Digital Mental Health and Addiction Tool (DMHAT)

Introductory Guide

Beta version 1.0 – November 2021

MINISTRY OF
HEALTH
MANATŪ HAUORA

Version control

Date	Version	Notes
22/06/21	0.1	Initial draft for MOH review
20/8/2021	0.2	Update following further vendor feedback and consumer engagement.
5/11/2021	1.0	Final changes to align with website

Nau mai, haere mai!

Welcome to Aotearoa New Zealand's digital shores. We extend you a warm welcome and look forward to working with you to create a safe, supported and robust marketplace for users and vendors alike.

As we are all aware, the digital space is moving at a phenomenal rate. As a result, the Aotearoa New Zealand market, and the literacy of its users, is increasing exponentially. This is particularly true in the context of health and wellbeing, as users become more aware of the opportunity to independently increase their sense of wellbeing by using technology to self-manage.

Our intent in this process is to support you, our digital service provider partners, in providing robust and appropriate options for our whānau (family), communities and populations. We understand and appreciate the critical role of developers and vendors in this rapidly evolving sector. We look forward to creating ongoing and sustainable success for everyone, most importantly for our whānau and the professionals who support them.

Ngā mihi nui (thank you so much) for supporting us in delivering this vision.

Tehei Mauri Ora!

Table of Contents

Introduction

The standardised assessment of digital tools is an emerging space in Aotearoa New Zealand.

The Digital Mental Health and Addiction Tool (DMHAT) Introductory Guide is intended to support anyone interested in the design and development of digital tools to deliver robust and appropriate options for our whānau, communities and populations.

The guide supports the evaluation process and includes relevant references, standards and rationales for each step of the assessment.

We appreciate you have chosen to use the DMHAT assessment pathway, which will allow clinicians and users access to trusted apps and tools that align with their unique requirements.

Please note this is a beta version and ongoing refinements will be made as we all continue to explore and understand what is required when assessing digital tools within the Aotearoa New Zealand context. You are welcome to join the DMHAT collaborative and to share your insights by following the pathway below.

DMHAT Assessment Framework

Designers and developers will be guided through what it takes to meet acceptable quality standards for New Zealanders, and the health professionals who support them. The assessment framework has two components. The first is an introductory guide to DMHAT that sets out the baseline standards expected of digital mental health tools for users in Aotearoa New Zealand. The second component is a self-assessment tool for designers and developers of digital mental health apps and tools, available either as an online tool or a downloadable document.

- ☐ **Introductory guide:** To help you become familiar with the DMHAT assessment framework, we've created this introductory guide. This guide is available to anyone, including those not registered on this site.
- ☐ **Self-Assessment**: Registration is required to allow full access to the current beta DMHAT self-assessment, and will also give us a way to keep you updated as this is developed further. Register now.

In due course, it is hoped a third component will be developed that will offer a formal accreditation pathway.

DMHAT Collaborative

A DMHAT collaborative is in development to help guide the ongoing refinement of the DMHAT criteria and assessment process.

It will bring together whānau with lived experience, clinicians, health providers, developers, IT experts, researchers, academics and agencies at all levels so that together we can contribute to, and participate in, the assessment's ongoing development, with a particular focus on the health and hauora space. The intention is to champion an open and inclusive approach in the pursuit of exceptional resources for those we love and serve, specifically with New Zealanders in mind.

The intention is to champion an open and inclusive approach in the pursuit of exceptional resources for those we love and serve, specifically with New Zealanders in mind. Learn more about the DMHAT Collaborative.

Why join

Be part of the journey

Partnerships with whānau, the lived experience community and everyday users of digital tools should be central to all health initiatives. The more diverse voices we have involved, the more appropriate, considered and effective our approach will be.

Join the community

Join our commitment to Te Tiriti o Waitangi and partnership by growing and supporting a community that practises authentic codesign and appreciates the voices of experience as having at least equal relevance.

Shape our future

The whakapapa (genealogy) of our future tupuna (ancestors) is being written by us now. We have a responsibility to future-proof their wellbeing, sovereignty, and cultural safety across the health, digital and global spaces. The tools we co-create and continue to develop now will nourish them and theirs long after we are gone.

