be better supported in ethics processes/more essential there.
- Resources are needed for Māori data sovereignty – examples of what is possible, how to deal with data, and data management plans. Consistency in practice is important.
- A focus on treaty frames is helpful – but a view of Māori as treaty people rather than treaty partners may be a better goal.
- Implications of results in clinical trials: worth pushing as funding not sufficient. Data coming from multiple projects of under resourcing and under funding. Argument for more funding is very strong throughout other projects too. Linking to translation and implementation, but in an ethnical manner.
- Irene Braithwaite and Vanessa Selak each presented on their experiences in recruiting Māori into clinical trials. Including: partnership with Māori researchers, the need for supportive allies; oversampling and overtargetting Māori participants; costs of 4:1 for recruiting Māori when compared to other participants; and designing research Māori want to participate in.

1.1.3 Survey of Māori researchers

The survey had a low level of participation from Māori researchers. 12 participants identified as Māori researchers (6 PI etc, 2 RN etc, 1 statistician, 0 database or IT, 0 health economists, and 3 “not involved” participants; 4% of the total sample). The main reason for this is likely the underrepresentation of Māori in these fields. The Māori rōpu also discussed that they figured the low response rate will be due to a small workforce to draw from, on top of them being a busy group.

An issue with the survey is that it asked whether someone identified as a “Māori researcher” and then branched Māori-focused questions from there. As “Māori” encompasses a range of identities – whakapapa, ethnicity, culture, research methods, knowledges, ways of life – it may be prudent to simply ask for ethnicity in future work. For example, someone may be Māori, but not identify as doing Māori research, especially when it comes to Western kaupapa like clinical trials: six participants were Māori, but not a Māori researcher, and six identified as Māori but not as Māori researchers.

There were small numbers, but the 9 Māori researchers were asked the following questions (underlined):

Māori Researchers Undertake a Broad Range of Duties

What roles or duties do you undertake as a Māori researcher in clinical trial research? (n=3)

- “Ensure mātauranga Māori is incorporated in our approach to patient experience within the clinical trial.
- That we uphold Te Tiriti o Waitangi in all that we do.
- Study design
- Data analysis
- Co-investigator
- Trial development
- Ethical review process
- Māori governance”

Other Māori, Supportive Work Arrangements, and Close Allies Help Māori Researchers

Tell us what has helped you work as a Māori researcher. (n=3)

- “Leaving the university
- Most importantly, working with other Māori health researchers. This creates a safe space.
- Non-Māori colleagues who: make an effort to increase their knowledge and understanding of Te Tiriti and matauranga Māori; don't take up a seat where Māori should be; support and encourage Māori success (without any personal gain from doing so); don't expect/assume Māori colleagues to know everything about Te Ao Māori; don't expect/assume Māori colleagues to speak on behalf of all Māori
- Having total support from my manager
- Having kaumatua I could call on when needed
- Being well trained in my profession; ethics, research, kaupapa Māori research, evaluation research, Te Tiriti o Waitangi, matauranga and tikanga Māori, relationship management, negotiation and mediating skills etc.
- Having years of experience in Māori health and health systems
- Having friends and whānau in the field
- Eventually being well paid to do the work
- Knowing the politics of the organisations I worked in
- Working with non-Māori who know their stuff
- Working with non-Māori who do not know their stuff but are willing to learn.”

Other questions

- The Māori sample had mixed views on their level of satisfaction with career development opportunities. They suggested that more Māori reviewers and more Māori to provide advice to teams would be useful.

Time, Resources, and Racism are Barriers to Effective Clinical Trials

Issues for the Māori researchers who filled out the survey

- “It takes a long time (years) to create meaningful relationships with tangata whenua, and it is very important to maintain this relationship (ongoing) to ensure information collected for research is gifted back to iwi. The reciprocal relationship is essential. Māori need to trust that data collected will be used (and stored) in a way that is going to be beneficial to them (and not just used to progress the researcher's career), and in

a way that includes Te Ao Māori (hence the importance of co-design). Feeding back to iwi and continuing the relationship to work on equitable health outcomes is a lifelong commitment.

- The funding allocation/model for setting up a clinical trial often does not include these approaches.
- Often even having this conversation is hard because peoples understanding of why we need to include this. And then having to explain the process (people not taking responsibility for their own learning and expecting others to teach them).
- Considered to be an expert only in 'the Māori stuff' and broad research skills, expertise and experience are not recognised.
- The underlying racism that manifests sometimes. For example, an investigator asked me to be a co-investigator on a study and then I found I was the 'cultural advisor'. In another instance I was asked to recruit Māori into the study (unpaid).
- Not being recognised as an academic by some non-Māori investigators
- Pharmaceutically driven clinical trials - the outcomes do not benefit Māori”

1.1.4 Interviews with Māori researchers

Provided with full interviews from 4 Māori researchers, notes from interviews with 2 Māori researchers

Collaboration and Networking Helps

Multiple interviewees suggested that collaborations and networks need to exist and be well resourced (Interview 2, 4, and 6). This could include establishing a Māori clinical trial network (Interview 2), although interview 4 added that it would need to be practical. Interview 4 summarised the importance of Māori environments as they can be reinvigorating for those working in Western science spaces where there are few Māori. Interview 5 reinforced that Māori need the space from others to be self-determining, and that often means carving out their own spaces, as good allies are few. Interview 6 also suggested ensuring there were connections across projects funded/based in different areas/departments.

Māori Workforce Development is Crucial, but Recognise that Māori are Diverse

Suggestions ranged from simply employing more Māori and ensuring workforce development (Interview 1), through to discussing the need for more resources, money for professional development (including releasing people from clinical work to undertake training), build capacity/capability (Interview 2). Participant 3 suggested this could come through Māori-specific scholarships. Interview 4 reminded us of the need to recognise Māori diversity – urban or rural, speaker or non reo speaker, and reinforced that the Māori who are active researchers currently need to be treated better. However, they summarised that we need more Māori workforce development, PhDs and Postdocs.

Interview 5 discussed the need to increase researcher pipeline through funding. They said that what exists is too limited, too competitive and Māori are finding other ways to conduct research and work at the same time. There need ways to invest in people rather than research in this space, as “No one goes into academia for the money.” They had some specific suggestions: “Colleges should have a role in making this a thing. Some scoring systems about research when making assessments for fellowships etc.”; “Funding through MOH or Universities to have people come out on the other side of it with the desire to go into academia”

Interview 6 reminded the researchers that Māori can, and do, run programmes that help bring more into STEM – more is needed for workforce development. Resourcing and developing what is already there in Māori communities – from recruitment to sampling, publications etc.

Māori Control needs to be Central to the Research Questions, Methodology, and Data

Māori need to drive the research questions. Participants suggested extending Kaupapa Māori methodology, and giving a forum for Māori communities to be able to have their say, all relating to the idea of sharing and great Māori control (Interview 1). Interview 2 summarised it as: “Tino rangatiratanga”: Māori led, involve Māori clinicians with patients at the centre, ownership by/accountability to iwi. This will make clinical trials at clinics “meaningful”.

Interviewees 2 and 3 commented on the importance of engagement with Māori communities, even when the researchers are Māori, and that champions can help but “education, data and reflection are needed” – so community champions are not the be all and end all. Interview 3 commented on the issue of just grabbing Māori research assistants rather than including Māori leadership, or having Māori simply review protocols/ethics rather than engage with those with the power or experience to lead.

Interviewees 5 and 3 emphasised the need to include Māori prioritisation, and were concerned that Māori may be excluded from clinical trials due to comorbidities/BMI. They also discussed the need for collective aims, research, and goal setting: “Have we identified some of the key areas that need to be researched as a collective?”

Interviewee 6 expressed concerns around data sovereignty: it needs to be clear how IP is shared, looked after and how Māori communities’ benefit, and there needs to be transparency around this process.

Māori Researchers Need More Funding but also Need to be Trusted with their own Budgets and Timelines

Interview 4 summarised this as universities seeming foreign to Māori communities and foregrounded their discussion in the histories of Māori with research. They said that budgets, timelines and milestones can seem like a different language to those who work in/with communities.

Interview 1 emphasised the need for better/more funding and support – including transparency and accessibility to more funding. They also suggested that money for meetings with/for communities would help with community relations.

Interview 4 cited two examples where the University’s budget regulations prevented them from spending their funding on what would best meet the needs of their project/the community (buying tyres for a research assistant and bringing takeaway chicken to a whare). They are now hosting projects through iwi organisations as it is hard to escape what people who do not understand the needs of Māori/researchers and communities, think research money *should* be spent on.

