



T1.2.1 REPORT ON INTERNATIONAL PRACTICE ON DIGITAL APPS

T1 Technology



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Authors

Søren Lange Nielsen

Edited by Dr Sanna Rimpiläinen

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GLOSSARY

AHA: American Heart Association

AMA: American Medical Association

BSI: British Standards Institution

CMA: Canadian Medical Association

CQC: Care Quality Commission

DAQs: Digital Assessment Questionnaire

eHealth: Electronic Health

EC: European Commission

EHR: Electronic Health Record

EMR: Electronic Medical Record

FDA: U.S. Food and Drug Administration

FTC: U.S. Federal Trade Commission

GDPR: General Data Protection Regulation

HSCPs: Health & Social Care Professionals

HIMSS: Healthcare Information and Management Systems Society

HIPAA: Health Insurance Portability and Accountability Act

HSCIC: Health and Social Care Information Centre

HSCN: Health & Social Care Network

ICT: Information and Communications Technology

ISO: International Organization for Standardization

mHealth: Mobile Health

MARS: Mobile Application Rating Scale

MHRA: Medicines and Healthcare Products Regulatory Agency

NIHR: National Institute for Health Research

OS: Operating System

OWASP: Open Web Application Security Project

PAS: Publicly Available Specification

PHR: Personal Health Record

SNOMED CT: Systematized Nomenclature of Medicine-Clinical Terms

SDKs: Software Development Kits

SoMe: Social Media

WHO: World Health Organization

EXECUTIVE SUMMARY

This landscape review provides an overview and examination of current international initiatives and practices to develop, assess and evaluate the use of mobile health and wellbeing apps and services. To accomplish this, seventeen academic, national, regional and international initiatives have been identified, examined and compared, detailing their wide-ranging approaches and scopes (Appendix 1).

The identified approaches include self-assessments questionnaires, independent accreditations, general guidelines / guiding principles, Codes of Conduct, risk-based assessments and Quality Assurance Frameworks. The examination and comparison of these drew attention to seven cohering quality parameters or criteria, which exist across many of the reviewed initiatives:

- 'Privacy / Data protection'
- 'Credible sources / Evidence-based information'
- 'Usability / user experience'
- 'Functionality'
- 'Security / authentication'
- 'Effectiveness / Impact'
- 'Interoperability'

These cohering parameters were identified in at least nine and up to sixteen instances, amongst the examined initiatives. Out of these 'Privacy / Data protection', 'Credible sources / Evidence-based information' and 'Functionality' were highly represented with sixteen and fifteen instances, while there is variation in their terminology and extent. The variation has been covered more extensively in section 1.1, where all seven indicators have been examined in-depth.

Out of the seventeen initiatives examined, only four include all seven cohering parameters. These are the UK based *Digital Assessment Questions (DAQs)* and *Quality Assurance Framework*, the Canadian based *Guiding Principles* and the WHO *MAPS toolkit*. Yet of these, the DAQs are the only one, which covers all seven parameters comprehensively and in detail, whereas the Canadian Initiative and MAPS toolkit is not as detailed or specific within all of the seven parameters and the *Quality Assurance Framework* is still being drafted.

The DAQs, created by NHS England can therefore be recommended to be used for approaching and assessing the hundred health and wellbeing apps in the clinical/wellbeing areas for the mPower interventions (The identified apps can be found in Appendix 2).

OVERVIEW

In recent years, the use of mobile technologies has increased significantly, and the number of mobile phone subscriptions has grown exponentially (Statista, 2017). Already today, there are more than 7,7 billion mobile subscriptions globally, and the number is only expected to rise further (Statista, 2017). In line with the increased use of mobile technologies, the coverage has also improved, and today *“mobile networks cover around 95 percent of the world’s population”* (Ericsson, 2017, p. 15). This exponential growth of mobile technologies has indisputably impacted today’s society and altered many of the existing societal processes (Deloitte, 2013).

This has also been the case for the field of health and care. The emergence of mobile health (mHealth) is *“transforming the way health services and information are accessed, delivered, and managed.”* (European Commission, 2014; WHO Global Observatory for eHealth, 2011, p. 5). mHealth itself can be defined as *“the delivery of healthcare services via mobile communication devices.”* (Healthcare Information and Management Systems Society, 2012) and has in recent years experienced a rapid growth (Statista, 2016).

In 2018 the global mHealth market is expected to be valued at USD 28 billion, more than tripling its value since 2015. By 2020, the market value is anticipated to reach USD 46 billion (Statista, 2016). The rapid growth of mHealth is also reflected in the number of health apps: there are currently more than 318,000 available health apps worldwide and counting, with more than 200 new health apps made available daily (IQVIA Institute, 2017).

The development and adoption of mHealth provides great opportunities for the healthcare sector, as it *“could improve treatment, empower patients, and foreseeably lower medical costs and streamline use of health care resources.”* (Bradway et al., 2017, p. 2). Furthermore, it provides a more equal access to healthcare, as it can enable patients in remote and underserved areas a better access to care and guidance, allowing them to better self-manage their healthcare from within their own home (European Commission, 2014; World Health Organization, 2016). This is especially relevant for the care and management of chronic illnesses, as patients can reduce the number hospital visits for routine check-ups and instead monitor and manage their clinical data from the comfort of their home (Anderson, Burford, & Emmerton, 2016; World Health Organization, 2016). The increasing level of self-management is also central for the growing demand for patient empowerment, *“as consumers demand more accessibility to their medical health professionals and transparency in health care becomes more important”* (Statista, 2016).

However, the overwhelming number of mHealth solutions also presents cause for concern, as due to *“their variety, consumers, patients or healthcare professionals may find it difficult to choose the right mHealth solution or app.”* (European Commission, 2014, p. 12). Furthermore, several academic and clinical reviews have revealed issues among numerous health apps, in terms of lacking data management, validity and adherence to evidence-based practices (Arxan, 2016;

Bardus, van Beurden, Smith, & Abraham, 2016; Breton, Fuemmeler, & Abrams, 2011; Dehling, Gao, Schneider, & Sunyaev, 2015; Pagoto, Schneider, Jojic, DeBiase, & Mann, 2013; Wicks & Chiauuzzi, 2015). Yet, as shown throughout this landscape review, several initiatives have already been implemented to tackle these issues, as the potential of mHealth is being recognised.

As clinical evidence for the mHealth efficacy and cost-effectiveness is still scarce, this may, along with safety and validity concerns, lead to hesitation among HSCPs for recommending mHealth solutions to their patients (Boudreaux et al., 2014; European Commission, 2014). Having said that, the evidence-base is rapidly growing, as *"continued investment in evidence generation continues across stakeholders."* (IQVIA Institute, 2017, p. 2).

There are currently more than 860 clinical trials on Digital tools and mHealth apps worldwide. Furthermore, several initiatives around the world are taking place to assess, evaluate and guide Health & Social Care Professionals (HSCPs), healthcare organisations, patients and app developers towards safe and secure mHealth solutions (Bradway et al., 2017). As the initiatives differ in their approach and extent, we come to the aim of this landscape review.

Aim and Approach of the Landscape Review

This landscape review was carried out for the mPower project to help the project partners to navigate the vast number of available health and wellbeing apps and services, and to help them to identify those necessary for achieving the key mPower project objectives:

- Establish cross sectoral collaboration across Ireland, Northern Ireland and Scotland to support greater mobility, confidence and reach of health and care professionals and services;
- Support 2,500 people to self-manage their health and wellbeing more effectively in the community;
- Deliver 4,500 eHealth interventions increasing awareness of their benefits in supporting sustainable service delivery;
- Deliver training programmes to 420 health and care providers;
- Effectively engage individuals, community organisations and services in redesign of health and care services.

To accomplish this, seventeen current international practices, frameworks, methodologies, guidelines and assurance processes for digital health and wellbeing services/apps have been identified, examined and compared. The review of these will enable the mPower project to draw upon consistent international themes/trends in the field and help them to choose the most suitable approach for assessing, evaluating and selecting mPower digital applications to support healthy and connected communities.

To support the overarching project objectives, the landscape review will also identify potential mPower services in the following clinical/wellbeing areas for intervention:

- Diabetes management
- COPD
- Positive mental health
- Physical activity and weight loss
- Healthy eating
- Cancer support
- Heart failure
- Sleep management
- What's on/Social networks
- Social isolation

By identifying, evaluating and eventually implementing mPower services in these areas, the targeted citizens will be enabled to live well, safely and more independently in the comforts of their own homes and communities.

Methods

This landscape review is based on a systematic literature search. An initial scoping of electronic databases (Google Scholar, PubMed, NCBI and more) was carried out to identify relevant literature, including both academic studies and grey literature relating to the current assessments of mHealth and health and wellbeing apps/services.

The search took place in November 2017, where the databases was searched for material from between January 2007 and November 2017, supplemented by reference tracking. This search provided sources, which include academic papers, governmental and vendor websites, policy documents, legislations, follow up reports, news items, technology reviews, end user experience reports, expert presentations, clinical trials etc.

Subsequently, a final search was conducted, where the identified sources have been reviewed with a set of inclusion/exclusion criteria, filtering the results and ensuring the validity and relevance of the sources (Inclusion/exclusion criteria can be found in Appendix 3). The selected sources have subsequently undergone a critical appraisal, where the content has been analysed in depth and compared against each other and the project requirements.

This report covers the findings, options, conclusions and recommendations for the future eHealth interventions of digital health and wellbeing mPower services.

1 CURRENT INITIATIVES FOR ASSESSING & DEVELOPING MHEALTH SERVICES

Within this section, seventeen international initiatives listed in Appendix 1 will be examined in depth, focussing on their concurring quality parameters. The various initiatives, frameworks and guidelines for assessing, using, recommending and developing mobile health and wellbeing apps and services include both academic, national, regional and cross borders initiatives from around the globe.

1.1 Concurring Quality Parameters

Several efforts are already globally in place to tackle the growing mHealth field. Even though these initiatives vary in their approach and targeted audience, several of the initiatives share a number of commonalities and concurring parameters, identified within their underlying groupings and taking into account the changing terminology. To gain a better overview of these commonalities, all the identified criteria and assessment parameters found in the initiatives have been gathered in Appendix 4. These have subsequently been grouped, leading to the following matrix, outlining the seven most common criteria, as seen below:

Criteria / Initiative	5.1.1.1	5.1.2.1	5.1.2.2	5.1.2.3	5.1.2.4	5.1.2.5	5.1.2.6*	5.1.2.7	5.1.2.8*	5.1.2.9	5.1.2.10	5.1.2.11*	5.1.2.12	5.1.2.13*	5.1.3.1*	5.1.3.2*	5.1.3.3
Privacy / Data protection		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Credible sources / Evidence-based information	X	X	X	X	X	X	X	X	X	X	X	X		X	X		X
Functionality	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
Security / Authentication		X	X	X	X	X		X	X	X	X	X	X	X	X		X
Usability / User experience	X	X	X	X	X	X		X		X	X	X		X			X
Effectiveness / Impact	X		X	X				X	X	X		X	X		X		X
Interoperability				X		X				X	X	X	X	X	X		X

*Currently not applied

1.1.1 Privacy / Data Protection

'Privacy / Data protection' is the most common quality criteria identified across all initiatives, having been identified in sixteen out of the seventeen initiatives covered. The criterion entails an assessment of whether an app has taken necessary measures to comply with data protection legislations and allows the users to manage their personal data. The examined initiatives use varying terminology to refer to this criterion, and it also has differing coverage, as seen in the next two examples.

Firstly, in the Andalusian initiative, the criterion has been identified within the area of 'Confidentiality and Privacy' (Section 5.1.2.1). Within this area, the transparency is assessed, among others, with regard to the *"data to be collected and the reason about the access policies and data treatment, and about possible commercial agreements with third parties."* (Agencia de Calidad Sanitaria de Andalucía, n.d.-b).

In the second example, the Xcertia initiative, the criterion is identified within the area of 'App Privacy', entailing the app's ability to protect *"the user's information, including Protected Health Information (PHI) in full compliance with all applicable laws, rules and regulations."* (Xcertia, 2017d, Section 5.1.2.13).

Other criteria or assessment areas, where 'Privacy / Data protection' have been identified include: 'Privacy', 'Security', 'Privacy and Security', 'Privacy & Confidentiality', 'Privacy and Data Protection' 'Data', 'Information Security' and 'Information Governance'.

1.1.2 Credible Sources / Evidence-Based Information

'Credible sources / Evidence-based information' is the second most common quality criteria identified among the initiatives, identified in fifteen out of the seventeen initiatives. The criterion involves assessing the information source the app uses, and the content of that information. These should preferably be evidence-based.

Examples of the varying terminology used to refer to this criterion include 'Information', as found in the MARS tool (Section 5.1.1.1), which assesses whether the app comes from a credible and legitimate source and whether the app's content has been *"verified by evidence"* (Stoyanov et al., 2015: Appendix 2).

Another example is found within the WHO MAPS toolkit (Section 5.1.3.3), in which 'Scientific basis' has been identified for effectively scaling up a health and wellbeing app (World Health Organization, 2015). The 'Scientific basis' assesses whether the app is *"aligned with scientifically validated health interventions"* (World Health Organization, 2015, p. 12) and potentially has local validation to ensure the app's appropriateness for the specific market.

These are just two examples from the examined initiatives. Other examples have been identified in the following assessment areas or quality criteria: ‘Authorship’, ‘Transparency’, ‘Content and Information Sources’, ‘Quality and Safety of Information’, ‘Sources’, ‘Indicators of Effectiveness’, ‘Reliability of information’, ‘Content’, ‘Accuracy of Information’, ‘App Content’, ‘Quality of General Medical Proficiency’, ‘Project Documentation’, ‘Evidence Base’ and ‘Health Content’.

1.1.3 Functionality

‘Functionality’ has also been identified within fifteen of the examined initiatives. This covers the app’s functionality and performance, assessing whether the app works as intended. As with the other criteria, this criterion covers divergent aspects of functionality using a varying terminology. For example, the Xcertia initiative (Section 5.1.2.13) refers to functionality by the term of ‘App operability’, which “*assess whether a mobile health app installs, loads, and runs in a manner that provides a reasonable user experience.*” (Xcertia, 2017d). To assess this, Xcertia presents seven underlying criteria, which cover aspects such as reliability and connectivity and whether the app “*installs, launches, and runs consistently*” (Ibid.).

Another example is found in ‘Reliability, performance and scalability’ within the Publicly Available Specification (PAS) for health and wellness apps developed by the British Standards Institution (BSI) (Section 5.1.2.10). The PAS covers this by addressing “*both the performance of the app itself, and the supporting infrastructure, such as web services that the app may rely on.*” (BSI, 2015, p. 5). This includes taking into account aspects such as loading time, data storage, battery usage and more (BSI, 2015).

Other characteristics of ‘Functionality’ have been identified within the following quality criteria and parameters: ‘Scientific basis’, ‘Functionality’, ‘Testing and Technical Stability’, ‘Technical functionality’, ‘Technical stability’, ‘Technology’ and ‘Technical content’.

1.1.4 Security / Authentication

The quality criterion of ‘Security / authentication’ has been identified in fourteen of the examined initiatives with varying terminology and extent. The criterion entails incorporating security and authentication methods in the app to avoid unauthorised access to personal data.

An example of the varying terminology and coverage is found in ‘Information Security’ within the Norwegian self-declaration scheme (Section 5.1.2.8). Within ‘Information Security’, the app should use verified authentication methods to authenticate the user, use encryption and preferably store all personal data locally on the device (Direktoratet for e-helse, 2016). Information detailing these efforts should also be easily available to the users of the app.

On the other hand, a more detailed and comprehensive example, is found within the French initiative (Section 5.1.2.5), in which the criterion of ‘Security/Reliability’ presents seventeen underlying cyber security functions, which are assessed (Haute Autorité de Santé, 2016). These range from authentication methods and encryption to threat analysis, data integrity, security maintenance, data breaches and much more.

The ‘Security / authentication’ criterion has been identified within the following criteria or areas of assessment: ‘Authentication’, ‘Logical Security’, ‘App Security’, ‘Information Security’, ‘Security and Privacy’, ‘Data’ and ‘Security’ and ‘Cyber security’.

1.1.5 Usability / User Experience

‘Usability / user experience’ has been identified within twelve of the examined initiatives. These cover the user experience, ease of access and general use of the app. As with the other criteria, there is great variance in terms of the extent of coverage and terminology. The Catalonian initiative (Section 5.1.2.4) has an especially extensive coverage for ‘Usability’ with forty-eight underlying quality criteria, including aspect such as the visual elements in the app, which should be easily *“identifiable elements and easy to use”* (TIC Salut, n.d.-a, p. :3). Furthermore, within the Catalonian initiative, ‘usability’ covers aspects such as fonts, sound alerts, colour inversion, intuitive navigation, boot time, information architecture, accessibility, colour coding and much more.

Another example of variation is found within the criterion of ‘Usability & accessibility’ from the DAQs (Section 5.1.2.9), which addresses the service’s ability to *“meet the needs of a diverse set of users, including people with disabilities or those with limited technical knowledge”* (Public Health England, 2017a). This includes assessing whether key principles of user centred design have been considered and whether users have been involved throughout the development of the service (Ibid.). Furthermore, it determines whether the service have conformed with current accessibility standards and guidelines (Ibid.).

‘Usability / user experience’ has been identified within the following criteria and assessment areas: ‘Usability’, ‘Usability/Testing’, ‘Usability/design’, ‘App Operability’, ‘Usability/Use’, ‘Scientific basis’ ‘Engagement’ ‘Design and Appropriateness’, ‘Functionality’, ‘Usability Standards’ ‘and ‘Information’.

1.1.6 Effectiveness / Impact

‘Effectiveness / Impact’ has been identified within ten of the examined initiatives, covering the perceived impact and the achieved benefit of using the health app intervention. Again, the criterion can be found with varying terminology and extent. An example of this is found in the DAQs (Section 5.1.2.9), within the ‘Indicators of Effectiveness’ (Health Developer Network, 2017). The ‘Indicators of Effectiveness’ covers the intended purpose and use, the general evidence base used in the development of the app, the specific evidence demonstrating the benefits and

effectiveness reached by using the app/service, and if applicable, any ongoing studies, assessing the achieved benefits of the app.