Evolve with us

The digital space is constantly evolving and changing. Join us on this ever-evolving journey of discovery to ensure our standards create safety, trust, quality and effectiveness for whånau, healthcare professionals, vendors and other stakeholders alike. Grow with us as we evolve together.
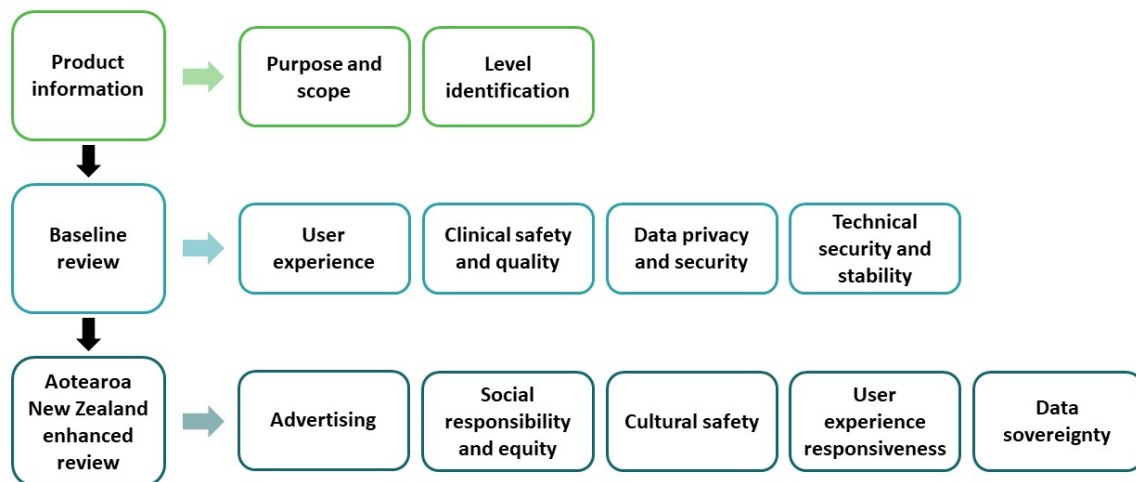
Learn more about the [DMHAT Collaborative](#).

DMHAT Assessment

The DMHAT assessment comprises three main sections:

1. Product information,
2. Baseline review
3. Aotearoa New Zealand enhanced review, which assesses elements that are more specific to the Aotearoa New Zealand context.

Components of the DMHAT Assessment

Product information	→	Purpose and scope	Level identification		

| Baseline review | → | User experience | Clinical safety and quality | Data privacy and security | Technical security and stability |

| Aotearoa New Zealand enhanced review | → | Advertising | Social responsibility and equity | Cultural safety | User experience responsiveness | Data sovereignty |

For the purposes of the DMHAT assessment, apps and digital tools are defined as "a digitally delivered product that is aimed at supporting mental wellbeing in some way". This can include "wellness" orientated apps if there is a clear health-related focus and benefit.

Product information

This section includes nominal, qualitative and categorical questions to enable you to describe your product. This information will be used to create a summary or overview description of the digital tool. Examples of information you will be required to provide include:

- What is the purpose of this digital tool?
- What are the main issues or conditions that this digital tool aims to address?
- Who are the intended users or target audience of the digital tool?
- What functional characteristics does the tool have?
- Describe the mode of care of this digital tool (ie, independent use by the consumer, or used by a consumer alongside or guided by a healthcare provider, or both).
- What benefits might users gain from this digital tool?

Dynamic assessment

A key and unique feature of the DMHAT Assessment is that the assessments are dynamic and responsive to the type and nature of the solution under review.

All apps and digital tools are not the same. There is a huge array of differing features, functions and areas of focus across the products available globally and locally. It is therefore crucial that any assessment approach is responsive to the specific characteristics of a solution, while at the same time ensuring that it is consistent and transparent, and that like-for-like solutions are treated the same way.

This has led to the introduction of a four-level, risk-based hierarchy to determine the appropriate assessment requirements for each digital tool:

- Level 1: Wellbeing.
- Level 2: General health.
- Level 3: Condition management.
- Level 4: Integrates with health records or are medical devices.

From the list below, select the options that best describe your digital tool's features. The highest level of features determines the digital tool's assessment level.

Level	Features
Level 1: Wellbeing	These digital tools are focused on general wellbeing with a health focus. ☐ Provides general information. ☐ Provides links and suggestions for local or national services that are relevant to its focus area.
Level 2: General health	These digital tools are focused on general health (see Level 3 for tools focused on specific health conditions). ☐ Provides functionality to allow users to monitor their conditions (this may involve simple recording of relevant data over time). ☐ Allows users to create a personal health record. ☐ Provides advice to users about their general health. ☐ Utilises behavioural change techniques. ☐ Captures user data. ☐ Allows users to share their data. ☐ Has its own or provides access to social networks relevant to its area of focus.
Level 3: Condition management	These digital tools are focused on supporting specific health conditions. ☐ Provides guidance on the treatment or management of a specific health condition. ☐ Allows remote monitoring of health data by healthcare professionals but does <u>NOT</u> integrate with health records (such as a PMS). ☐ Allows users to have online consultations with a healthcare professional. ☐ Provides pharmacy services to its users.
Level 4: Integrates with health records or is a medical device	These digital tools integrate with health records or are medical devices. ☐ Integrates with health records. ☐ Is a medical device. (see Medsafe for a definition)

Baseline review

The baseline review has been designed to align with current best practice standards and encompasses assessment criteria that are widely used across most app and digital solution assessment pathways internationally.

