Ethical and responsible development of wastewater-based epidemiology technologies

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CONTENTS

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1. EXECUTIVE SUMMARY

Wastewater-based epidemiology (WBE) is a recent field of study which uses chemical analysis to measure substances of interest in samples of wastewater, to provide population-level data. As an emerging set of technologies, ethical and public acceptance issues are actively being discussed by scientists, ethicists and policymakers. This interview-based study, informed by systems thinking approaches, contributes to the literature by investigating stakeholder views on ethical approaches appropriate for a Crown Research Institute to implement, with regards to WBE. The study concluded that an institution-wide responsible research and innovation (RRI) approach, supported by robust, strategic and coherent internal research assessment processes, was the most appropriate system for ESR. These processes should draw on a diversity of perspectives and enact a meaningful dialogue with Māori as indigenous partners under Te Tiriti o Waitangi. These processes and partnerships are essential for ESR to fulfil its legal and socially expected role of undertaking research for the benefit of all New Zealanders.

2. Introduction

Wastewater-based epidemiology (WBE) and related fields use analytical chemistry to analyse samples of wastewater (sewage) for substances of interest. The most common use of WBE technologies is to calculate the quantity of illicit drugs consumed by the population who contribute to the inflow of a wastewater treatment plant. The use of chemical analysis of wastewater to gain population-level insights has emerged over the last two decades and research is developing the potential of these technologies to other health-related applications (Gracia-Lor *et al.*, 2017, Choi *et al.*, 2018). A current application being explored is using WBE to monitor the quantity of the SARS-CoV-2 circulating in the community (Daughton, 2020, Farkas *et al.*, 2020, Gable *et al.*, 2020, Institute of Environmental Science and Research, 2020).

As WBE technologies develop into new and unknown areas, ethical and public acceptance issues need to be addressed. A start has been made with the publication of non-binding ethical guidelines (Prichard *et al.*, 2015), yet there are other frameworks that could inform this work thus raising questions about the application of general guidelines within specific country contexts. The Institute of Environmental Science Research (ESR) is the major research institution in Aotearoa New Zealand undertaking WBE research. It is therefore appropriate for ESR to lead work around ethics for this emergent field, as it applies to Aotearoa New Zealand.

ESR is one of seven Crown Research Institutes (CRIs), which carry out research for the benefit of New Zealand. The 1992 foundational legislation requires CRIs to pursue excellence, comply with all applicable ethical standards and exhibit a sense of social responsibility while operating in a financially responsible manner. The Ministry of Business, Innovation and Employment (MBIE) is the primary agency which monitors and funds CRIs. As part of the Crown's commitment to partnership with Māori[1] inherent in Te Tiriti o Waitangi (The Treaty of

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[1] Māori are the indigenous peoples of Aotearoa New Zealand

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Waitangi), MBIE has embedded the Vision Mātauranga policy into CRI funding and monitoring requirements. This policy aims to "use the science and innovation system to help unlock the potential of Māori knowledge, people and resources for the benefit of New Zealand".[2] Ethical issues in Aotearoa New Zealand science research, therefore, must take account of Māori perspectives.

This is the context for the ESR study on ethical and public acceptance issues related to WBE technologies. The study started with 'social licence to operate' (SLO), a concept from mining and other extractive industries which informs the process of gaining public acceptance for operations (Edwards and Trafford, 2016). However, an initial literature review found that SLO as a concept was insufficient to encompass the uncertain futures of emerging technologies in the context of publicly funded research. Four other approaches were identified as useful and are examined in the first part of this paper. They include the WBE ethical guidelines of Prichard *et al.* (2015), social justice approaches within Public Health Ethics, Māori research ethics (Hudson *et al.*, 2010), and the European Responsible Research and Innovation (RRI) framework (Stilgoe *et al.*, 2013). These frameworks were used alongside a Critical Systems Heuristics (CSH) approach (see methodology), to analyse interviews with WBE research stakeholders. The analysis section follows the CSH boundary issues of motivation, control, knowledge and legitimacy, and the discussion section draws all these threads together to gain insights for the ethical guidance for WBE technologies.

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[2] https://www.mbie.govt.nz/science-and-technology/science-and-innovation/agencies-policies-and-budget-initiatives/vision-matauranga-policy/

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3. Frameworks for WBE ethical guidance

Research ethics is a field with a large body of literature. The frameworks, briefly introduced here, were identified as the most relevant from the initial literature review of this study.

