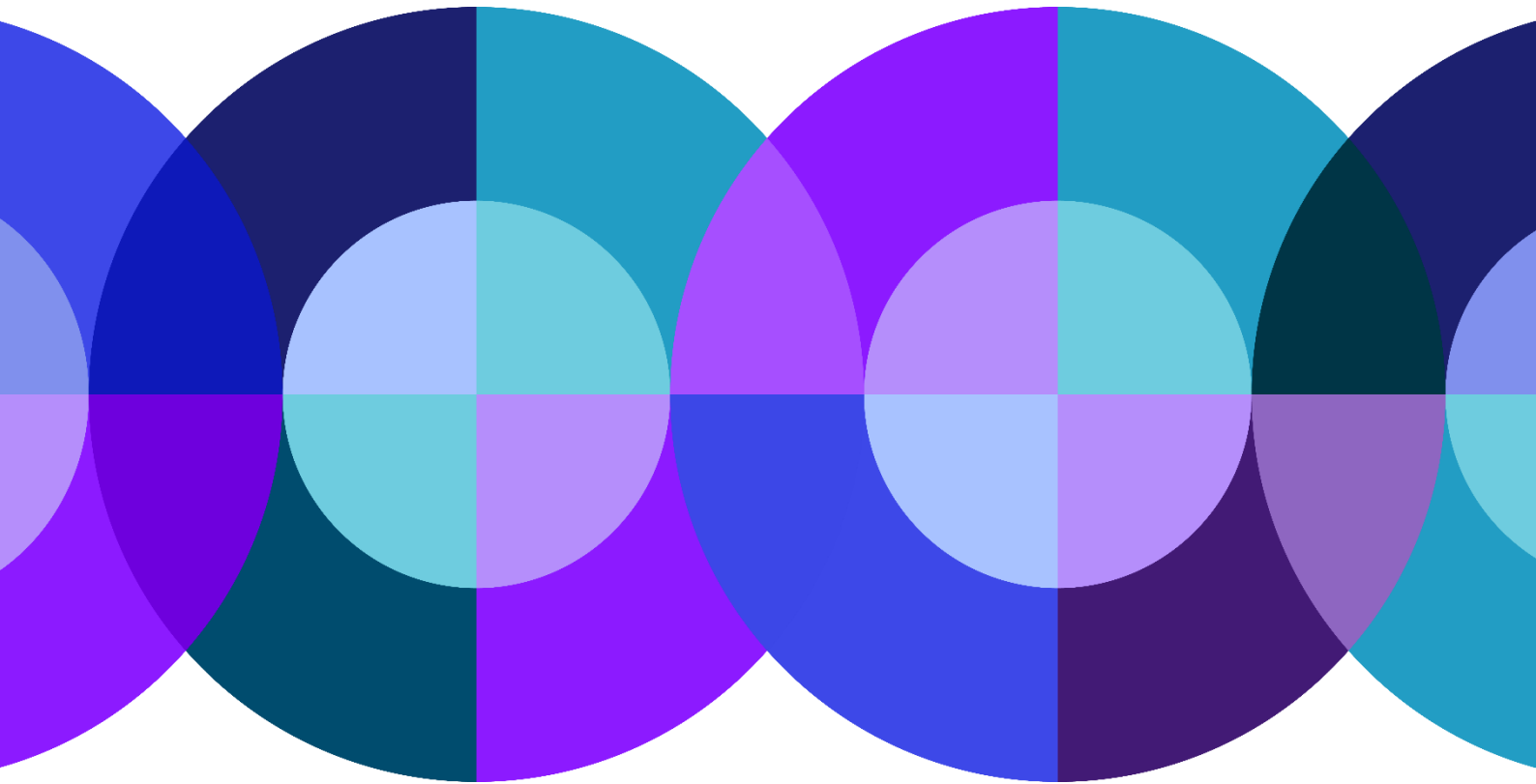




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Safety and Quality
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...
National Safety and Quality
Digital
Mental Health
Standards



Digital Mental Health Module for Primary Care

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Background



Background

The Digital Mental Health Module for Primary Care outlines a subset of actions from the National Safety and Quality Digital Mental Health Standards (Digital Mental Health Standards). This subset of actions can be used with the National Safety and Quality Primary and Community Healthcare Standards to meet accreditation requirements for both sets of standards.