Another example of 'Effectiveness / Impact' is found within the Australian initiative (Section 5.1.2.2), in which the 'behavioural change effectiveness' was assessed for the apps recommended through their app library (VicHealth, 2016b). To assess this, the CALO-RE taxonomy of behavioural change techniques was used, determining the apps' *"potential to affect behaviour change in relation to factors such as goal setting, action planning, barrier identification and problem solving"* (VicHealth, 2016b).

'Effectiveness / Impact' has been identified within the following terminology and areas of assessment: 'Indicators of Effectiveness', 'Scientific basis', 'Acceptability', 'App-specific', 'Evaluation research', 'Impact Evaluation', 'Demonstration of impact', 'Evaluation Research' and 'Quality of General Medical Proficiency'.

1.1.7 Interoperability

'Interoperability' has been identified within nine of the examined initiatives. This addresses the app's interoperability and compatibility with other platforms and information systems like EHRs. An example of the varying terminology used is found in the PAS (Section 5.1.2.10), in which interoperability is covered within the criterion 'Compatibility and Portability'. This covers the *"different platform configurations and the ways that information collected or used by the app may be reused, under appropriate privacy controls."* (BSI, 2015, p. 5).

Within the Canadian initiative (Section 5.1.2.3), 'Interoperability' is also briefly addressed in the characteristic of 'Fragmentation of health information', which refers to the growing range of apps and various destinations, where health information can be stored (Canadian Medical Association, 2015b). Due to this, it is recommended that HSCP should *"recommend mobile health applications which contribute to robust existing data repositories, especially an existing EMR."* (Canadian Medical Association, 2015b, p. 5).

The 'Interoperability' criterion has also been identified within the following quality criteria or areas of assessment: 'Standardisation', 'Compatibility and Portability', 'App Operability' and 'Interoperability'.

As seen above, the examined initiatives have a fair share of commonalities, though they are still *"happening in silos and are often specific to a single country or medical system"* (Bradway et al., 2017, p. 2). This might also be the reason for the low number of cross border initiatives, compared to the number of academic, national and regional initiatives identified. Although, as mentioned in the *Overview*, the evidence-base for mHealth is rapidly growing along with investments in the field, something that might lead to more cross border initiatives and shared efforts.

2 MAIN CHALLENGES

In this section, the main challenges and considerations for the mPower project to successfully assess and implement health and wellbeing apps on a cross border basis, will be briefly discussed.

The first challenge is proposed by the *fast pace and growth of the mHealth field*. The large amount of health and wellbeing apps can, as mentioned in the *Overview* become overwhelming and confusing for both patients and HSCPs when searching for specific apps to use or recommend. Furthermore, the fast pace of change makes identifying safe and effective apps even harder, as *“literature becomes outdated quickly because of the constantly evolving market”* (Boudreaux et al., 2014, p. 364).

Additionally, as the target group for the mPower project is the elderly population, *digital literacy* might also prove challenging (Loureiro & Barbas, 2014). A basic level of digital literacy will be necessary to successfully use health and wellbeing apps and gain the intended outcome in terms of better self-management (Neter & Brainin, 2012).

Another important aspect to consider is the approaching *General Data Protection Regulation (GDPR)*, which presents both HSCPs and app developers with new requirements, which they need to comply with for the safe and appropriate handling of personal data. Therefore, it becomes vital to ensure that the implemented apps have been adjusted to the new regulations. Factors to take into account include data protection by design and default, accountability, governance, transparency and consent requirements. It will also be necessary to consider if the mPower project partner organisations will need a data protection officer, if the role is not already in place (NHS Digital, 2018).

It is also important to consider the *involvement of app developers*, as many of the examined initiatives are based on self-assessment aimed at the app developer. This might complicate the evaluation by the mPower project, as some of the necessary information requires insight from the app developers. In addition to this, before the assessment can be carried out, it is vital to *determine whether the chosen app(s) are defined as medical devices*, as the regulatory and legal requirements for such are much more comprehensive. To determine this, the MHRA guidance 'Medical device stand-alone software, including apps' can be used (Medicines and Healthcare products Regulatory Agency, 2017). The assessment and quality assurance of medical devices has not been covered specifically within this paper, as the initial scope of the landscape review targeted the assessment of health and wellbeing apps and not medical devices.

Additionally, as the mPower project is a cross-border project between Ireland, Northern Ireland and Scotland, *the cross-border infrastructure and sharing of health data* might become necessary. However, currently such infrastructure for cross-border sharing is not in place in the UK. It might be beneficial to look to Finland and Estonia for inspiration for sharing health data across borders (e-Estonia, 2016). Furthermore, as the intended cross-border collaboration occurs in rural and remote

locations, *connectivity* might also become an issue, which needs to be addressed to ensure that the selected apps / services can function as intended.

Lastly, the potential *liability* needs to be identified, as “*liability arising from the use of an mHealth solution may be complex, because of the numerous actors involved*” (European Commission, 2014, p. 16).

3 KEY FINDINGS AND RECOMMENDATIONS

This section presents the key findings and recommendations derived from the examined initiatives, which predominantly revolves around the concurring quality parameters examined in Section 1.1. The seven concurring quality parameters are:

- 1 **Privacy / Data protection**
- 2 **Credible sources / Evidence-based information**
- 3 **Usability / user experience**
- 4 **Functionality**
- 5 **Security / authentication**
- 6 **Effectiveness / Impact**
- 7 **Interoperability**

These parameters provide a good overview and understanding of the potential quality parameters and criteria worth considering when developing, assessing, implementing and recommending mobile health and wellbeing apps. Furthermore, the seven parameters can act as an indicator of the current best practices around the world, something that can aid the mPower project in choosing their preferred approach. For example, the parameters can be used to combine or adapt current efforts and frameworks to the specific needs of the mPower project and ensure that all the necessary aspects are covered by whichever assessment process is decided upon.

Inspiration for such an approach can be found in the case of VicHealth (Section 5.1.2.2), which combined the recognised and easily available MARS tool (Section 5.1.1.1). This was done by supplementing and strengthening the original ‘Effectiveness / Impact’ assessment of the MARS tool with an established taxonomy for behavioural change techniques.

If the mPower project’s preference is for a complete pre-existing initiative, the DAQs developed by NHS England (Section 5.1.2.9) would be the author's recommended framework. The DAQs framework provides a comprehensive coverage of all seven identified parameters, which also have local relevance and adaption within the UK, contrary to the WHO and Canadian initiatives. Moreover, due to the temporary nature of the mPower project, it might be beneficial to work with a permanent national organisation in one of the partner countries to progress a suitable long-term solution instead of creating or combining a new framework.

However, as suggested in the French, German and Catalonian initiatives (Section 5.1.2.4-6), it might also be worth considering a risk-based approach, as “*Apps/SDs have different levels of risk*” (Haute Autorité de Santé, 2016, p. 14), and not all of these seven parameters will be relevant for all types of apps. For example, it will not be necessary to assess an app providing exclusively general health information and advice for ‘Privacy / Data protection’, ‘Security / authentication’ or for ‘Interoperability’, if the app does not handle personal data or connect with third party services. Yet on the other hand, ‘Credible sources / Evidence-based information’ ought to be assessed rigorously, ensuring the information is correct and not misleading users. Due to this, a risk-based assessment could be beneficial for adapting and selecting appropriate quality parameters or criteria necessary for assessing a specific app.

Finally, it should be noted that the initiatives covered within this report do not form an exhaustive list of the current efforts to develop or assess mobile health and wellbeing apps, as several commercial offerings also exist. These include among others Our Mobile Health (2017), Medappcare (2018) and ORCHA (2017b), as referenced in Appendix 2. However, these initiatives have not been included in the scope of this report, as the initial focus was primarily on national, regional and cross border initiatives. Furthermore, the commercial offerings review processes are often unpublished or very limited in their publicly available extent.

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5 APPENDIX

5.1 Appendix 1 – Current Initiatives

5.1.1 Academic Initiatives

There is an increasing number of national and international academic studies, literature reviews, systematic reviews, clinical studies and case studies examining the use of mHealth services (Boudreaux et al., 2014). One initiative in particular recurs in both the academic, regional and national initiatives: the Australian Mobile Application Rating Scale (MARS), which “*On an individual level, (is) the assessment scale found most often in the literature*” (Haute Autorité de Santé, 2016, p. 10). Consequently, the MARS tool has been included within this report and will be examined below.

5.1.1.1 Mobile Application Rating Scale (MARS)

The MARS tool was developed at Queensland University of Technology in 2015 to provide a standardized “multidimensional measure of the app quality indicators of engagement, functionality, aesthetics, and information quality, as well as app subjective quality” (Stoyanov et al., 2015, p. 6). These indicators were identified through an extensive literature search on “explicit Web- or app-related quality rating criteria” (Stoyanov et al., 2015, p. 2). As a result, a total of 372 explicit criteria were identified and extracted, and subsequently grouped into the five broad categories or indicators. Additionally, a sixth indicator, app-specific aspects, was added to obtain information on the perceived impact of the specific app. All six indicators will be examined below.

Engagement

‘Engagement’ objectively examines whether the app is “fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience” (Stoyanov et al., 2015: Appendix 2). In order to assess this, five underlying criteria or ‘items’ were created, each of which are rated using a five-point scale ranging from “1-Inadequate, 2-Poor, 3-Acceptable, 4-Good, 5-Excellent” (Stoyanov et al., 2015: Appendix 2). The five underlying criteria are seen below, along with their formulated descriptions:

- Entertainment – “Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification)?” (Stoyanov et al., 2015: Appendix 2).
- Interest – “Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way?”
- Customisation – “Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)?”

- Interactivity – “Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Note: these functions need to be customisable and not overwhelming in order to be perfect.”
- Target group – “Is the app content (visual information, language, design) appropriate for your target audience?”

Each of these are reviewed using individual descriptors for the five-point scale, where for example entertainment is rated between 1, the inadequate score for “*Dull, not fun or entertaining at all*” (Stoyanov et al., 2015: Appendix 2) and 5, the excellent score for “*Highly entertaining and fun, would stimulate repeat use*” (Ibid.).

As all five items are reviewed in this way, a mean score is calculated for the overall level of engagement of the app.

Functionality

‘Functionality’ entails the following: “*app functioning, easy to learn, navigation, flow logic, and gestural design of app*” (Stoyanov et al., 2015: Appendix 2), which is objectively reviewed with four underlying criteria, as seen below:

- Performance – “How accurately/fast do the app features (functions) and components (buttons/menus) work?” (Stoyanov et al., 2015: Appendix 2).
- Ease of use – “How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?”
- Navigation – “Is moving between screens logical/accurate/appropriate/uninterrupted; are all necessary screen links present?”
- Gestural design – “Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens?”

Each of these are reviewed using the tailored five-point scale, whereas for example in the criterion of ‘performance’, the rating ranges between the ‘inadequate score’ for “*App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)*” (Stoyanov et al., 2015: Appendix 2) and the ‘excellent score’ for “*Perfect/timely response; no technical bugs found/contains a ‘loading time left’ indicator*” (Ibid.).

Aesthetics

The ‘Aesthetics’ covers “*graphic design, overall visual appeal, colour scheme, and stylistic consistency*” (Stoyanov et al., 2015: Appendix 2), which have been divided into three underlying criteria:

- Layout – “is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed?” (Stoyanov et al., 2015: Appendix 2).
- Graphics – “How high is the quality/resolution of graphics used for buttons/icons/menus/content?”

- Visual appeal – “How good does the app look?”

These are rated as previously covered, where, for example, ‘graphics’ range from the inadequate score of *“Graphics appear amateur, very poor visual design - disproportionate, completely stylistically inconsistent”* (Stoyanov et al., 2015: Appendix 2) to the excellent score of *“Very high quality/resolution graphics and visual design - proportionate, stylistically consistent throughout”*.

Information

‘Information’ covers the quality of the information provided in the app, which should be based on credible sources, containing “high quality information (e.g. text, feedback, measures, references)” (Stoyanov et al., 2015: Appendix 2). To objectively assess this, seven underlying criteria have been developed:

- Accuracy of app description – “Does app contain what is described?” (Stoyanov et al., 2015: Appendix 2).
- Goals – “Does app have specific, measurable and achievable goals (specified in app store description or within the app itself)?”
- Quality of information – “Is app content correct, well written, and relevant to the goal/topic of the app?”
- Quantity of information – “Is the extent coverage within the scope of the app; and comprehensive but concise?”
- Visual information – “Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct?”
- Credibility – “Does the app come from a legitimate source (specified in app store description or within the app itself)?”
- Evidence base – “Has the app been trialled/tested; must be verified by evidence (in published scientific literature)?”

An example of the tailored five-point scale for the criteria of ‘quality of information’ range between an inadequate score of *“Irrelevant/inappropriate/incoherent/incorrect”* (Stoyanov et al., 2015: Appendix 2) to the excellent score of *“Highly relevant, appropriate, coherent, and correct”* (Ibid.).

App subjective quality

The ‘app subjective quality’ is assessed by four subjective questions:

- Would you recommend this app to people who might benefit from it?
- How many times do you think you would use this app in the next 12 months if it was relevant to you?
- Would you pay for this app?
- What is your overall star rating of the app?

As with previous assessment areas, the questions are answered using a tailored five-point score, where for example, the overall star rating range from 1, “*One of the worst apps I’ve used*” (Stoyanov et al., 2015: Appendix 2) to 5, “*One of the best apps I’ve used*” (Ibid.).

As the mean score is measured for each of the five areas covered above, an overall mean score for the quality of the app is reached by combining them all (Stoyanov et al., 2015). This overall assessment can subsequently be supplemented with the ‘app-specific’ indicators as seen below:

App-specific

The ‘app-specific quality’ has been added to assess “information on the perceived impact of the app on the user’s knowledge, attitudes, and intentions related to the target health behavior” (Stoyanov et al., 2015, p. 7). To accomplish this, six potential criteria have been created, which are rated with a generic five-point scale, ranging from 1 ‘strongly disagree’ to 5 ‘strongly agree’ (Stoyanov et al., 2015). These questions cover the following:

- Awareness – “*This app is likely to increase awareness of the importance of addressing [insert target health behaviour]*” (Stoyanov et al., 2015: Appendix 2)
- Knowledge – “*This app is likely to increase knowledge/understanding of [insert target health behaviour]*”
- Attitudes – “*This app is likely to change attitudes toward improving [insert target health behaviour]*”
- Intention to change – “*This app is likely to increase intentions/motivation to address [insert target health behaviour]*”
- Help seeking – “*Use of this app is likely to encourage further help seeking for [insert target health behaviour] (if it’s required)*”
- Behaviour change – “*Use of this app is likely increase/decrease [insert target health behaviour]*”

Since the MARS tool was developed, it has “*demonstrated high levels of reliability in rating the quality of mental health-related apps*” (Domnich et al., 2016, p. 2), and apps for weight loss, mindfulness, smoking cessation and more. Furthermore it, has been implemented or referenced within several national and regional initiatives examined in this landscape review (see section 5.2.2, 5.2.3, 5.2.5, 5.2.7). Recently, it has also been translated and validated in Italian (Domnich et al., 2016) and supplemented with an end-user version, the uMARS, a simplified version written in plain English (Stoyanov, Hides, Kavanagh, & Wilson, 2016).

5.1.2 National and Regional Initiatives

In line with the growing field of mHealth, several national and regional initiatives have emerged in recent years. These local initiatives are found across the globe, and within this landscape review, thirteen initiatives have been identified and examined as seen below.

5.1.2.1 Andalusia – Safety and Quality Strategy in Mobile Health Apps

The Andalusian initiative for safety and quality strategy for health apps started in 2012, in which *“the Andalusian public health system defined their own Recommendations for the design, use and evaluation of health apps.”* (European Commission, 2017: Annex 2). These guidelines create the basis for the assessment of health apps that receive the ‘AppSaludable Quality Seal’ and are included in their ‘Mobile Health Apps Catalogue’ (Agencia de Calidad Sanitaria de Andalucía, n.d.-a).

The ‘Recommendations Guide’ includes thirty-one recommendations, which are divided into four areas of assessment:

- Design & Appropriateness
 - Appropriateness
 - Accessibility
 - Design
 - Usability/Testing
- Quality and safety of information
 - Suitability for the audience
 - Transparency
 - Authorship
 - Information update/revisions
 - Content and information sources
 - Risk management
- Provision of service
 - Technical support/Inquiries
 - E-commerce
 - Bandwidth
 - Advertising
- Confidentiality and privacy
 - Privacy and data protection
 - Logical security

5.1.2.2 Australia – VicHealth

The Victorian Health Promotion Foundation (VicHealth), a government funded health organisation that focuses on promoting good health and preventing chronic disease have launched several initiatives for ensuring effective and evidence-based health & wellbeing apps (VicHealth, 2017b). This includes an app library with over 300 reviewed apps. The reviews were conducted in 2016 and recently a guideline for app developers has also been released by VicHealth. Both are covered below.

The Healthy Living Apps

The Healthy Living Apps library was completed in 2016 with the aim of helping *“users understand more about a selection of health and wellbeing apps that are available in app stores.”* (VicHealth, 2016b). The reviewed apps were gathered into a publicly available app library, along with the applied assessment approach, covered below.

The *“Selected apps were put through a six-step screening, review and rating process”* (VicHealth, 2016b), where they were assessed for their relevance, functionality and behavioural change effectiveness.

The first step was a search of the two biggest app stores, Google Play and Apple’s App Store, where apps with the terms health and wellbeing was identified (VicHealth, 2016b). Secondly, the identified apps were screened and filtered through three criteria, covering the language (English), their average user rating (at least 2.5) and recent updates (within the last 18 months).

The screened apps were subsequently divided into five focus areas of promoting healthy eating, physical activity, mental wellbeing and prevention of tobacco and harmful alcohol use. Next, the apps were screened with three more criteria: conflicts of interest, relevance for Australian users and targeting a specific clinical population.

Within the third step, apps that encourage behavioural change were selected on the basis of independent reviews of the app description, as these should mention or describe behavioural change elements (VicHealth, 2016b).

The fourth step covers the apps functionality, which was rated with the MARS toolkit mentioned in section 5.1.1 (VicHealth, 2016b). The assessment was carried out after a small pilot test to *“standardise the reviewers’ approaches.”* (VicHealth, 2016b). Subsequently, at least two reviewers went over each app, using these *“for about 10 minutes to familiarise themselves with its functionality and user experience.”* (VicHealth, 2016b).