3.1   WBE ETHICS GUIDELINES

A starting point is the guidelines specifically produced for WBE and related fields (Prichard *et al.*, 2015). These were developed by experienced WBE researchers as non-binding principles. Yet the guidelines were also clear that researchers and their institutions are responsible for ethical integrity of their research, including the application of WBE to ongoing monitoring and surveillance. The WBE ethics guidelines drew upon biomedical human research ethics principles of minimising harm to participants, maximising benefits, and respecting autonomy through informed consent. The conclusion was that since WBE is non-invasive and individuals cannot be identified, there is a very low risk of harm to participants while generating the assumed benefits, and this justified proceeding despite the impossibility of gaining informed consent from participants.

Two specific problematic ethical situations were outlined. One was erroneous or sensationalised reporting of the data, and the other was adverse effects from site-specific studies such as prisons, schools or festivals. In both cases, the concerns were around the labelling and stigmatisation of certain groups of people, and the potential for unfair enforcement measures to be taken against those groups because of the reported data.

Mitigation strategies recommended included research planning that anonymises data, careful communication of research outcomes, and ethics committee approval where possible. Relationships with stakeholders was also considered important, including verifying that an agency making a request for analyses was legitimate and relevant before researchers agree to collaborate.

The COVID-19 pandemic has prompted research into using WBE technologies for COVID-19 surveillance, with associated ethical discussions (Daughton, 2020, Farkas *et al.*, 2020, Gable *et al.*, 2020, Sims and Kasprzyk-Hordern, 2020). In general, these commenters agree with the basic premise of Prichard *et al.* (2015) that ethical risks are low because individuals cannot be identified. However, there is an interesting tension around the application of WBE to small catchment areas. The risk of community stigmatisation identified when measuring illicit drugs is still relevant when measuring infectious agents such as the COVID-19 virus. At the same time, WBE surveillance for infectious diseases for public health purposes is most useful when applied to small catchment areas, and this application appears to have widespread support. This indicates that ethical decisions will depend predominantly on the purpose for using WBE technologies.

3.2   PUBLIC HEALTH ETHICS

The biomedical ethics model is based on a one-to-one relationship between researchers and participants. It is complicated further in public health contexts where research is often in the form of surveillance and monitoring, in order to design appropriate interventions and services. Public Health ethicists have critiqued the biomedical ethics model for its inability to provide guidance for population level surveillance, interventions and research (e.g. Baylis *et al.*, 2008, Coggon and Gostin, 2019, Sheehan *et al.*, 2019). Childress *et al.* (2002) were one of the first groups to provide an alternative framework that balanced individual and public interests. They came up with five considerations for deciding whether a public health intervention was justified, using a broadly utilitarian cost/benefit perspective. These were:

- **effectiveness** - the intervention should be expected to produce the desired results;
- **proportionality** - maximum benefit with minimal harm, benefits and burdens of participating are distributed fairly;
- **necessity** - interventions that infringe liberties without informed consent must be necessary for the public good;

- **least infringement** – method with the least effort required from participants should be used;
- **public justification** – strong public good reasons, which can be justified in public debate.

More recent commenters have emphasised a social justice responsibility, alongside the utilitarian cost/benefit evaluation (Baylis *et al.*, 2008, Coggon and Gostin, 2019, Sims and Kasprzyk-Hordern, 2020). Coggon and Gostin (2019) described public health as having a two-part moral mandate, to act to improve population health and to mitigate unfair health inequalities. In other words, public health is seen as a social value and a means for social justice. Bayliss *et al.* (2008) suggested a social justice approach based on interconnected relationships, which recognised that people's choices are influenced by their context and social setting. Therefore, from a social justice perspective, public health research, surveillance and interventions which infringe individual rights need to be justified not only in terms of overall public good, but in terms of improving systemic disadvantage.

3.3 MĀORI RESEARCH ETHICS

Policy in Aotearoa New Zealand is shaped by Te Tiriti o Waitangi, which agreed a partnership between Māori and the Crown. This means that any research ethics framework should incorporate values from Te Ao Māori (Māori worldview). *Te Ara Tika* means 'the right path', and is a framework for human research ethics based on Māori cultural values of Whakapapa (relationships), Tika (research design), Manaakitanga (cultural and social responsibility), and Mana (justice and equity) (Hudson *et al.*, 2010). Whakapapa is the central principle and refers to the quality and the processes for relationships with both the participants of the research (people, sample and data) and people managing and conducting the research. *Te Ara Tika* describes three levels of relationships with Māori which move from inviting critique of the research or technological development design through to partnership with Māori on issues that involve Māori communities. According to *Te Ara Tika* a responsible approach to scientific research and development requires a focus on relationships and co-governance with Māori.