The National Safety and Quality Primary and Community Healthcare (Primary and Community Healthcare Standards) Standards were developed by the Australian Commission on Safety and Quality in Health Care (the Commission), in collaboration with community managed organisations, peak bodies, consumers, carers, healthcare providers, professional bodies, Primary Health Networks and other representatives of the sector. The Primary and Community Healthcare Standards provide a quality assurance mechanism that tests whether relevant systems are in place to ensure expected standards of safety and quality are met.

Digital Mental Health Standards

The Digital Mental Health Standards are applicable for services that provide mental health, suicide prevention or alcohol and other drug services that use technology to facilitate engagement and the delivery of care. This includes services providing information, digital counselling services, treatment services (including assessment, triage and referral services) and peer-to-peer support services via telephone (including mobile phone), videoconferencing, the web (including webchat), SMS or mobile health applications (apps).

There are three Digital Mental Health Standards:

- Clinical and Technical Governance
- Partnering with Consumers
- Model of Care.

The **Clinical and Technical Governance Standard** describes the clinical and technical governance, safety and quality systems, workforce qualifications and skills, and the safe environment (including privacy, transparency, security and stability of digital systems) that are required to maintain and improve the reliability, safety and quality of digital mental health care, and improve health outcomes for service users.

The **Partnering with Consumers Standard** describes the systems and strategies to create a person-centred digital mental health system in which service users, and where relevant their support people are included in shared or supported decision-making, are partners in their own care, and are involved in the development and design of quality digital mental health care.

The **Model of Care Standard** describes the processes for establishing and delivering the model of care, minimising harm, communicating for safety, and recognising and responding to acute deterioration in mental state.

Independent assessment against the Digital Mental Health Standards provides an assurance that the service is safe and high-quality.

Digital Mental Health Module

The Digital Mental Health Module describes the requirements of the Digital Mental Health Standards that are not covered by the Primary and Community Healthcare Standards, of which:

- **9 actions** are **partially matched** to the Primary and Community Healthcare Standards, this means services must implement some additional requirements of the action in the Digital Mental Health Module. The additional requirements are in **bold** in the Digital Mental Health Module.
- **8 actions** have **no direct match** to the Primary and Community Healthcare Standards, this means services must fully meet all additional requirements of the action in the Digital Mental Health Module.

Organisations implementing the Primary and Community Healthcare Standards and the Digital Mental Health Module will be assessed in a single assessment process.

Scope

Digital mental health services are defined as mental health, suicide prevention or alcohol and other drug services that use technology to facilitate engagement and the delivery of care. Digital products that are not used directly to facilitate engagement or the delivery of care do not meet the definition of a digital mental health service used in the Digital Mental Health Standards.

Standalone electronic health or medical records, decision-support tools for clinicians, analytic services, services that primarily provide support and education to health professionals, clinical practice management software, and clinical workflow and communication software are also excluded under the definition of digital mental health services used in the Digital Mental Health Standards.

The Digital Mental Health Standards are not intended to apply to telephone services used only for intake, or a single occasion of post-discharge follow-up for a service that is otherwise delivered entirely in person. However, these services may wish to be guided by the Digital Mental Health Standards.

The Digital Mental Health Standards are not intended to apply to more generic wellness services that do not offer specific health services to service users or their support people. However, providers of generic wellness services may use relevant components of the Digital Mental Health Standards to guide their service delivery expectations, especially in technical areas such as privacy, transparency, security, costs and advertising, usability, and accessibility.

Assessment

Assessment to the Digital Mental Health Module for Primary Care must be undertaken by an approved accrediting agency for both the Digital Mental Health Standards and the Primary and Community Healthcare Standards. Where there are any apparent conflicts in the requirements for assessment to the Digital Mental Health Standards and the Primary and Community Healthcare Standards, queries can be sent to the Advice Centre.

Telephone: 1800 304 056

Email: AdviceCentre@safetyandquality.gov.au

Digital Mental Health Module for Primary Care



Digital Mental Health Module for Primary Care

Actions are only listed in the *Digital Mental Health Module for Primary Care* if they are not already covered by the Primary and Community Healthcare Standards, therefore some actions may be omitted.

For example, action 1.01 is followed by action 1.06 as actions 1.02-1.05 were considered direct matches to the Primary and Community Healthcare Standards and not required as part of this Module.



Clinical and Technical Governance Standard

Criteria: Governance, leadership and culture

Service providers set up and use clinical and technical governance systems to improve the safety and quality of care.