To assess the app’s behavioural change effectiveness within the fifth step, the Coventry, Aberdeen & London – Refined (CALO-RE) taxonomy of behavioural change techniques was used (Michie et al., 2011; VicHealth, 2016b). This was to determine the apps’ *“potential to affect behaviour change in relation to factors such as goal setting, action planning, barrier identification and problem solving, tailoring the app to suit you, self-monitoring and feedback.”* (VicHealth, 2016b).

To conclude, an overall app rating was calculated by averaging the MARS functionality and the CALO-RE behavioural change rating, converting it into a five-star rating system (VicHealth, 2016b). In addition to this, information was gathered on whether the app included add-ons/in-app purchases, login, password protection, publicly available privacy policy, advertising, SoMe integration, reminders/push notifications and an associated app community.

Many of the apps reviewed scored high using the MARS toolkit, yet when combined with the behavioural change rating, the highest scoring apps received a three-star rating. This was due to the fact that few apps achieved “*a high rating on their potential to help users change their behaviour.*” (VicHealth, 2016b).

Guidelines for Creating Healthy Living Apps

In addition to the Healthy Living Apps library and above assessment approach, VicHealth has also released a guideline for app developers and organisations considering the creation of health and wellbeing apps (VicHealth, 2017a). The guideline presents five phases, outlining “*each step of the process for creating a healthy living app, starting with before you start building an app and ending with updating and improving your app.*” (VicHealth, 2017a, p. 8).

The five presented phases include the following:

- Before you start building your app
- Planning your app
- Building and testing your app
- Launching your app
- Updating your app

Among these, relevant aspects for this report are found within the building and test phase, where VicHealth proposes three principles for creating effective health and wellbeing apps, which provides “*guidance on best practice.*” (VicHealth, 2017a, p. 19). The three presented principles cover the following. The app has to be:

- Interesting, engaging and fun
- Well-designed user interface
- Simple and clear language

In order to ensure a high level of engagement with the app, VicHealth suggests making the app interesting, engaging and fun, and including engagement strategies like gamification, interactive visuals and customised advice (VicHealth, 2017a). By doing so, VicHealth suggest using the app will “*feel less like a chore for your app’s users.*” (VicHealth, 2017a, p. 19), ensuring their continued use and engagement.

Furthermore, a well-designed user interface is deemed vital, as it should be “easy to find, navigate and interact with the content” (VicHealth, 2017a, p. 19). To accomplish this, VicHealth suggest involving users in the development phase, ensuring the interface is logical and easy to navigate by the end users. By doing so, it is possible to “produce a better, more effective app” (VicHealth, 2017a, p. 19), more likely to be used by more users.

Lastly, the language in the “app’s name, description, navigation and content” (VicHealth, 2017a, p. 19) should be simple and clear, as this will ensure an easier use of the app. To achieve this, plain English, short sentences and paragraphs should be used, making sure the users will be able to easily understand and comprehend the language and content.

In addition to these three principles, the need for evidence-based information is also stressed, as “It is essential that healthy living apps include evidence-based information.” (VicHealth, 2017a, p. 20). To ensure this, VicHealth recommend involving a third-party reviewer who can confirm the information is up to date and adheres to current best practices. Along with the need for evidence-based information, VicHealth also suggests that basic privacy and data security measures are taken. This includes “password protection; adhering to the relevant health privacy principles; and providing a privacy statement or disclosure outlining what user information is being collected, by who, and for what purpose.” (VicHealth, 2017a, p. 17).

The complete guideline presents an extensive coverage for necessary considerations when developing an effective health and wellbeing app, including above aspects for assessing current apps (VicHealth, 2017a). Furthermore, it provides developers with additional resources, including guidance for design-thinking, user-centred design, behavioural change tools, the MARS toolkit and more.

5.1.2.3 Canada – Guiding Principles for Physicians Recommending Mobile Health Applications to Patients

In 2015 the Canadian Medical Association (CMA) created a set of guiding principles for physicians as “a high-level summary that spells out how to assess a mobile health applications” (Canadian Medical Association, 2015a). To develop the guidelines, the CMA build upon their earlier efforts, of ‘Physician Guidelines for Online Communication with Patients’, aimed at helping physicians to communicate appropriately through online communication platforms. Furthermore, relevant stakeholder groups were involved in the process, in which it was decided a more general approach would make the most sense for mHealth. This was due to alternative approaches of assessment or certification etc., would be too economically and logistically challenging and become ‘daunting’.

In addition to the set of guiding principles, which cover several considerations for HSCPs when recommending mHealth solutions, seven criteria for safe and effective

apps are presented in the finalized document (Canadian Medical Association, 2015b). Both areas will be examined below.

Guiding Principles

CMA presents eight guiding principles, which cover considerations for HSCPs to take into account, when recommending mHealth solutions to patients (Canadian Medical Association, 2015b). The overall objective with these principles is *“to enhance the safety and/or effectiveness of patient care or otherwise for the purpose of health promotion.”* (Canadian Medical Association, 2015b, p. 2). The guiding principles present mHealth as a complementary health service, which is not intended to replace the face-to-face relationship with patients. Furthermore, HSCPs are warned not to treat mHealth services as ‘one-size-fits-all’. Instead, they are recommended to consider the *“patient’s abilities, comfort level, access to technology, and the context of the application of care before recommending a mobile health application.”* (Canadian Medical Association, 2015b, p. 2).

The principles also emphasize that it is the HSCPs responsibility to adhere to existing regulations, legislations and professional obligations if and when they wish to recommend an app to a patient (Canadian Medical Association, 2015b). Having said that, the principles do this without referring to or mentioning any current or applicable regulations, legislations or obligations that should be taken into account. It is also recommended that the HSCPs should consider discussing the common elements of mHealth and the associated risks with their patients, so that they are aware of what to pay attention to. Lastly, it is encouraged that HSCPs share their experience of effective mHealth solutions with colleagues.

Characteristics of a Safe and Effective Mobile Health Application

The Canadian guidelines include seven characteristics, which are intended to be used as indicators for safe and effective apps, before recommending these to patients (Canadian Medical Association, 2015b). Having said that, the app does not need to fulfill all seven characteristics for it to be safe and effective. The presented characteristics include:

- Endorsement by a professional / recognized association/medical society/health care organization
- Usability
- Reliability of information
- Privacy and security
- Avoids conflict-of-interest
- Does not contribute to fragmentation of health information
- Demonstrates its impact on patient health outcomes

The 'Endorsement' criterion refers to whether or not the app has been developed or endorsed by a recognized healthcare organisation. This indicates a greater likelihood *"that the information in the mobile health application can be trusted."* (Canadian Medical Association, 2015c, p. 1). It is also more likely that the app is endorsed if it is in use in a clinical environment, association with current EMR platform(s) or it has been subject to a peer review process (Canadian Medical Association, 2015b).

The characteristic of 'Usability' raises "a number of usability factors than can complicate the use of mobile applications, including interface and design deficiencies, technological restrictions, and device and infrastructure malfunction." (Canadian Medical Association, 2015b, p. 3). To avoid these, the app should be updated within the last year and the HSCP should consider testing the app beforehand to check whether it is easy to use and functioning as intended. Furthermore, the HSCP might want to have a dialogue with patients on their respective "level of comfort with mobile health technologies" (Canadian Medical Association, 2015b, p. 4) and digital literacy, ensuring the usability of the app for the individual patient.

The 'Reliability of information' refers to information presented by the app, which *"should be appropriately referenced and time-stamped with the last update by the application developer."* (Canadian Medical Association, 2015b, p. 4). The HSCP should also have an understanding of how the patient intends to use the information, to ensure its timeliness and appropriateness.

'Privacy and security' addresses the "inherent security risks when a patient uses mobile health applications or enters sensitive information into their mobile device." (Canadian Medical Association, 2015b, p. 4). The HSCPs ought to indicate this risk for patients and advise them to check the privacy policy (if available) to understand how their data is collected and used. Furthermore, apps with additional authentication methods and encryption protocols should be preferred, ensuring the patient's data is kept secure.

The app should also avoid conflict of interest, as "There is a risk of secondary gains by mobile health application developers and providers where information about patients and/or usage is gathered and sold to third parties." (Canadian Medical Association, 2015b, p. 5). To counter this, the HSCPs should advise patients to consider who had developed the app and whether there is a conflict of interest statement available.

The characteristic of 'Fragmentation of health information' refers to the growing range of apps and various destinations, where health information can be stored (Canadian Medical Association, 2015b). Due to this, the HSCP *should "recommend mobile health applications which contribute to robust existing data repositories, especially an existing EMR."* (Canadian Medical Association, 2015b, p. 5).

The 'Demonstration of impact' addresses *“mobile health applications that have undergone validation testing to demonstrate impact of use on patient health outcomes.”* (Canadian Medical Association, 2015b, p. 5). Specifically, in cases where the app may claim a direct impact on patient's health outcomes from using the app, the HSCP should advise the patient to search for resources to validate the claim. The CMA also acknowledges, however, that not all apps have the necessary scale of use, nor do all developers have the capacity to demonstrate the impact on health outcomes.

In addition to these guiding principles and characteristics, CMA also created a one-page handout for patients, which includes four questions for patients to consider before using an app for managing their health (Canadian Medical Association, 2015c). The patient is encouraged to be aware of risks associated with storing personal information on a mobile device, whether the app has been endorsed by a healthcare organisation, if there is any conflict of interests and lastly, if the app has been updated within the last year.

Overall, the CMA's recommendations are intended to be very general and unspecific, giving only a very basic understanding of what to assess. Some of the criteria are not covered as extensively and in detail as is seen in the other initiatives. This is for example the case with the 'Reliability of information' criterion, where an aspect, such as basing the information available in the app on clinical evidence and recognized sources, is not covered. This is also the case with the 'Usability' criterion, where the recommendations only address what the HSCP should base their assessment of the app on, apart from their own subjective opinions acquired from testing it.

5.1.2.4 Catalonia – mHealth Office

The Catalan Health Department created the mHealth office in 2015 to connect the citizens to the social and healthcare services by means of mobile technology such as smartphones, tablets and laptop computers, and to enable rapid and personal interaction with these services. (TIC Salut, n.d.-b). To accomplish this, the Health Department developed an accreditation process, which assesses health apps to be included in their dedicated app library, 'AppSalut'. This can be used by HSCPs to recommend apps to their patients. The accreditation process consists of 120 criteria, grouped into four different areas, as covered below:

- Usability
 - Accessibility
- Technology
- Security
- Content

If and when the app passes this accreditation process, “random audits are performed to ensure that they keep meeting the criteria.” (TIC Salut, n.d.-a).

5.1.2.5 France – Good practice guidelines on health apps and smart devices

The good practice guidelines were developed by the French health authorities in 2016 with the aim of providing “guidance for, promote use of and increase confidence in health apps and smart devices, by supplying good practice guidelines for manufacturers and evaluators” (Haute Autorité de Santé, 2016, p. 5). To accomplish this, the authorities reviewed current literature for mHealth assessment and established an independent working group and a review group and included inputs from relevant stakeholders. From this process, the relevant criteria identified were grouped into five categories and fourteen subcategories as seen below:

- Informing users
 - Description
 - Consent
- Health content
 - Design of initial content
 - Standardisation
 - Generated content
 - Interpreted content
- Technical content
 - Technical design
 - Data flow
- Security/Reliability
 - Cybersecurity
 - Reliability
 - Confidentiality
- Usability/use
 - Usability/design
 - Acceptability
 - Integration/import

Each of these groups and their underlying criteria are assessed using a risk matrix, which helps to determine the most appropriate weighing of each specific criteria and whether it is ‘Desirable’, ‘Recommended’ or ‘Compulsory’ (Haute Autorité de Santé, 2016).

5.1.2.6 Germany – Digital healthcare products: Leveraging opportunities – developing safe routes to market

The German initiative was created in 2016 by IGES Institute on behalf of Techniker Krankenkasse, “one of the leading insurers in Germany” (TK, 2015) to explore the possibilities of a German authorization procedure for digital healthcare products, including mHealth (IGES Institute, 2016). To accomplish this, the initiative focuses on how an “*authorisation and reimbursement processes should be regulated for products which are targeted at consumers*” (IGES Institute, 2016, p. 7). This includes authorisation for digital healthcare products, including health apps, which will be covered in this report.

A risk-based categorisation for authorisation is proposed, “*based on the potential health risks associated with the products*” (IGES Institute, 2016, p. 7). This includes four proposed risk classes:

- Class 1a: General medical information
- Class 1b: Data collection and representation
- Class 2: Data processing for the purpose of supporting users
- Class 3: Data processing for the purpose of replacing care providers

These risk classes “*should be used as a basis for deciding whether authorisation is required and what it should look like.*” (IGES Institute, 2016, p. 35).

Class 1a

Class 1a covers digital healthcare products, “*which solely provide medical information without any reference to the user’s specific characteristics*” (IGES Institute, 2016, p. 27). This includes apps providing general information on medicine, health or lifestyle issues, where data is “*impersonal and could in principle be published in printed form*” (IGES Institute, 2016, p. 27). To assess such products, the initiative does not recommend regulations or authorisations, but instead it is suggested that the ‘Accuracy of information’ might be assessed and certified on a voluntary basis to increase trustworthiness in the product (IGES Institute, 2016). However, “*only 19% of users are in favour of a quality seal, and are more interested in making information easier to understand*” (IGES Institute, 2016, p. 37), implying that the users “*are confident in their own ability to distinguish between good-quality and poor-quality information*” (Ibid.).

Therefore an alternative approach is also introduced, in which the users independently assess the trustworthiness of the digital healthcare products on the basis of the information provided (IGES Institute, 2016). To support this self-assessment, it should be “*clear which authors are responsible for which parts of a product, and which sources they used as a basis for their work*” (IGES Institute, 2016, p. 38)

Class 1b

Class 1b covers digital healthcare products, which “are used to collect, store and graphically represent personalized data such as blood glucose levels and/or relevant environmental data” (IGES Institute, 2016, p. 28). This includes apps that collect data to provide personalised reports, helping users to self-manage and “more easily recognise patterns or connections” (IGES Institute, 2016, p. 28) in their personal health. To assess such products, the initiative raises ‘two points of debate’, data protection and the correct functioning of the software.

First of all, ‘Data protection’, as there is an “expectation that all data entered by users must be safe” (IGES Institute, 2016, p. 39). To ensure ‘Data protection’, the product needs to comply with German data protection legislation, observing any existing data protection rules (IGES Institute, 2016).

Secondly, the technical functionality of the app should be ensured, as “*Class 1b apps should also be reliable in technical terms*” (IGES Institute, 2016, p. 40). This includes correct and accurate data processing and presentation of the data to avoid any misinterpretations.

Furthermore, the approach of a voluntary quality seal for ‘Class 1a’ would also be applicable to Class 1b, as extensive authorisations procedures are deemed unnecessary for class 1b (IGES Institute, 2016).

Class 2 and Class 3

Class 2 covers products that “*go beyond merely collecting and representing data, and instead also process the data (whether current or historical).*” (IGES Institute, 2016, p. 28). This includes apps that support users with early detection, diagnosis, treatment decisions, treatment, monitoring and self-management of conditions. On the other hand, Class 3 covers products that “*replace care providers at the stage of diagnosis, treatment decisions and treatment.*” (IGES Institute, 2016, p. 29).

Currently these apps are still limited in numbers, as the underlying legal issues are as yet unregulated. This includes products, which provide diagnostic or treatment recommendations based on extensive calculations.

Class 2 and 3 products should be authorized as they “*intervene extensively in current decision-making processes and the doctor/patient relationship.*” (IGES Institute, 2016, p. 41). Therefore their accuracy should be authorized in terms of high sensitivity and specificity of information given, as just like “*in the majority of cases, treatment recommendations must correspond to the treatment recommendations that would be issued by a panel of experts*” (IGES Institute, 2016, p. 41).

Furthermore, for class 3 products, principles of medical confidentiality should also apply, as they “*process large amounts of medical data*” (IGES Institute, 2016, p. 40).

5.1.2.7 New Zealand – Guidance on Evaluating or Developing a Health App

The Ministry of Health in New Zealand released guidance for health app assessment in 2017. This was co-produced with relevant stakeholders in the sector to aid both clinicians, consumers and app developers in developing and evaluating apps (Ministry of Health, 2017b). The guidance itself is targeted at consumer-focused apps, and it seeks to provide clinicians, consumers and app developers with key points to consider. This includes considerations for clinicians when recommending apps to consumers, when consumers consider using health apps or when app developers initially set out to develop a health app.

The clinician and consumer guidance is based on New Zealand's Health Navigator app library, an app repository funded by the Ministry of Health (Ministry of Health, 2017a). The purpose of the app library *"...is not to recommend apps or approve them but to provide clinicians and consumers with a selection of apps and enough information to decide whether the app is likely to meet their needs."* (Ministry of Health, 2017a, p. 1).

The apps provided in the library are assessed using the previously mentioned MARS tool, which have been supplemented by a clinical review, a technical review, a user review and a relevance check for New Zealand (Health Navigator, 2017d). The clinical review is carried out by a HSCP, who assesses the app's clinical value, relevance and safety, whereas the technical review examines the security, privacy and performance of the app. The user review focuses on the users' subjective opinions of the app, its pros and cons and whether it lives up to their expectations. Lastly, assessing the app's relevance for New Zealand highlights aspects of the app that are relevant or irrelevant locally, such as the units of measurement used in the app.

In addition to the Health Navigator library, the guidance also refers to several national and international health app repositories and review sites. These includes the recent NHS app library, PatientView's health app library and the Canadian and Australian initiatives mentioned within this paper (Ministry of Health, 2017a). Furthermore, the guidance refers to several established assessment tools and frameworks for clinicians and consumers to undertake an independent assessment of an app with. These include the MARS tool, the App Chronic Disease Checklist (ACDC), the Royal College of Physicians checklist and the guiding principles for physicians recommending mobile health apps to patients from Canada.

For app developers, the guidance primarily refers to recognised external tools and sites, whereas app developers can either self-assess their app against established checklists/tools or submit it for an independent assessment process (Ministry of Health, 2017a). The referred tools and sites includes the MARS tool, the digital assessment questions from NHS, the Xcertia framework, FDA's distinction between health apps and medical devices and the good practice guidelines on health apps and smart devices from France.

The guidance itself is not as comprehensive or detailed as many of the current initiatives examined within this paper and relies heavily on already established efforts

from other nations and organisations. It should be noted that the Ministry of Health is currently working on “*A second piece of work, to provide an assessment framework for clinical apps...*” (Ministry of Health, 2017a, p. 1).