The recent revision of the National Ethics Guidelines for Health and Disability Research and Quality Improvement (National Ethics Advisory Committee, 2019) incorporated the principles from *Te Ara Tika*, to ensure that Māori ethical perspectives underpinned all parts of the guidelines. Similarly, the Royal Society of NZ recently reviewed their ethical guidelines. Members are now obliged to ensure that their practices are consistent with Māori codes of practice relevant to their discipline, for example with *Te Ara Tika* for those involved in research involving humans (Royal Society Te Apārangi, 2019). These examples show that *Te Ara Tika* is becoming embedded in the research ethics landscape of Aotearoa New Zealand.

3.4 RESPONSIBLE RESEARCH APPROACH

The initial literature review identified the European concept of Responsible Research and Innovation (RRI) as an appropriate approach for thinking about ethical issues and community acceptance with emerging technologies and publicly funded research. RRI extends the concept of being responsible for the current research impacts to encompass potential future impacts. One influential and useful definition of RRI is: "Responsible innovation means taking care of the future through collective stewardship of science and innovation in the present" (Stilgoe *et al.*, 2013, p. 1570). Stilgoe et al. outlined four dimensions of RRI. **Anticipation** meant that the research institution should make considered judgements about potential impacts of new technologies and research, and act to maximise benefits and minimise risks. **Reflexivity** required the institution to build in a transparent system for reflecting on its own values and potential different framings of the research. **Inclusion** of a diversity of voices in decision making was needed for public legitimacy. Finally, **responsiveness** involved both the capacity and willingness to change the direction of the research, in response to the outcomes of anticipation, reflexivity and inclusion.

Common across these four frameworks is a collective approach to ethics. The ethical subject is not an autonomous individual devoid of context, but a socially connected 'public'. Fundamental principles such as 'do good', 'do no harm', and 'be fair' are all interpreted as applying to the population as a whole, including past and future generations. These are bound

together not only by a respect for individual rights but also by recognition and respect for relationships within the collective. The approaches are all framed by a discourse of proactive and adaptive responsibility. Informed by this discourse, the interviews aimed to identify perspectives on what issues and processes ESR should consider for ongoing responsible and ethical conduct within the emerging field of WBE.

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4. Methodology

This social science study investigated potential ethical issues of WBE technology development using a literature review and interviews. As the project was considered low risk, an internal ethical process was followed, utilising peer review of draft research protocols against the Royal Society of NZ code of professional conduct and ethics[3]. Processes of informed consent, opportunity to review and alter interview transcripts and anonymity of study participants were included in the protocol. The study was informed by critical systems thinking, where systems are defined as consisting of multiple interconnected elements contained within implicit or explicit boundaries, from which outcomes emerge. Boundary definitions are important, as outcomes depend on what is included and excluded within the system, and who has power to determine inclusion and exclusion. For example, when an institution provides data to another agency in a service provider capacity, where and with whom do the boundaries of ethical responsibility lie?

Critical Systems Heuristics (CSH) was used to develop interview questions and guide thematic analysis (Ulrich and Reynolds, 2010). CSH examines four issues that influence system boundaries: motivation (what is the purpose and value), power (who has control of processes and resources), knowledge (what expertise is considered appropriate) and legitimacy (how the research is justified to those not directly involved). These four boundary issues were examined by asking stakeholders a series of twelve questions, as summarised in Table 1, adapted to the topic of WBE (Ulrich and Reynolds, 2010). The of interview participants were a purposeful selection from across the WBE science system including from local government (who control wastewater plants), university researchers and ethics specialists. commercial and non-commercial data analytics specialists, and current and potential users of WBE data within government departments. The original scope of the interviews was curtailed because

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[3] https://www.royalsociety.org.nz/who-we-are/our-rules-and-codes/code-of-professional-standards-and-ethics

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of the Covid-19 pandemic, with nine interviews being completed. Interview questions were based around WBE technologies in general, although discussion often came back to monitoring illicit drugs as the most concrete example currently available or went further to include views on research ethics in a broader sense.

The interviews were retroductively analysed (Byrne and Callaghan, 2014) to establish system boundaries and their causes. The CSH boundary issues and questions were used as a high-level coding framework for deductive analysis, while sub-codes were developed inductively from the data. Codes were iteratively refined, and themes drawn together from across the CSH boundary issues framework.

5. System boundaries

The analysis of boundary issues is summarised in Table 1 and explained in more detail below. CSH questions can be asked in two forms: the ideal and the actual, what the boundary *should* be and what it actually *is* (Ulrich and Reynolds, 2010). Since the interviews were focused on the potential current and future ethical issues of WBE in the context of unknown future technological development, the data reflects the ideal or 'should' version of the CSH questions.