Table 1 Actions for the *Governance, leadership and culture* criterion

Item	Digital Mental Health Standards action	Additional requirements
Governance, leadership and culture	<p>1.01 The governing body:</p> <ul style="list-style-type: none">a. Provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisationb. Provides leadership to ensure partnering with service users and their support peoplec. Sets priorities and strategic directions for ethical, safe and high-quality care, and ensures that these are communicated effectively to the workforce and service users and their support peopled. Endorses the organisation's clinical and technical governance frameworkse. Ensures that roles and responsibilities are clearly defined for the governing body, management, clinicians, peer workers, technicians and other members of the workforcef. Monitors the action taken as a result of analyses of clinical and technical incidents and trendsg. Reviews reports and monitors the organisation's progress on safety, quality, performance and effectivenessh. Establishes principles and practices within governance frameworks that support the organisation's ability to adapt to technology as it changes.	<p>This action is a partial match to the Primary and Community Healthcare Standards action 1.01</p> <p>This action only requires additional strategies for sub-action d.</p>

Item	Digital Mental Health Standards action	Additional requirements
Clinical and technical leadership	<p>1.06 The service provider:</p> <ul style="list-style-type: none"> a. Ensures clinical, peer worker and technical leaders understand and perform their delegated safety and quality roles and responsibilities b. Ensures clinical, peer worker and technical leaders operate within the clinical and technical governance frameworks to improve the safety and quality of health care for service users and their support people c. Engages clinical and peer worker expertise in the clinical governance of the service d. Engages technical expertise in the technical governance of the service. 	<p>This action is a partial match to the Primary and Community Healthcare Standards actions 1.17 and 1.19.</p> <p>This action only requires additional strategies for sub-action d.</p>

Criteria: Safety and quality systems

Safety and quality systems are integrated with governance processes to enable the service provider to actively manage and improve the safety and quality of care.

Table 2 Actions for the *Safety and quality systems* criterion

Item	Digital Mental Health Standards action	Additional requirements
Risk management	<p>1.10 The service provider:</p> <ul style="list-style-type: none"> a. Identifies and documents service risks b. Uses clinical, technical and other data collections to support risk assessment c. Acts to reduce risks d. Regularly reviews and acts to improve the effectiveness of the risk management system e. Reports on risks to the workforce, and service users and their support people f. Plans for and manages internal and external emergencies and disasters, including cybersecurity risks and threats. 	<p>This action is a partial match to the Primary and Community Healthcare Standards action 1.04</p> <p>This action only requires additional strategies for sub-action f.</p>

Criteria: Safe environment for the delivery of care

The environment promotes safe and high-quality care for service users and their support people.

Table 3 Actions for the *Safe environment for the delivery of care* criterion

Item	Digital Mental Health Standards action	Additional requirements
Safe environment	<p>1.25 The service provider maximises the safety and quality of care:</p> <ul style="list-style-type: none"> a. Through the design of services, the digital operating systems and internal access controls b. By ensuring the terms and conditions for use of services are fair and transparent and do not mislead service users and where relevant, their support people c. By ensuring devices and other infrastructure are fit for purpose and well maintained d. By developing and using processes for the prompt implementation of legislative and regulatory changes. 	<p>This action is a partial match to the Primary and Community Healthcare Standards action 1.22</p> <p>This action only requires additional strategies for sub-actions a and b.</p>
Privacy	<p>1.28 The service provider conducts a privacy impact assessment for each service in accordance with best practice.</p>	<p>This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.</p>
	<p>1.29 The service provider has privacy policies for each service that are:</p> <ul style="list-style-type: none"> a. Easy to understand and transparent for service users and their support people b. Uphold service users' rights and choices c. Readily available to service users and their support people before accessing and while using the services d. Compliant with privacy laws, privacy principles and best practice. 	<p>This action is a partial match to the Primary and Community Healthcare Standards action 1.22</p> <p>This action only requires additional strategies for sub-actions a, b and c.</p>
	<p>1.30 The service provider advises service users, and where relevant, their support people, of changes to privacy policies in a timely and comprehensible way.</p>	<p>This action is a partial match to the Primary and Community Healthcare Standards actions 3.22 and 3.25</p>