Interviewee 4 also highlighted the notion of time in clinical trials. They said that the use of community researchers makes a difference, including multiple visits to whānau. They highlighted tensions in how the time taken for Kaupapa Māori work is hard to fit into the idea of time taken to do clinical trials: Māori research can be on a completely different time frame to other research – not one that aligns with funding timelines. These timelines are hard for

laypeople/whānau to understand and relate to ethics too (i.e. relationship building, someone wanting to join a trial but the timelines wrong/finished).

Similarly, Participant 5 described it as the “squeeze within universities”, meaning less discretion for researchers to control their own budgets, and not enough discretionary money to keep people in/afloat. They said the solution was to prioritise Māori academics/projects in some way.

Māori Researchers Experience Racism

Four of the interviewees discussed racism related barriers, from doing the “cultural double shift” through to explicit racism. Interview 2 said there was racism/microaggressions and improvement was needed in order for Māori to work in “mainstream services”. For Interviewee 1 this manifested in tauwiwi not understanding Māori communities, or giving Māori communities credit for what they know – although they mentioned that this is getting better over time.

Interview 3 commented on racism, the potential for tokenism from colleagues, and needing to make sure there were Māori-only spaces. This can come through when data and research challenges their world views. They also discussed the need for allies/tauwiwi to leave Māori to control Māori spaces/research and that this can be a manifestation of entitlement from tauwiwi colleagues.

Interview 6 emphasised the need for people to be aware of cultural safety. They suggested there needs some general principles for dealing with Māori (organisations, researchers, individuals). This will make sure Māori are not double- or triple- burdened with cultural advice on top of their normal roles as researchers.

Knowledge Translation Needs to Improve

Interview 1 emphasised the need for “face to face dissemination” and “one page, plain language summaries – all to make people feel less “used””. Interview 5 discussed knowledge translation as a weakness. They emphasised that clinicians tend to stick with what they know, but that they – “need to move the evidence from journals to the practice”. The participant said that there is a tendency to finish the research then move on to the next thing and not report back to communities. The interviewee said that these issues are driven by grant system, and that universities and organisations need to talk to one another more to facilitate collaborations.

Researchers Need to Make Research Resources More Culturally Suitable

Interview 1 made a range of practical suggestions for researchers to modify their work to make it more culturally appropriate, these included: “accessible language”, “taking time to understand/kōrero”, “whānau and local kaimahi can become champions, which increases response”, and “showing that people have tried to engage helps”.

There is a need to get the research dynamics right with Māori communities. Participant 3 suggests that research is one sided to many people and human connection matters, that is, personal connections to researchers and clinicians. They add that alot of the research in this space can be deficit framed or focussed. In addition, they commented that the dynamic can be different for Pākehā vs other tauwiwi when engaging with Māori and being willing to engage with Māori/understand why they need to. They recognised this was a hard balance as we need non-Māori colleagues to get on board.

The New Health System Structure Presents Opportunities

Interviewee 3 lamented that it is hard to find space and establish clinical trials. They commented on the potential opportunity of funding being embedded in the new Māori health authority. However, in the clinical trials space they warned that standardised bodies can exclude Māori, or diminish their role to simply be a stakeholder. Interview 5 also commented that reforms around DHBs will streamline processes as currently it takes many months to get approvals through the different DHBs; the same applies for different ethics processes.

1.2 Māori Themes in the Overall Project

1.2.1 Summary of Māori Relevant Themes in the Overall Project

This section introduces and summarises the themes and data. Theme names are again presented in **bold**.

We read the overall literature review document with the goal of extracting Māori relevant themes. Building off of the sections on international best practice, it is clear that **Māori needs are important to centre in the development of any new infrastructure** because their review shows that **clinical trial work needs to better include and understand the experiences of Māori and diverse(/representative) populations**. In reviewing Indigenous examples of methods and methodologies it becomes clear that **Māori need control, partnership, and co-design in research, including using culturally appropriate methods/methodologies**. Practically, their report illustrates that **workforce development is needed for Māori and tauwi**. On a practical level, their review of data systems lends itself to the suggestion that any new **infrastructure needs Māori data sovereignty and governance, with consideration to tikanga Māori**.

We also examined the overall survey report to find Māori relevant content for this report. From the findings, it is clear that **participants want more training and need more support around Māori-relevant content**. It is a promising finding that **tauwi** report that they **are engaging with Māori-relevant methods/methodologies**. As was illuminated in the first section of this report, it does appear that **research has been conducted in locations that may not be culturally suitable for Māori participants**. Ultimately, this survey shows that **tauwi perceive a broad range of barriers to engaging with Māori** which emerge from the participant's comments on the survey.

We also examined two documents relating to the interviews with the broader (tauwi) group of participants. One document was an overview of the main themes from the interviews. This document confirms that **trial networks ensure quality and expertise is shared, New Zealand has a strong reputation for clinical trials that can only be enhanced by Māori**, workforce issues arose again emphasising that **Māori workforce development is important**. From the authors' suggestions it is clear that **there are resourcing issues which likely impact Māori more, there is a need for more knowledge translation, especially for Māori communities**, and while it is not mentioned in great detail in the document, **Māori data sovereignty will be important in the future of clinical trials**. As was the case in section 1.1 of this report, people are hopeful for the future, suggesting that **the health system could better engage with research, the new system presents opportunities**. The document that specifically summarises equity themes in the general interviews also discusses that **Māori workforce development is an issue that affects everyone**, it lends itself to the suggestion that **the tauwi workforce needs to develop better cultural skills**, but also two practical themes that (1) **the research tools and measures are lacking for work with Māori**, and (2) the very common theme that **Māori data sovereignty needs to be considered**. As was the case with the survey, the interviews also reaffirm that **there are many issues with research design not being responsive to Māori needs**.

Lastly, the World Café documents provide a number of suggestions as the sessions were organised around a number of identified topics/issues. It was suggested that **a new infrastructure could mean equity and Te Tiriti o Waitangi are embedded from the start**

especially since **structural changes to the health system present opportunities**. In this, various documents suggest that many express a desire that **Māori and Māori communities need to drive the research questions**. A number of practical barriers were discussed, including: **funding models could work better for Māori communities, clinical trials researchers need to engage better with Māori to reduce barriers between Māori communities and clinical trials**, and ultimately **there are process related problems that could be fixed to improve Māori equity**. Again, **workforce development was a thread that ran through many of the documents, emphasising its importance**, it was suggested that **Māori and Pacific researcher networks are needed, including mentoring**, that **Māori workforce development needs to build Māori leadership capability and capacity**, but recognises that **workforce development can start earlier in the pipeline**. In addition, it was suggested that **tauiwi need workforce development on Māori topics**, this could pair well with the suggestion that **more Māori in cultural support roles could lessen the “cultural double shift” for Māori researchers**. As part of this a very common theme in this report has been that there is a need to **build capacity, capability, and acknowledgement of the value of knowledge translation**. In addition, the point was again raised that **Māori data sovereignty systems are needed**, plus we again see the forward-facing theme that **the new health system presents opportunities for Māori health research**.

1.2.2 Literature Review Documents

The following section covers the provided literature review type documents by Sapere. We read this report with a Māori-centred lens and summarise the themes and information below, alongside recommendations that could flow from its words. This section provides a summary of the content, alongside a critical review (with a pro-Māori lens) of the documents.

Review of the International Practice in the Organisation of Clinical Trial Systems (Sapere, 2021)

Māori Needs are Important to Centre in the Development of Any New Infrastructure

Overall, the literature review suggests that potentially New Zealand could serve clinical trials better if we adopted a different model or relationship between public health and clinical trial research. In their literature review, Sapere also found that “Research must work with Indigenous populations, culture, and identity to be successful. Non-Indigenous research methods cannot be applied to Indigenous populations and expect the same results.”

If the system changes to embed clinical trials to a greater extent within the public health system, as suggested by the UK (1.2.1 of the literature review) and USA (1.2.2) examples in the literature review report, then Te Tiriti would need to be embedded from the start, including Māori expertise (e.g. science advisory roles in partnership with tauiwi roles, with authority and resourcing) and Kaupapa Māori approaches, in order to form a system that recognises Māori rights and needs. Any formation of a peak body for clinical trials within NZ provides the opportunity to partner with Māori in this space.

In the later parts of section 1.6, the literature review also looks at “best practice”. We think that from a Māori (and/or equity) lens we would caution the view that we need to look to the UK and US as best practice in clinical trials. Obviously the UK does not have an Indigenous population and the US Indigenous population is largely overlooked in policy, so that “best practice” framing might not be appropriate. Having a frame where we look to them as good examples of Western science for majority populations may be a better framing.

