AlHaMBRA PROJECT

Alcohol Harm
Measuring and Building
Capacity for Policy Response and Action

Background Document for the AlHaMBRA Project Thematic Capacity Building Workshop

Application of eHealth Tools to Reduce Alcohol-Related Harm

(Workshop version. To be finalised following the workshop)

Co-hosted by the Spanish Ministry of Health, with support from the Program on Substance Abuse of the Public Health Agency of Catalonia

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Contents

This document

This background document has been prepared to provide relevant background information to the participants of the AlHaMBRA Project workshop - *Application of eHealth Tools to Reduce Alcohol-Related Harm.*

It includes two parts:

1. General information regarding the workshop
2. A briefing document introducing themes and issues for debate in the workshop and provide a literature review of DHTs and their applications for the prevention and treatment of harmful alcohol consumption.

The Briefing document is prepared in stages as per the technical specifications of the AlHaMBRA Project contract

- For the workshop, a draft is prepared which is revised following review by an external expert in the field (contained in this document).
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The AlHaMBRA Project workshop, *Application of eHealth Tools to Reduce Alcohol-Related Harm*

This AlHaMBRA Project workshop takes place within the frame of the prevention strand of the EU beating cancer plan, focusing on behavioural interventions on lifestyle related risk factors for cancer prevention. The two interlinked online sessions will explore the state of the art in digital approaches to alcohol prevention and treatment strategies, including critical issues in the design, evaluation, accreditation and deployment of digital alcohol tools and programmes in general populations and specific groups, and best practices for research and policy to boost large-scale and sustained uptake of digital alcohol interventions.

Outputs will include a peer-reviewed scientific summary; a set of short videos introducing the evidence and on-going European initiatives and experiences; and a workshop report, including recommendations for research and policy at the national and European levels.

The workshop is the fifth in a series of seven workshop. Previous workshops:

Workshop	**Co-host/s**
1. Alcohol Advertising and Sponsorship in Traditional and Digital Media, December 2020	Charles University Prague and the Government of the Czech Republic
2. Alcohol and its relation to Cancer, Socioeconomic Inequalities, and Nutrition & obesity, March 2021	General Directorate for Intervention on Addictive Behaviours and Dependencies (SICAD), Portuguese Ministry of Health
3. Alcohol Taxation and Pricing Policies, including Unrecorded Alcohol and Cross-Border Issues, June 2021	Lithuanian Drug, Tobacco and Alcohol Control Department (NTAKD), Lithuanian University of Health Sciences, and the Lithuanian Alcohol Control Coalition (NTAKK).
4. Alcohol Agricultural Policy to Protect Health?, November 2021	National Institute of Public Health (NIJZ) Slovenia and the Ministry of Health of the Republic of Slovenia.

ACKNOWLEDGMENTS AND DISCLAIMER

This workshop is produced under the service contract for the **AlHaMBRA Project** (Alcohol Harm - Measuring and Building Capacity for Policy Response and Action, Contract No. 20197105). The information and views presented in the sessions are those of the speakers, and hence represent their sole responsibility. Accordingly, the information and views presented during sessions cannot be considered to reflect the views of the European Commission and/or the Health and Digital Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information presented during the workshop sessions.

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Workshop agenda

Session 1 – Tuesday 15th Feb 2022 – *Digital approaches to identify and reduce alcohol consumption and harm: do they work and how are they best used?*

Time (CET)	Topic (and format)	Speakers
13:25	Participants admitted to the meeting	
13:30	**Introduction and briefing** - Welcome from hosting Member State – Spain - Welcome from the EC hosts - Shaping Europe's Digital Future Strategy – the EU eHealth Stakeholder Group experience	Manuel Cardoso (chair) - Joan Ramon Villalbí, (MoH, ES) - Agnes Mathieu-Mendes (HaDEA) - Filip Karan (EPHA)
13:50	**Evidence update** (+ Q&A) - An overview of digital behavioural health approaches to tackle alcohol problems, obesity and sedentarism: Why, What, For & By whom - Evidence and roadmap on digital approaches to lifestyle-related risk factors: efficacy, acceptability, uptake, compliance, and feasibility	Toni Gual (chair) - Silvia Matrai (FCRB, ES) - Heleen Riper (VU, NL)
14:20	**Digital health: empowerment and equities** (+ Q&A) - eHealth approaches as tools to empower patients and citizens - How to choose what to use: validation and accreditation of digital tools through the Catalan mHealth Observatory	- Marcus Bendtsen (Linköping, SE) - Imma Grau (mHealth Observatory, ES)
14:50	10-minute break	
15:00	Expert summary + introducing discussions (live)	Fleur Braddick + Silvia Matrai/ Heleen Riper
15:10	Breakout discussions – (small parallel groups of 8-10 people): ▪ *Discussion question (TBC) – How can Member States design policy to promote more equitable and sustainable access to digital health tools to tackle alcohol problems? (3 top policy points)*	Moderators and rapporteurs pre-assigned to each group
16:00	Feedback to whole group - Brief summaries by rapporteurs/moderators + Round of comments	Fleur Braddick (Chair) Rapporteurs and Moderators
16:45	Wrap up by hosts and sub-topic experts	Fleur Braddick + Silvia Matrai/ Heleen Riper
17:00	End of session 1	

Session 2 – Thursday 17th February 2022 – *Practical implications - tailoring approaches to specific contexts and populations*

Time (CET)	Topic (and format)	Speakers
13:25	Participants admitted to the meeting	Toni Gual (Chair)
13:30	**Intro to the session & Messages from the last session** - Welcome from hosting Member State – Spain - Applying behavioural sciences to EU policy making	 - Pilar Aparicio, MoH, Spain - Hannah Nohlen (JRC, EC)
13:50	**Boosting scale-up of digital alcohol approaches** (+ Q&A) - Barriers and facilitators to using eHealth tools for patients and practitioners - Reducing disruption and intrusion to the user: wearables and Just in Time Adaptive Interventions (JITAI) - PAHO - Revolution in interaction: Scaling up human avatars to motivate population level change?	Fleur Braddick (chair) - Hugo Lopéz Pelayo (IDIBAPS, ES) - Donna Spruijt-Metz, (Uni. of Southern California, USA) - Maristela Monteiro (PAHO)
14:20	**Showcasing digital alcohol approaches - large scale deployments** (+ Q&A) - Results from the AlHaMBRA systematic review of school-based m/eHealth interventions targeting children and young people - General population approaches through primary care – Beveu Menys/Drink Less – A regional programme from Catalonia	 - Silvia Matrai & Silvia Grothe (FCRB, ES) - Joan Colom & Lidia Segura (ASPCAT, ES)
14:50	10-minute break	
15:00	Expert summary + introducing discussions (live)	Fleur Braddick + Silvia Matrai
15:10	Breakout discussions – (small groups of 8-10 people): ▪ *Discussion question (TBC) – Which are the priority settings for eHealth approaches to tackle alcohol consumption and problems and how can policy promote engagement with stakeholders in these areas? (3 priorities)*	Moderators and rapporteurs pre-assigned to each group
16:00	Feedback to whole group – - Brief summaries by rapporteurs/moderators + Round of comments	Toni Gual (Chair) Rapporteurs and Moderators
16:50	Wrap up by chair / organisers	Manuel Cardoso / Toni Gual
17:00	End of session 2	

Briefing document: Evidence to support the use of e-health technologies in the prevention and treatment of alcohol consumption

Sílvia Grothe i Riera and Silvia Matrai, Clínic Foundation for Biomedical Research, Barcelona, Spain

Executive summary

The Briefing document is prepared in stages as per the technical specifications of the AlHaMBRA Project contract

- For the workshop, a draft is prepared which is revised following review by an external expert in the field (this document).
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The AlHaMBRA Project's capacity building workshop *Application of eHealth tools reduce alcohol related harm* aims to support European Member States in knowledge gathering, sharing best practice and capacity building for evidence-based alcohol policy and harm-reduction across multiple sectors, adopting a health in all policies approach. This briefing document has been prepared to shed light on the potential of digital approaches to prevent harmful alcohol consumption, by addressing the following questions:

- Can digital approaches be useful to optimise the delivery of alcohol interventions in order to:
  - increase effectiveness?
  - increase tailorability, acceptability, accessibility and scalability?
  - reduce the delay between onset of problem alcohol use and help-seeking?
  - reduce health care costs related to the prevention and treatment of harmful alcohol use?
- What is the evidence on the effectiveness of digital alcohol interventions in specific population groups, namely socioeconomically vulnerable groups, school age populations, and young adults?
- Can digital alcohol interventions result in unintended negative and/or unexpected positive effects in terms of social and health inequalities?
- How have digital approaches impacted on traditional behaviour change theories, intervention evaluation methods, and behavioural and medical care approaches?
- Is it more effective to address lifestyle related health risk factors (alcohol use, smoking, addictive substance use, addictive behaviours, diet, physical exercise, sleep) separately or in combination?
- Are there any formally validated and accredited digital alcohol interventions that can be recommended for use in the general population and/or specific population groups
- What is needed for large-scale implementation of digital alcohol approaches?

Key findings

1. The literature concerning the effectiveness of DHTs tools and interventions to prevent and treat alcohol consumption in the general and specific populations is diverse, and **no robust conclusions on effectiveness have been reached yet.** There is insufficient high-quality data collected over long periods, and pilot studies might not replicate the "real world" conditions being too optimistic with the findings.
2. Regulatory **guidance and oversight** and robust validation processes of the quality of available digital technologies is **not widespread**, compromising patient safety and confidence of users.
3. **Not all populations benefit equally** in terms of access to and use of digital health technologies

related to alcohol consumption.