The most well-known international digital health standards and frameworks incorporated within the DMHAT baseline review through this collaboration include:

- **Evidence Standards Framework (ESF):** Guidelines published by NICE to measure the effectiveness or impact of apps.
- **Food and Drug Administration (FDA):** The FDA is responsible for protecting public health by ensuring the safety and efficacy of food products and pharmaceutical products. If relevant, we establish whether an app is FDA Approved or FDA Cleared.
- **General Data Protection Regulation/Data Protection Act (GDPR/DPA) 2018**: This assesses whether an app follows the correct data protection guidelines.
- **ISO 27001:** An International Data Management Standard, specifically concerning information security management.
- **ISO 9241:** App design standards.

For a complete list of the baseline review standards see Appendix A.

There are four main criteria assessed in the baseline review. These are further broken down into sub-sections.

1.User experience
Purpose
Usability, accessibility, user input and testing are crucial considerations in the design of a good healthcare app.
Assessment sections
1. Design and accessibility.
2. Usability.
3. Charges and costs transparency.
4. Technical support.

Detailed description

This section assesses how well a digital tool:

- complies with any currently recognised app design standards
- promotes accessibility such as options for users with poor sight or hearing difficulty
- supports broad-based reach such as availability on different platforms and in languages other than English
- creates a positive, personalised user experience
- ensures that charges are clear and explicit, so users have a clear understanding of the financial commitment and its duration
- provides support for users to contact developers about technical issues. The support offered should be appropriate to the tool – a higher level tool requires more rapid responses and appropriate assistance (see level identification).

Guidance documents

- NZ Government Design System
- NZ Government Web Standards

ISO and The International Customer Service Institute (TICSI) have published the following standards relating to this topic:

- ISO 9004 2018 on performance improvement
- ISO 9001 2015 on quality management in handling customer complaints
- ISO 10002 2018 on customer service conduct
- ISO 10003 2018 on dispute resolution
- ISO 10004:2018 on monitoring and measuring
- ISO/IEC 20000-1:2018 service management standard.

2. Clinical safety and quality

Purpose

This section assesses the clinical quality and safety of apps and digital tools. While apps have the potential to benefit consumers by offering interactive tools that help with treatment adherence and by improving access to information, they can also pose safety risks if they are inaccurate and unreliable, mainly because consumers may use the information from apps to make decisions about their health.

Many digital solutions show great promise, but there is a need to be certain that they do not put users at risk. In addition, to ensure that tools effectively contribute to people's mental health and wellbeing, testing and trial of tools should be promoted.

Assessment sections

1. Credibility and evidence.

2. Professional backing and usage.

Detailed description

This section assesses:

- claimed benefits of the app
- evidence of effectiveness of the app or evidence of the effectiveness of the technique used by the app (eg, such as mindfulness or CBT)
- whether appropriate healthcare professionals have been involved in the design and development of the digital tool.

Guidance documents

1. [Evidence standards framework for digital health technologies](#) NICE, UK, 2019
2. [Methods for evaluating the content, usability, and efficacy of commercial mobile health apps](#) JMIR mHealth and uHealth, 2017
3. [Actionable health app evaluation: Translating expert frameworks into objective metrics](#) NPJ Digital Medicine, 2020
4. [Do mental health mobile apps work: evidence and recommendations for designing high-efficacy mental health mobile apps](#) mHealth, 2018
5. [HISO 10024.2:2017 medical device terminology and identification standards](#) Ministry of Health, NZ

3. Data privacy and security

Purpose

This section assesses the data privacy and security safety measures undertaken during data collection, sharing, storage and transfer.

Includes

1. Data collection.

2. Data sharing and data use.

3. Privacy policy.

4. Data storage and transfer.

5. Data standards and management.

Detailed description

This section assesses:

- what data is collected by the tool (both information that is manually entered by users or indirectly through cookies)
- if it clear to the user whether any data entered into the tool can be shared, and whether they have control over who it is shared with and how
- if the tool has a privacy policy and whether it accurately reflects the data collection and usage of the digital tool
- whether users are adequately informed about storage and transfer of their data.

Guidance documents

- [New Zealand Privacy Act 2020](#)
- [Data privacy](#) data.govt.nz
- [Digital service design standard](#) digital.govt.nz
- [Privacy, security and risk](#) digital.govt.nz
- [Web security testing guide (WSTG – v4.2)](#) Open Web Application Security Project

Health Information Standards Organisation (HISO)

- [HISO 10029:2015 health information security framework](#) Ministry of Health, NZ
- [HISO 10046:2021 consumer health identity standard](#) Ministry of Health, NZ
- [HISO 10023.3:2017 PRIMHD code set standard](#) Ministry of Health, NZ
- [HISO 10033 SNOMED CT endorsement](#) Ministry of Health, NZ
- [HISO 10065:2018 allied health data standard](#) Ministry of Health, NZ

4. Technical security and stability

This section is applicable if the digital tool is a level 2,3 or 4 app.

Purpose

Technical stability assesses whether the app starts up reliably and completes its task without crashing, and technical security assesses whether information and systems are protected from unauthorised activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related risks to confidentiality, integrity, and availability are maintained at an acceptable level.