5.1.2.8 Norway – Self-Declaration Scheme mHealth

The Norwegian government released an action plan for a universally designed society, which set out with the vision for a society where everyone can participate equally (Regjeringen.no, 2016). To achieve this, the Norwegian government proposed a vast number of initiatives to create greater accessibility for all, while forming an environment that is safe and practical to use.

One of their proposed initiatives within the priority area of welfare and everyday technology is the ‘*Tiltak TEK2: Selvdeklareringsordning m-Helse*’, a self-declaration scheme for publishers/developers of health apps. The main goal with the scheme was to make it easier for HSCPs and especially individuals to navigate the many mHealth apps that are not regulated as medical equipment, enabling them to discover those based on objective and clarified quality requirements (Direktoratet for e-helse, 2016; Regjeringen.no, 2016).

Shortly after the action plan was released, the Norwegian Directorate of eHealth, who had been tasked with the initiative, held an open hearing, presenting views on it. This included a set of simplified quality criteria “*based on a known quality content and established frameworks for privacy and information security*” (Direktoratet for e-helse, 2016, p. 5). Their proposed framework covers the following four areas of assessment:

- Information security
- Privacy
- Quality of general medical proficiency
- Quality of specialist medical proficiency

Each of these areas was created with a set of underlying criteria, based on existing guidelines, Code of Conduct and recommendations for good practice (Direktoratet for e-helse, 2016). To make the four areas more accessible and understandable, they have been simplified and formulated so that both patients and app publishers can understand and realize them without difficulty.

Information Security

The assessment area of Information security builds on Norway's Code of Conduct for information security in healthcare, which the ICT solutions and medical devices used in the Norwegian health services are obliged to follow (Direktoratet for e-helse, 2016, 2017). Though the Code of Conduct does not normally apply to mHealth solutions aimed at individuals, it has been used as a guideline for the needed core principles of information security. This has led to four proposed simplified criteria.

First of all, the app should require authentication to protect the potential sensitive information collected by the app. This could be a biometric authentication, a pin code, a password or a similar solution to authenticate the user. Furthermore, the data gathered by the app must be encrypted and stored locally on the device as should any data shared with external services. This encryption ought to be described and mentioned in the user guide and verified. The security settings should also be easily available and gathered in one place in the app.

Privacy

The assessment area of privacy builds on previous work by the Norwegian Data Protection Authorities, who published a set of recommendations for good practice for app developers in 2014 (Datatilsynet, 2014; Direktoratet for e-helse, 2016). The recommendations presented several considerations and practical examples to consider from the start of the development of an app, to ensure it would comply with Norwegian privacy law and regulations (Datatilsynet, 2014). Building on these recommendations, seven underlying criteria were proposed by the Directorate of eHealth.

The underlying criteria cover the necessity for an explicit and active consent from users before sharing any data with third parties (Direktoratet for e-helse, 2016). Furthermore, the use of the app must not be inhibited in any way with locked functionality that can be unlocked by sharing data with third parties. All third-party services, which the app can connect to and share data with, must also be clearly indicated. The app must also clearly indicate when it is registering data, which should be initiated by pressing a distinct and recognizable icon. Likewise, the device should clearly indicate when any sensors in the device are in use. Lastly, the privacy settings and the privacy policy should be easily available and written as clearly and concisely as possible, without legal terminology to ensure it is easily understood by all users.

Quality of General Medical Proficiency

The criteria for the quality of general medical proficiency is based on the quality criteria already defined for healthcare services as defined in the Norwegian strategy for quality improvement in healthcare (Direktoratet for e-helse, 2016). The criteria outlined in the strategy include *effectiveness, safety, continuity, patient/user involvement, equal distribution* and *effective use of resources*. Similar criteria are

also used by several other national and cross border health services; including WHO, EU and NHS and by building upon these they intend to increase the level of recognition for the proposed criteria. From the criteria outlined above, six underlying criteria have been simplified and formulated, as presented below.

To begin with, the app must clearly describe the purpose and expected outcome from using the app, where the information on this, is easily available within the app (Direktoratet for e-helse, 2016). The information and knowledge, from which the app is based, on ought to be evidence-based where the original work is referred to. It should also be clearly described, how the evidence-based knowledge has been transformed into the features of the app.

During the development and test phase of the app, users, NGOs, patient-organisations and HSCPs ought to be involved, ensuring a high level of patient/user involvement. Information regarding this involvement should similarly be easily available for the users. Lastly, the app must be designed with accessibility in mind to ensure all patients and users can equally access and use the app.

Quality of Specialist Medical Proficiency

The last area of assessment is quality of specialist medical proficiency, which is specific for the diagnosis or treatment procedures supported by the app (Direktoratet for e-helse, 2016). At the moment, this area has not been included in the self-declaration scheme, as the Directorate believes the diversity needed for this, complicates the more general assessment process proposed. Furthermore, the area crosses into the mHealth solutions that provide an actual health service, where it will often be regulated as medical equipment, outside of the scope of the current self-declaration scheme. It is suggested that some specific medical areas can be covered at a later stage, but without disclosing which treatments or illnesses could be considered for this.

The assessment process itself would be carried out by the app publishers, who would score their app against the proposed criteria and assess whether or not the app meets the underlying criteria (Direktoratet for e-helse, 2016). This self-declaration will initially be under the administration of the Directorate of eHealth, who would publish the assessed apps. To ensure their compliance with the criteria, they would also carry out random checks of the self-declarations. The self-declaration scheme would potentially also lead to an independent certification process, where the self-declarations could be used as a basis assessment.

Alternative Norwegian Approaches

In addition to the self-declaration scheme and the proposed assessment areas, the Norwegian Directorate of eHealth discussed alternative approaches to tackle the growing number of mHealth apps and ensure their safety and quality (Direktoratet for e-helse, 2016). The proposals for a certification scheme, where apps are put through rigorous testing to ensure their quality and value was presented.

This approach was considered too demanding and expensive, and not suitable in the context of mHealth solutions for individuals. An option for declaring all mHealth solutions as medical equipment was also presented. This was dismissed due to the strict regulations connected with medical equipment, which is not deemed appropriate for many mHealth solutions.

The Directorate also considered the alternative of doing nothing, leaving patients, app publishers and HSCPs to decide for themselves what they deem the best solutions to be. This approach was also dismissed, as it would not achieve the goal of making *“it easier for users to find the apps developed by quality-focused manufacturers.”* (Direktoratet for e-helse, 2016, p. 6).

The final option presented is to introduce buddies, or trained counselors, who can assist in the development, selection and use of mHealth solutions. This approach was deemed simpler than the self-declaration scheme, as the proposed areas of assessment could be applied by the counselors, while this is not deemed an adequate solution to achieve the main goal of helping individuals to navigate the many mHealth apps.

Furthermore, the Directorate of eHealth also refers to and examines some of the current initiatives taking place, where their remarks and observations have been considered in the specific initiatives examined within this paper (Direktoratet for e-helse, 2016). The initiatives examined includes the work done by the European Commission, by the FDA, NHS England and the mHealthQuality framework applied in France.

The Reception of the Proposal

The proposed self-declaration scheme has been met with divided opinions by Norwegian NGOs, patient organisations, HSCPs associations and more (Bekkemellem & Alnæs, 2016; Fensli, 2016; Markussen & Sørli, 2016; Riise & Strøm, 2016; Trommald, 2016; Wistner, 2016). Generally, the initiative is welcomed, as there seems to be a consensus for the need of additional quality assurance for mHealth solutions intended for individuals. However, there are some disagreements on how to approach this issue, as some believe the current proposal could limit the innovation within mHealth, *“as developers will adapt their products and ideas to the requirements of the scheme.”* (Riise & Strøm, 2016, p. 1). Furthermore, many are concerned on the government’s role, as several argue that a potential self-declaration scheme should not be administered by a governmental organisation (Bekkemellem & Alnæs, 2016; Fensli, 2016; Riise & Strøm, 2016; Wistner, 2016). There are also doubts with regard to the self-declaration scheme, as that will require a high level of trust in the app developers and their self-assessment. To counter this, several organisations are calling for a more independent assessment method to ensure HSCPs and patients can *“choose the health apps that are safe, reliable and have high level of precision.”* (Markussen & Sørli, 2016, p. 1).

Lastly, several organisations are calling for international standards and collaborations, instead of a national approach, as they do not believe Norway could

have much impact on its own to get international app developers to self-declare their apps locally (Bekkemellem & Alnæs, 2016).

As to the current status of this initiative, there is currently no publicly available information regarding the progression of the self-declaration scheme. Please note that the Directorate of eHealth has been approached as part of this research work and a response is awaited.

5.1.2.9 United Kingdom – Digital Assessment Questions

The Digital Assessment Questions (DAQs) is a recent initiative created to assess and endorse apps for the NHS Digital Tools Library (Public Health England, 2017b). The questions have been developed by NHS England, who have worked “*with key partners to develop thorough Digital Assessment questions*” (Bauer & Murphy, 2017). The developed questions “*cover a series of clinical and technical standards, questions and best practice*” (Health Developer Network, 2017), which have been grouped into nine categories for extensively assessing digital health and wellbeing services. These include:

- Indicators of Effectiveness
- Regulatory Approval
- Clinical Safety
- Privacy & Confidentiality
- Security
- Usability & Accessibility
- Interoperability
- Technical Stability
- Change Management

The DAQs and these categories are still in beta version, currently being tested in pilot projects, so they might be updated and further developed (Health Developer Network, 2017). Their current form is examined below.

Indicators of Effectiveness

The ‘indicators of effectiveness’ have four underlying categories, which address the purpose and intended use of the service, its cost effectiveness as well as the evidence base for the service and its claimed benefits (Health Developer Network, 2017).

These are evaluated with a series of self-assessing questions, for which the app developer must provide supporting documentation, so the answers can be validated at a later stage (Public Health England, 2017c). These questions cover whether the app or service clearly states its health and wellbeing related purpose, who the

intended users are and how the service should be used to achieve the potentially claimed benefit (Health Developer Network, 2017). Furthermore, if the service uses behavioural change techniques, its evidence bases should be provided, including how the evidence has influenced the development of the service and whether there is “*evidence available to demonstrate the claimed clinical or behavioural effectiveness*” (Health Developer Network, 2017).

Regulatory Approval

The ‘regulatory approval’ is assessed with three underlying categories that cover the service’s applicability and potential registration with the Care Quality Commission (CQC) (Health Developer Network, 2017). In addition, if the app accesses the Health & Social Care Network (HSCN) or other national, clinical and/or patient services or records, the ‘regulatory approval’ requires the service to obtain the correct assurances from NHS Digital. Lastly, the category evaluates whether the digital service is eligible as a medical device, and whether it should be subject to regulations from the Medicines and Healthcare Products’ Regulatory Agency (MHRA).

Clinical Safety

‘Clinical safety’ refers to the compliance of the digital service with NHS England mandated safety standards (SCCI0129). The DAQs determine whether the service is subject to these standards or not (Public Health England, 2017a). This is determined by the app developer, who must clarify whether the service is “*used to record, track and/or maintain general health and wellbeing with no Clinical support*” (Health Developer Network, 2017). Furthermore, if the service integrates with current health and care systems, is used as a medical teaching aid or poses any adverse effects or risks to the users or the current health and care systems the service is subject to safety standards and its compliance with these must be evidenced and included in the assessment.

Privacy & Confidentiality

The ‘Privacy & Confidentiality’ addresses the services ability to “*capture and handle personal data legally and securely*” (Public Health England, 2017a), while also making sure users fully understand what happens to the data provided by them. To accomplish this, the DAQs includes questions on the processing of personal and sensitive data and whether this processing is “*made fair and transparent to the user*” (Health Developer Network, 2017). That includes specifying what, how and why any information is collected and whether it involves identifiable or sensitive personal data (Health Developer Network, 2017). Similarly, the service should specify how the information is to be used, who will have access to it and where it will be processed and stored. Furthermore, the DAQs are used to determine whether appropriate safeguards have been put in place, including encryption to store and/or transfer personal data and personal identifiable data.

Security

'Security' encompasses "*all security concerns and vulnerabilities*" within the service (Public Health England, 2017a). The app developer must demonstrate and explain how these concerns has been addressed. The DAQs presents nine categories, which extensively cover security concerns and vulnerabilities, such as data storage, privacy, architecture design, authentication, session management and network communication (Health Developer Network, 2017; Public Health England, 2017a). The extent of these varies depending on the service's security level, according to the Open Web Application Security Project (OWASP) security verification standards. The differing security levels presented in the OWASP partly depends on whether the service handles or store personal and sensitive data or not.

Usability & Accessibility

The 'Usability & accessibility' criteria addresses the service's ability to "*meet the needs of a diverse set of users, including people with disabilities or those with limited technical knowledge*" (Public Health England, 2017a). To accomplish this, the service ought to have applied user centred design processes in the development, ensuring the service is informative, easy to understand and operate. These criteria are assessed by determining whether key principles of user centred design have been followed, such as the six key principles presented in ISO 9241-210 (Health Developer Network, 2017). Furthermore, the developer must assess whether users have been involved throughout the process and to what extent. This entails both fully understanding the users' needs and subsequently involving them in the evaluations before and after the release of the service.

The accessibility is assessed by determining whether the service conforms "*to WCAG 2.0 and other W3C/WAI guidelines on accessibility*" (Health Developer Network, 2017). These include aspects such as colour contrasts used, interoperability with assistive technologies, testing of the accessibility and an accessibility statement.

Interoperability

'Interoperability' refers to the service's ability to communicate with third-party services and whether it "*complies with the relevant technical standards*" (Public Health England, 2017a), including those specified within the NHS interoperability toolkit. To assess this, the app developer must provide information on whether recognised standards or data structures have been used within the service and if so, which standards or structures have been applied (Health Developer Network, 2017).

Furthermore, if the service shares data with third-parties, the app developer must specify such arrangements, including information on any APIs used "*for allowing third parties to retrieve data*" (Health Developer Network, 2017).

Additionally, if the service uses or relies on third-party services to function as intended, such third-party services should be specified and detailed regarding their

necessity. This also includes the potential impact to the service, if such third-party services would be subject to change or experience disruptions. Lastly, if the service shares data with other organisations, it should be made clear whether this is “*for profit or to recover costs*” (Health Developer Network, 2017).

Technical Stability

‘Technical stability’ covers three underlying categories, which address quality assurance, service management and the future product development, as “*all apps must be robust and stable*” (Public Health England, 2017a). The quality assurances cover areas such as version control, audit, functional and non-functional testing, rollback capabilities, testing for malware and security vulnerabilities and regression testing to ensure the service continue to perform as intended (Health Developer Network, 2017). The app developer must therefore consider whether the service has taken the necessary steps within these areas and provide supporting documentation such as test plans and results of previous tests.

Service management addresses the need for proactive monitoring of the service to identify potential faults and technical issues, so these can be addressed accordingly. Furthermore, product development is covered by the stressing the need for “*a documented roadmap for future digital service development*” (Health Developer Network, 2017) as well as plans for decommissioning the service and its gathered data.

Change Management

‘Change management’ covers version control of the service and whether the app developer “*expect any changes to be made to the digital service in the next 6 or 12 months*” (Health Developer Network, 2017), This can potentially affect the functionality and usability of the app. If this is the case, the nature of the change and its potential impact must be determined and described.

The DAQs, in their current form present an extensive series of self-assessing questions for app developers, covering several aspects of quality criteria for health and wellbeing apps. However, the self-assessment is still just the first step in the process to ‘pass’ or ‘fail’ the service, as these also needs to be validated by a panel of reviewers who “*assess the app’s content from a number of more specialised angles*” (Public Health England, 2017c).

As the DAQs still are in beta version, this step has not been covered in detail in public, nor have we any detail on what such specialised angles might be, besides covering health content and behavioural change theory.

It should also be noted that DAQs aligns heavily with ORCHA, as referenced in Appendix 2 and that their review and assurance process “*covers many of the (same) elements*” (ORCHA, 2017a). However, ORCHA have not been included in the detailed analysis of this review, as covered in Section 3, while also avoiding unnecessary repetition.

5.1.2.10 United Kingdom – PAS 277:2015: Health and Wellness Apps. Quality Criteria Across the Life Cycle. Code of Practice

The Publicly Available Specification (PAS) for health and wellness apps was funded by Innovate UK and developed by the British Standards Institution (BSI) in collaboration with healthcare organisations and industry partners (BSI, 2015). The purpose of the PAS was to enable a code of practice in the United Kingdom and to “*form a set of principles for developers so that health care professionals, patients and the public trust their products and services.*” (MindTech, 2015). To accomplish this, BSI proposed a number of recommendations and guidelines, drawing on current standards for medical devices and the development of quality software (BSI, 2015). The proposed recommendations and guidelines include a set of quality criteria for health apps not declared as medical devices, “*which should be described or measured throughout a health and wellness app project.*” (BSI, 2015, p. 5). These cover the following:

- Regulatory and legal compliance
- Functionality
- Usability and user experience
- Reliability, performance, and scalability
- Security and privacy
- Safety
- Compatibility and portability
- Maintainability

In addition to this set of quality criteria, BSI also presents a series of life cycle phases, which should correspond to most projects in health app development (BSI, 2015). The life cycle phases cover the following:

- Planning
- Requirements analysis and research
- Design
- Application testing
- Implementation
- Release
- Maintenance
- Discontinuation of app project life cycle

Within these life cycle phases, “*The quality criteria should be referenced throughout*” (BSI, 2015, p. 5) and especially in the phases of requirements analysis, design and

application testing. The set of quality criteria defined by the BSI is elaborated on below.

Regulatory and Legal Compliance

The area of regulatory and legal compliance refers to the “*current compliance regulations governing, for example medical devices, data protection and other relevant standards*” (BSI, 2015, p. 8). To ensure compliance with any relevant regulations and laws, the app developer ought to do research into and be mindful of these, so that the compliance can be described in terms of the applicable regulations (BSI, 2015). The PAS do not specify which regulations and laws could be relevant, leaving these to the app developer to consider.

Functionality

Functionality “covers the functions that are required to support the intended use of the app for the user, and functions the app require to meet the relevant needs of any other stakeholders” (BSI, 2015, p. 5). To fulfil this, the app’s relevance and functional requirements for the specified type of care should be determined, and it should be clear how it intends to enhance or inhibit this care (BSI, 2015). To help determine and test this, case studies and user stories are suggested. If applicable, the app’s functionalities and content should also be age-appropriate, and only available for the intended users. Furthermore, the mentioned relevance and functional requirements of the app should also be included in the product description of the app.