TABLE 1: Summary of data from Wastewater Ethics interviews, based on table in Ulrich and Reynolds (2010)

	Social roles (stakeholders).	Role-specific concerns (stakes).	Key issues (stakeholding issues)
Motivation	*Beneficiary* People and communities, with a particular duty of care for disadvantaged communities	*Purpose* To provide data and research that improves peoples' wellbeing. The purpose of individual research or service projects should be clarified first, and data sources tailored to achieving the purpose. Some surveillance data is necessary to guide appropriate public services, with greatest support for data collected for health and social support services. WBE is for population level trend analysis, not for smaller fine-grained analysis, as smaller catchment areas can lead to negative impacts such as stigmatisation.	*Measure of improvement* The final measure of improvement is reduced social harm and improved community wellbeing. Before undertaking any research project or programme, there ought to be a thorough assessment of benefits, costs and risks. In the case of WBE research, it is necessary to show that the wellbeing benefits outweigh the risk of stigmatisation and the lack of informed consent.

Control	**Decision-maker** A group of people with diverse views should govern decisions, taking the place of individual informed consent. The group should enact a Tiriti-based partnership with Māori.	**Resources** Control should be guided by robust institutional policies and processes for scientific and ethical review Governance needs to include strong and enduring relationships with stakeholders, especially Māori.	**Decision environment** ESR is a publicly funded research institute with a national focus, and governance decisions should reflect this. In line with public accountability, research governance decisions, as well as data and outcomes, should be transparent and actively communicated to the public.
Knowledge	**Expert** Professional scientists and ethicists should work alongside those with knowledge of communities and mātauranga Māori.	**Expertise** The framework of western scientific knowledge organised in disciplines, is respected and seen as beneficially objective and impartial. This should be combined with practical ethical expertise. Mātauranga Māori is essential knowledge for research with Iwi and Hapū Māori. To achieve the aim of community wellbeing, local community knowledge provides valuable context for specific research projects.	**Guarantor** Professional scientists are expected to be self-regulated, both within their institution and through their professional peers.
Legitimation	**Witness** The general public, to who the publicly funded research institution is accountable. This relies on transparency and communication of research activity.	**Emancipation** Public service institutions are expected to act in the public's best interests. In contrast, profit-making companies do not have this same legitimacy. Public research institutions should not only make data available to particular communities for the communities' benefit, but the institution also has a role in supporting communities to interpret and use that data.	**Worldview** The ideal situation is a balance between a Māori worldview and the current dominant western science perspective. Ethical models based on collective responsibility are preferred to those based on individual liberties.

5.1   MOTIVATION

5.1.1   Research framing and intentions

When asked about potential ethical issues in WBE, participants often responded with their own questions about the research intentions. Judgements of the acceptability of the research

were seen to be based on *why* the research was being conducted, with the greatest support for those purposes that had direct links to health and social wellbeing. There was less general support for WBE used for law enforcement purposes, except where participants saw law enforcement as reducing social harm.

- What do they actually do with the data? … Is it measured for the purpose of monitoring health? Is it measured to see whether this area's got a high drug use so we need more support services? (WBE4)
- I think we've got a public licence to undertake such activity to keep people safe and as long as we're working within the intention of that public confidence … it is accepted that we're going to be doing this sort of stuff to keep people safe. (WBE5)

Participants expressed more concern about the negative impacts of data use than about the collection or storage of samples. The main concern was the potential for stigmatisation of communities or discrimination against sub-populations associated with sampling small catchment areas.

- I wouldn't really want to get it down to a suburb or something without consent. But perhaps at the collection point, that would be okay if it was being used for the right purposes and not made public, but I guess there's always a risk of it becoming public. (WBE9)
- As soon as you branch it out and try to look at a community, whether that's a suburb, or whether that's say the prison outflow, then you're targeting down into groups where I think it then starts to push towards infringing on liberties. (WBE8)
- It seems to me there's another level of maturity around resolution, around detail … that is starting to get closer to people and so people will notice this far more. ... I'm okay when a plane flies overhead [taking aerial photos] but when a drone drops down over my house? (WBE7)

This suggests that research with a clear link between the data produced and community wellbeing is likely to receive wider public support.

5.1.2 Matching research question and data source

Participants were clear that the research question should drive the choice of data source, not vice versa. The data source should be 'fit for purpose' to provide an answer to the research question, while providing the best and simplest data. WBE data was considered best suited to population trends analysis, because it is a methodology that does not distinguish between different groups of people but can easily provide data on a large scale. With small catchment sizes, more established ways of generating data are often available that may produce more useful information than WBE technologies, with less risk of stigmatisation.