4. Scalability from pilots to large-scale implementation is limited.
5. **DHTs should not replace face-to-face interactions**; instead, they should enhance preventive activities and treatment. The human factor in healthcare is highly relevant in clinical practice.
6. The human factor in healthcare should not be substituted by DHTs. Instead, they should be applied to optimize care pathways that are not as effective or are obsolete.

Recommendations for researchers and DHT developers

1. Evidence for the application of DHTs for the prevention and treatment of alcohol consumption is not yet robust enough, as it is restricted to short- and medium-term interventions in adult or student populations. **Future studies should assess the effectiveness, acceptability, and utility via long-term studies and in different populations subgroups**.
2. The digital divide is an enormous and complicated issue heavily interwoven with issues of social inequality. **It is important to guarantee that interventions are designed considering inequality** and special effort made to ensure that those most in need of care can access interventions.
3. Concerning development of DHTs, interventions should be **developed together with the relevant stakeholders** and include elements that have been demonstrated to increase effectiveness, such as using theory or establishing multicomponent interventions over long periods.
4. **Develop and validate new theories and behaviour change models** that fit the demands of emerging technologies that interact more frequently with the individual and don't assume a static relationship between risk and protective factors.
5. Conduct a **comprehensive review of DHTs develop by the alcohol industry.**
6. Develop evidence on how to **better safeguard and protect the privacy** of patients.

Recommendations for policy makers

1. There is a wide range of DHT solutions in the market; nationally and internationally. It is important to build a more robust regulatory framework to guarantee safety, effectiveness, and accessibility. Standards should cover:
    a. Privacy and security
    b. Minimum technical, clinical and integration system requirements to ensure the safety, effectiveness and usability of DHTs for patients
2. Establish **harmonised testing, reporting, classification and accreditation processes**. Nevertheless, this process should be mindful of not being too costly or lengthy.
3. Promote use of the EC Best Practice Portal to support exchange of digital best practices related to alcohol consumption and encourage researchers to enter their interventions and findings.
4. **DHTs should reach all the population regardless of socioeconomic level or place of residence.** Further developments in ICTs are key to advancing digitalized and equitable healthcare.
5. **Increase population technological literacy,** so users are aware of what they are consenting to when they agree to the terms and conditions of a digital application.
6. **Foster interoperability** between platforms to avoid duplicating data and optimise care pathways.
7. Further support Member States to launch national **strategies to boost health professionals'**

digital skills and raise awareness of the benefits that DHTs can bring to clinic practice.

Conclusion

The potential of DHTs is enormous and the digital transformation of care and public health is already underway. The application of DHTs for alcohol prevention and treatment is an exciting and rapidly growing field. The ability to provide interventions in a flexible and tailored manner holds considerable promise; however, it poses many challenges that need to be overcome to exploit their full potential. It is vital to set a strong evidence base, from which we can explore the possibilities that DHTs offer.

Background

Reducing the alcohol burden has been long recognised as a significant public health priority as Europe has one of the highest levels of alcohol consumption and alcohol-related harm globally (3, 4). Health professionals and experts agree that the use of digital technologies in health have great potential to enhance care delivery, as internet and computer usage worldwide is increasing year after year (5, 6).

The field of digital health is born from the intersection between healthcare and digital technologies. The World Health Organization (1) defines digital health as: *"The use of digital, mobile and wireless technologies to support the achievement of health*

There is growing evidence supporting the idea that digital health technologies can improve health and care outcomes (7). The application of digital technologies in healthcare will probably expand in the next decade, redefining the status quo of health and social care delivery and unlocking new ways to address diseases and their risk factors (8). Digital health technologies (DHTs) allow for novel delivery channels and enable better targeted and personalised medicine (9). DHTs enable patients to self-manage their treatment pathway and health status, freeing up time for healthcare providers and optimising resources (10, 11). For example, DHTs might facilitate the systematic collection of patient-reported data on lifestyle risk factors like alcohol consumption and improve clinical management by providing tailored feedback, point-of-care reminders, tailored educational materials, and referral to online self-management programs (11). Moreover, digital interventions facilitate detection, disclosure and monitoring of alcohol problems due to anonymity and 24/7 accessibility (12, 13).

Digital health technologies are already transforming how health professionals assess, prevent, and treat patients and how patients monitor their health and medical conditions, change their lifestyle and health behaviour and self-manage their treatments (7). Hence, it is important to discuss the effectiveness of DHTs to prevent and treat alcohol consumption and examine their potential for their large-scale implementation.

DHTs to prevent and treat alcohol consumption started appearing at the end of the 2000s, hand in hand with the increased digitalization of medicine and increased use of digital devices in daily life. However, 20 years later and with an overwhelming body of evidence, there are mostly small-scale pilot studies that prove their effectiveness, and examples of large-scale implementation are scarce. Moreover, while the use of computers and smartphones is widespread, technologies such as wearables, virtual reality, artificial intelligence, motivational robots or digital human advisors are just emerging.

Preparation of this document

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- For the workshop, a draft is prepared which is revised following review by an external expert in the field (contained in this document).
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Methodology

The aim of this background document is to **introduce the key points and issues for debate in the capacity building workshop** and provide a literature review of DHTs and their applications for the prevention and treatment of harmful alcohol consumption. Responding to the Technical specifications of the AlHaMBRA project [1] the preparation of this scientific background document uses a coordinated triangulation methodology (i.e. combine more than one approach to researching the topic) (14).

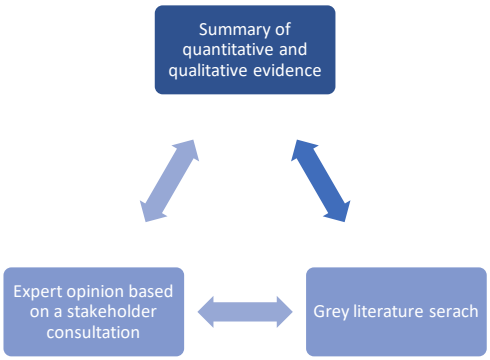

Figure 1. Methodological strategy

Articles were screened using PubMed and Web of Science. Keyword searches related to two terms were undertaken: Digital Health (ehealth, telehealth, medical informatics applications, mobile applications, computer-based, web-based) and alcohol (binge drinking, drinking behaviour, problematic drinking). Then, relevant publications were retrieved and reviewed. The inclusion criteria included: 'peer-reviewed articles', 'full-text available', and 'English language'. The search leading to the current iteration of this background document was completed in May 2021 and will be updated following the workshop to include more recent evidence in the final version Given the emerging nature of the topic and the limited amount of critical evidence, this review includes commentaries and editorials for a more comprehensive coverage of the topic. Additionally, a grey literature search was performed by reviewing the websites of EU institutions (European Commission (EC) and EMCDDA), international organisations such as WHO, OECD and the International Drug Policy Consortium, the Public Health Best Practice Portal of the EC (15) (Ref) and RARHA Joint Action on Reducing Alcohol Related Harm (16).

Multiple stakeholder profiles with expertise in behaviour change; healthcare (both clinical practice and management), users (both patients and general population, in particular, young people), digital technology and design, education and health communication, public health (prevention), and policy have been identified for consultation and invited to participate in an online survey. Their input will be integrated into the next iterations and the final version of the background document.

The last section of this background document is a mapping exercise through the literature search and targeted stakeholder consultation in order to identify large scale interventions and promising pilot studies. At the end of the document, directions for future research and policy recommendations are provided based on the results.

[1] Call for Tenders Chafea/2019/Health/05 concerning support to Member States in studies and capacity building activities to reduce alcohol related harm. https://etendering.ted.europa.eu/cft/cft-display.html?cftId=5792

Subtopic 1: Current state of play of digital health technologies for alcohol prevention and treatment

Findings of the literature review

Purpose and setting of digital health technologies

Digital health technologies (DHTs) are meant for users to gain control over their health by obtaining health and medical information beyond their interaction with a health professional to increase their health literacy; having access to clinical information about their health status and/ or condition(s); and self-screening, self-monitoring and self-managing their health risk behaviours such as alcohol use.

Table 1. Settings and examples of DHTs

Setting	**Goal**	**Example**
Primary prevention	Increase people's knowledge of the harms of alcohol consumption and increase awareness of the impact in their health (17-19).	Publicly available websites with information and multimedia tools about alcohol consumption, games aiming to expand alcohol literacy and daily digital habits trackers.
Secondary prevention	Focus on early detection, monitoring and providing brief advice or interventions to mitigate the impact of risky alcohol consumption (20).	Electronic screening and brief intervention (e-SBI), blood alcohol content (BAC) trackers, mobile data analytics, and machine learning programmes (21).
Tertiary prevention	Facilitating treatment initiation and adherence and promote self-management and self-care (7).	Games, virtual reality and text-message reminders are associated with higher treatment adherence (22)

Can digital approaches be useful to optimise the delivery of alcohol interventions?