Usability and User Experience

Usability and user experience refers to the “considerations of accessibility for different types of users, and how using the app might fit in with related activities that the user performs.” (BSI, 2015, p. 5). By considering this, the app developers can ensure that the app meets the users’ needs and is accessible for the targeted users, while ensuring a consistent user experience. To achieve this and avoid user errors, all data collected should be validated to ensure that users are filling in the correct data. Furthermore, any restrictions to the app’s accessibility should be addressed. In addition to this, the PAS refers to “useful and relevant guidance in the medical device standards. For example, BS EN 62366-1 or the FDA’s usability guidance [10].” (BSI, 2015, p. 8).

Reliability, Performance, and Scalability

Reliability, performance and scalability cover “*both the performance of the app itself, and the supporting infrastructure, such as web services that the app may rely on.*” (BSI, 2015, p. 5). To ensure the reliability and performance, several conditions potentially affecting the app’s functions and use should be addressed and assessed, whether it is an unstable network connection or temporary loss of power (BSI, 2015).

Furthermore, the apps requirements for memory and processor power, data storage and battery usage should be addressed and specified, so it is possible to detect and

act upon, if the app performs outside of an acceptable range. Lastly, time-related behaviours of the app, such as loading and response times should also be considered.

Security and Privacy

Security and privacy covers “effective controls over the app and information that it collects, while ensuring that before choosing to use the app, the user is made aware of how personal information is collected, stored and used.” (BSI, 2015, p. 5). To ensure the users are aware of this, an easily available privacy policy should be present, detailing what information is recorded, whether the information is stored and if applicable, where it is stored. Furthermore, the policy should inform the users how they are able to manage their data and share it with third-party services and apps. The policy should also inform users whether their data is removed when they delete the app and what “triggers the removal of personal data” (BSI, 2015, p. 9) when it is no longer relevant.

In addition to the privacy policy, “*Requirements for confidentiality, data integrity, non-repudiation, accountability and authenticity should be addressed.*” (BSI, 2015, p. 8), while also keeping the data secure. Lastly, if the app utilises personal data, it should be anonymized, so it is not indirectly identifiable, maintaining users’ anonymity.

Safety

Safety includes “*patient safety 1) where relevant, as well as safety considerations that would apply to any software product.*” (BSI, 2015, p. 5). To achieve this, the app should be designed so it can detect implausible values and results of the entered data and inform the users, so they can either correct the data or confirm it. Furthermore, if the app uses advertising, this should be clearly distinguishable from the actual content, ensuring that advertising is not interfering with, or not misinterpreted as health information.

Additionally, the PAS refers to ‘Patient Safety’ from NHS England for more information (BSI, 2015).

Compatibility and Portability

Compatibility and Portability include the “compatibility of the app with different platform configurations and the ways that information collected or used by the app may be reused, under appropriate privacy controls.” (BSI, 2015, p. 5). To accomplish this, the app should rely on standards and industry guidelines to ensure the app is interoperable and able to share healthcare “information or is used alongside other information systems.” (BSI, 2015, p. 9). For apps intended to interact with NHS England, SNOMED CT and The HSCIC interoperability toolkit framework are recommended. If the app is relying on other services to function as intended, it should be stated which services and versions are compatible and what functionality they can add.

Furthermore, “*The app design should take into account the range of platforms that need to be supported.*” (BSI, 2015, p. 9). This includes implementing processes to enable users to switch to another device or platforms, if appropriate. By doing so, the users should be able to either transfer the app and their personal data to another device or by making the app “usable on multiple devices with the same data.” (BSI, 2015, p. 9). Likewise, the users should also be able to uninstall the app and transfer their data to a replacement app, if needed.

Maintainability

Maintainability “cover all the considerations that are relevant to the reliable and cost effective provision of maintenance services (see 6.7) and configuration control” (BSI, 2015, p. 5). Such considerations are vital, as these help to ensure the app can continue to perform as intended. To achieve this, maintenance processes should be in place, so the developers can receive, track and resolve any potential issues reported (BSI, 2015). Likewise, unintended uses should be identified and assessed for safety risk, which need to be addressed as should any potential opportunities for extending the intended purpose of the app.

The users should also be informed of any available app upgrades and in some cases require users to upgrade to the newest version, before the app is available for use again (BSI, 2015). The developers should also carry out a “*periodic review of health information and knowledge incorporated in the app and product description*” (BSI, 2015, p. 12) to ensure the information is maintained and up to date.

It is also suggested that the app is developed using a modular design, while also considering “frameworks, components and toolkits including those that have been designed specifically for health and wellness app development” (BSI, 2015, p. 11). Such a framework could for example be the HSCIC interoperability toolkit.

The PAS extensively covers the various aspects of developing health and wellbeing apps, while also defining the above examined quality criteria. Even though the PAS is primarily aimed at app developers, it still presents valuable considerations for HSCPs to use when selecting apps to recommend (BSI, 2015).

5.1.2.11 United Kingdom – Quality Assurance Framework: Mobile Apps for NHS Scotland Healthcare Professionals

The Quality Assurance Framework is an initiative currently being drafted for NHS Scotland, which “aims to ensure that mobile apps for healthcare professionals in NHS Scotland serve as tools to support consistent, safe, high quality care, and reduce waste” (Wales, 2017, p. 3). The framework intends to provide quality assured apps for HSCPs in Scotland and provide an evidence base for NHS Scotland to measure the impact of using apps in healthcare (Wales, 2017). Furthermore, it intends to increase the confidence among patients and citizens in apps used by HSCPs and offer guidance and support for app developers and providers, so they

can “ensure that their apps can be recognised as suitable for use within NHS Scotland.” (Wales, 2017, p. 3).

The framework itself is meant for all kinds of apps targeted at HSCPs, including those classified as medical devices, which are supposed to be self-assessed through the framework’s three parts (Wales, 2017). These are the following:

Part 1: Compliance with standards, legislation and regulatory requirements

Part 2: Adherence to quality criteria defined for NHS Scotland

Part 3: Impact evaluation

These will be examined further below.

Part 1: Compliance with Standards, Legislation and Regulatory Requirements

The first part of the framework covers the app’s “*compliance with standards, legislation and regulatory requirements*” (Wales, 2017, p. 15) for information security, information governance, accessibility standards, usability standards, interoperability standards, and if applicable, the app’s registration with the MHRA.

To ensure the app’s compliance and adherence with applicable standards, legislations and regulations, the framework refers to relevant standards etc. for each area, where the app publisher should provide documentation for their compliance (Wales, 2017). For example with regard to information security, the app should adhere to the “*ISO27001 standards for software development security*” (Wales, 2017, p. 15). If the app is used to process or to store data, evidence should be provided for its adherence to one of the following certifications: Cyber Essentials, Cyber Essentials Plus or ISO/IEC 27001:2013. If the app stores data online, documentation should be provided for its compliance with the five principles of “*communication, consent, control, transparency, independent and yearly audit*” (Wales, 2017, p. 15) found in ISO/IEC 27018. Lastly, the app should provide a completed version of the NHS Scotland systems security policy form.

This comprehensive assessment and referral to applicable standards etc. is carried out within each of the listed areas, which creates a practical overview of the necessary compliances and adherences for the app (Wales, 2017).

Part 2: Adherence to Quality Criteria Defined for NHS Scotland

The second part of the framework assesses how the app adheres to current quality criteria defined by NHS Scotland (Wales, 2017, p. 18). These include:

Evidence Base

To assess the quality of evidence used in the app, details of “*the evidence sources which inform the content*” (Wales, 2017, p. 18) of the app should be provided along with information on how the evidence has been sourced and evaluated. Furthermore, the apps alignment with current best practices in NHS Scotland should be assessed and detailed. Lastly, “*if the app includes guidance and medicines information that is*

not relevant or appropriate for NHS Scotland” (Wales, 2017, p. 18), the assessment should specify how NHS Scotland users are directed away from this.

Authentication

‘Authentication’ covers the authentication methods employed within the app and potentially at remote endpoints, if the app provides access to such (Wales, 2017). This includes details on the app’s password policy and its enforcement and how *“the app respond when incorrect authentication credentials been submitted an excessive number of times”* (Wales, 2017, p. 19). The guideline should also cover how the app handles existing sessions, when the users log out and how *“the remote endpoint authenticate client requests”* (Wales, 2017, p. 18).

Interoperability for NHS Scotland Mobile App Development and Delivery Platform

‘Interoperability’, as covered in ‘Part 1’ of the framework, details how the app adheres to applicable interoperability standards (Wales, 2017). However, within ‘Part 2’ of the framework, the interoperability should be addressed in more detail regarding how the app enables *“sharing and re-use of content and functionality with other NHS Scotland apps”* (Wales, 2017, p. 19). Additionally, the app developers should also provide further details on *“any APIs employed by the app, including where these are published and how they are accessed.”* (Wales, 2017, p. 19).

Testing and Technical Stability

‘Testing’ covers the potential tests and trials of the app, from which the app developer should provide *“Details of tests performed and the outcomes of those tests”* (Wales, 2017, p. 19). The ‘Technical Stability’ of the app includes details of the arrangements and monitoring in place *“to identify faults and technical issues”* (Wales, 2017, p. 19) in the app, and how the developers intend to address such issues.

Sustainability

‘Sustainability’ covers the planned maintenance of the app’s content and software, for which it should be described how the app developers intend to review and update *“the evidence base and content of the app in a timely manner”* (Wales, 2017, p. 19). Similarly, the planned maintenance of the software should be described, including how the developers plan to maintain and sustain the app’s software, when for example, new OS versions are released.

Furthermore, to ensure the upkeep of the app’s quality, a follow-up review of the app should be arranged, for which the *“Default review date is 2 years from acceptance”* (Wales, 2017, p. 20).

Part 3: Impact Evaluation

The third part of the framework is ‘Impact Evaluation’, where the impact of the app is evaluated using an outcomes chain and contribution analysis (Wales, 2017). This approach has been adopted as it supports measuring both short, intermediate and long term impact outcomes, while also *“focusing on ‘how’ rather than ‘if’ impact is achieved”* (Wales, 2017, p. 21) and on much more. Furthermore, outcomes chain and contribution analysis approaches are already highly recognised within NHS Scotland, as *“they are used by Healthcare Improvement Scotland and Health Scotland to evaluate their improvement programmes”* (Wales, 2017, p. 22).

To realise this approach, the app developer would, as part of the self-assessment, fill out an impact assessment matrix, defining *“the indicators to be used at each level of the outcomes chain”* (Wales, 2017, p. 23) along with the means to gather the needed data. Moreover, potential risk factors should be defined so that these can *“be managed to maximise chances of success at each level of the framework.”* (Wales, 2017, p. 24). As the framework is currently being drafted, this matrix is not available to include in the review at the time of writing this report.

Overall, the quality assurance framework gives a comprehensive coverage of app assessment, with many of its principles transferable to a wider context, including apps for citizens (Wales, 2017). Specifically, its coverage of applicable standards and regulations, relevant for NHS Scotland, can be useful for the mPower project in the assessment of the pending mPower services. The coverage of the quality criteria for assessment is not as extensive as seen with other initiatives within this report, but as the framework is still being drafted this could likely change. Furthermore, the framework’s coverage of ‘Impact Evaluation’ might be beneficial to investigate further as it becomes available.

5.1.2.12 United States - Mobile Health App Developers: FTC Best Practices

In 2016, the U.S. Federal Trade Commission (FTC) published a guideline of best practices for app developers working with health apps (FTC, 2016). The guidelines presents eight best practices for app developers to incorporate *“sound privacy and security practices”* (FTC, 2016). These include the following:

- Minimize data
- Limit access and permissions
- Keep authentication in mind
- Consider the mobile ecosystem
- Implement security by design
- Don’t reinvent the wheel
- Innovate how you communicate with users
- Don’t forget about other applicable laws

'Minimize data' raises two aspects for app developers to consider, in which the first covers the necessity for collecting and retaining users' data, as app developers should abstain from collecting data that is not integral for the functioning of the app (FTC, 2016). The second aspect refers to the app developers' ability and commitment to keep the data in a de-identified form to protect the users' privacy. They should therefore consider if they can maintain the apps *"functionality while maintaining and using that information in de-identified form"* (FTC, 2016).

'Limit access and permissions' presents three aspects, which should be considered (FTC, 2016). The first is the app's need for permissions, as it should only require permission to the local resources essential for its functionality. Secondly, if the OS allows it, trusted user interface components should be used instead of direct API access, as it enables the app to further limit its access data collection. Lastly, the app developer should consider using privacy-protective default settings, to ensure both experienced and inexperienced users' privacy is protected.

'Keep authentication in mind' raises four aspects for consideration, in which the first has to do with the app's generation of credentials *to "ensure that the person accessing a particular account is the legitimate owner"* (FTC, 2016). Secondly, the app developer should consider implementing strong password requirements and prevent the user from using a default password. The third aspect refers to the storing of passwords, as these should not be stored in clear text, but instead through using password hashing to make it harder for these to be compromised. Lastly, the access to any data should be limited *"to trusted clients or parties with a legitimate need to use the data"* (FTC, 2016).

'Considering the mobile ecosystem' includes three relevant aspects to take into account (FTC, 2016). The first one relates to whether the app relies on the inbuilt security features on the mobile platform to protect sensitive data. If this is the case, the developer should test and confirm the protection to ensure users' data is secure regardless of the platform (FTC, 2016). The second one has to do with the protection of data provided by any third-party services used, as the data collected should also be safeguarded if the app, for example, uses a third-party service to store the data in the cloud. Lastly, the third aspect relates to the use of code or components from third-party libraries or companies, which should be tested to ensure they are free of vulnerabilities that could compromise users' privacy.

'Implement security by design' includes six aspects for considering data security, in which the first is developing a 'culture of security' where employees are encouraged *"recognize and speak up about vulnerabilities"* (FTC, 2016). Secondly, data security should be incorporated at every stage of the *"app's lifecycle: design, development, launch, and post-market"* (FTC, 2016), meaning it should be tested, evaluated and updated continuously through the lifecycle. The third aspect refers to the encryption methods used, as this is vital to protect the users' collected data. To ensure this, FTC suggest *"using well-known, off-the-shelf products for this"* (FTC, 2016). Fourthly, the app developer should consider the app's protection against common vulnerabilities and take necessary steps to counter such vulnerabilities. This includes

rate-limiting “*traffic sent to or received by a network to reduce the risk of automated attacks*” (FTC, 2016). The fifth aspect refers to keeping the app up-to-date and current to counter emerging security vulnerabilities and plan how this should be provided. The sixth, and final aspect involves how the app developer is keeping track of the data collected and stored for which it is suggested to have “*an up-to-date inventory of the information*” (FTC, 2016).

‘Don’t reinvent the wheel’ contain a single underlying aspect, referring to the established efforts already taken to “*safeguard consumers’ personal information and help protect their privacy*” (FTC, 2016). The app developer is encouraged to take advantage of these efforts, including SDKs, software libraries and tools for testing the app.

5.1.2.13 United States – Xcertia

Xcertia is a recent non-profit initiative taking place in the United States, where several healthcare organisations have come together to develop a framework for assessing mHealth apps and create “*industry guidelines for safe and effective mobile health applications*” (Xcertia, 2017e). The collaborating organisations include the American Heart Association (AHA), the American Medical Association (AMA), the DHX Group, and the Healthcare Information and Management Systems Society (HIMSS). Additionally, the group have invited interested partners from industry and healthcare to partake in the ‘Xcertia Collaborative’, which currently accounts for more than 30 members.

As part of the collaborative, members will gain access to the guidelines and partake in their continuous development through workshops and various work groups. The collaborative recently released a preliminary version of their proposed guidelines, which are currently undergoing an open call for evaluation and potential changes until the 15th of March 2018. The guidelines includes four overarching categories: App Operability, App Privacy, App Security and App Content (Xcertia, 2017d). Each of these categories along with their six to seven underlying guidelines and their one to thirteen connected performance requirements will be examined below.

App Operability

The app “Operability will assess whether a mobile health app installs, loads, and runs in a manner that provides a reasonable user experience.” (Xcertia, 2017d). In order to assess this, seven underlying guidelines have been suggested, which cover several factors including the consistency and reliability of the app, and whether it functions on the intended device(s), operating system(s) and network(s) (Xcertia, 2017b). If applicable, the app should also consistently connect (With consent) to third party devices, mobile applications, software and online user accounts, while informing users of any issues affecting this connection. This also covers certified EHR and PHR systems where the interoperability should be specified and documented. The data, which “the app saves, sends to, and/or receives” (Xcertia,

2017b) from each system should be provided and only occur in a HIPAA-compliant and secure manner.

Furthermore, the app operability also covers the information provided in the description of the app, in which it should be made clear which devices, operating systems and system versions are supported (Xcertia, 2017b). The description should also address how users can contact the app publisher/developer for technical support and general feedback to potentially improve the user experience. Information on prior releases and updates should similarly be easily available, detailing any changes that have taken place over time.

App Privacy

“Privacy will assess whether a mobile health app protects the user’s information, including Protected Health Information (PHI) in full compliance with all applicable laws, rules and regulations.” (Xcertia, 2017d). To assess this, six underlying guidelines have been proposed. These include a privacy policy, which should be easily available and disclose all data points collected, how they are collected and by whom and to what purpose it is collected, accessed and used. The policy should also disclose the retention period of any gathered data and inform users on how to get a copy of their collected personal information. Moreover, the policy should advise users how to access/request, update and potentially delete any of this information, if needed. The policy should also address the use by children under the age of 13 and how the app has measures in place to protect them. Such measures include age verification, age-restricted content and parental consent before collecting/sharing any data.

The app privacy also addresses the app’s access to local resources, as it should be clearly explained which resources are accessed and why these are necessary. The local resources presented includes mobile network, Wi-Fi, SMS/MMS, email, Bluetooth, camera/microphone, GPS, address book, calendaring/ alarm system, PSTN and social networking sites, where a prior consent should be obtained before accessing any of them. Finally, the app should not share any data with third-parties, unless the user has given an affirmative consent and even then, measures ought to be taken to anonymise the data. Furthermore, before sharing data with any third-parties, an agreement should be in place to safeguard the data. The user should likewise be able to easily opt-in or out of sharing such data with third-parties.