Item	Digital Mental Health Standards action	Additional requirements
Transparency	<p>1.31 The service provider has systems for the collection, use, disclosure, storage, transmission, retention and destruction of data that provide service users and where relevant, their support people with:</p> <ol style="list-style-type: none"> Information on the types of data collected and how the information is used Information on any interoperable healthcare services Information on who has access to their data, including through data sharing agreements, provision or sale to third parties, and if transfer of data outside of Australia occurs Timely information if requests to access data by external parties are granted by the service provider Protection of their data that was provided anonymously or using a pseudonym Prevention against the unauthorised re-identification of anonymous or de-identified data Notification if the service ceases operation or changes ownership Information on where their data will go if the service ceases to operate or changes ownership Information on the legacy of their data. 	<p>This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.</p>
	<p>1.32 The service provider has mechanisms for service users to:</p> <ol style="list-style-type: none"> Consent to the use of personal data and records for any purpose beyond direct care Consent before any personal data and records are used in research, unless it is de-identified Withdraw or withhold consent for the collection, storage or distribution of their personal data and records Opt out from the sharing of their personal data and records Access, copy and amend their personal data and records Request deletion of their personal data and records. 	<p>This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.</p>
Costs and advertising	<p>1.33 The service provider provides service users and where relevant, their support people with clear and transparent information on the:</p> <ol style="list-style-type: none"> Direct costs to access the service Estimated data usage requirements for using the service. 	<p>This action is a partial match to the Primary and Community Healthcare Standards action 2.07</p> <p>This action only requires additional strategies for sub-action b.</p>

Item	Digital Mental Health Standards action	Additional requirements
	<p>1.34 The service provider ensures that in-product sales or advertising:</p> <ul style="list-style-type: none"> a. Complies with Australian Consumer Law and regulatory requirements b. Is appropriate for service users. 	This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.
Security and stability	<p>1.35 The service provider has information security management systems and uses a risk-based approach to:</p> <ul style="list-style-type: none"> a. Assign responsibility and accountability for information security b. Complete and maintain an information and data inventory c. Protect data in transit and at rest d. Protect against interruption, damage or disconnection of the service e. Assess the size and extent of threats to its information assets f. Consider and mitigate vulnerabilities and threats g. Conduct regular updates, reviews and audits of information security h. Detect, respond and report to the governing body, workforce, service users and their support people on information security incidents and technical faults. 	This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.
Continuity and updates	<p>1.36 The service provider:</p> <ul style="list-style-type: none"> a. Manages platform and operating system updates and patches b. Manages the continuity of services, backup and recovery mechanisms c. Effectively communicates service changes or interruptions to service users and where relevant, their support people. 	This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.



Partnering with Consumers Standard

Criteria: Partnering with service users in design and governance

The service provider partners with service users and their support people in the design and governance of digital mental health services.

Table 4 Actions for *Partnering with service users in design and governance* criterion

Item	Digital Mental Health Standards action	Additional requirements
Accessibility	<p>2.11 The service provider partners with service users and their support people to:</p> <ul style="list-style-type: none">a. Minimise barriers to accessing services associated with the hardware, software, data requirements and platform of the services, or the language, location, age, culture and ability of the service users and their support peopleb. Ensure services are compatible with commonly used assistive technologiesc. Meet relevant standards for web page or web applicationd. Regularly review access to services and take action to improve access by service users and their support people.	<p>This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.</p>



Model of Care Standard

Criteria: Establishing the model of care

The service provider ensures that the model of care for each digital mental health service is goal-directed and can achieve the stated outcomes of care for service users and their support people.

Table 5 Actions for *Establishing the model of care* criterion

Item	Digital Mental Health Standards action	Additional requirements
Designing the model of care	3.01 The service provider: <ol style="list-style-type: none"> Documents the purpose and intent of the model of care for each service and the context in which it will operate Defines the intended service user demographic and matches the model of care to the service users and their support people Monitors and evaluates the performance and effectiveness of the model of care Assigns accountability for maintaining and improving the effectiveness of the model of care. 	This action requires additional strategies by the service provider as it has no direct match to the Primary and Community Healthcare Standards.
Information for service users and their support people	3.03 The service provider provides product information on each service to service users and where relevant, their support people that: <ol style="list-style-type: none"> Aligns with the current template endorsed by the Australian Commission on Safety and Quality in Health Care Is easy to understand and meets their needs. 	This action is a partial match to the Primary and Community Healthcare Standards actions 2.06 and 2.07 This action only requires additional strategies for sub-action a .
Correct identification	3.07 The service provider has processes to: <ol style="list-style-type: none"> Routinely ask if a service user is of Aboriginal and/or Torres Strait Islander origin and to record this information in administrative and clinical information systems Authenticate service users and match them to their care Protect the anonymity of the service users where this is part of the model of care Use appropriate identifiers for service users according to digital services best-practice guidelines. 	This action is a partial match to the Primary and Community Healthcare Standards actions 3.22 and 3.25 This action only requires additional strategies for sub-actions b and c .