- When we have the granular, more micro decisions, and you're using a data set designed for macro decisions [the question is] whether or not the data set that you have is fit for purpose in terms of solving that. And if it isn't, don't try and shoehorn it. (WBE3)

- In what ways does that information that comes out of this process add value to what decisions people might have to make within those places, and is that the best way to do it or not? (WBE8)

- That was my first reaction when we encountered this technology, which I've got to admit our initial reaction was, "Wow, that sounds so cool". We started running away, "What could you look for? And you could do all this and this and this" and then the more we read the more we went, "Oh, yeah, but there are other ways of doing it and people do seem to have objections". (WBE7)

The alternative view of that for public health surveillance of infectious diseases small catchment sizes are preferable, as they give more valuable epidemiological data than large catchments (Sims and Kasprzyk-Hordern, 2020), was not raised by participants. It should be noted that public media on WBE Covid-19 monitoring occurred after the interviews had been completed.

Along with ensuring methodology matches research objectives, participants understood best practice to be that research institutions undertake rigorous assessments of the benefits, costs, risks and ethical issues before setting up research projects or programmes. It was generally assumed that ESR had such assessment procedures in place.

- I have to believe that they'll have audit processes, and that they will review things, and that they will have policy and practices in place. (WBE1)
- I would rely on the methodology and the ethics that are in ESR, or in scientific studies, the ethics of the actual task, does your ethics board give you permission to launch the study? (WBE6)
- Putting it through a really good policy test or process, would be really sensible. I know ours would really take an idea like that to a good task, in a rigorous way. … It's mainly that kind of evaluation at the beginning. (WBE7)

The importance attached to matching the research question or intentions with the data source suggests that research development should focus on research questions that progress objectives of population health, safety and wellbeing, and use WBE technologies where appropriate, rather than focusing on finding research projects with which to use WBE.

5.2 CONTROL

5.2.1 Engaging diverse perspectives

The general view of participants was that ESR should not consider benefits and risks of research projects in isolation. Inclusion of diverse perspectives would aid thorough assessment of the benefits, risks, and implications of proposed research, and therefore such decisions should not be left to individuals. Participants considered representations of Māori perspectives essential, and community perspectives useful for locally based projects. There was an expectation that engagement of diverse perspectives would be formalised in policies and procedures.

- Other places it's not formal, but people put in place institutional bodies. So, whether they're ethics bodies or advisory bodies, and things like that, which then become that de facto place for that community consultation. That's akin to an ethics committee. (WBE8)
- Clearly with respect to the Treaty there is a role that Māori need to play ... many agencies have a shared board or a reference group at the very least. (WBE7)
- Which is why again I come back to a committee. … So for instance, every time I see a piece of research with a person who is working on a Māori community who doesn't have really deep ties to it, I ask them to slap a Māori reference group on top of it, because those older men or women will be able to see the problems that a researcher might generate without the researcher even knowing. (WBE2)

5.2.2 Acting in the public interest

ESR was seen as a reputable public agency which acted for the public good. This implied the expectation that ESR had a *responsibility* to act in the public interests, in common with other parts of the public service. This view echoes the CRI legislation under which ESR was established.

- If it's well-framed research then it's in the interests of the New Zealand public, and understanding the nature of general wellbeing in the population. It comes right back down to that outcome. (WBE2)
- I think ESR's got to be responsible because if it's going to be the generator of this data it has to be giving some thought to the potential future uses of it. (WBE8)

In contrast, participants were generally against ESR providing public data to commercial companies. This was not seen to be acting ethically or in the public interests, because of the profit-making objective of commercial companies.

- From my perspective, I think that selling public information and commercialising public information that is being collected for the purpose of the public good, I don't agree with

it… I think the analysis of data, that's where people can commercialise things and give their insights and make it and visualise it, but no, I don't think anybody should be selling public data. (WBE4)

Caution should therefore be applied to ESR contracts with third parties who are not part of the public service, because of potential conflicting priorities and objectives of commercial companies and CRIs.

5.2.3 Providing services, conducting research

ESR has a dual role within the public service, both to conduct research to further scientific knowledge and to provide scientific services to other agencies. Participants were clear that ESR had full responsibility for ethical integrity when carrying out its own research projects. There were more mixed views with regards to ESR being a service provider, yet the dominant theme was that ESR should be responsible for collaborating with its clients to ensure ethical integrity of the science or data use. ESR was assumed to act as a partner with other public service agencies, and therefore be able to question and influence outcomes.

- Your role is to provide the data, into an understandable format that represents what you're seeing in the testing process and providing that is presented in a way that is useable. (WBE5)

- I think it's the same with ESR. Where things are requested of you that are ethically or morally wrong then you should have the ability to say, "No, that's outside the scope of what we're here to do". (WBE5)

- And if [ESR] decides that there's some risks that emerge by providing all bits of it [the data], then it needs to think about how might limit those things. And that's a responsibility you have to take on yourself. You can't do anything about information you pass on and what others then do with it. (WBE8)

5.3 KNOWLEDGE

5.3.1 Scientific knowledge

Scientific knowledge, and ESR as producers of such knowledge, was generally held in high regard by participants. This came with expectations of professional conduct and peer accountability. It was expected that ESR scientists and the wider scientific community would hold themselves to account with regards to scientific rigour, ethical integrity and working for the public good.