App Security

The App Security “*will assess if the application is protected from external threats.*” (Xcertia, 2017d). In order to do this, Xcertia have proposed six underlying guidelines, which covers aspects of “*Administrative, physical, and technical safeguards to protect users’ information from unauthorized disclosure or access*” (Xcertia, 2017c). These includes authentication methods to authenticate users at a session level and encrypting any personal information that is collected, stored or transmitted through recognized and industry accepted methods “e.g., FIPS 140-2, ISO/IEC” (Xcertia,

2017c). Furthermore, the app should also have safeguards to authenticate users' identity, in case their username/password is lost or forgotten, so they can receive reminder or create a new one.

The app and any third-party code used must also be free of malicious code or malware, which should be determined through scanning software (Xcertia, 2017c). Additionally, the app publisher must ensure *“that the app’s security procedures comply at all times with generally recognized best practices and applicable rules and regulations jurisdiction(s)”* (Xcertia, 2017c) the app is intended for.

Moreover, the app’s security procedures and compliances should be described and be easily available for the users, so they can affirmatively consent. The app publisher should also have mechanisms in place to review and update security procedures *“to ensure that they comply at all times with applicable rules and regulations”* (Xcertia, 2017c).

Lastly, the app publishers should have mechanisms in place to notify users, if the app is banned or recalled and ensure the app is rendered inoperable (Xcertia, 2017c).

App Content

App *“Content will assess whether the information provided in the mobile health app is evidence-based, current and accurate.”* (Xcertia, 2017a). To ensure this, six underlying guidelines have been proposed, covering the information and functions provided through the app. First of all, the content should be based on credible and recognized information sources. Such recognized sources include current protocols, published guidelines, evidence-based practices, peer-reviewed journals and more, where the documentation should be provided, so users can easily access it. If the content is based on non-recognized sources, its relevance and reliability should be explained and documented, along with when and how it was formulated. Moreover, if the content deviates from these sources, it should be clearly specified and explained. In general, the content and description ought to be *“truthful, fair, and not misleading.”* (Xcertia, 2017a), while producing accurate and reliable readings (if applicable), which can be verified independently. Furthermore, to ensure the app’s appropriateness for the users, the content should also be formulated and designed with the intended users in mind, whether it is HSCPs or patients. Should the app contain advertising, it should be clearly identifiable as advertisements to ensure users can easily separate app content and advertisements, so misunderstandings are avoided.

Lastly, a method or a protocol should be in place to determine if and when the content requires updating and how that will be updated, ensuring the content is always based on up-to-date information (Xcertia, 2017a). If this is not the case and the content becomes medically dangerous, a documented process should be in place to notify users and to retract the outdated version.

The Xcertia initiative and the four criteria covered above are more extensive than most initiatives covered within this report, which is mostly due to the comprehensive list of performance requirements created for each underlying criterion. Within these, each underlying criterion is extensively specified down to minimal technical requirements, referring current practices, standards and methods etc. Due to this, it is also becoming rather technical and it is unlikely that a HSCPs or healthcare organisation can assess the app without help from developers or professionals with a technical background.

However, the Xcertia initiative is, as mentioned earlier, still new and on-going, and the guidelines are in their preliminary form, awaiting comments and feedback until the 15th of March 2018. When they are finalised, Xcertia plans to *work “with third parties to develop certifications based on those standards”* (Comstock, 2017).

5.1.3 Cross Border Initiatives

5.1.3.1 European Commission – Working Group on mHealth Assessment Guidelines

The European Commission (EC) appointed a working group in February 2016, mandated to draft a set of common guidelines for “assessing the validity and reliability of the data that health apps collect and process” (European Commission, 2017, p. 3), as previously recommended in their green paper on mHealth (2014). The working group comprised of relevant stakeholder groups from across Europe including patients, HSCPs and providers, payers, industry, academia and public authorities. As the working group was announced, the expected guidelines quickly became highly anticipated and welcomed as a much-needed initiative to accommodate the requirement for a shared method for assessing app data. However, as the working group began their work, a majority of the members wanted to expand the scope of the guidelines to encompass a broader assessment of mHealth initiatives. For this, 13 assessment criteria were suggested, which the separate groups examined from their respective points of view. The suggested criteria are the following:

- Privacy
- Transparency
- Safety
- Reliability
- Validity
- Interoperability
- Technical stability
- Effectiveness

- Efficacy
- Efficiency
- Accessibility
- Usability/desirability
- Scalability

Most of the working group agreed upon 'Privacy', 'Transparency', 'Reliability', 'Validity', 'Interoperability' and 'Safety'. The industry stakeholders only wished to adhere to the original mandate of 'Validity' and 'Reliability' of data. However, industry still acknowledged that the other criteria might be useful for a broader assessment, but instead suggested a stepwise approach with the two originally mandated criteria as a starting point. In general, Industry had *"no support for inclusion of any criterion other than reliability and validity (of data)."* (European Commission, 2017: Annex 1) among the industry stakeholders.

In addition to the six criteria mentioned above, 'Technical stability' and 'Effectiveness' were also deemed relevant by most stakeholder groups (European Commission, 2017). 'Technical stability' was considered appropriate by groups such as Patients, Public Authorities, Payers and Social Health Insurance. 'Effectiveness' was, on the other hand, seen as a relevant criterion by interested parties such as Patients, Healthcare Professionals, Payers and Social Health Insurance.

Although there was some discrepancy among the different stakeholder groups' understanding of the criteria, "it could be concluded that there is a consensus on the relevance of the following five criteria" (European Commission, 2017, p. 8):

1. Privacy
2. Transparency
3. Reliability
4. Validity
5. Interoperability.

An example of divergent understanding of criteria can be found with 'Transparency'. Patients understood this as the "Identification of the originators/sponsors of apps" (European Commission, 2017: Annex 1), while also informing users of the necessary data for a 'smooth' functioning of the app. Furthermore, they also understood this to include how the collected data should be handled and who that is shared with.

HSCPs viewed 'Transparency' as providing them "with relevant and trustworthy information about the app and the developer" (European Commission, 2017: Annex 1), as they deemed it essential for their reliable decision making process of the app.

Public Authorities perceived 'Transparency' as essential to enable users to understand what information is collected by the app. Additionally, the Andalusian authorities believed it covered *"absence of conflict of interests, authorship, funding sources, etc"* (European Commission, 2017: Annex 1).

Payers and Social Health Insurance representatives saw ‘Transparency’ as a way to ensure “the users must know what he gets” (European Commission, 2017: Annex 1), for which they presented three topics to cover: 1) who financed, developed and distributed the app, 2) the evidence base of the app and 3) the data collected by the app and what it is used for.

Industry, Research and Academia understood ‘Transparency’ as overlapping with ‘Privacy’. Industry believed “Many of the ‘criteria’ that Working Group members believe should fall into this field is actually covered by data protection law.” (European Commission, 2017: Annex 1). Additionally, Research and Academia presented a concept of ‘Transparency-by-design’, enabling “users and external observers to keep a close watch on the origin, quality, neutrality, value of data” (European Commission, 2017: Annex 1).

Nevertheless, even as the working group failed in their efforts to issue and endorse a set of common guidelines, their work has still provided valuable insights into the participating stakeholder groups perception of the criteria. These can prove beneficial when examining other initiatives, as the work involves a comprehensive understanding and discussion of the suggested criteria. Furthermore, the varying perceptions stress the importance of a clear and common understanding of the defined criterions and can provide a useful basis for the mPower project.

5.1.3.2 European Commission – Code of Conduct on privacy for mHealth

In 2016, the European Commission submitted a draft code of conduct for approval, which aims to provide app developers with a “*specific and accessible guidance on how European data protection legislation should be applied in relation to mHealth apps*” (European Commission, 2016, p. 1). To achieve this, the code of conduct applies a broad approach, for which it can be used both in the development of an app, but also for app developers to “*assess and declare the compliance of its app*” (European Commission, 2016, p. 3). This includes ‘Practical guidelines for app developers’ and a ‘Privacy impact assessment’, which needs to be completed, if the app developers wish to voluntarily declare their adherence to the code of conduct.

Practical Guidelines for App Developers

The practical guidelines are comprised of eleven self-reflecting questions, which cover aspects such as obtaining consent, main principles of app development, appropriateness of necessary security measures, showing advertisements, data usage for secondary purposes and sharing data with third-parties (European Commission, 2016). An example of these questions is examined below:

“*Which are the main principles that I must respect before making an mHealth app available?*” (European Commission, 2016, p. 7). To answer this question, five principles are presented, which include purpose limitation, data minimisation, transparency, privacy by design and privacy by default and data subject rights.

'Purpose limitation' should be covered by designing the app *"to only collect and process data concerning health for specific and legitimate purposes"* (European Commission, 2016, p. 7), while also specifying such purposes and their relation to the app's functions.

'Data minimisation' entails *considering "what data is strictly necessary for your app to provide its desired functionality, in line with the purposes"* (European Commission, 2016, p. 8). This means that the app should not collect, process or store data beyond what is necessary for it to function correctly.

'Transparency' covers informing the users of the app *"with a clear description of the purposes for which their personal data will be processed"* (European Commission, 2016, p. 8) so they can easily understand what personal data is collected and why.

'Privacy by design' means considering and implementing aspects to address privacy implications throughout the app development and ensure the app *"will support the privacy of your users wherever possible"* (European Commission, 2016, p. 8). On the other hand, 'privacy by default' entails integrating pre-selection of the *"least privacy invasive and compliant choice"* (European Commission, 2016, p. 9), whenever the users can make a choice related to the processing of their personal data.

'Data subject rights' refers to the app users *"right to access any personal data relating to them"* (European Commission, 2016, p. 9) stored by the app developer, for which they should be able to correct or demand the deletion of. To accommodate this, the app should have a user friendly interface implemented, which facilitates *"the exercise of these rights"* (European Commission, 2016, p. 9).

Privacy Impact Assessment

'The privacy impact assessment' is intended to determine whether the app developer has followed the guidelines and requirements presented in the code of practice and *"followed good privacy practices before making the app available"* (European Commission, 2016, p. 19). The assessment includes seven questions, which have been articulated so they do *"not require specific legal or technical expertise"* (European Commission, 2016, p. 19).

These questions covers the following: The kind of personal data collected, the purposes of such data, the obtained consent for collecting the data, whether there is a contact person for privacy related questions, HSCPs involvement in the development to determine the data's relevance, security objectives and sharing data with third parties (European Commission, 2016).

The code of conduct provides valuable insights for app developer into the necessary aspects of privacy and data protection in accordance with both *"the current Data Protection Directive and the General Data Protection Regulation"* (European Commission, 2016, p. 4). These insights might also prove beneficial for a more general assessment of privacy concern for mHealth, due to the broad approach taken in the code of conduct.

5.1.3.3 WHO – The MAPS toolkit: mHealth assessment and planning for scale

In 2015, WHO released a toolkit for mHealth Assessment and Planning for Scale (MAPS) to “*advance discussions on how to scale up mobile health (mHealth) innovations and maximize their impact*” (World Health Organization, 2015, p. ii). The toolkit presents an extensive self-assessment and planning guide for project managers and teams, whose aim is to increase the scale of impact on already deployed mHealth products. For this purpose, “*the Toolkit covers six major areas (referred to as the “axes of scale”) that influence the scaling up of mHealth*” (World Health Organization, 2015, p. iv):

- Axis 1. Groundwork
 - Parameters of scale
 - Contextual environment
 - Scientific basis
- Axis 2. Partnerships
 - Strategic engagement
 - Partnership sustainability
- Axis 3. Financial health
 - Financial management
 - Financial model
- Axis 4. Technology & architecture
 - Data
 - Interoperability
 - Adaptability
- Axis 5. Operations
 - Personnel
 - Training & support
 - Outreach & sensitization
 - Contingency planning
- Axis 6. Monitoring & evaluation
 - Process monitoring
 - Evaluation research

These ‘Axes of scale’ each have underlying domain areas, which are self-assessed with a series of questions, providing a ‘baseline assessment’ with tangible indicators for mHealth projects to “*review progress and develop plans to improve their ability to*

scale up and achieve sustainability” (World Health Organization, 2015, p. 1). The six axes of the toolkit will briefly be covered below:

‘Groundwork’ is “the initial steps of specifying the key components of the project’s approach to scaling up, assessing relevant contextual influences, and taking stock of the scientific basis for the product” (World Health Organization, 2015, p. 10). To accomplish this, three underlying domains are presented, which need to be addressed before scaling up a mHealth project. These include: 1) ‘Parameters of scale’, 2) ‘Contextual environment’ and 3) ‘Scientific basis’.

‘Partnerships’ covers “Collaborations with external groups to support the process of scaling up, including strategies for identifying, developing and sustaining fruitful partnerships” (World Health Organization, 2015, p. 25). Within ‘Partnerships’, two underlying domains are presented, which include ‘Strategic engagement’ and ‘Partnership sustainability’.

‘Financial health’ is “*The projection of scale-up costs, and the development of a financial plan for securing and managing funds over the long term*” (World Health Organization, 2015, p. 37). In order to understand this, two underlying domains are presented, including ‘Financial management’ and ‘Financial model’.

The ‘Technology & architecture’ cover the “Steps taken to optimize the mHealth product for scaling up based on its anticipated user base, purpose, integration with information systems and compatibility with other components of the information systems architecture” (World Health Organization, 2015, p. 48). To assess this, three underlying domains are presented, covering the 1) ‘Data’, 2) ‘Interoperability’ and 3) ‘Adaptability’.

‘Operations’ is the “Organizational and programmatic measures for supporting the implementation, use and maintenance of the product throughout the scaling-up process” (World Health Organization, 2015, p. 62). Within ‘Operations’, four underlying domains are presented, which includes: 1) ‘Personnel’, 2) ‘Training and support’, 3) ‘Outreach and sensitization’ and 4) ‘Contingency planning’.

Lastly, ‘Monitoring & evaluation’ refer to the “Decisions and activities that enable effective process monitoring and in-depth outcome evaluation, based on project and stakeholder needs” (World Health Organization, 2015, p. 76). To assess this, two underlying domains are presented, which include ‘Process monitoring’ and ‘Evaluation research’.

The domains found within ‘Groundwork’ and ‘Technology & architecture’ might provide beneficial aspects for app assessment, including ‘Contextual environment’, ‘Scientific basis’, ‘Data’, ‘Interoperability’ and ‘Adaptability’. Furthermore, the MAPS toolkit could be beneficial to consider for the mPower project in their efforts of including mHealth interventions and aiding the scale of impact.

5.2 Appendix 2 – Potential mPower Services/Apps

Within this section, 100 potential mPower services will be identified, drawing on previous reviews and assessments of health and wellbeing mobile apps and services. Furthermore, several services have been identified using high user ratings from the two largest app repositories, Apple App Store and Google Play.

The identified services have been categorised within ten health and wellbeing conditions/symptoms provided by mPower project team on the most prevalent conditions/symptoms needing support:

- Diabetes management (15 apps / services identified)
- COPD (5 apps / services identified)
- Positive mental health (18 apps / services identified)
- Physical activity and weight loss (11 apps / services identified)
- Healthy eating (13 apps / services identified)
- Cancer support (6 apps / services identified)
- Heart failure (8 apps / services identified)
- Sleep management (11 apps / services identified)
- What's on/Social networks (6 apps / services identified)
- Social isolation (7 apps / services identified)

The identified services and the included description and rating/review was available and accurate at time of the writing of this report. Though subsequently, they might be subject to change or be discontinued entirely.

5.2.1 DIABETES MANAGEMENT

App/Service	Description	Platform	Rating/Review
mySugr: Diabetes Tracker Log	<p>“The free mySugr logbook app is an easy and complete diabetes tracker for your iPhone!</p> <p>Start today and face the challenges of diabetes with confidence: log and monitor your daily blood sugar level, record your insulin, use the app to track your carb count, and note whatever else is helpful for your therapy!” (MySugr, 2018)</p>	iOS & Android	83% / 100% (ORCHA, 2018h)
Lincus Companion	<p>”Lincus is a free to use, state of the art, quantified self app. Lincus allows you to track and improve your health and wellbeing, to get the most out of life. Lincus has been designed with you in mind, whether you are fit and healthy or have complex health needs. Lincus helps you track your life and learn what works for you (and what doesn’t) in an easy to use, accessible app.” (Rescon Technologies, 2017).</p>	iOS, Android & Web	89% / 100% (ORCHA, 2018c)
Diabetes Tracker	<p>“Specifically designed for smart phones this amazing app is intended to help diabetics to manage better their diabetes and keep it under control.” (Mig Super, 2017)</p>	Android	5 / 8 (Izahar et al., 2017)
My Glycemia	<p>“The application allows you to save all your glycemia values, per day, and per week, organized by time slots before and/or after meals. All these values can be exported to your doctor via email directly from the application.” (InSyncApp, 2016)</p>	iOS & Android	5 / 8 (Izahar et al., 2017)

5.2.1 DIABETES MANAGEMENT			
App/Service	Description	Platform	Rating/Review
Diabetes & Diet Tracker	“MyNetDiary’s Diabetes & Diet Tracker app is the easiest and most comprehensive diabetes tracker app for Android. MyNetDiary can help you better understand and control diabetes and pre-diabetes - along with improving your diet, losing weight and providing feedback, support and motivation.” (MyNetDiary.com, 2018)	iOS & Android	3.65 / 5 (Bardus et al., 2016)
Track3 Diabetes Tracker	“Track3 Diabetes Tracker makes living with diabetes easier than ever by tracking all of the factors that keep blood glucose balanced.” (Coheso, 2015)	iOS, Android & Web	Recommended at: (My Health Apps, n.d.-b)
Mumoactive - Diabetes Tracker	“mumoActive is the diabetes app that lets you manage your health and GET ON LIVING. - Track your values - Add notes and messages - Sync across devices (iOS, Android, and Web apps) - Share with family, friends, and your care team - Fast, secure, and simple” (mumoActive, 2017)	iOS & Android	Recommended at: (NHS Apps Library, 2017e)
MyHealth-Fabric	“Earn points, for healthier living and claim rewards. Allow health and wellness professionals to monitor your progress by booking online appointments from a range of health and wellness experts. These experts will have self-management plans that you can follow on a daily or weekly basis.” (Health Fabric, 2017)	iOS & Android	Recommended at: (NHS Apps Library, 2017c)