Effectiveness

Evidence shows that digital alcohol interventions may offer low-threshold (i.e. making minimal demands on the user), acceptable help options for problem drinkers, and are perceived as a less stigmatising context that facilitates disclosing drinking problems (23). These interventions are available in guided and fully automated formats and are typically based on the same therapeutic principles and components of alcohol brief interventions, the most frequently used being: feedback on behaviour, social comparison, information about social and environmental consequences, feedback on outcomes of behaviour, behaviour substitution (what to do instead of drinking), social support, and referral to credible sources of advice (24). Online alcohol screening has been shown to elicit reliable responses on alcohol use and digital alcohol interventions have been found to be as effective as conventional alcohol prevention techniques in various settings, including primary healthcare (20).

Screening, Brief Intervention, and Referral to Treatment (SBIRT) allows addressing alcohol use related problems even when the patient is not actively seeking an intervention, with proven effectiveness in reducing hazardous and harmful alcohol use. Despite the growing evidence on the effectiveness of alcohol SBI in primary health care (PHC) settings and the significant number of patients seen in PHC who drink at hazardous or harmful levels, the implementation of SBI in routine clinical practice is far from being generalised. Although there is evidence demonstrating that many PHC patients (≈50% in some studies) would like to receive information and advice on drinking, less than 10% of those who drink excessively report having received advice on their alcohol use, (25) and half of the patients receiving a brief intervention reported initiating the discussion of drinking themselves (26). Given the increasing levels of digital usage and literacy in the general population, electronic alcohol screening and brief intervention (e-SBI) delivered via multiple digital devices can be considered a promising option in PHC to increase the typically modest screening and intervention rates

at a reasonably low cost, (27, 28, 29) and reduce workload and time-pressure for PHC professionals, and facilitate referral for those who need specialised treatment (30). The efficacy of alcohol e-SBI does not seem to significantly differ depending on the type of technology used to deliver the intervention (computer, website, mobile, telephone, video), and most studies indicate that these interventions increase motivation to change drinking behaviours, reduce problem drinking or related harm, and appear to perform better than non-technology-based approaches, including treatment as usual. Regarding the context of delivery, combined patient-facing and provider-facilitated interventions were found more efficacious than each separately (31).

Feasibility, scalability, time to seek care

Facilitated access to e-SBI has proven non-inferior to face-to-face SBI and can be successfully implemented in primary care, with acceptable rates of patients who log on (near 50%) following their GP's advice, undertake screening, engage actively, download content and make multiple entries. It could bring more benefits at lower costs than face-to-face BI (70%+ chance), (32). However, most published studies on uptake and adherence of digital alcohol interventions are short and medium-term pilot studies (30), and there is a need to design and deploy studies to collect high-quality data over longer periods (28, 31). One reason it is hard to study long-term effects is because DHTs commonly show low levels of user engagement and high drop-out rates. Specifically, in randomized trials, participant dropout may result in attrition bias i.e. systematic differences between people who leave the study and those who continue, which hampers the generalizability and validity of results. Common reasons for dropping out include personal motives unrelated to the digital intervention, discomfort with the intervention protocol, and satisfaction with the positive results achieved (33).

Although *provider-facilitated referral to alcohol e-SBI in PHC has been found cost-effective and shown positive results*, it has been repeatedly found not successful (34) or not sustainable over time, (20) mainly due to lack of motivation of the professionals to use the referral, related to low levels of perceived usefulness in terms of time-saving; concerns about applicability in vulnerable populations (elderly and lower socioeconomic status); (31) limited digital skills in the PHC workforce; (35) and the lack of involvement of healthcare professionals in the development of digital tools (36). Moreover, the lack of integration between digital alcohol interventions and routine care processes and electronic health record systems also hinders scale-up and sustainability.

Patient-initiated brief interventions on alcohol use in PHC have been associated with over twice the reduction in alcohol use on average than provider-initiated BIs (26). Self-initiators seem more likely to present with depressive symptomatology and alcohol withdrawal symptoms, thus providing opportunities for self-test and self-referral may facilitate treatment seeking in more severe cases of alcohol use (26). Anonymous alcohol e-SBI has been found both feasible and acceptable in PHC users (patients), and those with problem alcohol use seem significantly more likely to start using an alcohol digital tool through self-initiation (37). Automated brief interventions (e.g. via interactive voice response) prior to a PHC visit seem to promote discussion about unhealthy drinking and facilitate professional advice on changing drinking behaviour (38). Therefore, self-initiated alcohol e-SBI may reduce time to seeking help and access treatment in particular in high-risk patients.

Tailorability

Overall, tailored interventions on lifestyle behaviours such as alcohol use have been found more effective than generic or waitlist control groups. Tailoring can be done in a variety of ways, such as based on physiological and psychological parameters, information on health status and medication use, health-related behaviours, user location, user health literacy, and user technological skills. These data for tailoring can be obtained in a number of manners such as digital questionnaires and user-entered data (e.g. diaries), wearables, monitoring of user's digital usage, retrieving data from electronic health records.

Digital technology enables designing interventions to deliver real-time behaviour change support that is matched to when users most need or want support. A number of terms have been used for such interventions, such as ecological momentary interventions (EMI) and just-in-time adaptive interventions (JITAIs). These interventions are meant to address situations when people are likely to engage in an unhealthy behaviour, for instance when feeling anxious or being near or in a bar where people with problem alcohol use are likely to experience the urge to drink. Typical EMI/ JITAI interventions use sensors and built-in digital functions of the user's smartphone to monitor environmental data and physiological and psychological parameters related to mood and emotions. These data serve to interpret the user's current context and psychological state and deliver appropriate and timely behaviour change support (39).

Artificial Intelligence (AI) algorithms can be used to tailor motivational messages to increase people's willingness to change their health behaviour; in particular, machine learning can provide an intervention programme that learns over time and becomes responsive for the user to support their behaviour change in an individually meaningful and timely manner. AI-driven digital (virtual) human care providers take responsive digital health behaviour change interventions solutions even further by offering autonomous interactive human-like agents that initiate face-to-face conversation and respond to both verbal and non-verbal communication cues. User-facing digital human interventions have been found significantly more effective than other conversational agents like *chatbots* and smart speakers (40) to improve user engagement in health thus enhance health literacy, promote behaviour change and improve management of health conditions. AI-driven digital health solutions such as motivational social robots and digital humans are perceived by users to have no social judgement and provide objective feedback. Patients presenting with stigmatised health problems such as harmful alcohol use, who often feel shame, fear and embarrassment, can be expected to show a higher consultation scheduling intention with an AI-driven digital health care provider than with a human provider, thus can be more likely to take early screening and access advice and treatment (41, 42).

Engagement with digital health solutions

Engagement with digital health is a concern in multiple disorders, but especially in mental health disorders (43, 44). User involvement from design to implementation is key for ensuring engagement (45). Additionally, facilitated access and gamification are promising strategies for improving adherence to digital health tools.

Facilitated access

Facilitated access (FA) is defined as referring to online interventions by healthcare professionals (HCP, e.g. primary care nurse or medical doctor). HCP are in a privileged position of being able to offer evidence-based online interventions to their patients due to their established relationship and the possibility of receiving feedback and incorporating it into the regular treatment, among other reasons. Nonetheless, the HCP more engaged in FA are those who are already familiarised with digital tools (46).

FA to alcohol reduction websites showed positive results in at least two randomised controlled non-inferiority trials (47, 48). Interestingly, it has also shown to be a cost-effective strategy (32). However, FA is not exempt to barriers such as the influence of professionals' perception of tool utility (31).

Gamification

The Cambridge dictionary defines gamification as "the practice of making activities more like games in order to make them more interesting or enjoyable". In other words, gamification consists of using elements from games to (re)design a non-game task to enhance the user experience through gamified applications. 'Serious games' are entire "games that do not have entertainment, enjoyment or fun as their primary purpose" (49) their primary purpose being education, training, or health care (50). Gamification and serious games are

usually based on well-stablished theoretical frameworks such as Self-Determination Theory, Transtheoretical Model of Behavior Change, Intrinsic and Extrinsic Motivation or User-Centered Design (50, 51). Game elements such as points, leaderboards, achievements/badges, levels and challenges, are used as motivational features (52).

With a large body of evidence in education (52-54), research into gamification and serious games for lifestyle changes (e.g., nutrition, physical activity, (55-57) and mental health disorders has been growing in recent years (50). Preliminary results suggest that gamification increases the efficacy of brief interventions (58, 59), and is promising in alcohol cognitive impairment (60-62). Several studies of digital gamified tools have been running in different vulnerable populations to prevent harmful alcohol use (63, 64) Examples of these include Alcohol Alert that integrates the self-reported amount of alcohol consumed into the game to address binge drinking and the Fling serious game to train behavioural control in adolescents (65, 66) , and the CampusGANDR social game addressing peer norms about drinking in college students, (67). Consequently, the role of gamification in e-health for heavy drinking in terms of efficacy and improving adherence will be clarified in the following years.

What is the evidence on the effectiveness of digital alcohol interventions in specific population groups?

Even though there is a steady evidence base for digital alcohol interventions in general populations, there is a lack of evidence in sectors of the population which might be expected to be excluded, such as people from low socioeconomic status and ethnic minority groups (68). While transition towards digital approaches and services in health promotion and care are becoming increasingly normative and accelerated by the ongoing COVID-19 pandemic, most digital health designs and research have been made in advantaged populations, with limited or no participation of population groups at risk of socioeconomic, health and digital inequalities. These populations might experience the greatest benefit from using digital technologies to prevent and treat alcohol consumption, as they are less likely to turn to and access usual alcohol-related services (6). The review of evidence in specific populations is presented below.