The literature review proposes multiple models adopted and grounded in Western knowledges and contexts, we would tend to warn against adopting any of these models without input by Māori experts and Māori communities (sections 1.4 and 1.5). How could these be adopted to the NZ context to ensure Māori interests are built in and accounted for? There is a potential for a study on this/further research in that space with input from Māori stakeholders.

Clinical Trial Work Needs to Better Include and Understand the Experiences of Māori and Diverse/(Representative) Populations

The literature review has a specific section (1.6) called “Western scientific trial design and conduct must accommodate indigenous populations, not the other way around”. This section tended to review the literature from a point of grouping Māori, Pacific, and rural peoples together. It draws on historical trauma, not explicitly recognising that many would argue that this is ongoing for Māori (e.g. the COVID response, and “Oranga Tamariki” were media issues on the day we were writing this). The review also speaks of colonisation in the past tense, which does not align with many Māori understandings of colonisation.

The literature review rightly touches on how colonisation means that Indigenous peoples develop less trusting relationships with healthcare providers. Again, to locate this in historical trauma is an interesting framing, given many argue that it is ongoing. The review is also framed in a way that lays blame at the Indigenous populations and not the medical/clinical trials profession for not having the skills or empathy or expertise to create trusting relationships, free of or low on the various -isms.

Section 1.6.2 moves to “decolonisation of health care to improve equitable health outcomes for indigenous peoples” it recommends the same sort of measures everyone has recommended for decades – decolonising health care and that this will have flow on effects to clinical trials.

Māori Need Control, Partnership, and Co-Design in Research, Including using Culturally Appropriate Methods/Methodologies

The literature review talks about greater autonomy for Indigenous peoples in the “design, conduct, and integration of clinical trials in the community”, and while it specifies that “treatments, interventions, and settings that are culturally significant for indigenous peoples to build trust and meaningful relationships with researchers” will help participation, there were very few practical suggestions here. Refocusing research questions is one of their suggestions (p. 17).

Section 1.6.3 starts to talk about “partnership, indigenous led, and population-driven design, and research techniques”. There are specific papers suggested, including Glover et al. (2015), which is a systematic review of participation in RCTs for Indigenous peoples in NZ, Australia, and North America. The barriers for Indigenous involvement in clinical trials were summarised in a table as lack of access due to social disadvantage, distrust of Western systems, problems with research materials/their cultural appropriateness, and high mobility of participants making them hard to retain. The facilitators mentioned were: partnership with communities, culturally appropriate study design, employing Indigenous people as staff, targeting Indigenous participants with specific strategies, and making sure Indigenous people edit any recruitment materials to ensure that they are culturally appropriate.

Similarly, the Lowitja Institute and Australian Institute of Indigenous and Torres Strait Islander Studies have explored this for their own peoples. The literature review summarises their findings as: research needs to show benefits for Indigenous peoples and communities, Indigenous people need to control the research and help to design and conduct it, cultural sensitivity is needed in building partnerships, and there needs to be recognition and reimbursement of the financial costs involved in participation.

Haozous and Neher (2015) are also cited and it is reported that their work discusses partnerships with Indigenous North American populations. The review says that solutions must be “culturally tailored” for the specific peoples, there should be trust and communication, and “culturally congruent care”. They also comment on the need to “honour indigenous values and worldviews”.

The review refers to Maar et al. (2019; Section 1.8.3), a five year trial of hypertension in Indigenous peoples in “low- and middle- income countries”. They recommend the following generic principles: building respectful relationships, making an effort before, during, and after the research, clear and consistent communication, support for local teams during trials, commitment to codesign with Indigenous peoples, and reflecting on mistakes to make future work better.

Section 1.6.4 is based on McDermott, Schmidt, Sinha, and Mills (2001) – the take home message is that Indigenous people should be the ones running the administration. This reinforces a large body of literature that people more like the participants should be the ones people see *kanohi-ki-te-kanohi*. In section 1.6.5 they state that interventions and tools need to be planned carefully and be sensitive to the specific culture and geographic location. Part of this may be engaging those from Indigenous communities and training them to do the work, so workforce development here is key.

The next section of their review 1.6.6 makes the general point that much of the Indigenous health care research can be generalised to what works for clinical trials. In particular they recommend centering culture in the design of any intervention, lowering barriers to participation – they specifically zero-in on remote geographic locations and Australian research, although we can see that this may apply for Māori too (e.g. it got us thinking of Tairāwhiti and the donation-funded vaccination bus).

Workforce Development is Needed for Māori and Taiwi

The literature review discusses general workforce development.

For example, in section 1.6.6, flowing on from international examples, the authors emphasise workforce development. In section 1.6.7 they draw on a Western Australian plan for Aboriginal healthcare development as a case study.

We think that consideration of Māori-specific workforce development considerations are important – considering socio-economic pressures and job security, *whānau*, parenting, and other caring commitments, experiences of -isms in their day-to-day lives and pursuing careers, and relevant mentors (*tuākana/teina* relationships) are important to build into any workforce development.

Section 1.8.2 talks about building capacity in big data, making sure there is thought around Māori workforce development, and workforce development in those who communities can access and afford. The report also cites overseas examples of centres which develop

researchers. For the examples cited to be NZ relevant there presents an opportunity to embed Māori focused content within alot of these materials (rather than simply a Māori unit or course or credit).

Infrastructure Needs Māori Data Sovereignty and Governance, with Consideration to Tikanga Māori

The literature review discusses big data and data governance. Section 1.8 around the uniformity of data and data access/registries need to be interpreted through a Māori data sovereignty lens in order to best serve Māori rights and interests. There is literature in both general Indigenous (CARE, Global Indigenous Data Alliance) and Māori data sovereignty (Te Mana Raraunga principles) that could be drawn on for any development of guidelines for data in Aotearoa.

Similarly, sections 1.9.4-.6 talks about data governance, open access data, and discussing open access publishing. All of this content could be viewed through a Māori data sovereignty lens – where open access for communities is important but may need to be balanced against other community needs (to control their own data and how they are presented/mana-enhancing “nothing about us without us”).

The next section reviews data storage (1.8.4). Data sovereignty and control is important here too. If there is not NZ based storage researchers would need to consider the Māori data sovereignty implications of storing or analysing data offshore and how to protect Māori interests/how that might look symbolically (i.e. “here is a Māori research team to collect your data, but X country is where the data are stored and analysed”).

There are several toolkits discussed across different nations – we think that it goes without saying that an NZ one would need to be developed in partnership with Māori researchers/communities.

In section 1.9.3 the literature review turns to Indigenous peoples in Canada, North America, and Australia. They discuss how these might not be applicable to Māori but summarise the general principles as: “early relationship building, self-determination and research guidance from Indigenous peoples, operation in culturally safe spaces, and open and continual communication and collaboration”.

This review then summarises various ethical engagement type frameworks; alongside those discussed, many Māori focused frameworks exist. These could build a base for any toolkit that is developed or process of developing a toolkit (i.e. someone could do this as a research project).

1.2.3 The Overall Survey Findings

This section reviews the survey overall for Māori relevant themes in the questions. In some places the figures are reproduced from the survey report to provide context for the reader. Note also that alot of Māori relevant questions were only asked of the PIs, where it could have been interesting to see how this varies across the sample and their career stage (i.e., early career versus established and so on).

Participants Want More Training and Need More Support around Māori-relevant Content

The survey shows a great basis for increasing Māori cultural competency in the workforce. Participants (n=234) were asked what further training they would like and 50% (n=118) wanted Kaupapa Māori methodology training, 45% (n=105) wanted Māori data sovereignty training, 28% (n=66) wanted further training in “Māori specimen collection, storage, and disposal”, and 18% (n=41) in “equal explanatory power”. See Figure 1 below.