5.2.1 DIABETES MANAGEMENT

App/Service	Description	Platform	Rating/Review
Glooko - Track Diabetes Data	“Glooko is a subscription-based diabetes management platform that may help you understand how food, activity and medication affect your blood glucose (BG). We also provide a digital logbook, reminders, integration with activity trackers and more.” (Glooko, 2018)	iOS & Android	5 / 8 (Izahar et al., 2017)
Glucose Companion Free	“Glucose Companion is a handy blood sugar and weight tracker. Use Glucose Companion now to monitor your blood sugar and share your measurements with your doctor, it will help greatly to your physician to diagnose and treat your diabetes, you can also use this app to calculate the units of insulin you need to inject.” (Maxwell Software, 2017)	iOS	5 / 8 (Izahar et al., 2017)
SiDiary Diabetes Management	“You can track all relevant data for your therapy like blood glucose, carbohydrates, medication like insulin and so on quick in a simple data mask to make it visible on your Android device. You can analyze it with the statistic function or with our trend analysis.” (SINOVO GmbH & Co KG, 2017).	iOS, Android, Windows Phone & PC	68% / 100% (ORCHA, 2018a)
Glucose Buddy Diabetes Tracker	“Our tracking tools make it easy to manage your diabetes in one place. Manage your diabetes: Track blood sugar, insulin, medication, food, and more. Gain Insights: Get a summary for each day as well as your long term trends.” (Glucose Buddy, 2017)	iOS & Android	57% / 100% (ORCHA, 2018g)

5.2.1 DIABETES MANAGEMENT

App/Service	Description	Platform	Rating/Review
Health2Sync - Diabetes Care	“Health2Sync helps you combat diabetes by making blood sugar tracking more meaningful. You can easily log your blood sugar, blood pressure, weight, medication, diet, exercise, and mood through the app. Health2Sync provides you helpful feedback based on your blood sugar records to help you manage diabetes.” (H2, 2018)	iOS & Android	5 / 8 (Izahar et al., 2017)
Diabetes Pal	“Diabetes Pal helps track, analyze, and share blood glucose, medication, and food data manually AND automatically.” (Telcare LLC, 2018)	iOS & Android	5 / 8 (Izahar et al., 2017)
InRange Diabetes Management	“InRange is the easiest to use bolus calculator and diabetes logbook app available, helping you to quickly and accurately track your blood glucose levels. How it works? 1. Set your blood glucose level 2. Add a meal and track your carbs 3. Get your recommended insulin bolus 4. Keep track of your data” (InRange, 2017)	iOS & Android	63 % / 100% (ORCHA, 2018e)

5.2.2 COPD			
App/Service	Description	Platform	Rating/Review
myCOPD	“myCOPD helps people with COPD to better manage their condition. Use it to perfect your inhaler technique, improve your breathing, reduce exacerbations, track your medication and more.” (NHS Apps Library, n.d.)	Web application (Most devices)	NHS Approved (NHS Apps Library, n.d.)
Zephyr Guide	“Free Animated Guide for 'Press and Breathe' Metered Dose Inhalers (MDI's) Inhaler technique guide suitable for patients using inhalers such as Atrovent inhaler, Salamol inhaler, Clenil Modulite inhaler, Flixotide Evohaler, Fostair inhaler, Flutiform inhaler, Qvar inhaler, Seretide Evohaler, Ventolin Evohaler, Sirdupla inhaler and Symbicort inhaler.” (Cambridge Medtech Solutions, 2017).	iOS & Android	87% / 100% (ORCHA, 2018h)
Manage Your Health	“Using computer generated characters, interactive quizzes and information resources, the app downloads updates to help patients with asthma, COPD, diabetes and back pain with additional conditions to follow.” (School of Pharmacy, Keele University, 2017)	iOS & Android	59 % / 100 % (ORCHA, 2017k)
Air Quality AirVisual	” Welcome to the first and only app to provide real-time and forecast air pollution and weather data for more than 10,000 cities around the world. Health Recommendations: follow our advice to lower your health risk and achieve minimum exposure to pollutants. Relevant information for sensitive groups with asthma or other respiratory (pulmonary) diseases. “ (AirVisual, 2018)	iOS & Android	User rating: 4.4 / 5 (AirVisual, 2018)

5.2.2 COPD			
App/Service	Description	Platform	Rating/Review
Propeller	<p>“Asthma and COPD don’t have to hold you back. Breathe easier and move your life forward with Propeller.</p> <p>Propeller is a FDA-cleared, CE-marked technology that works with existing asthma and COPD inhalers to help people understand their symptoms and gain control. We’ve created small sensors that simply clip onto your current inhalers. The sensors determine when you use your inhalers and send this information to the Propeller app. The Propeller app generates personalized insights and reminders to keep you on track. Propeller users experience more symptom-free days and up to 79% fewer asthma attacks.” (Reciprocal Labs, 2018)</p>	iOS & Android	User rating: 4.4 / 5 (Reciprocal Labs, 2018)

5.2.3 Positive Mental Health			
App/Service	Description	Platform	Rating/Review
Pacifica	<p>”Daily tools for stress, anxiety, and depression alongside a supportive community. Based on cognitive behavioral therapy & mindfulness meditation.” (Pacifica, 2018)</p>	iOS, Android & Web	4,5 / 5 (Practical Apps, 2017b)

5.2.3 Positive Mental Health			
App/Service	Description	Platform	Rating/Review
Headspace	“Headspace is the simple way to reframe stress. Sleep trouble? Meditation creates the ideal conditions for a good night’s rest. Relax with guided meditations and mindfulness techniques that bring calm, wellness and balance to your life in just a few minutes a day.” (Headspace, 2018)	iOS & Android	4 / 5 (Practical Apps, 2017b)
Big White Wall	”Big White Wall is an online mental health and wellbeing service offering self-help programmes, creative outlets and a community that cares. When you're dealing with everyday stressors or major life events, we'll help you get through it.” (Big White Wall, 2017)	Web application (Most devices)	Recommended on NHS Choices - User reviews: 3 / 5 stars (NHS Choices, 2015a)
Best-You	“A FREE space designed to support you to take time out to think about the important areas of your life and how you can make positive changes... Your health Your lifestyle Your mental wellbeing Your community” (Best-You, n.d.)	iOS & Android	71% / 100% (ORCHA, 2018i)

5.2.3 Positive Mental Health			
App/Service	Description	Platform	Rating/Review
Brain in Hand	<p>“Brain in Hand is an assistive technology designed to help individuals with support needs to achieve more.</p> <p>It is based on well-established therapeutic principles such as CBT, solution focussed therapy, and recovery based rehabilitation allowing the learning from these approaches to be turned into a set of patient centred strategies.” (Brain in Hand, 2018)</p>	Android	82% / 100% (ORCHA, 2017c)
CogniFit - Brain Fitness	<p>“CogniFit stimulates and rehabilitates your cognitive functions with memory games, puzzles, reasoning games, educational games, and learning games to challenge your brain.” (CogniFit, 2018)</p>	iOS & Android	75% / 100% (ORCHA, 2017f)
Smiling Mind	<p>“Smiling Mind is modern meditation, a unique web and app-based program developed by psychologists and educators to help bring balance to people’s lives.</p> <p>Just as we eat well and stay fit to keep our body healthy, meditation is about mental health and looking after the mind.” (Smiling Mind, 2018)</p>	iOS, Android & Web	4.30 / 5 (Stoyanov et al., 2015)
Daylio – Diary, Journal, Mood Tracker	<p>“Daylio is collecting recorded moods and activities in the statistics and calendar. This format will help you to understand your habits better. Keep track of your activities and create patterns to become more productive!” (Daylio, 2018)</p>	iOS & Android	4 / 5 (MindTools, 2017)

5.2.3 Positive Mental Health			
App/Service	Description	Platform	Rating/Review
HelloMind	“HelloMind helps you battle issues like stress, bad sleep, weight gain and low self-esteem. Choose a treatment, then relax and listen to the sessions with your headphones. HelloMind helps you take back control; the app can improve your motivation and enjoyment of life.” (HelloMind, 2018)	iOS & Android	65% / 100% (ORCHA, 2017e)
BrainyApp 2.0	“BrainyApp is a fun way to help you look after your brain health to reduce your risk of dementia.” (Dementia Australia, n.d.)	iOS & Android	4.29 / 5 (Stoyanov et al., 2015)
Happier	“Happier helps you stay more present and positive throughout the day. Our Apple Watch app is like your personal mindfulness coach -- use it to lift your mood, take a quick meditation pause, or capture and savor the small happy moments that you find in your day.” (Happier Inc., 2015)	iOS	74% / 100% (ORCHA, 2017I)
What’s Up? – A Mental Health app	“What's Up? is a fantastic free app utilising some of the best CBT (Cognitive Behavioural Therapy) and ACT (Acceptance Commitment Therapy) methods to help you cope with Depression, Anxiety, Anger, Stress and more! With a beautiful, modern design, simple heading and easy-to-follow methods, you can get to what helps you the most in seconds!” (Tempra, 2016)	iOS & Android	User rating: 4.4 / 5 (Tempra, 2016)

5.2.3 Positive Mental Health			
App/Service	Description	Platform	Rating/Review
Tomo	“Tomo is a helpful robot that lives on your phone and helps you manage your mental wellbeing. Tomo is also a community of people all struggling with the same sort of problems you are. As you talk to Tomo, it will learn about your lifestyle and how you handle challenges, and start to make suggestions of new habits you should make. Each time you complete a habit, Tomo invites you to anonymously share a photo of your achievement with the community.” (Hellotomo, 2018)	iOS	73% / 100% (ORCHA, 2018j)
Moodlytics, Smart Mood Tracker	“Moodlytics is the best in class mood tracking/journal/diary app with easy to understand data analysis. You can also export your mood history in nice PDF report to share with your doctor.” (AnantApps by Avinashi, 2016)	iOS & Android	3.97 / 5 (Stoyanov et al., 2015)
Breathe2-Relax	“Breathe2Relax is a portable stress management tool which provides detailed information on the effects of stress on the body and instructions and practice exercises to help users learn the stress management skill called diaphragmatic breathing.” (T2, 2016b)	iOS & Android	Clinician Rating: 4.2 / 5 (MyTherappy, 2016)
Virtual Hope Box	“The Virtual Hope Box (VHB) is a smartphone application designed for use by patients and their behavioral health providers as an accessory to treatment. The VHB contains simple tools to help patients with coping, relaxation, distraction, and positive thinking. Patients and providers can work together to personalize the VHB content on the patient's own smartphone according to the patient's specific needs.” (T2, 2016c)	iOS & Android	Clinician Rating: 4.6 / 5 (MyTherappy, 2017b)

5.2.3 Positive Mental Health			
App/Service	Description	Platform	Rating/Review
T2 Mood Tracker	<p>“T2 Mood Tracker is designed to help you track your emotional experience over time and to provide you with a tool to share this information with your health care provider.</p> <p>This app comes with six pre-loaded issues: anxiety, depression, general well-being, head injury, post-traumatic stress, and stress” (T2, 2016a)</p>	iOS & Android	<p>Clinician Rating:</p> <p>3.9 (MyTherappy, n.d.)</p>
Cove: The musical journal	<p>“Create music to help express complex feelings. Cove is a personal musical journal to help you with your emotional and mental health.” (Humane Engineering, 2017)</p>	iOS	<p>Currently being tested at: (NHS Apps Library, 2017h)</p>

5.2.4 Physical Activity and Weight Loss			
App/Service	Description	Platform	Rating/Review
Fitbit	<p>“Live a healthier, more active life with Fitbit, the world’s leading app for tracking all-day activity, workouts, sleep and more.” (Fitbit, 2018)</p>	iOS, Android, Windows Phone & Web	<p>86% / 100% (ORCHA, 2018b)</p>
Lifesum	<p>“With Lifesum, tracking your healthy habits (and the not so healthy ones) becomes a breeze. We’ll help you pick the right food, and eat the right portion sizes, to reach your personal health goals.” (Lifesum, n.d.)</p>	iOS & Android	<p>74% / 100% (ORCHA, 2017h)</p>

5.2.4 Physical Activity and Weight Loss			
App/Service	Description	Platform	Rating/Review
Weight Loss Tracker - RecStyle	<i>“An app aimed at anyone wanting to monitor their weight, whether for diet or for muscle training.”</i> (Health Navigator, 2015c)	iOS & Android	3 / 5 (Health Navigator, 2015c)
Monitor Your Weight	“As the name indicates, you will be able to enter your weight on a regular basis and monitor your progress accordingly through means of statistics and graphs.” (Al-Bustan, 2017)	iOS & Android	3 / 5 (Health Navigator, 2015a)
Noom Coach: Health & Weight	“Noom’s proven psychology-based approach identifies your deep-rooted thoughts and triggers, and builds a custom game plan to help you form healthy habits, faster.” (Noom Inc, 2018)	iOS & Android	4 / 5 (Health Navigator, 2015b)
Carbs & Cals	“The Carbs & Cals App is perfect for those counting calories, monitoring carbs, looking to improve portion control or lose weight. We’re proud to say that the app won New Product of the Year at the Complete Nutrition Awards.”(Carbs & Cals, 2017)	iOS & Android	57% / 100% (ORCHA, 2017d)
SitFit	“SitFit lets you exercise from the comfort of your own chair. If you are unable to stand for very long, these short exercises are for you. SitFit gives you a free preview of the Team Pink armchair exercise DVD.” (Candihat Studios, 2016)	iOS & Android	Clinician Rating: 4.3 / 5 (MyTherapy, 2017a)

5.2.4 Physical Activity and Weight Loss			
App/Service	Description	Platform	Rating/Review
My Diet Diary	“The elegant and simplest weight loss app to track your food, calories, exercise, weight, cholesterol, carbs, calories burned, other nutrition data. Proven success as millions of people worldwide have used this app to reach their weight goal!” (StayWell, 2018)	iOS & Android	3.5 / 5 (Bardus et al., 2016)
Pedometer, Step Counter & Weight Loss Tracker App	“Pedometer, Step Counter & Weight Loss Tracker App” syncs steps & calories w/ MyFitnessPal and Fitbit! Track your step, walking & weight loss with this free health counter. Lose weight and track walk distance and calories burned using 24/7 step counting from our pedometer, step counter & health tracker app.” (Pacer Health, 2018)	iOS & Android	3.4 / 5 (Bardus et al., 2016)
Workout Trainer: personal fitness coach	“Work out anywhere, anytime with Workout Trainer - at your fingertips! Whether you like working out at home or lifting weights at the gym, we’ve got you covered with thousands of free workouts and custom training programs led by expert coaches.” (Skimble, 2017)	iOS & Android	69% / 100% (ORCHA, 2018k)
Lark - 24/7 Health Coach	“Unlike any other program, we’re able to offer every member unlimited 1-on-1 support from their Personal Lark Coach, thanks to cutting edge A.I. and health monitoring technology. We deliver evidence-based care in an award-winning experience that evolves with data & interactions, making it infinitely more intelligent & effective.” (Lark, 2017)	iOS & Android	4.1 / 5 (Bardus et al., 2016)



5.2.5 Healthy Eating			
App/Service	Description	Platform	Rating/Review
MyFitnessPal	" MyFitnessPal is a free weight loss app that counts calories. Log exercise and use the large food database to enter your food." (VicHealth, 2016a)	iOS, Android & Web	3 / 5 (Health Navigator, 2014; VicHealth, 2016a)
Calorie Counter	"Keep track of your food, exercise and weight, using the world's highest quality food and nutrition database and most supportive community. Connect with a global community of people looking to make a change for the better and start losing weight and achieve your goals the healthy way." (FatSecret, 2018)	iOS, Android, Windows Phone, Blackberry & Web	4 / 5 (Health Navigator, 2016)
YouFood	"No more diets. No more calorie counting. YouFood takes the world's most proven weight loss method - keeping a food journal - and supercharges it with social accountability" (YouFood, 2017)	iOS & Android	3.2 / 5 (Bardus et al., 2016)
My Diet Coach	"My Diet Coach will help you find your inner motivation, help keep you on track, let you make healthy lifestyle changes and resist food cravings, emotional eating, avoid exercise laziness and other weight loss difficulties:" (InspiredApps, 2018)	iOS & Android	4.6 / 5 (Bardus et al., 2016)
My Diet Diary	"The elegant and simplest weight loss app to track your food, calories, exercise, weight, cholesterol, carbs, calories burned, other nutrition data. Proven success as millions of people worldwide have used this app to reach their weight goal!" (StayWell, 2018)	iOS & Android	3.5 / 5 (Bardus et al., 2016)

5.2.5 Healthy Eating			
App/Service	Description	Platform	Rating/Review
SparkPeople Calorie Tracker	“SparkPeople is your personal diet and lifestyle coach. Get healthy with customized workouts & meal plans; lose weight by tracking food & planning your diet.” (SparkPeople, 2018)	iOS, Android & Web	4.4 / 5 (Bardus et al., 2016)
MyPlate Calorie Tracker	“Tracking calories works! Join the millions who have lost weight with LIVESTRONG.COM’s MyPlate Calorie Tracker — the most user-friendly way to track your calories and stay fit on your Android Phone. LIVESTRONG.COM makes tracking calories EASY.” (LIVESTRONG, 2017)	iOS & Android	3.5 / 5 (Bardus et al., 2016)
Zingy – Better life through nutrition	“Zingy helps you to optimise your nutrition for your own personal goals. Whether you’re training for a marathon, slimming down, or simply want to eat better to feel better, Zingy shows you how to make the right choice of food for you.”	iOS	65% / 100% (ORCHA, 2017i)
One You Easy Meals	“One You is here to help you live more healthily and make the changes that matter. Sometimes it’s hard to know what to prepare, or think of new meal ideas. Remembering ingredients and keeping track of calories can be a hassle. This app helps you to do all of this and more!” (Public Health England, 2017d)	iOS & Android	Recommended at: (NHS Apps Library, 2017b)
EaTracker	“Use eaTracker to check your food and activity choices, analyze your recipes and plan your meals. Sign up to set goals and track your progress.” (Dietitians of Canada, 2017)	iOS & Android	3,5 / 5 (Practical Apps, 2017a)