- ESR are now a partner in this, right, … so they have a say in how the data is interpreted. I think it gives a degree of credibility to the data to have a scientist in the background. (WBE5)
- That's where I think ethics committees, we just have to believe in researchers. Because if you do bad research and you try to publish it, your discipline is going to hold you to account. They're going to say, 'we're not comfortable with how you've designed your project'. Or the funders are not going to be comfortable. (WBE1)

The expectation that scientists are self-regulating needs to be met, or the reputation and trust in the research institution will suffer - whether ESR is solely responsible for the research or whether it supplies data to another agency. A further risk is that scientists being held to account by their peers, publication editors or funders, are all retrospective mechanisms of regulation. If a research project is not well thought out, or if people are harmed due to inadequate protections, the damage to the trust in the research institution is immediate. The risk may therefore be better managed through proactive assessment of research ethics instead of retrospective peer review.

5.3.2 Other knowledges

Diverse knowledges were intrinsically valued and seen as necessary and complementary to science knowledge.

- It is important to have the different perspectives. The idea that you would absolutely make sure you had indigenous voices in there, that you had Māori perspectives on this. (WBE1)
- What you do want generally when you're getting advice or advisory groups, you want different people that think differently. You actually want to be challenged. You don't want a group of people to go, "Yes, yes, that's great, go ahead". You do want people to ask the hard questions. That is to make sure that there's diversity of thought in guidance. (WBE4)

Participants anticipated that incorporating different knowledges in research governance would lead to some tension that would need to be resolved. It was precisely this tension and resolution, however, that was seen to produce robust, publicly defendable decisions.

5.4 LEGITIMACY

5.4.1 Trust in the institution

Participants exhibited a high level of trust in ESR. This trust was based on the perception of ESR as impartial and unbiased providers of scientific information, staffed by professional scientists, and focused on working for the good of all New Zealanders on a national-wide scale. Legitimacy for the participants was strengthened by assumed policies and processes to protect and ensure these factors.

- I think that goes back down to when you originally set up your programme of work, what are the kind of core values, why you've set the things up, and going back to your vision and your strategy around the wider ESR organisation about what it is that you're trying to do, and understanding where the limits are and where your boundaries are, and sticking to that. (WBE3)
- To ask, "Was this produced ethically? Is it going to be managed ethically? Can we rely on the proper and right conduct of the people doing the work?" I think we might just assume that away inside of the ESR brand which has significant strength, because

we're dealing with a seasoned professional. So, I think that's the truth of it, we'd go, "No, look, these are good people, they're heavily credentialed, heavily experienced, they're working for a Government agency that we should trust" and we may not press those buttons as hard as we should. (WBE7)

This suggests that in order to perform its function as a publicly funded research institution and scientific services provider, ESR must live up to its reputation of having processes to ensure that all its research programmes have high standards of ethical integrity and good governance oversight. It is that reputation which gives ESR its legitimacy from a stakeholder perspective.

5.4.2 Sharing data

The participants distinguished between two categories of sharing data, depending on intended use for public information or community benefit. It was felt that ESR and its public service partners had a responsibility to make WBE data publicly available, but only at an aggregate level to avoid stigmatisation of communities. Participants advised on careful editing and presentation of data before release to the general public, as there was no way of controlling the subsequent use of this data.

- Government Departments collect information in the course of their activities, but when they're making it available for other people there might be limitations around some bits of it, or they don't provide all of it, or if you know it's going to end up in an open space, you're conscious about what it might be able to say and so you remove some of the bits of information which you might have so it can't be used out of context. It only lets you do things to certain scales, there's only a certain level of granularity it can produce. (WBE8)
- I would want to think of it being treated like the Census data is, you don't just release, you have rules around how it can be released. Normally we try to protect an individual, but in this topic, maybe you should be protecting it at a much higher level because people haven't chosen to give that data up. (WBE9)

For communities, however, participants made the case that fine-grained data should be made available on request, for the use and benefit of those communities. This relies on communities knowing what data sets are possible, implying a responsibility for ESR to be transparent and actively communicate what data are being collected on a regular basis. Participants suggested that fine-grained WBE data should not be released to communities without support or interpretation. It was felt that ESR had an ethical responsibility to ensure that data were understood, used appropriately and for the benefit of the community.