Young people: interventions in young adults and schools

The mental health of young people is greatly affected by social factors at personal, family, community, and national levels (69). In the European region, a high and increasing rate of mental health problems have been reported in adolescents, with depression and anxiety being leading causes, 10% being regular weekly drinkers by the age of 15 (70) and a prevalence rate of 35% of heavy episodic drinking (71). In young adults aged 18-24 years, research shows a tendency toward binge drinking in their late teens and early/mid-twenties, and that heavy drinking is present in this age group regardless of whether they are college students or not.

Young people aged 12-24 years are the generation that are growing up as “digital natives” and expect convenience and speed through digital interactions with the services they use, including health consultation and care. Thus, they are driving increasing demand for mental health related consultation, but they seem far more likely to turn to digital resources than to human health advisors and care providers for support, with social media being the most consulted resource and >70% preferring telemedicine to in-person appointments (72). As young people typically avoid traditional counselling and treatment services, less resource intensive, self-initiated and self-guided digital interventions may be a potential approach to preventing lifestyle related risk factors in this population.

In young adults, digital interventions to reduce drinking levels usually consist of: online single-session interventions providing personalized normative feedback that highlights discrepancies between perceived and

actual peer norms to correct misperceptions of peer drinking levels; alcohol literacy modules as part of general academic curriculums; or screening and brief interventions to detect problematic alcohol use and motivate to change drinking behaviour. The available literature on standalone digital approaches overall show positive results in preventing excessive alcohol consumption, but the effect sizes of the interventions are relatively small compared to practice as usual/face-to-face interventions (29) and effects seem to disappear after a year (13). The majority of these digital interventions are delivered via a computer or web browser, but mobile apps are thought to be more suitable for young adults given the flexibility, interactivity, and their spontaneous nature [12]. However, a recent review assessed mobile apps developed with the purpose of managing alcohol consumption found that the evidence is promising but still inconclusive given the mixed results [13].

Also, the majority of research have been conducted in university settings mostly in the United States and America, thus caution should be exercised when interpreting the results for this population group characterised by their high levels of drinking and unlikeliness to access traditional health services, and generalising to other young adult population groups (6). Furthermore, reviews and meta-analyses that synthesise the available evidence are difficult to perform because of the heterogeneous nature of the digital interventions and the lack of completeness and objectivity when reporting the results of the studies (28).

Although there seems to be less of a stigma around mental health in general in younger generations, when it comes to problem alcohol use, recent findings in young people on stigmatising 'weak-not-sick' attitudes and preference to avoid alcohol misusing peers are consistent with the evidence in older generations (73). Therefore, increased focus on healthy lifestyle behaviours rather than alcohol use might be beneficial to create a less stigmatising and welcoming atmosphere and increase healthy behaviour overall, and increase and prolong the effect sizes regarding drinking outcomes (33-35). Common combinations are cannabis, tobacco, mental health and physical activity. Additionally, using theory and adding elements of personalisation in intervention design, for example provide tailored text messages, are reported as being beneficial in increasing their effectiveness (25).

Previous reviews on lifestyle-related DHT interventions **in school settings** or aimed at youth show that they can be effective, but effects are small and hard to sustain in the long-term (74-78). Champion, Newton (74) conducted a systematic review of school-based digitally driven alcohol and other drug prevention programs, which showed that computer and internet-based programs in schools are a potentially efficacious method of delivering drug and alcohol prevention to adolescents. Delivering universal and digital preventative programs at schools might be suitable because students spend most of their time in this space, where social ties with peer groups are formed (79, 80). Additionally, a large number of students can be reached (81). However, in relation to adherence in school-based digital alcohol interventions, some studies found that drop-out students differed from students who completed the intervention in terms of drinking a higher average number of glasses per week, being in lower levels of education and being older (18). A systematic review on school-based digital approaches to prevent alcohol misuse has been produced and will be annexed to the final version of this document.

Alcohol exposed pregnancies

Alcohol consumption during conception and pregnancy may result in a series of adverse effects to the fetus including congenital anomalies and behavioural, cognitive and adaptive deficits. Despite drinking during pregnancy being the leading cause of birth defects and child developmental disorders in the EU, many pregnant women continue drinking with consumption rates ranging from 25% in Spain to 79% in Ireland and the UK (82). The adverse health effects of prenatal exposure to ethyl alcohol have been grouped under the term of Fetal Alcohol Spectrum Disorders (FASD), which include Fetal Alcohol Syndrome (FAS), alcohol-related

neurodevelopmental disorder and birth defects. The European Region has the highest overall prevalence of FASD estimated at 19.8 per 1000 population (83). Research show that DHTs may be especially suitable for reducing alcohol use among women of childbearing age (84). DHTs might help these women feel less embarrassment and fear of judgement, making it easier to discuss their drinking-status and feelings (85).

Workplace

Significant numbers of heavy drinking at work have been reported in the working population in a number of European countries, especially in some sectors including construction, hotels and restaurants, transport, agriculture, and security services (86). DHTs can also be applied in the workplace, a setting where large part of the adult population spends a large portion of their time. Health programmes online and off-line at work have gained popularity over the last two decades. Howarth, Quesada (87) conducted a systematic review to assess the impact of pure digital health interventions in the workplace on health-related outcomes, including alcohol consumption and harm. The review found that purely digital interventions can be effective if they are firmly embedded into the workplace setting and are targeting health behaviours that are part of the workplace routine such as eating. In case of alcohol use that extends beyond the workplace environment, purely digital interventions may not be adequate to address risky and harmful drinking, and more interactive approaches with human support may perform better.

Long-term unemployed (i.e. for 12 months or more) comprise a specific vulnerable group with worse self-assessed health status that is strongly associated with a lower socioeconomic status, weak social networks, and health-related reasons for unemployment. Digital approaches to assess and address risky lifestyle behaviours have hardly been researched in this population group. An ongoing study is currently evaluating a digital tool in long-term unemployed to screen chronic disease risk factors and increase motivation to change unhealthy lifestyle behaviours including heavy alcohol use, in comparison with nurse-led health assessment and patient-reported health problems (88).

What is needed for a large-scale implementation of digital alcohol approaches?

Despite the large pool of evidence on digital health interventions, there is growing concern regarding low scalability from pilots to large-scale implementation, this is known as the **telehealth paradox** (89). This also makes the evaluation of effectiveness in real-life circumstances difficult (9). Regardless of the policy-level talk triggering a digital revolution in service delivery and the advance of many small-scale proof-of-concept examples, DHT services are rarely mainstreamed or sustained (90). This phenomenon is attributed to several factors, represented in Figure 2. The first barrier is the lack of financial resources and incentives to implement and scale up digital initiatives, this is mostly because the initial investment needed to design and develop interventions is high compared to face-to-face treatments (91).

Another factor that hampers the large-scale uptake of DHTs is **data security and privacy.** Despite their great potential to improve health and care practices, DHTs have been confronted with a fair share of ethical and social scrutiny (21). Privacy in medical informatics is defined as an individual's right to control the acquisition, use, or disclosures of their identifiable health data and confidentiality (92). Security is the physical, technological, or administrative safe-guards or tools set in place to protect identifiable health data from unwanted access or disclosure (92). A high-security system protects the user's identity and secures the data they are providing so that if an unauthorised person were to access the tool, they would be incapable of linking the information with a particular person. Data security and privacy are especially relevant for digital technologies designed to prevent and treat a sensitive and highly stigmatised topic such as alcohol consumption (93). Additionally, the topic of data security and privacy is complex, as there is a need to strike a

balance between creating a fair and functioning digital market with opportunities for growth and innovation while also protecting the fundamental right to data protection and freedoms of individuals regarding the processing of personal data (21).

Safeguards to protect health information, and informed consent to share and receive health data are in place in most DHTs. Tools like *double-authentication* and *encryption* are applied to make interventions safer (92). However, security varies greatly between interventions and tools. A problem often reported in the literature is relatively low **technological literacy** among DHT users. This implies that users usually know how to use the devices but rarely understand the implications of accepting the terms and conditions, or technological concepts such as encryption (92). Therefore, the approach to ensure better data security and privacy in DHTs should be two-fold. On the one hand, it is essential to make systems more robust, functional and user-friendly. On the other hand, it is essential to improve users' education and their understanding of what they are agreeing to. This will help better protect individuals' rights and increase trust of digital technologies.

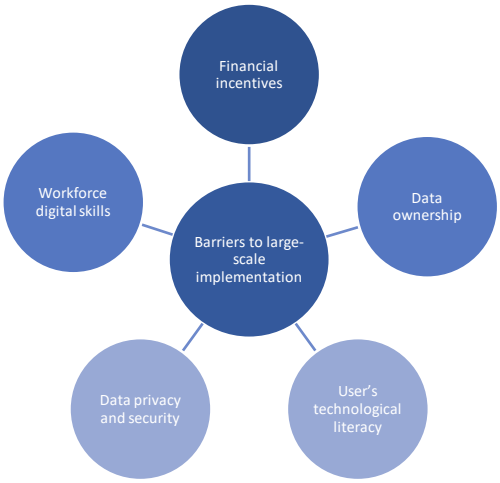

Figure 2. Barriers to large-scale implementation

Another pressing issue strongly related to data privacy in the framework of DHTs is **data ownership**. Although individuals may be classified as data subjects, information about them may be simultaneously "owned" by different individuals, organisations, governments, and society (94). There are unprecedented amounts of data being constantly collected. This begs the question: Who owns the data? It is essential to recognise that patients have ownership of the data, but at the same time, the analysis of such data could bring large benefits to public health (95). Consequently, it is important to ensure that legislation keeps pace with technological advances and to learn from other fields and adopt successful features. The introduction of the GDPR in 2018 had a significant impact on the development and commercialisation of eHealth tools, introducing several new compliance obligations and setting out the basis for better data protection (9). Moving forward, it is essential to build models of trust to provide an environment that facilitates the responsible use of health data with robust identity protection and collective and participatory ethical data sharing mechanisms (95).