Would you like further training in any of the following areas? Select all that apply. (n=234)

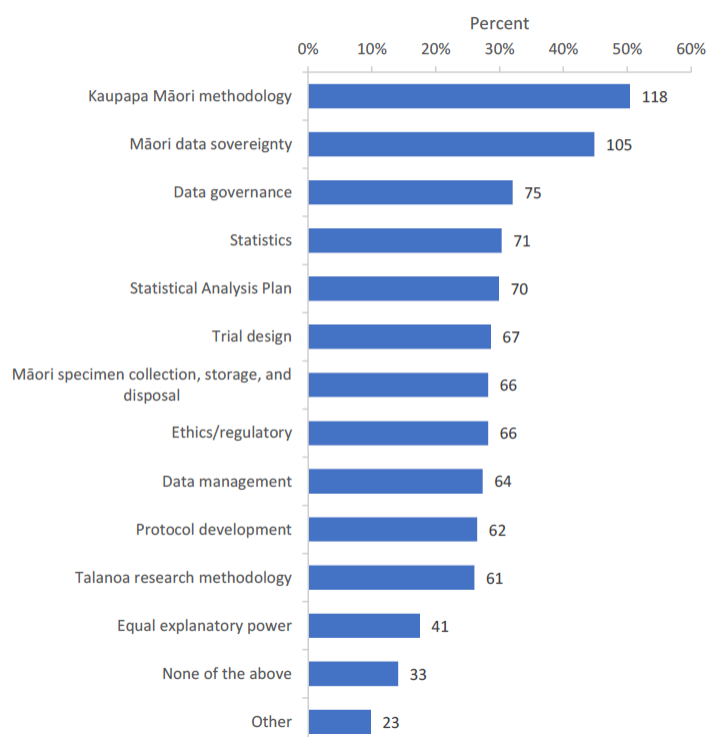


Figure 1. Graph from page 9 of the survey report from Sapere.

Those completing the PI survey (n=133) were asked whether support was available for a range of aspects of trial development. 35% (n=47) had free access to Kaupapa Māori methodology, 37% (n=49) required funding for it, and 20% (n=27) said support was not available. For “Māori responsiveness” 61% (n=81) had free access, 42% (n=34) required funding for it, and 11% (n=15) had no access. These actually compare reasonably to the other support. To put this in perspective, 74% had access to ethics, 68% locality assessment, and 65% to budget support through their institution. Whereas Kaupapa Māori methodology was rated only slightly behind health economic support (23%) for factors where PIs had no support.

Institutions tend to provide Māori related support, with 61% (n=78/129) getting support for Kaupapa Māori methodology, 78% (n=100/129) for Māori responsiveness. 11% (n=14/129) received Kaupapa Māori support from “Another NZ insitution”, 16% (n=20/129) for Māori responsiveness. 5% (n=7/129) got Kaupapa Māori support from a “Clinical Trial Network” with around 5% receiving support from a network on the other Māori relevant topics. However, it would have been interesting to see what the helpfulness/usefulness level was,

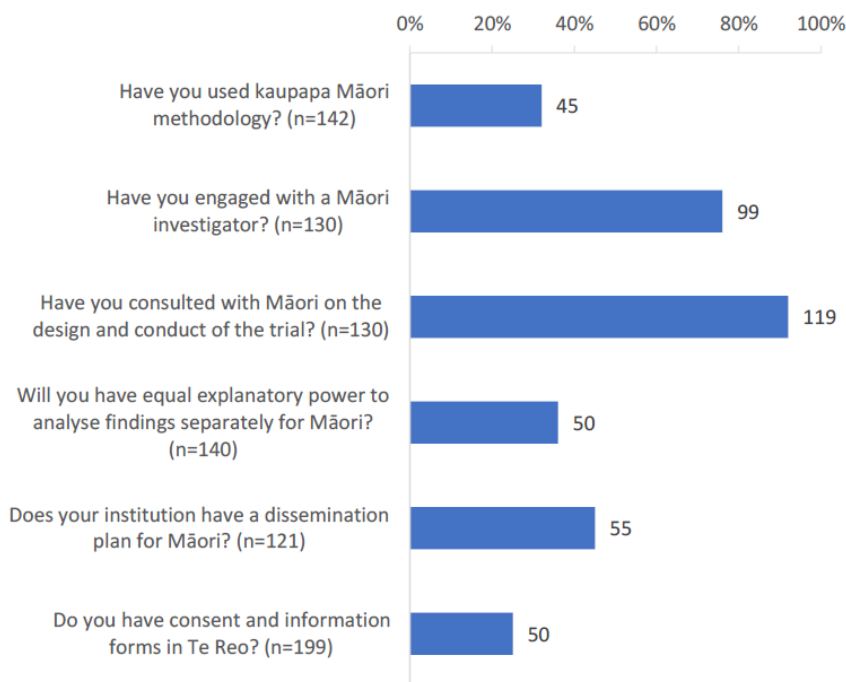
given that the participants desired further training in these areas. Future work could audit/see what institutions could do to provide higher quality content in these spaces.

Participants were asked about the barriers to effective clinical trials. 7 participants had commented that “better Māori consultation processes and support for design etc. were a barrier” and 16 cited “Ethics, Māori (and locality) approval hurdles and inconsistencies”.

Tauwi are Engaging with Māori-relevant Methods/Methodologies

The results from the survey indicate that tauwi are reporting that they are engaging with Māori-relevant methods/methodologies.

As shown in Figure 2 below, participants were asked about the various ways they have engaged with Māori in research. 32% had used Kaupapa Māori methodology (note that given the low number of Māori who had responded overall, this means many tauwi are saying they have participated in Kaupapa Māori projects), 76% had engaged with a Māori investigator, 92% had engaged with Māori around the design and conduct of a trial, 36% had equal explanatory power in a trial, 45% said their institution had a dissemination plan for Māori, and 25% had translated consent and information into te reo Māori.



Includes those that completed the PI, RN and Statistician surveys (survey group asked varies by question).

Figure 2. Graph from page 38 of the overall survey report from Sapere.

Across other questions there is evidence of participants engaging with Māori, diversity, and communities. Small numbers of participants (3%; n=7/242) had been involved in trials with a “Māori health provider” and 30% (n=72/242) with community providers. Similarly, 66% (n=84/127) have engaged a consumer representative in the design and conduct of a trial. For those who had not, issues identifying suitable representatives was the main barrier.

There was a Māori data sovereignty-specific question in the survey: “Do you or your institution have a system in place for ensuring the principles of Māori data sovereignty are adhered to?” This was asked of PI, statistics and data participants (n=161). 52% answered yes (n=84), with about 1% answering no (n=16), and 38% were unsure (n=61).

For RN participants (n=72), participants were asked if their group/institution has a system for the storage and disposal of samples from Māori participants, and 67% did (n=48; 28% selected “unsure”).

The RN sample participants were asked if they had received cultural safety training for Māori or Pacific participants 70% (n=49/70) had for Māori and 32% (n=22/69) for Pasifika. 72% (n=48/67) had had training regarding handling specimens from Māori and 76% (n=51/67) for the disposal of Māori specimens.

Research has been Conducted in Locations that may not be Culturally Suitable for Māori Participants

The data in the survey reflects well on what the Māori rōpu commented on around needing suitable locations for clinical trial participants. The RN participants were asked where they see clinical trial participants 56% (n=19/34) had access to a dedicated space, 37% (n=13/35) travel outside of their primary institution to see participants. In the location question 25/72 saw participants in hospital wards, 20/72 in DHB hospital outpatient facilities, 12 in university research centres, 11 in participants’ homes, 4 in the community, 4 in a DHB/hospital research centre, and 5 selected “other”. We thought that this content was interesting given cultural differences and the power imbalances inherent in many of these locations.

Tauwi Perceive a Broad Range of Barriers to Engaging with Māori

Finally, participants were asked throughout the survey to specify other options and asked in a final question if there was anything else to add. We wrote to Sapere requesting Māori relevant content. They sent us a number of quotes. The barriers ranged from:

- The researchers showing biases through their comments around not understanding why Māori are relevant to a study (2 comments)
- Similarly, expressing frustrations with administrative burdens, Māori were listed as one of these
- Issues with open access data not being culturally appropriate, yet being asked for by international journals
- Māori and tauwi diversity in the way that samples are handled/disposed of (e.g. Māori not wanting karakia, but tauwi wanting it).
- Tauwi wanting support from their institutions around Māori cultural considerations (2 comments)
- A lack of prioritisation for Māori (2 comments)
- The desire for more Māori perspectives at all parts of clinical trials, including in interacting with participants/whānau, and the recommendations and findings

1.2.4 Equity Content in Interviews

Document: Enhancing Clinical Trials in NZ: Summary of Information about the Current State (Love, Moore, Woock, & Hambling, 2021) from Sapere about equity themes in tauwi

interviews. The document notes that these were not taken from Māori interviews, although some of the quotes used came from the Māori interviews.