Includes

1. Technical security.

2. Technical stability.

Guidance documents:

- [ISO/IEC 27001](#) Information security management
- [ISO/IEC 27014: 2020](#) Governance of information security

- [ISO/IEC TS 27110:2021](#) Cybersecurity framework development guidelines
- [ISO/IEC 27005:2018](#) Information security risk management
- [ISO/IEC 27002:2013](#) Code of practice for information security controls

Sample questions:

1. How often is third party (independent) application and_code level security testing/assessment completed? [Free text]
2. Are there policies and processes in place for secure coding practices? [Yes/No]
3. Is there a documented process for conducting regular system security access audits? [Yes/No]
4. Have you implemented role-based access controls for developer team members? [Yes/No]
5. Is there a documented process for reviewing and revoking role-based access to systems where a person changes role or leaves the organisation? [Yes/No]
6. Are there policies in place to secure health information in transit and at rest? [Yes/No]
7. Are there policies and processes in place for incident logging, response, handling, escalation, and recovery? [Yes/No]
8. Are there policies and processes in place to notify all affected parties of the security incident and possible data breaches? [Yes/No]
9. What safeguarding measures are in place to ensure the security of information and to protect information from unauthorised access and intrusion? [Free text]
10. Are there policies in place that govern retention periods and safe destruction of health records? [Yes/No]
11. Is personal health information stored in a cloud environment? [Yes/No]
12. Has the developer undertaken a risk assessment conducted using the GCIO cloud assessment tool? [Yes/No]
13. Is the developer compliant with their requirements under HISO 10029? [Yes/No]
14. What organisation category of HISO 10029 is the organisation compliant with? [Free text]
15. Does the scope/statement of applicability include the product and associated services? [Yes/No]

Aotearoa New Zealand enhanced review criteria

This section assesses the criteria specific to the use of the digital tool within the Aotearoa New Zealand context. It comprises the following five sections that the tool will be assessed on: advertising, social responsibility and equity, cultural safety including Māori cultural safety, user experience feedback and data sovereignty. He Ara Oranga (*Report of the Government Inquiry into Mental Health and Addiction*) has led the way by painting a clear picture of the additional attributes around mental health and addiction services needed and how these will improve our broader outcomes.

Aotearoa New Zealand enhanced review	→	Advertising	Social responsibility and equity	Cultural safety	User experience responsiveness	Data sovereignty
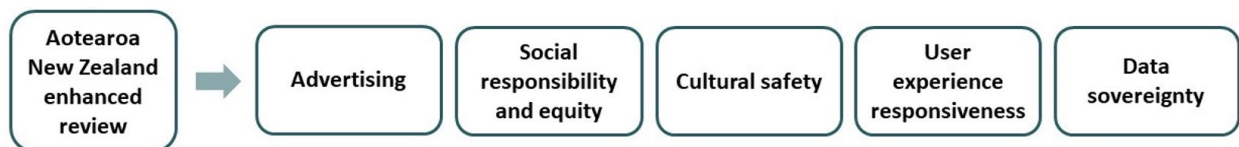
1. Advertising

Purpose

When assessing advertising, there are two aspects to be considered:

- advertising of the digital tool
- advertising appearing within the digital tool (in-app advertising).

It is important that any advertising is in keeping with the codes and standards as set out by the New Zealand Advertising Standards Authority.

Guidance documents

All digital tools with a health focus need to comply with the Therapeutic and Health Advertising Code.

- Therapeutic and Health Advertising Code

The following advertising codes are also applicable if the digital tool has in-app advertising, depending on the type of ads included.

- Advertising Standards Code
- Children and Young People's Advertising Code
- Code for Advertising and Promotion of Alcohol (Current)
- Alcohol Advertising and Promotion Code (New)
- Code for Financial Advertising
- Gambling Advertising Code

2. Social responsibility and equity

Purpose

Social responsibility is an ethical theory in which organisations are accountable for fulfilling their civic duty, and their actions must benefit the whole of society and not solely the organisation.

In Aotearoa New Zealand, people have differences in health service access and outcomes that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes.

Sample questions

(see the guidance documents below for assistance)

- What measures are taken to incorporate ethical principles or values, most notably Te Tiriti o Waitangi, Aotearoa New Zealand's founding document?
- How does your digital tool address inequity and support social responsibility?
- Considering the question above, how will you monitor these initiatives and their ongoing relevance, and address any changes necessary?
- Are measures taken to prevent coercion within the digital tool?