Another issue is the **digitalization of the workforce**. Although healthcare professionals regularly use eHealth in their work, studies show that their eHealth competency is not developed to the optimal level (96). Implementing eHealth without simultaneously ensuring a competent workforce may have unfortunate consequences for the functioning of healthcare organizations, and thus patient health. Hence, it is important to train professionals in using these technologies in daily practice and motivate them to use them. Furthermore, health professional trust and acceptance is rather low (20, 31). The following SWOT analysis identifies barriers and opportunities for large-scale implementation.

SWOT analysis

Based on the literature review, a SWOT analysis has been applied to analyse the strengths, weaknesses, opportunities and threats of DHTs for prevention and treatment of risky and harmful alcohol use. Specific topics require a more comprehensive explanation; thus, they will be further developed in the following sections below.

Table 2. SWOT analysis

Strengths	**Weaknesses**
• Potential for high population reachability (13) • Relatively low costs (91) • Standardisation of care processes (7) • Potential for high personalisation opportunities (97) • Low stigmatising context (93) • Reduced workload and time-pressure for healthcare professionals (98) • Reduction in the time between onset and help-seeking interventions (98) • Potential for patient empowerment (10) • Increased ability to access interventions autonomously (99) • Potential to improve low help-seeking rate for alcohol problems (13) • Do not necessarily rely on the skills, motivation, or time of the facilitator (100) • Greater flexibility in when and where can be delivered (101) • Systematic and standardised collection of patient-reported data (11)	• Examples of large-scale implementations are limited (102) • No conclusive scientific-based evidence for benefits and effectiveness (6, 29, 103, 104) primarily because of : – High heterogeneity of study design and evaluation (99, 103) – High participant drop-out rates (33) • Requires patient to develop a new set of skills and digital competencies (7) • Reduced access for poor, rural, elderly and handicapped populations with limited access to internet connection or to a computer(105) • Low technological literacy population (92) • Non-adoption or early abandonment of DHTs, attrition bias (106) • Health professionals resistance: Low engagement and low perception of intervention usefulness (31)
Opportunities	**Threats**
• Potential interconnectivity with other health platforms like electronic health records (102, 107) • Political interest and investment in technology and chronic disease prevention and management (4) • Widespread use of mobile devices and technologies to access digital health technologies (108) • COVID-19 pandemic has accelerated people's use of digital technologies in their care (109).	• Limited digital competencies in the workforce (96) • Rapid obsolesce of digital technology and design features (77) • Health platforms are yet not interoperable (7, 107) • Cyber-attacks and data breaches (92) • Development of counterproductive DHTs by the alcohol industry • Outdated legal framework and lack of standards and guidelines (2, 21) • Potential loss of doctor-patient relationship and social link (21) • Adaptation of treatment routines (6) • Currently limited available DHTs accreditation systems (2)

Subtopic 2: Improving the development, evaluation and use of digital health interventions

Comprehensive literature review

Mapping of existing actions and issues in DHT development and implementation

Development of e-health technologies

The literature suggests that several topics should be taken into consideration when developing and implementing DHTs. First, the **application of theory** has been identified as one of the most crucial factors to change people's behaviour, as they guide how to influence and change behaviour (100). The most common, but also more grounded theories, applied in the design of behaviour change techniques are Social Cognitive Theory (110), the Health Belief Model (111) and the Transtheoretical Model (112). Others models also applied in interventions are the A.S.E model and the I-change model. All these theories stress the importance of personal control and self-efficacy in promoting lifestyle modification (21). The theories also support explanations and predictions about average change in behavioural outcomes in groups and are based on **largely static generalisations** (113). Some digital health interventions have acquired these traditional behavioural theories to design their interventions (114, 115). Although the use of theory is identified as an essential element, their use is not as widespread. A systematic review by Tebb, Erenrich (100) found that roughly half of the digital interventions included in their review did not adopt any evidence-based behavioural change theory. Only some interventions included elements of theoretical constructs such as self-efficacy or an intervention technique like influencing social norms and personalised normative feedback. This is a common problem also in non-digital interventions.

Some emerging technologies are unable to benefit from behavioural change theories mentioned above. For instance, *just-in-time adaptive interventions* (JITAIs) adapt over time to an individual's behaviours and provide feedback adapted to the micro-scale, this implies that JITAIs provide the type of support precisely when needed (116). For example, when entering a bar, the patient is exposed to a "high risk" environment. Old behaviour theories are based on a static relationship between risk and protective factors, but digital innovations like JITAIS acknowledge that risk and protective factors change continuously and are being influenced constantly by mood, location and social interactions; hence, the use of old health behaviour change theories is unsuitable. In other words, JITAIS require a theory that can take into account variations in individual characteristics and context and recognise that the variations will change over time (113). In brief, old behaviour theories seem appropriate for use when processes that were traditionally face-to-face are being translated into the digital practice, for instance a computer-based intervention that provides tailored feedback on the risk of alcohol consumption. However, old behaviour change theories appear inadequate to inform more novel DHTs that interact with the individual at a much greater frequency, like mobile technologies, sensors, wearables or JITAIS. Therefore, digital health technologies that strive to provide a tailored intervention should develop and apply new theories and models that are more precise to the individual's contextual factors.

Second, it is essential that interventions are **developed through co-creation, i.e. together with those who are the ultimate recipients of the intervention** and shift away from the old conception of a single voice dominating the design process (117). A heterogeneous group of stakeholders such as citizens, customers, policymakers, researchers, educators, businesses, and universities increase the chances of ensuring that user solutions identified are feasible and appropriate for the population targeting (117).

Moreover, evidence shows that co-creation with users can lead to more innovative ideas and better address users' needs (118). Co-creation increases patient empowerment and further allows patients to take control over their treatment pathways (119). For the design of digital health interventions, relevant stakeholders such as patients, psychiatrists, and psychologists are necessary. A proper stakeholder mapping is crucial to identify those who should be part of the co-creation process *(see stakeholder consultation).*

Evaluation, validation and accreditation of digital health alcohol tools

Health professional trust towards the usefulness of DHTs is relatively low (20). This can be mitigated by building more objective, transparent, and standards-based evaluations of digital health products (2, 20). Regulatory guidance and oversight and robust validation processes of the quality of available digital technologies is not widespread, compromising patient safety and confidence; and can lead to discrepancies and misleading claims, as well as reduce the quality of interventions and tools, especially those developed by the alcohol industry which tend to downgrade the harms associated with alcohol consumption (2).

Validation should be considered at three different levels (2):

Technical	How accurately does the solution measure what it claims?
Clinical	Does the solution have any support for improving condition-specific outcomes?
System	Does the solution integrate into patients' lives, provider workflows, and healthcare systems?

Independent local initiatives have developed mechanisms to validate and certify digital technologies, such as *TIC Salut* Foundation in Catalonia, Spain (120). *TIC Salut* Foundation offers an Accreditation Service for mobile applications and devices in the health and social welfare environment. They assess to a pre-established accreditation criterion, which outlines the essential requirements for creating a tool whose quality and reliability is guaranteed. The National Health Service (NHS) in the United Kingdom until recently hosted a Beta site for Digital Apps Library of "NHS approved" medical apps across an array of medical conditions (121). The aim of these two platforms is to reflect high-quality, safe, effective, accessible, credible and usable apps for which published medical evidence supports their use (2). The European Commission's Public Health Best Practice Portal also appears to provide some validated examples on the use of DHTs to prevent risky and harmful alcohol consumption.

The road to systematic validation of digital health technologies is complex and potentially very resource-intensive. Enforcement of certification is complicated as interventions can be made available online without a certification. Furthermore, rapid advances in DHTs make it harder to keep pace. The literature suggests that interventions should be designed and developed following the upfront requirements, based on safety, effectiveness and usability of DHTs for patients and health professionals *(2).*

Evaluation, validation and accreditation is especially necessary in a context where multiple commercial enterprises including the alcohol industry develop their own alcohol information and promotion tools and make them publicly available online. Current trends suggest increasing involvement of the alcohol industry in areas that traditionally have been the dominated by public health, such as scientific research and alcohol education (122). The alcohol industry has developed alcohol-related apps and educational websites on the harms of alcohol consumption. Resources published by the alcohol industry explaining the implications of alcohol and health are plentiful. These

may downgrade the harms associated with alcohol consumption and claim that alcohol consumed in moderation is not harmful to human health, claims that are not aligned with the most recent evidence.

The alcohol industry has also been involved in developing or sponsoring apps to boost alcohol consumption, such as Beer Buddy (see Figure 3). On the one hand, enormous public health efforts are being made to develop and implement large-scale digital interventions to prevent and treat harmful alcohol use, while on the other hand, there is a rise in apps developed by the alcohol industry to convert daily alcohol use into a social norm and drinking as a centre of social interactions. This means that there could be apps intended to increase alcohol literacy and prevent risky alcohol use and apps promoting the consumption of alcohol in the same device, which can have considerable implications for the overall effectiveness and credibility of interventions.