The main findings of the interviews were summarised by the authors as (quoting, section 2 headings):

1. There is enormous diversity in trial activity
2. There are many different institutional settings in which trials are managed
3. Trial networks can provide significant support
4. New Zealand has a strong reputation
5. Workforces are often fragile
6. Access to key infrastructure is patchy
7. Information needs are changing
8. Prioritisation is rarely practiced systematically
9. There is relatively little focus on translation
10. Funding and costing is problematic in many ways
11. Health system culture

Particular areas of this report that may be relevant to Māori:

Diversity and Institutional Setting (1 & 2)

There was no mention of Māori providers or Māori relevant projects in this part of the report.

The importance of trial networks (3)

The report states that networks are good to make sure quality and expertise is shared. This suggests that whanaungatanga between researchers and colleagues is important, would need Māori branches of networks or a Māori network to facilitate this. Therefore, a relevant theme is:

Trial Networks Ensure Quality and Expertise is Shared

New Zealand's reputation (4)

The researchers share that participants state that NZ has a strong reputation in clinical trials. We would suggest that this could be enhanced by greater inclusiveness of Māori communities. In addition, this a theme that could be drawn on to bring others on board to including and resourcing Māori (in a pragmatic sense), i.e., when people draw on Indigenous innovation themes, this enhances NZ's reputation in other areas. This can be summarised as:

New Zealand has a Strong Reputation in Clinical Trials that can Only be Enhanced by Māori

Workforces are often fragile (5)

We think that the workforce concerns raised by participants and the review could be approached from a Māori/equity lens. It is likely that if the study had a higher Māori participation rate then themes around Māori workforce development, the specific issues identified by Tara McAllister, Sereana Naepi and others (in their series of papers on Māori and Pasifika researchers) would have come through too and the need for Māori specific pathways. Therefore:

Māori Workforce Development is Important

Resourcing issues: Access to key infrastructure is patchy (6), Prioritisation is rarely practiced systematically (8), and Funding and costing is problematic in many ways (10)

Any issues with access to resources likely impacts Māori more:

There are Resourcing Issues which Likely Impact Māori more

Information needs are changing (7)

This theme relates to data skills and data governance, the researchers have recognised here that Māori data sovereignty was stated by a few participants, and that many were aware of sovereignty issues and would like guidance on best practice.

Māori Data Sovereignty will be Important in the Future of Clinical Trials

There is relatively little focus on translation (9)

We know this matters more to Māori communities, the researchers also mentioned “niche findings”. This seems to relate to other sections of the current report that recommend allowing Māori communities to help drive research questions and incentivise translation e.g. PBRF related and promotion, but also fund translation either as separate (e.g. HRC knowledge translation grants) or part of bigger projects (although do not ask researchers to do more with what they currently have). Interviewees suggested backing from HRC/MBIE and said it needs to be resourced. Note specific skills needed here for general but also for Māori community translation – which is its own expertise.

There is a Need for More Knowledge Translation, especially for Māori Communities

Health System Culture (11)

Participants reflected that the current health system does not engage with research well. We think that this theme reinforces the need for any stages of the Māori Health sector reforms to have pathways to engagement with Māori research and perhaps clinical trials.

The Health System Could Better Engage with Research, the New System Presents New Opportunities

Interview Document that Summarises Equity Themes

This section reviews content from a provided document that summarised the interview themes around equity topics.

Māori Workforce Development is an Issue that Affects Everyone

There were multiple suggestions relating to equitable workforce development and to Māori specifically. There was the suggestion that there needs to be a national approach within clinical trials around Māori workforce development and Māori advancement. There was recognition of the need to prioritise Māori health and Māori health concerns, and Māori workforce development.

Researchers say they need Māori at all parts of the research process, but struggle to find people. They also mentioned issues with distribution of Māori researchers across DHBs, a lack of Māori in Dunedin was mentioned as a barrier.

However, there was recognition that the Māori workforce needs Māori skills development too: “Just being Māori does not mean you have the capabilities [for kaupapa Māori research]”.

The Tauwi Workforce Needs to Develop better Cultural Skills

There was recognition that it takes time to build cultural competency. Emphasis here was on ensuring workforce development. Tauwi colleagues recognise the need to include Māori workforce development, acknowledge their Māori colleagues are overburdened, and the need to develop their own skills.

There were suggestions for cultural competency training, and to build it into programmes so people can take part as they come through education. From this document, it also is not clear the participants really know what mātauranga Māori means in this context at all or what “Kaupapa Māori” is. There are places throughout the documentation where participants talk about the importance of equity, but reflect that others might not be on the same kaupapa. The document suggests: “Equity is not well understood, and people lack guidance and resources”. This all seems to suggest that the tauwi workforce needs skill development around Māori culture and knowledge.

The Research Tools and Measures are Lacking for Work with Māori

There were suggestions that tools are lacking in relation to measuring quality of life for Māori and Pacific populations. Issues were also mentioned with the use of ethnicity/ethnic prioritisation in measures.

Māori Data Sovereignty Needs to be Considered

It was suggested that more support is needed around Māori Data Sovereignty, including the need for national standards.

There are Many Issues with Research Design not Being Responsive to Māori Needs

There were a number of points made that reinforce the need for research design to be more responsive to Māori/appropriate for Māori. These are the same issues that have emerged in earlier places in this report:

- Discussion about low Māori response rates and engagement
- The comment that ethics processes are weak and tokenistic
- The financial costs of equal explanatory power were discussed
- Someone mentioned that internationally, people do not understand Kaupapa Māori which can cause admin issues and issues with helping/making them understand
- “Proactively consider inequity on the grounds of ethnicity and locality specifically. Has to be part of something, not a ‘nice to have’.”
- The need for research priorities and questions need to come from Māori communities
- Make relationships with Māori providers less on an individual-basis
- “Always start with the intervention and trial designed around those with highest needs and populations that otherwise miss out”
- Prioritisation needs to include an equity lens, Māori views and needs
- Relationship building takes time

- Throughout the document, there were particular places where participants framed lower Māori engagement as a lack of consumer input rather than a lack of researcher engagement with communities.

1.2.5 World Café

Provided with a range of notes and write ups based on the different topics and scenarios that were at the World Cafe.

The world cafe explicitly asked participants to explore “the value of health research, clinical trials, and the national support infrastructure” with a focus on Māori and Pasifika outcomes (alongside workforce resilience, healthcare systems and health outcomes). The overall value proposition exercise document considers Māori and Pacific interventions to be urgent and NZ specific problems, and increase the number of Māori and Pacific researchers.

We initially grouped notes according to topics and topic groups:

- Māori and Pacific Topic Document
- Collaboration Document
- Consumer Engagement Document
- Equity Topic Document
- Workforce Capability Document
- Knowledge Translation and Implementation Document
- Infrastructure and Prioritisation Documents
- Data Systems and Governance and use of Data Documents

Then organised the notes by the following themes.

A New Infrastructure could Mean Equity and Te Tiriti o Waitangi are Embedded from the Start

The Māori and Pacific topic document described a number of points around why creating a health research and clinical trials infrastructure is important for Māori and Pacific peoples, including: “Creating a learning infrastructure with a sound cultural foundation (culturally safe/competent) that values Māori and Pacific research and equitable outcomes and opportunities.”

And from the equity document: “A Treaty-based science structure needs to be at the foundation of any new infrastructure. The first important step is to develop a clear high-level vision that embeds Vision Mātauranga and describes what participation looks like at all levels from governance down through the whole system.”

Structural Changes to the Health System Present Opportunities

The Māori and Pacific topic discussed providing a more comprehensive, coordinated approach that is aligned with the Māori Health Authority and other organisations. This approach will reduce duplication and allow leveraging of existing relationships, summarised well as: “Building on current strategic momentum (e.g. use Wai2575 principles to build the infrastructure).”

Māori and Māori Communities need to Drive the Research Questions

The consumer engagement document generalises this idea that all marginalised groups: move towards co-design and doing all of the ground work before obtaining funding, and making sure representation is more than tokenistic.

The equity topic had multiple suggestions, given Māori will feature in any equity discussions in Aotearoa. Generally, there were suggestions relating to: broadening engagement, meeting Māori needs with clinical trials, including Kaupapa Māori, building a Māori workforce and including Māori, and basically how to do this. The cited issues were a lack of co-design and resourcing co-design, a small and over-stretched Māori workforce, a lack of Māori involvement in decision making, issues with international trials relating to Māori data and ethnicity data, Māori being excluded in clinical trials due to comorbidities, plus, not a clear pathway to a career for Māori. The document also adds that research needs to be driven by Māori priorities, and making the tone and language right.