Glossary

The following terminology has been adopted in the Digital Mental Health Module to complement the glossary in the Primary and Community Healthcare Standards. A full list of glossary definitions can be found in the [National Safety and Quality Digital Mental Health Standards](#).

accessibility: the design of products, devices, services or environments so as to be usable by people with the widest possible range of abilities, operating within the widest possible range of situations. For example, web accessibility means that websites, tools and technologies are designed, and developed so that people with disabilities can use them.

anonymity: the condition of being anonymous; an individual dealing with an entity cannot be identified and the entity does not collect personal information or identifiers.²

clinical governance: an integrated component of corporate governance of healthcare organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to service users and their support people, and the community for assuring the delivery of safe, effective and high-quality services. Clinical governance systems provide confidence to service users and their support people, and the healthcare organisation that systems are in place to deliver safe and high-quality health care.

clinician: a healthcare provider, trained as a health professional, including registered and non-registered practitioners.

and levels of an organisation to seek solutions to vulnerabilities; and a willingness of the organisation to direct resources to deal with safety concerns.

cybersecurity: the practice of protecting systems, networks, and programs from digital attacks.

data at rest: data stored on a hard drive, laptop, flash drive, or archived or stored in some other way.

data in transit: data actively moving from one location to another such as across the internet or through a private network, from network to network or being transferred from a local storage device to a cloud storage device.

data security: the process of protecting digital data from destructive forces and the unwanted actions of unauthorised access and data corruption throughout its lifecycle. Data security includes a range of measures such as data encryption and tokenisation, and key management practices that protect data across all applications and platforms.

destruction of data: the process of destroying digital data (for example, stored on tapes, hard disks and other forms of digital media) so that it is completely unreadable and cannot be accessed or used for unauthorised purposes.

digital health: the convergence of digital technologies with healthcare to enhance the efficiency of healthcare delivery and make medicine more personalised and precise. It may include both hardware and software solutions and services, including telemedicine, web-based analysis, email, mobile phones and applications, text messages, wearable devices, and clinic or remote monitoring sensors.

digital literacy: the ability to identify and use technology confidently, creatively and critically to meet the demands and challenges of life, learning and work in a digital society.

digital mental health service: a mental health, suicide prevention, or alcohol and other drug service that uses technology to facilitate engagement and the delivery of care. The service may be in the form of information, digital counselling, treatment (including assessment, triage and referral), or peer-to-peer service that is delivered to a service user via telephone (including mobile phone), videoconferencing, web-based (including web-chat), SMS or mobile health applications (apps).

governance: the set of relationships and responsibilities established by a service provider between its executive, workforce and stakeholders (including service users and their support people). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal, human resources) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of different participants in the organisation to achieve the organisation's objectives. In the NSQDMH Standards, governance includes both clinical and technical governance, which are integrated components of corporate governance.

hardware: any physical device used in or with your digital service – for example, a computer, monitor, mouse, telephone or videoconferencing unit.

information and data inventory: a high-level list of the data and information that an organisation collects, where it is held, with whom it is shared, and how it is used.

information security: the practice of preventing unauthorised access, use, disclosure, disruption, modification, inspection, recording or destruction of information.

in-product sales: the offering of products for sale embedded within a digital mental health service.

interoperability: the ability of computerised systems to connect and communicate with one another readily to exchange and make use of data and information. In the health system, interoperability of digital systems means seamless and secure connections are made between clinical information systems that previously were disconnected and siloed, and that patient information can be shared and clinical decisions made in light of all the relevant data available, delivering better care as a result.

peer-to-peer support service: a system of giving and receiving help founded on key principles of respect, shared responsibility, and mutual agreement of what is helpful. Peer support is not based on psychiatric models and diagnostic criteria. It is about understanding another's situation empathically through the shared experience of emotional and psychological pain. When people find affiliation with others they feel are 'like' them, they feel a connection. This connection, or affiliation, is a deep, holistic understanding based on mutual experience where people can 'be' with each other without the constraints of traditional (expert/patient) relationships.

peer support: a system of giving and receiving help founded on key principles of respect, shared responsibility, and mutual agreement about what is helpful. It is about understanding another's situation empathically through the shared experience of emotional and psychological pain. When people find affiliation with others they feel are 'like' them, they feel a connection. This connection, or affiliation, is a deep, holistic understanding based on mutual experience in which people are able to 'be' with each other without the constraints of traditional (expert–patient) relationships.