Figure 3. App that promotes alcohol consumption
Source: https://apps.apple.com/us/app/beer-buddy-drink-with-me/id1487915470

Use of digital health technologies

Digital reach: The use of digital technologies has greatly increased in the last 20 years. The ability to access ICT technologies has become increasingly important in society. However, access to ICT is unequal across and within countries. The term ***digital divide*** has traditionally been understood as the growing gap between less privileged members of society, like poor, elderly and handicapped populations, concerning both their opportunities to access ICTs and their use of the Internet for a wide variety of activities (105). However, in the most recent years, understanding the digital divide has broadened to include other concerns related to digital and technological literacy, health literacy, and other socioeconomic and cultural factors. Carey, Noble (11) suggests that greater risks for disparities can happen outside the clinic than inside the healthcare facility. While in a hospital the engagement and acceptability of technologies provided does not seem to be determined by socioeconomic level, for instance a touchscreen in the waiting room, outside the clinic outcomes appear to be different among less privileged populations. A systematic review identifying the sociodemographic factors of the use of DHTs in people with chronic diseases found that older persons and persons with lower income and lower education are less likely to use DHTs (123). Furthermore, people with chronic diseases living alone are less inclined to use DHTs because family members often help with difficulties experienced while using DHTs. An important factor influencing the use of DHTs is the place of residence. People living in rural areas have structurally less access to DHTs. This is worrying as these are the people most in need of care assisted by digital technologies to overcome scarcity in health

care provisions in these distant areas (123).

The **COVID-19 pandemic** has exposed the digital divide even further (124). For example, those who owned a computer or had an available computer at home had the opportunity to continue their alcohol use disorder treatments online, whereas those who did not experienced a greater level of difficulty. Nonetheless, the pandemic has also been an unprecedented event that has led to boosted uptake of digital devices for the population and increased digital skills for the entire population which could be of great advantage for improving the scalability and large-scale implementation of DHTs.

The digital divide remains an enormous and complicated issue heavily interwoven with the fight against social inequalities. It is important to guarantee that interventions are designed conscious of this social gap. Moreover, it is crucial that during the implementation steps are taken to ensure that those most in need of care have the proper access to digital devices to access interventions. Many features can be built into DHT programs such as language, layout, and graphics, to reduce the **health literacy gap** (11).

Current programmes

This section provides a list of current programmes of digital intervention which address the issues referred to above and will be further complemented by the stakeholder consultation towards the full version of the background document.

1. Programmes in school aged population
    - Results from the AlHaMBRA Project's systematic review
    - Experiences in the classroom from Switzerland
    - Ongoing digital alcohol pilot study in adolescents in the Netherlands
    - Applying behavioural sciences to EU policy making – lifestyle prevention in preadolescents
2. General population approaches
    - 'Drink Less – Better Health' in UK's NHS
    - Piloting self-initiated digital alcohol self-screening, brief interventions tailored by alcohol risk, and referral to treatment appointment scheduling in the Catalan primary health care system
3. Improving uptake and compliance
    - Integrating tools in the most widely used digital contexts: mobile apps and social media based approaches
    - Reducing disruption and intrusion to the user: wearables and Just in Time Adaptive Interventions (JITAI)
    - Motivating the user through Serious Games for Health
    - Revolution in motivational interviewing: from social robots to human avatars
    - Learning to control alcohol use in safe environments: Virtual Reality solutions

Main policy areas and areas of overlap

Numerous policy areas are related to the topic of DHTs for alcohol consumption. There are key overlaps in policy that should be considered to reduce alcohol consumption though DHTs. These range from health and consumer protection agencies to internal market and regulatory affairs.

EC departments and agencies, stakeholders

Current initiatives at the EU and international level are taking place to boost the use of digital technologies. In 2005, WHO urged Member States to consider drawing up long-term strategic plans for developing and implementing e-health services (80). In 2020, the WHO launched the Global strategy on digital health, which aimed to strengthen health systems by applying digital health technologies for consumers, health professionals, health care providers, and industry to empower patients to achieve a Health in All Policies (HiAP) approach (81). Furthermore, numerous EU initiatives focus on developing the digital landscape. The 2015 Digital Single Market Strategy for Europe (DSM) did not focus specifically on digital health and care, but there were several references to e-health (82).

Further, the e-Health Action Plan 2012-2020 provides a roadmap to deliver smarter, safer and patient-centred health services in the European Union (83). Finally, the uptake of e-health technologies contributes to the European Commission to build a more digitalised future in the European Digital Strategy: A Europe fit for the digital age. Moreover, the Commission Communication on Enabling the digital transformation of health and care in the Digital Single Market sets out several objectives, one of which refers to the digitalisation of health and care though the integration of eHealth technologies and practices with the goal of creating a "European-wide ecosystem for data-driven healthcare" (82).

The EU has a policy framework to support the advancements of digital health technologies; however, what it is still lacking is a regulatory framework that sets out technical, clinical and integration system standards to ensure the safety, effectiveness, accessibility of DTHs. The following list of European Commission departments and agencies are key actors to ensure that DHTs reach their full potential. An overview of overlapping policy issues and multi-sectoral priorities is provided in Table 3, which lays out possible alliances and inter-related interest across directorates generals of the European Commission.

Table 3. Areas of policy overlap

DG SANTE – Directorate General for Health and Food Safety
DG CONNECT - Directorate-General for Communications Networks, Content and Technology
DG GROW - Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG JUST - Directorate-General for Justice and Consumers
DG EMPL - Directorate-General for employment, social affairs and inclusion
DG RTD - Directorate-General for research and innovation
HADEA – European Health and Digital Executive Agency
JRC – Joint-Research centre - European Commission's science and knowledge service
Data Protection Officer (DPO) – Service Department
EU-OSHA - European Union information agency for occupational safety and health (health and wellbeing of employees)

Policy area	Sectors with stakeholders (non-exclusive list) and interest related to the policy
Data privacy and security There are unprecedented amounts of data being collected constantly when using DHTs. Stakeholder collaboration is needed to ensure that legislation keeps pace with technological advances and that a balance is found between data ownership and privacy and mass sharing of data to bring enormous benefits to public health.	**DG CONNECT –** Safeguarding the interests of digital technologies consumers and ensuring that networks and services are secure and resilient. **DPO -** Guarantee that the data-sharing processes when using DHTs comply with the relevant data protection rules. Moreover, it is essential to identify and address any unnecessary hurdles hindering data sharing and the use of privately-held data by companies. **DG JUST –** Provide a legal framework that ensures that research data is shared equitable, ethical, and efficient. **DG SANTE –** it is a priority of the public sector to ensure that data sharing brings additional epidemiological benefits and helps develop better technologies to prevent, screen and treat excessive alcohol consumption. **JRC -** Cybersecurity research at the JRC provides support to the EU to respond to cyber-attacks and reinforce rules on personal data protection and ensure that critical networked systems are sufficiently secure and resilient.
Innovation in DHTs Innovations can accelerate product design, prototyping and testing and find new ways to optimize the prevention, detection and treatment of risky alcohol consumption.	**DG RTD –** Create a space for research that fosters innovation by sharing data and results between research groups. Additionally, place Europe as a global leader in using DHTs to improve human health and healthcare systems. **HaDEA –** Provide financial incentives for innovation in digital health technologies in alcohol prevention and treatment through different programs funded by the European Commission, such as the EU4Health programme (€4,7 billion) and Digital Europe Programme (€0,8 billion) **DG GROW –** Advanced health technologies present enormous growth potential for Europe. It is crucial to monitor the development of advanced technologies in the healthcare industry or provide financial and political support to small and medium enterprises (SMEs) to innovate in this field. **DG SANTE –** Ensure that innovations are appropriate and adequate to improve healthcare pathways for patients.
Accreditation Regulatory guidance and oversight of the available DHTS is an enormous challenge. The lack of an accreditation system compromises patient's safety and confidence, and can lead to discrepancies and misleading claims.	**DG SANTE–** Provide a legal framework that sets out minimum requirements and standards for DHTs, like those set out by the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices. Additionally, it should provide safety monitoring of the available products. **JRC -** The JRC actively supports and provides independent scientific advice on implementing EU legislation on medical devices.

System interoperability The success of DHTs will significantly depend on the system interoperability. Nowadays, medical data is not interoperable as it is isolated in independent databases, incompatible systems and proprietary software that make data challenging to exchange, analyse, and interpret (107).	**DG CONNECT –** The digital health infrastructure across the European Union is unequal within and between countries. This makes large-scale interoperable data processing a very complex challenge. National and international interoperability of DHTs will a more harmonized European Digital Market. **DG RTD -** Using interoperable formats to collect and store data opens up various opportunities for researchers to perform large-scale observational studies at regional, national or global levels of the usefulness of digital technologies and collect tremendous amounts of epidemiological data on other diseases. Furthermore, system interoperability would allow the improvement of artificial intelligence and machine learning methods. **DG SANTE -** Critical parts of health data are lost as patients move through the healthcare system. This leads to inefficiencies in care and sometimes poses severe risks for patients. Integrating the health information generated in the different digital health devices, such as smartwatches and electronic health records (EHRs), will make it easier for physicians and other healthcare professionals to care for the patients, thus improving treatment pathways. Additionally, interoperable DHTs can also help patients to manage their health more actively. Data interoperability is also crucial to improve cross-border care and allow patients to move freely across the Union. **JRC –** A unit at the JRC is involved in developing and running software tools and methods to organize, store, retrieve and analyse large volumes of biological data is what bioinformatics is all about.
Workforce digitalization Implementing DHTs without simultaneously ensuring a competent workforce may have unfortunate consequences for the functioning of healthcare organizations, and thus patient health. It is vital to train professionals on how to use these technologies in daily practice.	**DG EMPL –** Provide support to national strategies that provide lifelong learning and digital skills to the workforce. The DG provides support on the update of the Digital Education Action Plan, to ensure that digital skills are adequately addressed at all levels of education and training and the implementation of the Digital Europe programme, with a focus on high-level digital skills; **EU-OSHA -** An EU-OSHA foresight project looks at the impact on the work of rapid developments in digital technologies, including artificial intelligence and robotics, and the potential resulting impact on occupational safety and health.