Guidance documents

General

- [Achieving equity in health outcomes: Summary of a discovery process](#) Ministry of Health, NZ, 2019
- [He ara hauora Māori: A pathway to Māori health equity](#) Medical Council, NZ
- [Health equity](#) Health Navigator NZ
- [Report highlights inequity of mental health service quality and outcomes for Māori](#) Health and Disability Commissioner, NZ
- [New Zealand's mental health and addiction services: Monitoring indicator update 2017 & 2017/18](#). Health and Disability Commissioner, NZ, 2019 ([summary](#))
- [Prevalence and consequences of barriers to primary health care](#) Ministry of Social Development, NZ, 2021
- [Social responsibility and ethics](#) Pachamama Alliance

Te Tiriti o Waitangi

- [Digital inclusion through a Māori lens](#) digital.govt.nz

- [Treaty of Waitangi principles](#) Ministry of Health, NZ

- [Intro to core principles](#) Mauri Ora Associates

- [Introduction to the Treaty of Waitangi](#) University of Otago

- [How to answer the Treaty of Waitangi question](#) Tertiary Education Commission

Diversity

- [Diversity, belonging and inclusion in Aotearoa New Zealand: A review of consultation and community engagement](#) Capturing the Diversity Dividend of Aotearoa New Zealand (CaDDANZ), 2021

Coercion

- [The coercive potential of digital mental health](#) American Journal of Bioethics, 2021

3. Cultural safety

Purpose

Culture is not defined exclusively by any one factor. It is the various aspects of our self-determined identity that we use to create and form a shared cultural identity. Race, ethnicity, nationality, gender, sexual orientation and social class are relevant considerations.

Ethnicity is a measure of cultural affiliation. It is not necessarily a measure of race, ancestry, nationality or citizenship. Ethnicity is self-perceived and people can belong to more than one ethnic group. An ethnic group is made up of people who have some or all of the following characteristics:

- a shared sense of common origins or ancestry
- a common geographic origin
- one or more elements of common culture, for example language, customs, or religion.

Cultural safety means an environment that is physically, spiritually, socially and emotionally safe for all people. This includes that there is no assault, challenge or denial of a person's identity and what they need. In Aotearoa New Zealand, cultural safety is of particular importance for Māori and Pasifika.

Sample questions

- Have target communities been involved in the design, uptake and ongoing review of the digital tool?
    - If yes, please describe how they have been involved.

- o If no, how will you undertake ensuring this is addressed through culturally relevant user review and feedback?
- Does the digital tool support cultural identity and preferences, such as through language, icons and imagery?
    - o If yes, describe how appropriate advice was received on this.
- Does the digital tool acknowledge practices outside western medicine?
    - o If yes, please describe what they are and how appropriate advice was received on this.
- How are data-trained biases addressed in the algorithms of offering services to users?

Guidance documents

- [Why cultural safety rather than cultural competency is required to achieve health equity: A literature review and recommended definition](#) Journal of Equity in Health, 2019
- [Statement on cultural safety](#) New Zealand Medical Council
- [Understanding bias in health care](#) Health Quality and Safety Commission
- [Cultural safety modules](#) Health Navigator NZ, Health Literacy NZ
- [Māori health models](#) Health Navigator NZ
- [Pacific models of health](#) Health Navigator NZ
- [Asian models of health](#) Health Navigator NZ
- [Introduction to te ao Māori](#) Kii Tai Culture Code, NZ
- [Cultural safety – What does it mean for our work practice?](#) Robyn Williams, Lecturer in Indigenous Health, Australia

4. User feedback responsiveness

Purpose

This section assesses how you provide a communication pathway or feedback loop for users based on their personal experience of the digital tool. Considerations for users may include culture, social responsibility, perceived harm or accessibility concerns.

A robust feedback process demonstrates the commitment to continuous improvement of the user experience within the digital tool. This section assesses the collection, assessment, action and follow-up of the user experience data (see [Appendix C](#)).

Sample questions

- Can users share their experience of using the digital tool?
    - o If no, why not?
    - o If yes, describe how users can do this.
    - o If yes, describe your process for responding to user experience feedback.
    - o If yes, how will you monitor and/or action this feedback.

         ○   If yes, describe your follow-up communication process with the user.

Guidance documents

- [In-app feedback: How and why to capture user feedback in your app](#) UserVoice
- [Principles of online engagement](#) digital.govt.nz
- [Progressing consumer engagement in primary care](#) Health Quality and Safety Commission, NZ
- [Engaging with consumers](#) Health Quality and Safety Commission, NZ
- [Ethnicity](#) Stats NZ

5. Data sovereignty

Purpose

The concept of data sovereignty is linked with indigenous peoples' right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as their right to maintain, control, protect and develop their intellectual property over these. ([Indigenous data sovereignty: towards an agenda](#) Victoria Tauli-Corpuz, UN Special Rapporteur on the Rights of Indigenous Peoples)

Indigenous data sovereignty is critical. This becomes increasingly challenging due to open data environments and data being stored in foreign countries and therefore subject to their laws. Sovereignty reinforces indigenous ownership of that data. In an effort to respect and preserve indigenous rights of self-determination and ownership, both here in Aotearoa New Zealand and globally, we seek clarity on how the data is collected, stored, accessed, assessed, managed and disseminated.