- But I also think that the Primary Health Organisations and the City Councils and people like that, should know the regional data. …. To me, unless they could justify it really well, I think national level data is all that should be publicly reported. (WBE2)
- There's a responsibility and a catchment when we're producing knowledge, when we're producing some new way of looking at a thing, you can't quite just hand it over altogether, there's some handholding, "after sale service" that goes with it. (WBE7)

Defining appropriate conditions for the release of data was therefore seen as a responsibility of ESR, regardless of whether the data were being provided for a third party or not.

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6. Boundary critique & theoretical alignments

This research aimed to identify perspectives on what issues and processes ESR should consider for ongoing responsible and ethical conduct within the emerging field of WBE. Nine interviews were conducted with informants across the WBE science system. Interview questions and analysis where informed by the CSH method for exploring what is included and excluded by the boundaries of a system, focused on issues of motivation and purpose, power and control, knowledge and expertise, and legitimacy from those not involved but affected by the system.

The findings covered two areas. One was specific ethical considerations for WBE, which aligned with existing literature and guidance on WBE. The second and more substantial area of findings were the wider processes for responsible research within which WBE should operate. Table 1 above summarises the findings in terms of the twelve CSH questions, and Table 2 below summarises the identified boundary issues.

The participants raised and agreed with the issues outlined by the WBE ethical guidelines of Prichard *et al.* (2014). This included seeing WBE technologies as minimal risk because they are non-invasive and operate at a population trend level, with greater risk of negative impacts from smaller catchment areas. The mitigation strategies of Prichard *et al.*, of thorough planning of the research and careful communication of research outcomes, were echoed by the participants. One particularly relevant congruence was that the research institution is responsible for the ethical integrity of the research even when contracting for services to a third party. This implies that ESR should have the integrity and courage to decline to participate in service contracts if it is not satisfied with the ethical protections, and to maintain positive relationships which enable dialogue with clients around ethical issues.

Public health ethical frameworks, in contrast to more individualist biomedical ethical frameworks, justify health interventions and research on the grounds that the benefits to the

collective outweigh the need to obtain individual consent, especially from a social justice perspective. Again, the participants raised similar points in the interviews, with an emphasis on being able to justify that WBE research produced improved collective social and health wellbeing and protected those who are already marginalised in society. The participants also emphasised what Childress *et al.* (2002) term 'effectiveness', where research that infringes of people's autonomy must be shown to be effective in addressing public issues. WBE technologies should only be used when it can be shown to be the best way of producing meaningful data to answer a well-defined research question.

Māori research ethics encompass the principles of Te Tiriti o Waitangi and the concept of tino rangatiratanga (Māori sovereignty over their own affairs) (Hudson and Russell, 2009). Where research involves and concerns Māori then there should be consideration of Māori cultural issues, with best practice being Māori governance. This implies that research governance structures within CRIs should have Māori representation at a minimum, with greater legitimacy for governance structures which enact a Tiriti-based partnership and provide multiple Māori views. Research on experience of Māori on advisory groups within the health sector highlights difficulties of real partnership if there is only one representative amongst many (Came *et al.*, 2019). True dialogue should fully incorporate indigenous knowledge holders into planning and decision-making, as opposed to having advisory roles (Hepi *et al.*, 2018).

The findings related to RRI processes gave a strong sense of the primary purpose of CRIs being to provide scientific knowledge to benefit the public of Aotearoa New Zealand, and that protection for the public lay in CRIs routinely adhering to professional standards of scientific rigour, ethical integrity and informed debate. The participants framed this in terms of principles and responsibility, collaboration and communication. Formal internal structures for the purpose of enacting a CRI's responsibilities should be based on principles and dialogue, and not become too rigid or become an end in themselves in order to maintain a high degree of responsiveness.

As an overall framework, the RRI approach appears to align well with participants' comments and the context for research governance at a CRI. Based on responsibility rather than regulation, the elements of RRI according to Stilgoe *et al.* (2013) include anticipation of benefits and impacts, reflexivity of the institution's values and purpose, inclusion of a diversity of voices and responsiveness to community input, and were all echoed in the participants' interviews. One benefit of adopting an RRI approach is that it accommodates adaptability to local context, both to Aotearoa New Zealand as a whole and to local communities.

Another important aspect of RRI is its future focus, with emphasis on assessing research not only for its risks but also for potential benefits. If research is to benefit all of society in Aotearoa New Zealand, then it must address the systemic disadvantage currently faced by Māori. This also aligns with Public Health ethics frameworks such as that of Baylis *et al.* (2008) which recognise that people are socially and culturally situated, and social justice demands that this be taken into account when making research decisions. *Te Ara Tika,* in explaining Māori research ethics, takes the view that not only should research with Māori do no harm, but it should address the needs and aspirations of Iwi Māori, including future generations. Being proactive and positive is also an important part of the RRI approach, making it an appropriate framework for CRIs to consider. RRI can be used to guide a process of dialogue, alongside Te Tiriti o Waitangi, to inform decision-making regarding research priorities and design. It provides a framework within which the more limited scope of biomedical-informed research ethics processes can operate. Importantly, embedding research ethics within RRI recognises that ESR needs a wide ethical lens, as a responsible public agency and Te Tiriti o Waitangi partner.