Key findings

1. The literature concerning the effectiveness of DHTs tools and interventions to prevent and treat alcohol consumption in the general and specific populations is diverse, and **no robust conclusions on effectiveness have been reached yet.** There is insufficient high-quality data collected over long periods, and pilot studies might not replicate the "real world" conditions being too optimistic with the findings.
2. Regulatory **guidance and oversight** and robust validation processes of the quality of available digital technologies is **not widespread**, compromising patient safety and confidence of users.
3. **Not all populations benefit equally** in terms of access to and use of digital health technologies related to alcohol consumption.
4. Scalability from pilots to large-scale implementation is limited.
5. **DHTs should not replace face-to-face interactions**; instead, they should enhance preventive activities and treatment. The human factor in healthcare is highly relevant in clinical practice.
6. The human factor in healthcare should not be substituted by DHTs. Instead, they should be applied to optimize care pathways that are not as effective or are obsolete.

Recommendations for researchers and DHT developers

1. Evidence for the application of DHTs for the prevention and treatment of alcohol consumption is not yet robust enough, as it is restricted to short- and medium-term interventions in adult or student populations. **Future studies should assess the effectiveness, acceptability, and utility via long-term studies and in different populations subgroups**.
2. The digital divide is an enormous and complicated issue heavily interwoven with issues of social inequality. **It is important to guarantee that interventions are designed considering inequality** and special effort made to ensure that those most in need of care can access interventions.
3. Concerning development of DHTs, interventions should be **developed together with the relevant stakeholders** and include elements that have been demonstrated to increase effectiveness, such as using theory or establishing multicomponent interventions over long periods.
4. **Develop and validate new theories and behaviour change models** that fit the demands of emerging technologies that interact more frequently with the individual and don't assume a static relationship between risk and protective factors.
5. Conduct a **comprehensive review of DHTs develop by the alcohol industry.**
6. Develop evidence on how to **better safeguard and protect the privacy** of patients.

Recommendations for policy makers

1. There is a wide range of DHT solutions in the market; nationally and internationally. It is important to build a more robust regulatory framework to guarantee safety, effectiveness, and accessibility. Standards should cover:
    a. Privacy and security
    b. Minimum technical, clinical and integration system requirements to ensure the safety, effectiveness and usability of DHTs for patients
2. Establish **harmonised testing, reporting, classification and accreditation processes**. Nevertheless, this process should be mindful of not being too costly or lengthy.

3. Promote use of the EC Best Practice Portal to support exchange of digital best practices related to alcohol consumption and encourage researchers to enter their interventions and findings.
4. **DHTs should reach all the population regardless of socioeconomic level or place of residence.** Further developments in ICTs are key to advancing digitalized and equitable healthcare.
5. **Increase population technological literacy,** so users are aware of what they are consenting to when they agree to the terms and conditions of a digital application.
6. **Foster interoperability** between platforms to avoid duplicating data and optimise care pathways.
7. Further support Member States to launch national **strategies to boost health professionals' digital skills** and raise awareness of the benefits that DHTs can bring to clinic practice.

Topics recommended for discussion

1. How can Member States design policy to promote more equitable and sustainable access to digital health tools to tackle alcohol problems?
2. Which are the priority settings for eHealth approaches to tackle alcohol consumption and problems and how can policy promote engagement with stakeholders in these areas?
3. What are the key areas that that future studies of DHTs should focus on? e.g. effectiveness, scalability and implementation?
4. Should public health practitioners and policy makers be concerned about the involvement of the alcohol industry in the development of DHTs for alcohol use? Should, and how can, this be regulated?

Conclusion

The potential of DHTs is enormous and the digital transformation of care and public health is already underway. The application of DHTs for alcohol prevention and treatment is an exciting and rapidly growing field. The ability to provide interventions in a flexible and tailored manner holds considerable promise; however, it poses many challenges that need to be overcome to exploit their full potential. It is vital to set a strong evidence base, from which we can explore the possibilities that DHTs offer.

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Annex 1. The situation in the hosting member state, Spain

Consumption in Spain

Approximately 9% of the Spanish population consume alcohol on a daily basis (1) and five percent of the population aged 15-64 show a pattern of risky alcohol use (6.7% men; 3.7% women) (2). Addressing alcohol related harm is one of the largest public health challenges in Spain with alcohol causing significant health and social harm affecting individuals, communities, families, and the economy. As is frequently seen in other countries there is a social gradient when it comes to alcohol-related harm in Spain with the most disadvantaged groups suffering the most harm (2).

Current official advice in Spain states that there is no risk-free level of alcohol use, however, below 10g/day for women and 20g/day for men is considered "low-risk" (3). An estimated 18.6% of those aged 15-64 drink at above these levels (2) putting them at greater risk of non-communicable diseases including cancer, being involved in an accident, and needing treatment for an alcohol-related cause.

There is a visible gender difference in drinking among people aged 15-64 years in Spain, with men consuming more alcohol than women overall, except in the 14 to 17 years age group where girls consume more than boys (1, 4).

Alcohol and young people

The average age for first trying alcohol in Spain is 14 years according the Survey on Use of Drugs in Secondary Education (ESTUDES), for both sexes. In the same study, 47% of boys and 52% of girls between 14 and 17 reported having been drunk at least once (2).

Among this age group rates of alcohol consumption are higher for girls than boys both for binge drinking and for alcohol consumption overall (4).

Binge drinking is rising in Spain, particularly among young people, with 32% of 14-18 year-olds having practiced binge drinking during the previous month. Among young people early initiation to drinking, binge-drinking and drinking to drunkenness are a target area for prevention efforts (2) within broader action such as pricing policies, restrictions on availability and restrictions on advertising, sponsorship and promotion of alcohol (5)

Health impact of alcohol use in Spain

Between 2010 and 2017 there were over 15 000 alcohol-attributable deaths in Spain, with over half of these being in people under the age of 75 (6). In 2019 over 27 000 people were admitted to treatment for alcohol abuse or dependence, and alcohol use was the legal drug present in 40% of emergency admissions related to drug use[2] (2).

Despite alcohol use being the leading disease risk factor among 15 to 49 year olds in Spain (3) perception of risk associated with alcohol use is low in Spain and there are strong cultural issues when it comes to alcohol consumption. Concerningly, only half the Spanish population consider binge drinking (more than 5 or 6 alcoholic beverages in one session) on the weekend to be a health risk (1).

[2] In Spain emergency admissions related to drugs only record alcohol use when in conjunction with another substance

Policy actions to address alcohol related harm in Spain

Alcohol use is considered both within the context of drugs and addictions, and of health promotion and prevention. National surveys, research studies and other information systems as well as EU level strategies and strategies from other countries inform policy and actions in these areas.

The Spanish National Strategy on Addictions 2017-2024, developed in collaboration with public administrations, NGOs, research centres and other stakeholders, builds on two previous strategies (National Drugs Strategy 2009-2016 and National Drugs Strategy 2000-2008) and the three Action Plans developed under these (the National Action Plan on Drugs 2005-2008, and the Action Plans on Drugs covering 2009-2012 and 2013-2016). The 2017-2024 Strategy also draws on the EU Drugs Strategy (2013-2020), on the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) Strategy 2025, and other national strategies from countries such as Germany, UK, Italy, France, Sweden and Australia.

The Action Plan on Addictions 2021-2024 outlines actions to achieve the objectives of the National Strategy organised around goals and defined actions. Among other areas it includes action on a program for early detection and brief intervention for alcohol use in health services and identification, evaluation and implementation of ehealth tools (7).

The Government Delegation for the National Plan on Drugs (Delegación del Gobierno para el Plan Nacional sobre Drogas, DGPNSD) is responsible for the general coordination and supervision of the services whose remit is to update and implement the National Plan on Drugs in Spain.

The **Strategy for Health Promotion and Prevention in the National Health System** (Estrategia de Promoción de la Salud y Prevención en el SNS) was implemented in 2013 and includes alcohol consumption as one of the principal risk factors for chronic and non-communicable disease (8). The Strategy supports integration and coordination for health promotion and prevention between all levels, sectors and stakeholders and aims to strengthen universal primary prevention and health promotion considering equity and the social determinants of health.

The Strategy includes evidence based information on healthy lifestyles aimed at health professionals, the general population and specific groups (including pregnant women, young people, older people)[3]. In 2020 the Ministry published revised guidance on low-risk alcohol consumption emphasising that the only completely safe level of consumption is no consumption and that the health risks increase with consumption over 10g/day for women and 20g/day for men (3).