The Māori and Pacific topic document adds that improving the reach of communication to communities and working with communities is needed. Tangata whenua input and more of a cultural lens across everything is essential to learn and grow from each other. The desired approach is more of a collective view for meaningful involvement.

Funding Models could Work Better for Māori Communities

The Māori and Pacific document suggests ensuring funding and its criteria are set in ways that support engagement of Māori participants and stakeholders (e.g. funding/time to meet). It suggests that “hard” funding is better than “soft” funding as Māori are likely to leave if they get stuck on 1–3 year contracts. The document also suggests the need for advocacy aimed at educating funders about the value of supporting Māori and Pacific communities, and the importance of funding capability to encourage participation of Māori and Pacific populations to improve their outcomes.

Clinical Trials Researchers need to Engage Better with Māori to Reduce Barriers between Māori Communities and Clinical Trials

The collaboration document noted that it is hard to access clinical trials and information on them. Māori/Indigenous participants identified that this is a particular barrier – the write up/document attributed this to lack of confidence or experience. We think that “barriers to partnership” from the viewpoint of Māori organisations/iwi would be a more effective/interesting way to approach this.

The consumer engagement document talks about consumers and seems to not include Iwi/Māori organisations under this umbrella term. Generally, this was not clear in most documents – i.e. Māori as tangata whenua versus just another stakeholder or consumer group to respond to. The document speaks of power imbalances between researchers and “consumers”, this framing generally is inappropriate for Māori. We think that the consumer framing would need to better speak to the differential status of Māori as tangata whenua.

The telehealth suggestion pops up a lot throughout the documents (in this case in the equity document), but this needs to be culturally appropriate, cold calls might not work so well for Māori e.g. from an Auckland number, and kanohi-ki-te-kanohi contact might be needed first.

In the consumer engagement document, the theme emerges of an awkward balance between the researchers saying the public needs to improve i.e. trust them more, versus that

researchers need to be better at communicating. However, we are not sure that it is reasonable to expect Māori to learn tonnes on research in order to participate and the onus needs to be put on the researchers. It may be that there needs to be space to educate them on knowledge translation and perspective taking, given they are the ones on salaries and this is firmly within their job description.

Within the consumer engagement topic there was a suggestion to conduct research on what meaningful engagement is. We would suggest that we also probably need to do this with everyday, regular Māori – do they want to know how the work contributes to science/the community or would they just like some money?

Within the consumer engagement document there was also the suggestion of promoting participation in clinical trials it as a public service e.g. like blood donation, but we think that for Māori it might be more helpful to link it to Māori communities specifically and Māori values in some way.

There are Process Related Problems that could be Fixed to Improve Māori Equity

The equity document suggests ensuring that the correct ethnicity information is collected in the research process.

The consumer engagement document points to the practical costs and realities of research participation, and points to recognition that there is a need to lessen barriers to participation such as time, transport etc. We think these may be even more of a barrier for Māori participation.

The Māori and Pacific topic document also adds the need to design an ethics process that includes cultural frameworks and ensure a specialised ethics committee can provide support for Māori and Pacific research methods.

Māori and Pacific Researcher Networks are Needed, Including Mentoring

In the Māori and Pacific document, networking was described as a way to facilitate better equity, within this there were suggestions that mentoring would help too or specific funding for Māori.

There were also suggestions (e.g. in the consumer engagement document) of a consumer council type group in infrastructure, we would say this probably needs to be separate to Māori infrastructure or groups – safe spaces/places for Māori to express views without prejudice. Diverse and intersectional Māori are needed. When Māori health needs are so central, a couple of seats on a council will not be sufficient.

Workforce Development was a Thread that ran through many of the Documents, emphasising its Importance

Of course, it was the topic of the workforce development document. Participants commented that there is not enough of a Māori workforce for a partnership – this quote summarised it well: “Workforce development for Māori has been on the table for about 50 years and we're still saying we need more Māori around the table.”

Within the workforce development topic document other issues were mentioned. The lack of a pipeline and pathway was mentioned; issues with research funding and opportunities. Solutions here: offering support to the “in between” groups and offering early support, even

high school level, through training health care assistants in DHBs; stronger collaborations between universities and wānanga; the new health authority and iwi partnerships board provides opportunities; mentorships. Discussion of the need to grow and protect the Māori researcher workforce also came through in the infrastructure and prisonisations document.

The Māori and Pacific topic discussed several points around workforce development. This included: allocating funding for Māori and Pacific workforce development and increased support (e.g. scholarships for Māori and Pacific research students) for underrepresented groups to study for key occupations (e.g. health economics); focussing on developing the Māori workforce, especially nurses as they are the largest workforce. The issue was put well in this quote: “Increasing the number of Māori and Pacific researchers and increasing interest in physician scientists as a career choice. This will help to decrease the burden on the small number of cultural experts. Health is competing with other sectors for the researchers (e.g., environment), therefore it needs to be made easier to do research in the health sector.”

Workforce Development needs to Build Māori Leadership Capability and Capacity

A thread in the World Café relates to all levels. Similar issues came up in the equity document: a solution to many of the issues Māori have is making sure there is Māori representation in governance and leadership; but this does relate to the issues around workforce development. The Māori and Pacific topic discussed focussing on Māori leadership development as it is critical to ensure excellent governance.

Workforce Development can Start Earlier in the Pipeline

The equity documents point to the need to figure out what Māori students at all levels need – including research at high school levels too. It discusses the need at undergraduate levels for universities be less racist and lift Māori pass rates, including more research training in medical degrees/fields and make clinical trials research seem like a viable standalone career option and not as “an add on”.

Tauiwi need Workforce Development on Māori Topics

The Māori and Pacific topic document discussed improving the cultural capability of the workforce, including “introducing a ‘competency passport’ for working with Māori, whānau etc.”

In the Māori and Pacific topic document a participant suggested that there could be a two or three year endorsement on someone’s (presumably non-Pacific tauiwi) ability or certification to work with Māori or Pacific communities. Given that Māori/Pacific workforces are so overworked.

More Māori in Cultural Support Roles Could Lessen the “Cultural Double Shift” for Māori Researchers

In the equity document, the authors suggest more resources and support for the small Māori workforce, but besides paying them more there is this suggestion: “A centralised support and resource mechanism was suggested to act as a central knowledge pool. This could include the establishment of cultural coordinator roles and the idea of researchers working in cohorts rather than as individuals therefore sharing the load more evenly.” Other suggestions relate to better partnering with Māori and recognising the knowledge of those from Māori communities to be able to help.

There was a suggestion for cultural outreach in the funding space, from the equity document: “New Zealand could use this appetite as an opportunity to create a national level (to give mana to create change) cultural researcher/coordinator role to work at an international to begin to educate international industry sponsors about New Zealand’s Māori and Pacific populations needs including the need to retain local control of ethnicity data for international trials and other aspects of equitable trial opportunities.”

Māori Data Sovereignty Systems are Needed

There were a number of world café topics where the issue is MDS, MDS, MDS. In summary, it seems like a national code is needed here. Summarised well by this participant: “There needs to be standards set for data sovereignty and the use, sharing, and storage of Māori data specifically. Iwi would be most appropriate parties to lead the creation of these standards. Iwi leadership forum will set standards for all of New Zealand.”

Data systems document – technology needs

It is clear from these documents that there needs to be better technology relating to data storage, software, and analytics. Data sovereignty is cited as an issue. The suggestion from this part of the world café is that there needs to be a tech and governance strategy; the main issue for Māori here will be Māori data sovereignty.

Governance and use of data document

Many relevant issues came up including: culturally appropriate storage, use and sharing; issues arose with data being off shore; data as taonga; concerns around AI; lack of consistency around the use of storage and data. Solutions: a consistent code for data storage – transparent; PIS need to be understandable; NZ specific education module needed.

The New Health System Presents Opportunities for Māori Health Research

This is raised in both the infrastructure options and prioritisations documents. Participants raised the need to base clinical trials firmly within the health service, so participants raised the relationship between any new infrastructure and the new Māori health authority: could it be a commissioning agency? This would allow it to be better embedded in Māori communities and based in Te Tiriti.

This again comes up in the equity documents. Relationship building at the Māori health authority level was suggested. In addition, there was a suggestion of a centralised clinical trial recruitment base, potentially relating to the Māori health authority.

Build Capacity, Capability, and Acknowledgement of the Value of Knowledge Translation

The knowledge translation topic documents outline issues largely relating to capacity, capability and time recognition. There is no specific funding for the translation work. A lot of this topic talks about building knowledge translation into funding or requiring it. Knowledge translation is essential for health gains and influencing public health, and social care practitioners, but also for participants. The document talks about any new infrastructure having specific roles for translation. There was nothing Māori specific in the document, but we think it is easy to see how it relates to Māori (i.e., specific Māori translation roles, plus potential for needing to consider how different research may be useful for Māori providers).