5.2.5 Healthy Eating			
App/Service	Description	Platform	Rating/Review
Runtasty - Healthy Recipes & Cooking Videos	“Get tons of easy healthy recipes and kitchen hacks! Your complete healthy food recipes book right in your phone. Want a low calorie healthy treat to satisfy your sweet tooth? Need a quick post-workout healthy recipe to fuel the gains? Or maybe some vegan recipes to wow your meat-eating friends! Pop open your Runtasty cooking recipes app and head to the market. The ingredients for the healthy food recipes are practical, the cooking recipes are simple and your belly will be happy.” (Runtastic, 2017b)	iOS & Android	User rating: 4.5 / 5 (Runtastic, 2017b)
Ultimate Food Value Diary - Diet & Weight Tracker	“Track your food values, exercise, weight & measurements all in one place. This is the ultimate app for you! (Fenlander Software Solutions, 2018)	iOS & Android	User rating: 4.6 / 5 (Fenlander Software Solutions, 2018)
Mealime - Meal Plans & Recipes with a Grocery List	“Mealime is a simple way for busy singles, couples, and families to plan their meals and eat healthier. Our meal plans & recipes are highly customizable so you can easily personalize a plan that works with your unique tastes and lifestyle.” (Mealime Meal Plans, 2018)	iOS & Android	User rating: 4.6 / 5 (Mealime Meal Plans, 2018)

5.2.6 Cancer Support			
App/Service	Description	Platform	Rating/Review
Cancergraph	“An app to help people with cancer to track symptoms and side effects over days, months and years.” (My Health Apps, n.d.-a)	iOS & Android	Recommended at: (My Health Apps, n.d.-a)
Cancer.Net Mobile	“Get easy-to-use tools to help you plan and manage care – from diagnosis through treatment and beyond – provided by Cancer.Net, including the latest oncologist-approved cancer information. Brought to you by the American Society of Clinical Oncology” (ASCO, 2017)	iOS & Android	61% / 100% (ORCHA, 2018d)
Pocket Cancer Care Guide	<p>“The emotional aspects that accompany cancer, together with the complex details of treatment, can be overwhelming. You need to know that it’s okay to ask your doctor questions and expect answers in terms you can understand.</p> <p>That’s why NCCS has created the Pocket Cancer Care Guide, an app for you and your family, friends and loved ones to quickly and easily build lists of practical questions used to guide conversations between you and your doctors and nurses.” (National Coalition for Cancer Survivorship, 2014)</p>	iOS	User rating: 3.9 (National Coalition for Cancer Survivorship, 2014)
BELONG Beating Cancer Together	<p>“The Belong.life app provides people with cancer and their families a unique and innovative personalized solution to help manage and fight cancer more effectively.</p> <p>Using Belong, you will find support groups for every type of cancer such as breast cancer, lung cancer, ovarian cancer and many more.” (BelongTail, 2018)</p>	iOS & Android	User rating: 4,7 / 5 (BelongTail, 2018)

5.2.6 Cancer Support			
App/Service	Description	Platform	Rating/Review
iCancerHealth: Medocity Patient Virtual Care	“Medocity’s iCancerHealth was developed for patients to virtually connect with their care professionals between visits. The experience is personalized for the specific needs of a patient with cancer. Patients can send secure messages, report symptoms, track medication and get reminders, access valuable educational resources and much more. And, it’s available on smart phone, tablet and PC.” (Medocity, 2018)	iOS & Android	User rating: 4.4 / 5 (Medocity, 2018)
ESMO Cancer Guidelines	“The ESMO Guides for Patients are designed to assist patients, their relatives and caregivers to better understand the nature of different types of cancer and evaluate the best available treatment choices. The medical information described in the Guides for Patients is based on the ESMO Clinical Practice Guidelines.” (European Society for Medical Oncology, 2014)	iOS & Android	User rating: 4.4 / 5 (European Society for Medical Oncology, 2014)

5.2.7 Heart Failure			
App/Service	Description	Platform	Rating/Review
Symple	<p>“Symple is the easiest way to track how you feel, to monitor your health, and to improve your wellbeing.</p> <p><i>Designed by both clinicians and regular people, Symple is an enjoyable way to connect to better health.”</i> (Masterson Creber et al., 2016, p. 7)</p>	iOS	4.3 / 5 (Masterson Creber et al., 2016)
Heart Failure Storylines	<p>“Developed in partnership with the Heart Failure Society of America, this app makes it easy to record your symptoms, vital signs, medications, and more to help you manage heart failure and congestive heart failure (CHF).” (Health Storylines, 2017)</p>	iOS & Android	Currently undergoing review (Health Navigator, 2017b)
ManageHF-4Life	<p>“ManageHF4Life is a symptom tracking and educational app for patients with heart failure. It is designed to help patients monitor and manage the symptoms of heart failure. It is based on evidence that self-monitoring can improve patient outcomes and quality of life. The app was designed by researchers at the University of Michigan.” (The University of Michigan, 2017)</p>	iOS & Android	Not yet reviewed
FAQs in Heart Failure	<p>“FAQs in Heart Failure provides answers to many of the questions related to the anatomy and pumping function of the heart, causes, risk factors, types and symptoms of heart failure, diagnostic tests, managing heart failure by means of medications, implantable devices, and surgery, to guidelines to prevent heart failure, and precautions to be taken when implanted with a cardiac device or having undergone a heart surgery. The text is supported by lifelike videos and relevant images.” (Focus Medica India, 2014)</p>	Android	3.6 / 5 (Masterson Creber et al., 2016)

5.2.7 Heart Failure			
App/Service	Description	Platform	Rating/Review
Quealth – Health Scoring App	“Score your health with Quealth™ Score, track progress towards your health goals and be guided and supported to the healthiest you by Quealth Coach – your digital, personalised health coach.” (roadtohealth group, 2018)	iOS & Android	70 % / 100 % (ORCHA, 2017m)
Continuous-Care Health App	“Save and share health data, test reports and track your health using Personal Health Records (PHR). This helps your health providers make better decisions about your care. Whether it is for self-management of health or for consultations with providers, your PHR is a life-saver.” (ContinuousCare, 2018)	iOS, Android & Web	4.0 / 5 (Masterson Creber et al., 2016)
WebMD	“WebMD for Android helps you with your decision-making and health improvement efforts by providing mobile access 24/7 to mobile-optimized health information and decision-support tools including WebMD’s Symptom Checker, Drugs & Treatments, First Aid Information and Local Health Listings. WebMD the App also gives you access to first aid information without having to be connected wirelessly – critical if you don’t have Internet access in the time of need.” (WebMD, 2018)	iOS, Android & Web	4.4 / 5 (Masterson Creber et al., 2016)
HF Buddy	“HF Buddy aims to empower the heart failure patient with the knowledge and tools to improve the overall understanding of the condition, and to better manage his/her heart failure.” (Singapore Health Services, 2016)	iOS & Android	User rating: 4.8 / 5 (Singapore Health Services, 2016)

5.2.8 Sleep Management			
App/Service	Description	Platform	Rating/Review
Sleepio	“Sleepio is designed to teach you how to overcome even long term poor sleep without pills or potions. Download the companion app for instant access to your daily sleep diary and schedule, and your virtual sleep expert, The Prof.” (Big Health Ltd, 2017).	iOS & Web	86% / 100% (ORCHA, 2018f) Also recommended on NHS Choices - User review: 4/ 5 stars (NHS Choices, 2015b)
Sleep Cycle alarm clock	“Sleep Cycle alarm clock tracks your sleep patterns and wakes you up during light sleep. Waking up during light sleep feels like waking up naturally rested without an alarm clock.” (Northcube AB, n.d.)	iOS & Android	72% / 100% (ORCHA, 2017j)
Pzizz - Sleep, Nap, Focus	“We utilize effective psychoacoustic principles to create beautiful dreamscapes that will help you fall asleep fast, stay asleep, and wake up feeling refreshed” (Pzizz, 2018)	iOS & Android	Currently undergoing review (Health Navigator, 2017c)

5.2.8 Sleep Management			
App/Service	Description	Platform	Rating/Review
CBT-i Coach	“The app will guide users through the process of learning about sleep, developing positive sleep routines, and improving their sleep environments. It provides a structured program that teaches strategies proven to improve sleep and help alleviate symptoms of insomnia.” (US Department of Veterans Affairs, 2017)	iOS & Android	Currently undergoing review (Health Navigator, 2017a)
Relax & Sleep Well Hypnosis & Meditation	“Relax and Sleep Well is a high quality hypnosis and meditation app by best-selling self-help audio author Glenn Harrold. This fantastic app includes 4 free hypnosis and meditation recordings and many in-app purchases. The in-apps include over 80 of Glenn’s highly acclaimed hypnosis and meditation range.” (Relax & Sleep Well, 2017)	iOS, Android & Windows	60% / 100% (ORCHA, 2017g)
Sleep Easily Guided Meditation for Relaxation	“Sleep Easily gently guides you through every step of the way to relax your whole body and mind. This meditation leaves you refreshed, renewed and resonating so much more from your heart and a place of stillness.” (Diviniti Publishing, 2017)	iOS & Android	3.24 / 5 (Stoyanov et al., 2015)
Sleepo: Relaxing sounds, Sleep	“Sleepo brings great collection of HD sounds that can be mixed into the perfect relaxing ambiances. You can choose from different types of rain, nature sounds, city sounds, white noise or instruments. Save your favorite sound mixes so they are always by hand with you.” (Relaxio, 2018)	Android	User rating: 4.8 / 5 (Relaxio, 2018)

5.2.8 Sleep Management			
App/Service	Description	Platform	Rating/Review
Relax Melodies: Sleep Sounds	“Thanks to Relax Melodies, the #1 app for sleep and relaxation, you can regain control over insomnia, night time anxiety and tinnitus. Create your own mix with nature sounds, white noise and melodies, and sleep like never before!” (Ipnos Software, 2018)	iOS & Android	User rating: 4.5 (Ipnos Software, 2018)
Pillow: Smart sleep tracking	“Pillow is an advanced sleep tracking alarm clock that can effortlessly measure and track your sleep quality. Wake up refreshed and learn more about the benefits of great sleep. Included in Best New Health & Fitness apps on the App Store. Featured in The New York Times, The Washington Post, CTV Canada AM, The Guardian, The Hindu and many more.” (Neybox Digital Ltd., 2018)	iOS	4.5 / 5 (Neybox Digital Ltd., 2018)
Sleep Better with Runtastic	“Track your sleep cycle, monitor dreams, improve bedtime habits & wake up better with the free Sleep Better sleep tracker app with smart alarm clock from Runtastic! Sleep Better offers you a simple and engaging way to get better sleep using a sleep tracker and sleep timer.” (Runtastic, 2017a)	iOS & Android	User rating: 4.1 / 5 (Runtastic, 2017a)
Calm - Meditate, Sleep, Relax	“Calm is the #1 app for mindfulness and meditation to bring more clarity, joy and peace to your daily life. Start your journey to a calmer mind with the app that’s trusted by millions and featured in the New York Times.” (Calm.com, 2018)	iOS & Android	User rating: 4.6 / 5 (Calm.com, 2018)

5.2.9 What's On / Social Networks			
App/Service	Description	Platform	Rating/Review
COPD Support/ MyCOPD-Team	“MyCOPDTeam is the social network for those living with COPD. The goal of MyCOPDTeam is to offer perspective and validation of others by sharing one's own personal story. MyCOPDTeam aims to create a safe place where members feel comfortable discussing their experiences.” (MyCOPDTeam, 2018)	iOS, Android & Web	User rating: 4.3 (MyHealthTeams, 2018)
Talking Point	“Talking Point is an online community for anyone affected by dementia. The app is a space for you to ask questions, share experiences about any aspect of dementia and, most of all, feel supported.” (NHS Apps Library, 2017g)	Web	Recommended at: (NHS Apps Library, 2017g)
Health-Unlocked	“HealthUnlocked is a social network for health. By finding others with similar health backgrounds people can take on day to day health concerns together. And because our communities are set up by leading health organisations people have access to credible support.” (HealthUnlocked, 2018)	iOS & Web	Recommended at: (NHS Apps Library, 2017d)
Cypher	“Cypher (formerly Silent Secret) is the anonymous peer to peer social network to share your secrets, give help, build a network, connect to support organisations and be happy. • Share your moments, give help to others, build a support network and be happier.” (Cypher App Ltd, 2018)	iOS & Web	Currently being tested at: (NHS Apps Library, 2017a)

5.2.9 What's On / Social Networks			
App/Service	Description	Platform	Rating/Review
Facebook Support Groups	"Social media, and Facebook groups in particular, could be a helpful tool for increasing patient engagement and satisfaction, according to a study published in Surgery." (Lovett, 2017)	iOS, Android & Web	
Quora	"Quora is a Q&A platform that empowers people to share and grow the world's knowledge. People come to Quora to ask questions about any subject, read high quality knowledge that's personalized and relevant to them, and share their own knowledge with others. Quora is a place to share knowledge and better understand the world." (Quora Inc, 2018)	iOS, Android & Web	User rating: 4.5 / 5 (Quora Inc, 2018)

5.2.10 Social Isolation			
App/Service	Description	Platform	Rating/Review
CareVision	“The CareVision mobile app allows families and friends to keep track of their loved one's care requirements, manage tasks, manage a shared calendar, keep track of who is visiting mum or dad and when, keep track of who did what for your loved one and how much it cost, start a discussion with the family to plan care or social events with your loved ones.”(CareVision, 2018)	Android	User rating: 5 / 5 (CareVision, 2018)
Rally Round	“It's an easy to use online tool that family and friends can use to support someone they care about. Everyone in a network can share and discuss jobs and volunteer to help out. Text and email notifications keep everyone in the loop.” (Rally Round, n.d.)	Web	Recommended at: (NHS Apps Library, 2017f)
Link-ages Hub	<p>“Link All Generations Of Your Family With Our Elderly-Friendly App A Family Of Apps For The Elderly With Secure Messaging, Photo-Sharing And Calendar Functions</p> <p>Link-ages is designed to connect families. The apps are designed with the elderly in mind to help them communicate with their family in a simple and secure app environment.” (Link-ages, 2018)</p>	iOS	No reviews available

5.2.10 Social Isolation			
App/Service	Description	Platform	Rating/Review
TalkLife - You're Not Alone	"Life can be incredibly tough for anybody. It can suck, it can feel lonely, and let's admit it: that's tough to say out loud. We all know that, and maybe, sometimes, we've just been made to feel a little afraid to say it. TalkLife is here for everyone and anyone who just needs someone to talk to. Who just needs someone to listen. Because, hey, we all do." (TalkLife, 2018)	iOS & Android	User rating: 4.5 / 5 (TalkLife, 2018)
Replika	"Replika is an AI friend for emotional growth and awareness. Talk to your Replika to feel better and learn about yourself." (Luka Inc, 2018)	iOS & Android	User rating: 4.3 / 5 (Luka Inc, 2018)
SAM	"SAM can be downloaded in April 2018. SAM comes from the Dutch word "samen", which means "together". There are many communities and initiatives that are fighting social loneliness. But most of them are only taking place at one specific location (e.g. one city/ neighbourhood) and are reaching only one specific target group (e.g. one small community/one age group). We therefore need a time and place independent solution, which facilitates meaningful social contact and helps people to do things they like most." (SAM, 2018)	iOS & Android	Not yet released
Mobile Age	"Mobile Age, which is set to be released next year, will provide the elderly with real-time information about public transport, local events, the opening hours of public toilets, daylight hours, weather and parking." (Brooke-Battersby, 2017)		Not yet released



5.3 Appendix 3 – Inclusion / Exclusion Criteria

Inclusion Criteria	
Types of studies	Publication date 2007-present
	Studies from any geographical location
	English or Scandinavian language
	Evaluating mHealth applications or discussing quality criteria for assessing, developing or recommending mobile health and welfare apps

Exclusion Criteria	
Types of studies	Non English or Scandinavian language
	Published pre-2007
Inactive or outdated website	

5.4 Appendix 4 – Full Matrix of The Quality Criteria / Assessment Parameters

Criteria / Initiative	5.1.1.1	5.1.2.1	5.1.2.2	5.1.2.3	5.1.2.4	5.1.2.5	5.1.2.6*	5.1.2.7	5.1.2.8*	5.1.2.9	5.1.2.10	5.1.2.11*	5.1.2.12	5.1.2.13*	5.1.3.1*	5.1.3.2*	5.1.3.3
Engagement	X		X					X									
Functionality	X		X					X			X						
Aesthetics	X		X					X									
Information	X		X	X				X									
App subjective quality	X		X					X									
Appropriateness		X															
Accessibility		X			X					X		X					
Design		X	X			X											
Suitability		X		X													
Usability		X		X	X	X				X	X	X					
Transparency		X												X			
Information update		X															
Authorship		X															
Sources		X															
Risk management		X															
Technical support		X															
E-commerce		X															
Bandwidth		X															
Advertising		X															
Privacy/Data protection		X	X	X			X		X	X	X		X	X	X	X	

Criteria / Initiative	5.1.1.1	5.1.2.1	5.1.2.2	5.1.2.3	5.1.2.4	5.1.2.5	5.1.2.6*	5.1.2.7	5.1.2.8*	5.1.2.9	5.1.2.10	5.1.2.11*	5.1.2.12	5.1.2.13*	5.1.3.1*	5.1.3.2*	5.1.3.3
Logical security		X															
Behavioural change effectiveness			X														
Evidence-based information			X									X					
Endorsement				X													
Reliability of information				X													
Avoids conflict-of-interest				X													
Does not contribute to fragmentation of health				X													
Impact				X								X					
Technology					X												
Security					X	X		X		X	X		X	X		X	
Content					X									X			
Reliability						X											
Health content						X											
Technical content						X											
Accuracy of information							X										
Software functionality							X										
Clinical value								X									
Safety								X		X	X				X		
Relevance								X									
Performance								X									
Information security									X			X					
General medical proficiency									X								

Criteria / Initiative	5.1.1.1	5.1.2.1	5.1.2.2	5.1.2.3	5.1.2.4	5.1.2.5	5.1.2.6*	5.1.2.7	5.1.2.8*	5.1.2.9	5.1.2.10	5.1.2.11*	5.1.2.12	5.1.2.13*	5.1.3.1*	5.1.3.2*	5.1.3.3
Effectiveness										X							
Regulatory approval / compliance										X	X	X					
Clinical Safety										X							
Technical stability										X		X					
Change management										X							
User experience											X						
Maintainability											X						
Compatibility/											X						
User experience											X						
Interoperability										X		X			X		X
Reliability/ performance/ scalability											X				X		
Evidence base												X					
Sustainability												X					
Authentication												X	X				
Operability														X			
Validity															X		
Parameters of scale																	X
Contextual environment																	X
Scientific base																	X
Data																	X
Adaptability																	X

*Not currently applied