peer worker: someone employed on the basis of their personal lived experience (of mental health issues, suicidal thinking or behaviour, or alcohol and other drug use) and recovery (consumer peer worker) or their experience of supporting family or friends with mental health issues, suicidal thinking or behaviour, or alcohol and other drug use (carer peer worker).

platform: a group of technologies that are used as a base upon which other applications, processes or technologies are developed. Historically, application programs written for one platform would not work on a different platform. New standards-based interfaces and open interfaces allow application programs to run on multiple platforms. Additionally, software developers have developed software tools that allow applications to run on multiple platforms.

product information: information written by the service provider responsible for the digital mental health service that provides objective information about the quality, safety and effectiveness of the service as well as its purpose and intended users.

risk-based approach: an approach that identifies, assesses, and understands the risks, and takes appropriate mitigation measures appropriate to the level of risk.

service provider: an organisation that provides digital mental health services to service users, and where relevant, their support people, either free of charge or at a cost. A service provider may make available one or more services from which service users and their support people can select, and has in place a system to oversight the delivery of the service. A developer of a digital mental health service that makes the service directly available to service users and their support people is a service provider.

service user: a person who has used, or may potentially use, a digital mental health service. A service user may be a consumer or a carer or a support person, depending on the nature of the service.

support people: individuals who provide support and reassurance to service users (for example, a family member, friend or paid support worker).

technical governance: the system by which the current and future use of information and communication technology is directed and controlled. It is an integrated component of the corporate governance of healthcare organisations and includes leadership, organisational structures, strategy, policies and processes to ensure that the organisation's information technology sustains and extends the organisation's strategies and objectives.

usability: the extent to which a product (such as a device, service, or environment) can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.

Appendix - Mapping of the Digital Mental Health Standards to the Primary and Community Healthcare Standards

The Digital Mental Health (DMH) Standards were mapped against the Primary and Community Healthcare (NSQPCH) Standards to understand where there was overlap that could be removed from a streamlined assessment process. The mapping in this appendix identifies where there was a partial match or no direct match to the intent of the actions between the two sets of standards. Actions with wording differences alone were not considered sufficient to categorise a partial match or no direct match.

Table 6 Mapping of the actions within the Clinical and Technical Governance Standard

DMH	Mapping outcome	NSQPCH	DMH	Mapping outcome	NSQPCH	DMH	Mapping outcome	NSQPCH
1.01	Partial match	1.01	1.13	Full match	1.07	1.25	Partial match	1.22
1.02	Full match	1.01	1.14	Full match	1.08	1.26	Full match	1.23
1.03	Full match	1.09, 1.10	1.15	Full match	1.09, 1.10	1.27	Full match	1.23
1.04	Full match	1.01	1.16	Full match	1.11	1.28	No direct match	–
1.05	Full match	1.01	1.17	Full match	1.13	1.29	Partial match	1.22
1.06	Partial match	1.17, 1.19	1.18	Full match	1.15	1.30	Partial match	1.22
1.07	Full match	1.02	1.19	Full match	1.15	1.31	No direct match	–
1.08	Full match	1.03	1.20	Full match	1.16	1.32	No direct match	–
1.09	Full match	1.03	1.21	Full match	1.18	1.33	Partial match	2.07
1.10	Partial match	1.04	1.22	Full match	1.19	1.34	No direct match	–
1.11	Full match	1.05	1.23	Full match	1.19	1.35	No direct match	–
1.12	Full match	1.06	1.24	Full match	1.17	1.36	No direct match	–

Table 7 Mapping of the actions within the Partnering with Consumers Standard

DMH	Mapping outcome	NSQPCH
2.01	Full match	2.01
2.02	Full match	2.02
2.03	Full match	2.03
2.04	Full match	2.04
2.05	Full match	2.06
2.06	Full match	2.06
2.07	Full match	2.08
2.08	Full match	2.06
2.09	Full match	2.08
2.10	Full match	2.07
2.11	No direct match	–

Table 8 Mapping of the actions within the Model of Care Standard

DMH	Mapping outcome	NSQPCH
3.01	No direct match	–
3.02	Full match	1.20
3.03	Partial match	2.06, 2.07
3.04	Full match	3.21
3.05	Full match	3.31, 3.32
3.06	Full match	3.31, 3.32
3.07	Partial match	3.22
3.08	Full match	3.29, 3.30
3.09	Full match	3.27
3.10	Full match	3.31
3.11	Full match	3.31
3.12	Full match	3.31



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