Guidance documents

- [Data collection and disaggregation for indigenous peoples](#) United Nations
- [United Nations declaration on the rights of indigenous peoples](#) United Nations
- [Technology and architecture](#) digital.govt.nz
- [Cloud risk assessment tool](#) digital.govt.nz
- [Explanation and notes of the Hapū Data Sovereignty Dataset](#) Karaitiana Taiuru, NZ, 2021
- [Principles of Māori data sovereignty](#) Te Mana Raraunga, NZ
- [The State of Open Data: Histories and Horizons](#) Davies, T., Walker, S., Rubinstein, M., & Perini F, 2019
- [Pacific Data Sovereignty Network. Consultation document](#) Moana Research, 2021
- [HISO 10001:2017 Ethnicity Data Protocols](#) Ministry of Health, NZ
- [NZ Stats Ethnicity V1.0.0 standard](#) Stats NZ
- [Aria](#) Stats NZ

Scoring

In its current format, DHMAT uses a self-assessment approach. A self-assessment approach helps you to determine how well your digital tool meets internationally accepted digital standards and helps you monitor progress towards full concordance. Rather than a punitive, pass/fail approach, the self-assessment approach fosters self-evaluation, along with self-verification and self-enhancement. It is a platform to involve all people concerned in the design and development of the tool and is an impetus for decision-making for ongoing improvement.

At the end of each subsection is a scoring rubric (set of instructions) that uses the ratings of poor, fair, good, very good and outstanding. The rubric is an attempt to communicate expectations of quality around each of the criteria. It allows vendors and assessors to evaluate criteria, which can be complex and subjective. Rubrics enable vendors to evaluate their own performance and focus their efforts to improve quality and meet best practice expectations.

The description of five grades of the rubric are as follows:
- **Poor:** Less than minimal level of expectation. The vendor has not addressed the criteria in this subsection.
- **Fair:** Minimally expected level of performance. The vendor has made some attempt to address the criteria in this subsection, however, there is considerable room for improvement.
- **Good:** Expected level of performance. The vendor has addressed most of the criteria in this subsection.
- **Very good:** Expected level of performance. The vendor has addressed all the criteria in this subsection.
- **Outstanding:** Vendor meets and exceeds expectations.

Scores of each assessment section will be assessed individually and not combined into a composite score. Presenting these items as a summary score for each section acknowledges that individual measures address quite different issues and aspects of quality. While composite scores may be valid if quality is consistent across different criteria, this is often not the case. In future versions, the pros and cons of composite scores will be explored further.

Below is a summary of the overall scoring matrix.

Criteria	Poor	Fair	Good	Very good	Outstanding
User experience					
Design and accessibility	☐	☐	☐	☐	☐
Usability	☐	☐	☐	☐	☐
Charges and costs transparency	☐	☐	☐	☐	☐
Technical support	☐	☐	☐	☐	☐
Clinical safety and quality					
Credibility and evidence	☐	☐	☐	☐	☐
Professional backing and usage	☐	☐	☐	☐	☐
Data privacy and security					
Data collection	☐	☐	☐	☐	☐
Data sharing and use	☐	☐	☐	☐	☐
Privacy policy	☐	☐	☐	☐	☐
Data storage and transfer	☐	☐	☐	☐	☐
Data standards and management	☐	☐	☐	☐	☐
Technical security and stability					
Technical security	☐	☐	☐	☐	☐
Technical stability	☐	☐	☐	☐	☐
Aotearoa New Zealand enhanced review					
Advertising	☐	☐	☐	☐	☐
Social responsibility and equity	☐	☐	☐	☐	☐
Cultural safety	☐	☐	☐	☐	☐
User feedback responsiveness	☐	☐	☐	☐	☐
Data sovereignty	☐	☐	☐	☐	☐

Out of scope

Given the complexity of artificial intelligence (AI) and cognitive computing technologies, these are both out of scope for assessment in this version of the DMHAT Assessment. Future iterations may be expanded and adjusted to cover these areas in due course.

This Assessment only assesses the digital tool (app or online programme) submitted for appraisal and not any associated devices, add-ons or products supplied, such as dermascopes.

Also out of scope is assessment of service delivery by a third-party organisation using the digital tool or app as part of their programme. There are existing procurement and service delivery assessment frameworks already designed to assess these aspects such as the national Social Services Accreditation Framework.

Appendix A – Baseline review standards

Appendix A details the wide range of international standards, legislation, regulatory groups and digital tool assessment criteria reviewed by the ORCHA team and incorporated into this version of the baseline review where appropriate:

CQC – Care Quality Commission
The independent regulator of all health and social care services in England. If an app provides a health service to the user, it may need to be registered with the CQC.

Caldicott Principles
The Caldicott Principles ensure that any patient information which could identify them is protected and is only used and shared when it is appropriate to do so.

DSPT – Data Security and Protection Toolkit
This is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's 10 data security standards.

ESF – Evidence Standards Framework
Guidelines published by NICE used to measure the effectiveness or impact of apps.

FDA – Food and Drug Administration (US)
The FDA are responsible for protecting public health by ensuring the safety and efficacy of food products and pharmaceutical products. If relevant, we establish if an app is FDA Approved or FDA Cleared.