The consumer engagement document reflected on the need to build trusting relationships; a participant suggested that better knowledge translation might help here e.g. being able to give concrete examples of how clinical trials have improved lives for others, and in particular, where this might improve the lives of others like them.

PART 2

After presenting the work to the Māori Rōpu, additional deep dive analyses were requested. The task was re-reading and revisiting data on the following two points:

- Workforce needs: Recruitment and retention
- Māori view of clinical trials: Outlining where clinical trials fit in with the broader Māori health view, including a rongoā perspective.

We went through each document afresh and have summarised anything that was relevant to these topics in the bullet points below. A lot of the content is in Part 1 of the report, but this section allowed for more specific suggestions to come through in the data. Some of the content is only tangentially related; the best source of additional content was the six Māori researchers' interviews – notes and transcripts (it was clearly the best method within the overall project to explore these topics further, especially the second one). This section of the report starts with summaries of both areas and then moves on to data-source specific notes on each topic area.

2.1.1 Summary of Māori Workforce Recruitment and Retention Section

In summary, multiple sections of the project affirmed the need for Māori workforce recruitment and retention to improve, and that this is a long-term goal. Māori recruitment and retention was also noted as being important for other areas of clinical trials relating to Māori: participant recruitment, community partnership, to improve access for Māori, and to ask different research questions/conduct different trials (that may be more useful for Māori). Universities were noted as needing “to get their act together around this” and a particular barrier was that salaries are not competitive and often insecure/not long-term. Racism was discussed as a barrier and the lack of recognition for the skills of Māori staff. It was noted that there is a need to be aware of time frames and make sure there were clear development plans, both short- and long- term, including succession planning. Another noted barrier was some projects bringing in junior researchers/research assistants to tick a box, rather than having Māori researchers fully and legitimately involved. Similarly, when Māori are offered scholarships, it was noted that it is often without adequate cultural supervision.

Specific suggestions were: to include communities/community workers more when running research, increase scholarships, provide pathways where people can continue working and studying with scholarships, salary supplements/salaries to do PhDs, releasing people from clinical work for training, having clear pathways to the career path from secondary school/rangatahi levels, starting a Māori clinical trials network and formal mentoring programmes, funding Māori to create programmes to recruit and retain staff, making research more important for fellowships, having more faculty positions ready for the Māori PhD students when they finish, making sure Māori are paid fairly for all of their roles, more te reo fluent science teachers in schools, more use of Māori research methods through education and training, listening to what Māori students want/need and what they think would help, encourage universities to include Māori student/staff targets in their strategic plans, thinking of pathways to clinical trials work for health care assistants and other parts of the Māori workforce. Supportive managers and tauwiwi colleagues, and social supports (whānau, colleagues, kaumatua) were noted as things that help retain Māori researchers, alongside having personally developed technical skills and workplace politics skills.

2.1.2 Summary of the Section for Māori view of clinical trials: Outlining where clinical trials fit in with the broader Māori health view, including a rongoā perspective

This is a big question or topic, and little depth came through, possibly due to constraints around the methods used, the number of Māori in some of the research, or the type of questions asked. For example, this type of question is not well suited to surveys, but came through in some of the interviews. Regardless, multiple documents and data discussed similar topics, including: the need for Māori communities to be better involved in clinical trials, for them to drive the research questions, include “traditional practices”, for methods to be culturally responsive and grounded, and for Māori data to be of the highest quality and use relevant measures, to include Indigenous methodologies, to engage at a more-than-tokenistic level, to empower co-design, listen to Māori suggestions, support Māori organisations to run Māori research, the need to develop Māori data sovereignty standards, and the need to be cautious when applying non-Indigenous methods to Indigenous populations. The survey data also shows that tauwiwi clinical trials researchers want more training in Kaupapa Māori methodologies and Māori data sovereignty, suggesting a level of general interest in this topic.

Some parts of the data mention the need to give effect to Te Tiriti and incorporate mātauranga Māori into clinical trials, and to include Māori governance at all levels, but with no more specific suggestions. The importance of relationship building is mentioned throughout the work, and for budgets to allow for this (the example of HRC’s tikanga allowance was used). Related suggestions include: the importance of co-locating researchers in communities, the need to make sure that Kaupapa/Mātauranga Māori/Intellectual Property is not appropriated or colonised by non-Māori colleagues (including internationally), that tauwiwi colleagues are monitored for this in case they violate trust, that training – as it stands – does not go deeply enough into Māori research, that Māori research stretches across many Western disciplinary lines, how the nature of time/cultural understandings of time and relationality do not fit well within clinical trials, similarly, the foreignness of budgets and timelines to many communities. One suggestion was that sometimes a Kaupapa Māori approach can appear in Western spaces as a function of who is involved (e.g. Māori kaimahi). A survey participant mentioned that pharmaceutically-driven trials do not benefit Māori, but did not expand. The Māori rōpu hui notes affirmed the need to consider Māori perspectives, and to focus on outcomes; and that this is broader than drug intervention trials/that there needed to be a distinction between public health and drug trials in the current work. However, it is not clear how/if this comment was carried through to the overall project. Finally, one interview participant cautioned that it is important that Māori master Pākehā methods too.

2.2 Workforce needs: Recruitment and retention

Literature Review

- Notes that a facilitator for involvement is “employing Indigenous staff throughout the research process for consultation and partnership”
- Mentions the value of a “culturally appropriate and skilled workforce” and similar points, but nothing specific to Māori.
- The Western Australian Aboriginal Health and Wellbeing Framework 2015-2030 is mentioned, and specific notes relating to the topic are:
 - “Aboriginal workforce development by building the confidence of Aboriginal people to seek and access employment opportunities within WA Health, create

a culturally safe and supportive work environment, develop clearly defined career pathways for Aboriginal peoples in health, etc.”

Current State Review Document

- The importance of making sure efforts goes to:
 - “Enabling, training, and encouraging indigenous people to take responsibility for programmes and services that affect their health and for them to work closely with existing health systems”; the importance of trained staff is noted, nothing more specific is suggested.

Māori Rōpu Meeting Notes

- The April meeting minutes note that: “To improve clinical trial access for Māori, support will be needed for a different workforce”.
- The following note appeared under “general thoughts” in the April meeting notes:
 - “If looking for a remedy for infrastructure, the workforce is key; Only 4% of the researcher workforce is Māori; There is a need for more Māori workforce and less feeling of “otherness” with whānau”; “
- The Rōpu made notes around workforce needs and the timeline:
 - “There are longer-term needs, like developing the workforce and short-term needs to create a structure that works together.”; “Workforce development is longer-term; will need to be explicit about the timeframe”; “Short-term: can point to best practice; need to move from “ticking” the Māori box exercise to doing best practice. Rōpu noted the need for the universities to get their act together around this.”
- It was noted that this workforce is hard to survey as they have a heavy workload; the rōpu mentioned the idea of getting community workers involved in clinical trials – as they may be interested, and mentioned that it is hard to retain the Māori workforce as private employers are paying more. There were some specific suggestions”
 - “There is increased interest in research but a lack of resources (e.g., scholarships) to bring up the workforce”
 - “An opportunity for Māori RN PhDs to continue working and studying with scholarships”
 - “Having this will benefit research; if a more diverse group of people are undertaking research, they will ask different questions and undertake different trials.”
 - “Mihi for early researchers – offering salary supplement or salary to do a PhD”
 - “Develop workforce career pathway and succession planning”

Survey

- Very few Māori participants completed the survey (n=12) and very few completed the Māori-specific questions. Three responded to an item on satisfaction around career development opportunities – 1 was satisfied, 1 felt neutral, and 1 was dissatisfied.
- Three answered questions around what challenges they had faced, identifying the following recruitment and retention issues:

- Skills not being recognised by institutions/teams; racism and being viewed as a Māori researcher rather than a researcher; not being recognised as an academic.
- Things that had help to retain these Māori researchers:
 - Leaving the university; supportive tauwi colleagues who make an effort to understand and not assume; a supportive manager; having kaumatua for support; being well trained in their profession; having experience; having friends and whānau in the field; eventually being well paid; knowing the politics of the organisations they work in.