TABLE 2: Boundary critique for Wastewater Ethics

	Boundary Critique.
Motivation	Participants were clear that the beneficiary of ESR research and services ought to be the Aotearoa New Zealand public, even when ESR is providing the data and outputs of its activities to a third party. ESR was seen to have a responsibility to ensure that the end result of its activities is an improvement in social, health and environmental wellbeing. In tandem with a responsibility to the population as a whole, ESR also has a responsibility to honour Te Tiriti o Waitangi, and actively address systemic disadvantage with respect to Māori.
Control	ESR was expected to have robust policies and procedures which ensure that its research and services achieve the overall aim of improving public wellbeing, with ethical integrity. This extended to ESR providing services to third parties, in which case ESR was expected to be a collaborator more than a contractor, and therefore have some influence over eventual outcomes. Decision making around research was expected to actively include various perspectives, changing as required for particular research projects or programmes. Overall, however, there was seen to be a need for continuity of decision making, and to give effect to a Tiriti-based partnership for research governance.
Knowledge	Scientific knowledge was well respected, bringing with it expectations of self-regulation within the organisation and within scientific peer networks. Other knowledges and expertise were also seen as valuable. Participants saw it as essential that research involving Māori should involve people with knowledge of tikanga me mātauranga Māori (Māori cultural practices and knowledge systems), as well as people who understand the local Iwi and Hapū (tribe and sub-tribe) context. The need to include a variety of knowledges, including different science disciplines, tikanga Māori (Māori cultural practices) and research ethics, suggested a process for dialogue between knowledges and perspectives.
Legitimacy	There was general acceptance of the benefits of wastewater-based epidemiology technologies, and minimal concerns about its harmful effects due to non-invasiveness and population level data. However, this acceptance was predicated on a trust in ESR as a public research institution that was committed to improving the population's wellbeing, that self-regulated for high standards of scientific rigour and ethical integrity, and worked in an open, transparent and collaborative manner. Addressing the ethics of wastewater-based epidemiology should therefore be focused on ensuring that internal processes live up to the public's expectations.

7. Conclusion

Wastewater-based epidemiology is a new field of analytical chemistry that can provide useful population-level data which can be used for a variety of public health and law enforcement purposes. The advantages of WBE is that it is non-invasive, logistically simple method to sample large population areas, and the data contain no personal identifiers. However, the lack of ability to characterise the people included in the samples is also a disadvantage for guiding public health interventions which seek to improve the wellbeing of specific sub-populations. This makes it important to carefully match the use of WBE to the research question, so that public health ethical criteria of effectiveness, necessity and public justification can be met.

In the context of Aotearoa New Zealand and Crown Research Institutes, a responsible research approach has been shown to be appropriate and match perspectives from interview participants. The RRI approach focuses on assessing the responsibilities of the research institution, which are wider than mitigating ethical risks. This would allow, for example, for formal structures based on a Tiriti-partnership, so that Māori needs and aspirations can be addressed through research.

The plan for this research included collecting the perspectives of a wider range of people, including health policy and health providers, Pacific people and the Police. However, the Covid-19 pandemic situation meant that these people were extremely busy and focused on the urgent needs generated by the pandemic, so were not able to be interviewed. This is acknowledged as a gap in the data, and future research could include checking to see whether these perspectives align with the findings in this paper.

GLOSSARY

Aotearoa	The Māori name for New Zealand
CRI	Crown Research Institute
CSH	Critical Systems Heuristics
ESR	Institute of Environmental Science and Research
Hapū	Māori sub-tribe grouping
Iwi	Māori tribe
Mana	Respect, status, dignity
Manaakitanga	Hospitality and care of people
Māori	The indigenous people of Aotearoa New Zealand
Mātauranga	Māori knowledge systems
RRI	Responsible Research and Innovation
SLO	Social Licence to Operate
Te Ao Māori	Māori worldview
Te Tiriti o Waitangi	The Treaty of Waitangi, signed in 1840 by Māori chiefs and representatives of the British Crown, which opened the way for a British settler state to be established in Aotearoa New Zealand
Tika	Correctness, rightness
Tikanga Māori	Māori cultural practices
Tino rangatiratanga	Māori phrase meaning to have sovereignty or autonomy over one's own affairs. This was a promise contained in Te Tiriti o Waitangi: that Māori would retain tino rangatiratanga.
WBE	Wastewater-based epidemiology
Whakapapa	Genealogy, relationships

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