GDPR/DPA 2018 – General Data Protection Regulation/Data Protection Act 2018.
This Act assesses whether digital tools follow the correct data protection guidelines.

GPhC - General Pharmaceutical Council
The independent regulator for pharmacists, pharmacy technicians and pharmacy premises in the UK. If relevant, we assess whether an App constitutes a pharmacy service, which would need to be registered with the GPhC.

HSCN – Health and Social Care Network
The HSCN provides a reliable and efficient way for health care organisations to access and exchange electronic information.

ISO 13485
Quality management system for medical devices.

ISO 14971
Application of risk management to medical devices.

ISO 27001
An International Data Management Standard, specifically concerning information security management.

ISO 9241
App design standards.

NICE – The National Institute for Health and Care Excellence

NICE provides guidance, advice and information services for health, public health and social care professionals. NICE published the ESF guidance (see p22) to measure the effectiveness or impact of apps.

WCAG 2.0 AA/WCAG 2.1 AA – Web Content Accessibility Guidelines 2.0 and 2.1

This guideline outlines appropriate app design standards.

Appendix B – Full list of frameworks

Below is a full list of digital health and health technology assessment frameworks, which have been used in the creation of the baseline review.

- AQEL
- ISYScore
- RCP Health Informatics Unit Checklist
- MASUN
- MARS
- uMARS
- Xcertia
- APA
- mHealth Belgium
- TAx Heuristics
- APPLICATIONS
- HEALTH-ITUES
- mHealth Andalousie
- CONSORT e-Health
- mCAPP
- mHealth Quality
- mERA
- NHS Digital Assessment Questionnaire
- AppSalut
- HAS
- GGD Holland

Appendix C – Communication and feedback pathways

Traditional feedback loops, such as the ACAF (ask, categorise, act, follow-up) customer feedback loop model, only include the customer at a single point in the communication loop (#4 follow-up).

The A.C.A.F. Customer Feedback Loop

4. Follow-up
Follow-up with customers who gave feedback on your plans so they know you're truly listening.

1. Ask
Ask your customers for feedback on your product or service.

3. Act
Act on the feedback by sharing it with others at your company who can implement changes.

2. Categorize
Categorize the feedback into different buckets that are meaningful to your business.
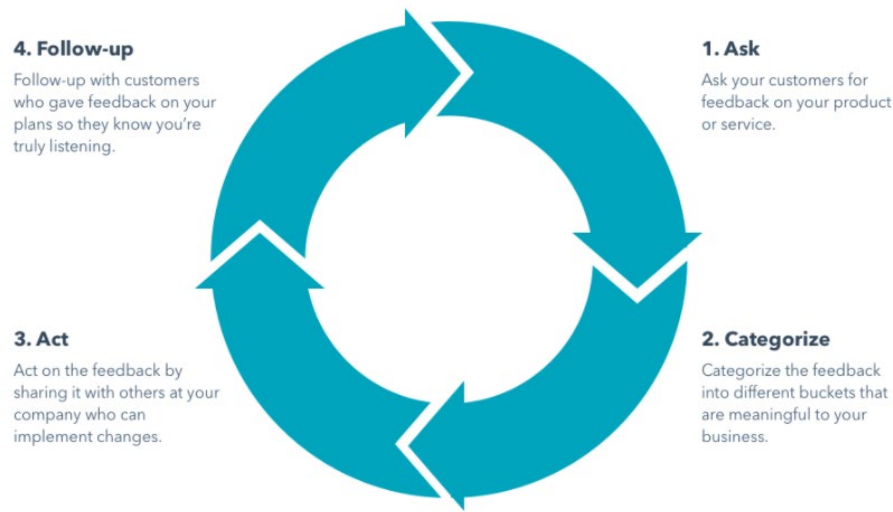
This model has been adapted to include customer communication at various points during the feedback pathway.

Communication and feedback pathway

User interaction → Receive → User interaction → Assess → User interaction → Adjust → User interaction → Check in → (back to User interaction)

26
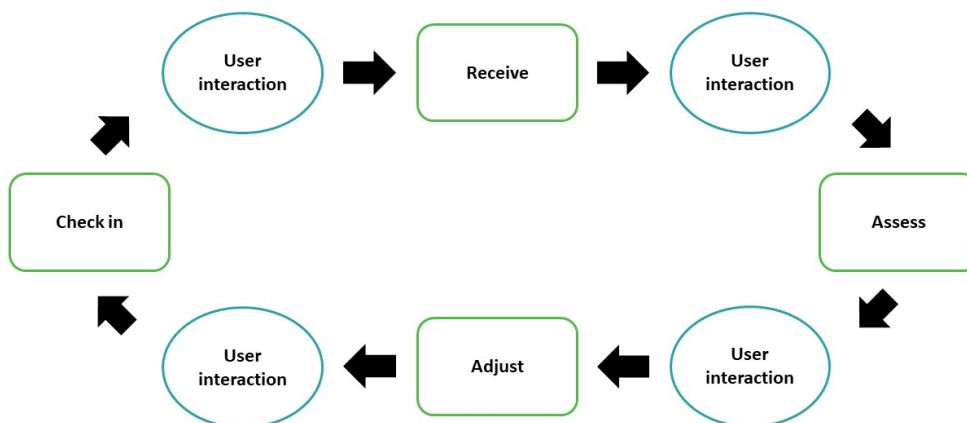
This approach can be used to support all types of feedback including:

- [technical support](#)
- [user feedback responsiveness](#)
- [cultural safety support.](#)

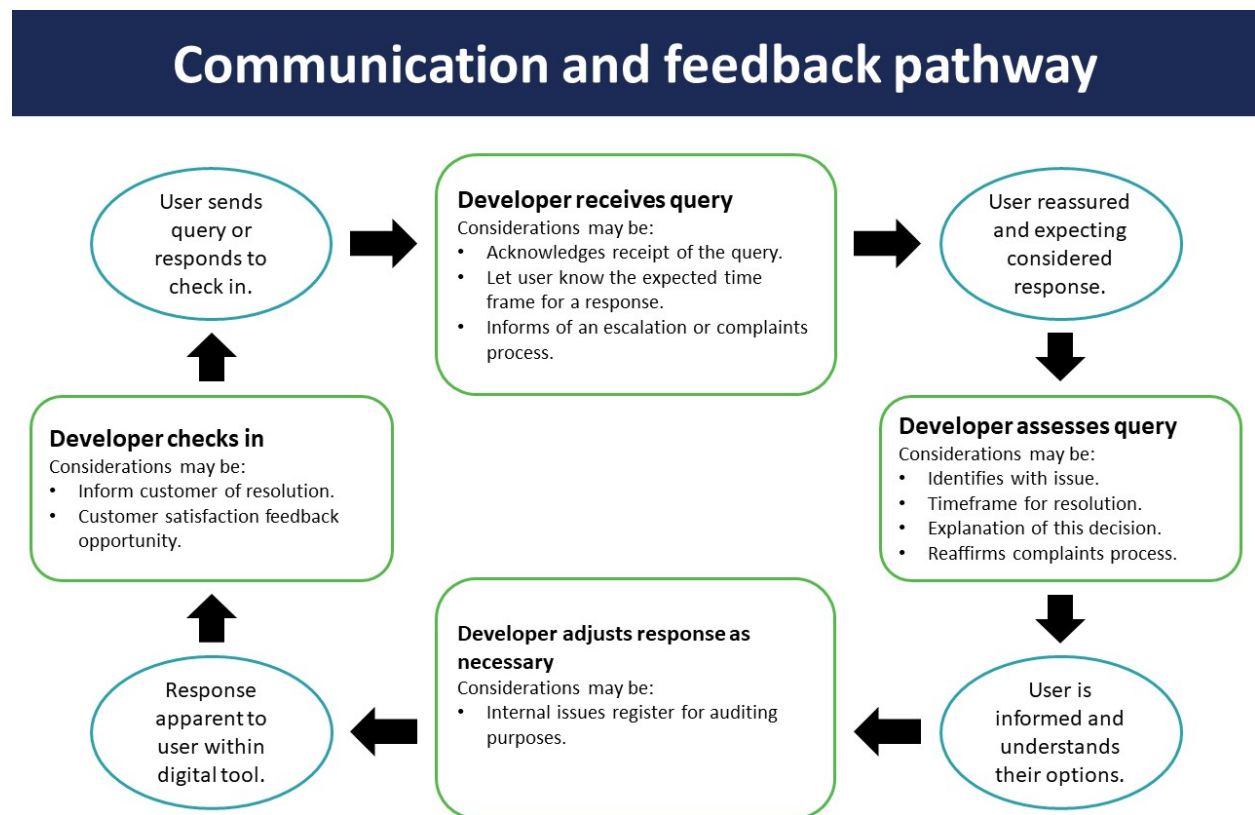Using the feedback pathway may make questions and responses in the feedback assessment sections more straightforward. The following example includes some considerations to support you.

Communication and feedback pathway

User sends query or responds to check in.

Developer receives query
Considerations may be:
- Acknowledges receipt of the query.
- Let user know the expected time frame for a response.
- Informs of an escalation or complaints process.

User reassured and expecting considered response.

Developer assesses query
Considerations may be:
- Identifies with issue.
- Timeframe for resolution.
- Explanation of this decision.
- Reaffirms complaints process.

User is informed and understands their options.

Developer adjusts response as necessary
Considerations may be:
- Internal issues register for auditing purposes.

Response apparent to user within digital tool.

Developer checks in
Considerations may be:
- Inform customer of resolution.
- Customer satisfaction feedback opportunity.

References

1. [He Ara Oranga](#) *Report of the Government Inquiry into Mental Health and Addiction, 2018*
2. [Evidence standards framework for digital health technologies](#) NICE
3. [Digital health](#) Ministry of Health, NZ
4. [Digital government](#) New Zealand Government