Interviews

- Six Māori researchers were interviewed, these are the points that they made around recruitment and retention:
 - The current training isn't sufficient; surgery and medical spaces are not safe spaces for Māori.
 - Issues around the only Māori staff being junior; a part time research assistant. The need for Māori researchers to be fully and legitimately involved.
 - Tauwi groups may have scholarships for Māori but not culturally adequate/Kaupapa Māori supervision.
 - A Māori clinical trials network might help.
 - Release people from clinical work to undertake training.
 - Need clear training pathways for rangatahi and up.
 - Māori know how to recruit Māori into these career paths; need to be funded to do so.
 - Protect Māori from the double or triple -time cultural extra shifts.
 - Pay Māori for their time in all roles.
 - More funding/scholarships needed at all stages; sometimes to develop researchers rather than a specific research project.
 - People don't go into academic for the money; contingent on individuals/individual relationships rather than "a systematic way of getting there".
 - Help to facilitate Māori community to conduct more research in their communities themselves.
 - More faculty positions are needed to "pick up more researchers" coming through; making things/pathways easier.
 - Could modify scoring systems for fellowships so research is more highly weighted/or Māori research.
 - One interview had several notes around the pipeline: "Trying to grow future researchers, needs to be element of funding to increase pipeline – i.e., early-stage research, PhD, post-doc or academic roles (rate-limiting area currently and disincentivised)."; "Chicken and the egg situation currently. Not an easy or short-term solution but need to grow the pipeline of Māori academics."
 - A "squeeze" is on universities, making this all worse; hope with reforms to PBRF and Māori researchers becoming a higher priority.
 - Very few te reo speakers in the space.
 - Need good Māori collegiality at all levels.

World Café Documents

- The equity document mentions that the Māori researcher workforce is small and overstretched; no clear pipeline for students; the need for Māori governance/at leadership level; and more funding/resources. The following specific suggestions were made by participants:
 - “Increase the number of schoolteachers with the capability to teach science in Te Reo.”
 - “Included more research in training across all fields (e.g. medicine, nursing, allied health) to make it visible and model the use of Māori and Pacific research methods and frameworks to students at school and university levels. If people see themselves in research that will encourage participation.”
 - “Listen to Māori and Pacific students to find out what will help to bring them to undertake a career in research.”
 - “Make research a career option rather than an add on.”
 - “Universities to include an aspirational objective in their five-year plan to build research particularly for Māori and Pacific students.”
- The collaboration document suggests that “the lack of confidence and/or experience is also present for Indigenous researchers and likely acts as a strong barrier to involvement.”
- The infrastructure document reaffirms the need to grow the Māori researcher pipeline; as important for infrastructure.
- The workforce capability document also states the need for clear pathways from secondary school onwards (for Māori and Pacific researchers); it highlights the lack of postdocs and not retaining people post-PhD due to uncertain funding:
 - “It starts right at the very beginning. If we want clinical research trials to increase, particularly in the DHB sector then we have to have trained clinicians to do research. The pay is a big disincentive to start. As a registrar thinking about doing research, you will take a big pay drop if you stop that to do a PhD. Then trying to get a postdoctoral research fellowship short of a few trusts is not possible because there are such limited opportunities.”
 - The document discusses the need to really understand why Māori do not go down the clinical trials research pathway, and reaffirms the need for clear pathways from high school onwards. Another practical suggestion was:
 - “In the DHB, but we have a group of Health Care Assistants that we train up and they get experience within the hospital working with real patients. And then from there they decide whether they want to be a nurse or a doctor. If we arrange something like that [for research], maybe people could decide what sort of pathway they want to go on at some stage.”
 - Mentors and mentoring programmes are suggested.
- The value proposition exercise summary document (other than restating the need to train and retain Māori kairangahau) highlights the need to retain and upskill Māori nurses in clinical trials; that Māori working in clinical trials will act as a type of role model and bring in more Māori; that allocated funding is needed; and that Māori are likely to not be retained if on 1-3 year “soft funding”.

2.3 Māori view of clinical trials: Outlining where clinical trials fit in with the broader Māori health view, including a rongoā perspective

Throughout the documents/data there were several mentions around the edges of the topic/idea but no specific information. We present a series of notes on points related to this question, below.

Literature Review

- Notes that a facilitator for involvement is: “Culturally appropriate study design guided by Indigenous peoples, driven by the needs of the population and traditional practices.”
- There were many general points about the need for methods to be culturally responsive, but nothing Māori specific (a lot of international Indigenous literature cited). For example, the Native American Center for Excellence was used as an example and the following material included:
 - “Employ blended research methods – must be sensitive to the need to employ culturally-grounded qualitative methods in data collection protocols that include indigenous ‘ways of knowing’ as valuable approaches to scientific enquiry.”

Current State Review Document

- Makes the explicit point, in summarising the literature review:
 - “Research must work with Indigenous populations, culture, and identity to be successful. Non-Indigenous research methods can’t be applied to Indigenous populations and expect the same results.”
- Another specific point is summarised from the literature review is:
 - “Western scientific trial design and conduct must accommodate indigenous populations, not the other way around”; methodologies and ways of doing research are mentioned as being important, but nothing more specific.

Māori Rōpu Meeting Notes

- There were several points speaking to this in the first (April) meeting minutes, such as:
 - “Any definition needs to consider the Māori perspective”; “The rōpu noted that the project documents are well defined, but do not fit into the Māori perspective. The Māori perspective is broader than drug intervention clinical trials”; “Compared to western thought, in Māori health, there is no distinction between drug trials and public health trials/interventions. The primary focus is on outcomes.”
- The rōpu notes mentioned co-locating researcher in communities, Māori responsiveness broadly, Māori data sovereignty and data quality, and Māori leadership/co-governance.

Survey

- Survey methods do not lend themselves to exploring these kinds of thoughts, especially as the Māori researcher sample only consisted of 12 people. Overall, the results show a pattern of desire for further training on Kaupapa Māori methodology

and Māori data sovereignty, suggesting a level of interest and support for Māori clinical trials research.

- The few Māori participants suggested their current duties involved: “Ensure mātauranga Māori is incorporated in our approach to patient experience within the clinical trial.”; “That we uphold Te Tiriti o Waitangi in all that we do.” And “Māori governance”.
- The three participants who answered the challenges question identified issues around Māori not trusting research; needing co-design and relationships; and that pharmaceutically driven trials do not benefit Māori.

Interviews

- Six Māori researchers were interviewed, these are the points that they made around the relationship between views of Māori health and clinical trials:
 - Concerns around clinical trials only tokenistically engaging with Kaupapa Māori – as a tickbox, rather than genuine.
 - Tauwiwi colleagues moving into Kaupapa Māori spaces; this being obstructive/colonising/entitled.
 - The current training is not enough to wed these viewpoints.
 - May be able to better work out the place of mātauranga Māori when structures change e.g., the Māori health authority.
 - Important for Māori to be able to use Pākehā methodologies too; although they tend to be too simplistic for hauora Māori.
 - Sometimes a Kaupapa Māori approach happens naturally for Māori kaimahi; it’s not on purpose or “academic”, it can be just what happens.
 - The need for Māori researchers to monitor tauwiwi ones in Māori spaces, “check-up” on them; largely around power imbalances and surgery.
 - Some Māori kaimahi are always in a Kaupapa Māori space, even when they are situated in White spaces; because it is who they are.
 - Listening to whānau in recruitment processes; doing what they say (suggested forum for Māori communities to have their say).
 - Support Māori organisations to run Kaupapa Māori research.
 - Need to protect mātauranga from cultural appropriation or theft of intellectual property at both a national and international level. Need to be clear how IP will be treated/looked after and then that relationship to Māori communities.
 - Research budgets and milestones can seem like “a different language” from a Māori community perspective.
 - Comments around the nature of time/cultural understandings of time and relationality; these notions not fitting well within clinical trials frameworks.
 - Māori research tends to stretch across multiple domains; is less stuck within Western disciplinary boundaries.
 - More flexible funding helps realise Māori aspirations e.g., the HRC’s tikanga funding section of the budget.

World Café Documents

- The equity document mentions the need for Māori governance/leadership (and links this to workforce issues, mentioned above). Relationships and governance needed at multiple layers of authority to enable Kaupapa/Mātauranga Māori.

- The collaboration document suggests more investment is needed in the space.
- The governance and use of data document raises issues around tikanga and data; storing data offshore; data as a taonga and not a commodity; suggestion is that a national Māori data sovereignty code is established with input from Iwi.
- The infrastructure document suggests that work is Māori-led through the Independent Māori health authority, and driven by Te Tiriti.
- The value proposition exercise summary document restates the need for Māori equity, including community input and increasing cultural capability generally.