In 2020, the Ministry of Health, launched a Working Group for Alcohol Use Prevention, comprising professionals from the autonomous cities and communities and professionals from the Health Ministry. This group identified a series of actions to establish a roadmap for addressing alcohol use including: 1) Promoting the prevention of alcohol consumption as a public health priority prevention; 2) Establishing a common framework for the prevention and treatment of alcohol consumption; and 3) Coordinating health care for prevention and treatment of alcohol consumption in the National Health System with a focus on equity.

Actions and strategies to reduce alcohol-related harm are based on current evidence and align with international strategies such as the WHO Global Strategy to Reduce the Harmful Use of Alcohol (9),

[3]https://www.sanidad.gob.es/profesionales/saludPublica/prevPromocion/Estrategia/estrategiaPromocionyPrevencion.htm
https://estilosdevidasaludable.sanidad.gob.es/home.htm

the WHO SAFER Initiative (10), Objective 3.5 of the UN Sustainable Development Goals, and national strategies, along with local and regional plans.

Digital health strategies

The Digital Health Strategy of the National Health System

The Digital Health Strategy of the National Health System (2021) aims to contribute to the health of the population and strengthen the public health system by taking advantage of the potential of digital technologies. The strategy provides a framework for the development of initiatives and actions by the various health administrations which supports the National Health System to undergo a coordinated digital transformation (11).

eHealth within the National Drug Plan

Within the National Drug Plan, eHealth tools are considered in Action Area 1: Integrated and Multidisciplinary Care. The Plan proposes the use of eHealth tools to achieve the following objectives: To identify users and problem users who don't access treatment, especially cannabis users and; To improve adherence to treatment. The objectives are to be achieved by:

- Reviewing the eHealth tools available in addictions
- Designing eHealth tools
- Disseminating and implementing eHealth tools.

In recent years the number of actions funded and the amount of funding for eHealth initiatives by the National Drug Plan has been progressively increasing with both the number of eHealth programs and the amount of funding doubling between 2017 and 2020 (12).

National and regional online and digital actions to address alcohol consumption

A number of online and digital initiatives at the national and regional level have been implemented in Spain. These include resources and support for health professionals to integrate screening for and addressing alcohol use in their daily practice, and for the general population to provide information about the risks of alcohol use, including for specific populations such as pregnant women and where to access help to reduce drinking.

Mójate con el alcohol

https://www.sanidad.gob.es/gl/profesionales/saludPublica/prevPromocion/Prevencion/alcohol/mojateAlcohol.htm

Mójate con el alcohol is an online training resource directed at health professionals to support them in integrating screening for risky alcohol use and brief interventions into their daily practice. It is a collaboration between The Spanish Society for Community and Family Medicine and the Spanish Ministry of Health. Over 3500 health professionals have been trained.

Beveu Menys (Drink Less) – Catalonia

http://beveumenys.cat/index.aspx

For primary health care professionals Beveu Menys targets primary health care professionals and the general population, especially this at risk of harmful alcohol use. It offers training and support to

health care professionals for managing alcohol use and resources and information for the general population about alcohol use and where to get help and support.

Estilos de vida saludable (Healthy lifestyles) web site, Ministry of Health

https://estilosdevidasaludable.sanidad.gob.es/consumo/home.htm

The Estilos de vida saludable web site provides information to consumers on leading a healthy lifestyle. It brings together information on physical activity, smoking, healthy eating, safety and accidents, emotional wellbeing and alcohol use. The site includes information on unit sizes, low-risk consumption and tools for consumers to assess their own alcohol use and personalised advice for reducing alcohol-related risks. Two online tools allow users to access information advice about their drinking:

¿Cuánto bebo? (How much do I drink?) Is a questionnaire to help users to calculate how much they drink. https://encuestas.msssi.gob.es/limesurvey/index.php/481849?lang=es

¿Tengo que preocuparme? (Should I worry?) Is a questionnaire to help users identify their drinking pattern and offers personalised advice for reducing associated risks. https://encuestas.msssi.gob.es/limesurvey/index.php/768276?lang=es

European collaboration

Within alcohol use and digital/eHealth Spanish health and research organisations have collaborated in a number of European actions, particularly in screening and brief interventions. For example:

The Joint Action on Reducing Alcohol Related Harm (RARHA https://rarha-good-practice.eu/) 2014-2016 was funded by the European Union under the second EU Health Programme and was aimed at supporting Member States to take forward work on common priorities in line with the EU Alcohol Strategy and to strengthen Member States' capacity to address and reduce the alcohol related harm.

Committee on National Alcohol Policy and Action (CNAPA https://ec.europa.eu/health/alcohol/overview_en#committee-on-national-alcohol-policy-and-action-cnapa) under the EC (closed July 2021), was composed of national delegates and played a major role in facilitating cooperation and coordination between EU countries, and contributing to policy development. Its main objectives was sharing best practices and seeking convergence of national alcohol policies within the EU.

The ODHIN Project (https://www.odhinproject.eu/) focused on the implementation of identification and brief intervention (IBI) programmes for hazardous and harmful alcohol consumption in primary health care (13).

The EFAR study, a randomised trial in Catalonia compared facilitated access by primary healthcare professionals to a web based brief intervention to standard face-to-face brief interventions (14, 15).

The DEEP SEAS, FAR SEAS and AlHaMBRA Projects (https://www.deep-seas.eu/, https://far-seas.eu/)

These three EC funded projects aim to build capacity in EU Member States for policy response and action in relation to alcohol related harm. They included a series of intersectoral workshops around a range of alcohol-related areas including advertising and marketing, taxation and pricing policy, cancer, fetal alcohol spectrum disorders, digital approaches (this workshop), and labelling; as well as research reviews, pilot projects and guideline development.

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Annex 2. Peer-Review Report on first draft

AlHaMBRA Project - Background Document to the Thematic Workshop *Application of eHealth Tools to Reduce Alcohol-Related Harm*

The comments contained in this reviewer report have been considered and addressed in this version of the briefing document. The report will be finalised following the workshop to include learnings from the workshop outcomes.

This report is intended to compliment the information provided in the briefing documents and executive summary which have the aim of giving relevant background information to the participants of the AlHaMBRA workshop - *Application of eHealth Tools to Reduce Alcohol-Related Harm.*

The workshop objective is to facilitate clear communication and exchange of perspectives and priorities, and to establish sustainable connections which can endure after the events to enhance and promote health in all policy initiatives. To achieve this, participants need a grounding in the topic which enables them to join in discussions and address the most relevant overlapping cross-sectoral concerns.

Reviewer: Professor Emeritus Paul Wallace, Clinical Director Digital, Health Innovation Network; Academic Lead, DigitalHealth.London Generator; Professor Emeritus Primary Care, UCL

Title of background document: Application of eHealth Tools to Reduce Alcohol-Related Harm

Short biography – Position, institution and background in the field:

Professor Paul Wallace is an academic general practitioner of international stranding. He is Professor Emeritus of Primary Care at UCL, Clinical Director Digital at the Health Innovation Network, London UK, and former Director, NIHR Primary Care Research Network. Paul is internationally renowned for his pioneering research on screening and brief interventions for alcohol in general practice and on digital health evidence generation. He is past President of the European General Practice Research Network and co-founder of the European Society of General Practice/Family Medicine. He was Chief Medical Advisor to the alcohol awareness charity, Drinkaware between 2009 and 2016. He is a Fellow of the Royal College of General Practitioners and the Faculty of Public Health Medicine at the Royal College of Physicians and in 2013 he was awarded the RCGP President's Medal.

His early work concentrated on research into screening and brief interventions for excessive alcohol consumption. His first multi-centre trial involving the UK MRC General Practice Research Framework reported in 1988. Subsequently, working with Elizabeth Murray, Stuart Linke, Jim McCambridge and others, he went on to explore the potential to apply internet-based digital technologies to deliver interventions to people with alcohol problems. This work led to the development of the Down Your Drink website www.DownYourDrink.org.uk and subsequently to a large scale on-line randomised controlled trial of which he was the chief investigator. Paul's most recent work has concentrated on the potential for digitally mediated alcohol interventions to be used in primary care settings and he has led an international programme of research into the effectiveness of GP facilitation of digitally mediated screening and brief interventions for alcohol problems.

Global evaluation of the briefing document:

Overall: Useful document but would benefit from substantial revision to achieve greater consistency and clarity for the reader.

Executive summary: needs to be expanded to include key findings, discussion of the key messages to be inferred from the findings and recommendations

Methods: there needs to be clarity about what work was undertaken and by whom with appropriate reference methods adopted eg for the comprehensive review methodology and the SWOT analysis.

Findings: need to be substantially re-ordered so that they are set out clearly and in accordance with the key questions which the review was designed to address (pp6)

Recommendations for researchers and DHT developers: important to ensure that these correspond clearly to the findings of the review. If possible go beyond simply highlighting the limitations of the evidence base, and endeavour to identify indications of potentially fruitful pathways to overcome these.

Recommendations for policy makers: these are currently very broad and as a result risk being written of simply as a "wish list" If possible, you should define more precisely realistic steps which policy makers could implement, and/or a pathway to eventual achievement.

Specific areas or messages to add or amend: I have made comments and amendments throughout the document. I recommend referral to these. You make little reference to mechanisms for enhancing user/patient engagement including gamification, financial incentives and facilitated access. There is a literature about these which you should consider (see below)

Further references or information of interest in this area:

Gamification:

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Facilitated access:

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Standardisation of reporting studies on DHTs

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