Medicines &
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Regulatory Agency

Digital Mental Health Technology:

Research on identifying and reporting harms associated with the use of DMHT and awareness of the MHRA Yellow Card Scheme

Research report from Woodnewton

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James Humphreys
Mark Gill
Zaaki Ahmad

Contents

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James Humphreys
Mark Gill
Zaaki Ahmad

Executive Summary

The research aimed to explore how current or potential users of digital mental health technology (DMHT) (including carers, family and friends) and intermediaries (such as healthcare professionals (HCPs), therapists, mental health support workers and school safeguarding leads):

- Understood the potential for harm posed by DMHT.
- Might recognise the occurence of harm to themselves of others.
- Could be encouraged and facilitated to report harm via the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card scheme, including through integrating reporting into apps and app stores.

The research included 24 focus groups with adults identified as current or potential users of DMHTs, including those with diagnosed mental health conditions and those with prior experience of using DMHT; six focus groups with children and young people; and 30 in-depth interviews with a range of intermediaries in health, care and education.

The focus of the report is on the perceptions held and expressed by participants. These may not be accurate: one of the main reasons for conducting this kind of research is to understand the differences between perceptions and an objective reality. This means that the perceptions reported in this report should not be interpreted as providing a true and complete picture, for example in relation to the care provided by the health, care or education systems in the UK. In particular, they should not be seen as an endorsement or criticism of any individual product or service.

DMHT Perceived Risks

Most users had some experience of using apps to support their mental health or wellbeing, though few if any recognised the term DMHT. Many did not think DMHT posed any risk. If an app did not work, they would just

stop using it. They were much more concerned about the wider problems caused by social media and other digital technologies, including causing or contributing to isolation, anxiety, depression and self-harm. Some did have specific concerns, and these were shared by intermediaries:

- **Screen time.** It would contribute to excessive screen time and could make conditions or symptoms such as isolation or alienation worse.
- **Financial exclusion.** The apps were developed more to make money than to help users, and those who could not afford the apps would be disadvantaged.
- **Use of AI.** Where AI was being used to replace human treatment and support, this would in many cases make problems worse.
- **Self-treatment.** Using DMHT in isolation from professional support would exacerbate risks such as misdiagnosis or managing suicidal ideation.
- **Misdiagnosis.** DMHT could provide false or misleading diagnoses, and this might prevent users from seeking appropriate help or reinforce negative self-image or behaviours.
- **Addiction and isolation.** As with other digital technologies, DMHT could be addictive and divert users from developing human connections or undertaking real-world activities.

Participants recognised that these risks would be hard for users to recognise for themselves, which underlined the need for DMHT to be used in a supervised way and ideally as part of a care plan supported by family and friends. DMHT itself could support this by allowing HCPs or others to access data on how patients or clients were using it or for the app to monitor and 'check in' with users who were displaying concerning behaviour.

Reporting Concerns

Most users said that, even if they recognised or suspected harm from using DMHT, they would not make a report or provide feedback because they would not know how, or would expect it would make no difference, or it would be hard to do while also struggling with their mental health condition. The one exception was if the DMHT had been provided or recommended by an intermediary in which case they were likely to inform them directly.

Users felt that if there was a simple and reliable way to provide feedback, they might do so. Some felt feedback should go direct to developers, but others thought there needed to be an independent body, similar to an ombudsman or regulator.

Integrating Yellow Card

Few users had heard of the Yellow Card scheme. None – including HCPs and other intermediaries – spontaneously linked the need for a reporting route for

harms arising from DMHT to the Yellow Card scheme. But almost all thought that if Yellow Card were the appropriate route, then all DMHT users should know about it and be able to access it easily. However, there was a strong view that there should be a single feedback channel covering both positives and negatives, which could then link on to Yellow Card. This could also lead to advice and support (as with campaigns such as Drinkaware).

Information on risks and reporting should not rely on a single channel but could include:

- **First use.** When users first signed up for or downloaded an app (similar to a patient information leaflet for medicine, but much shorter and clearer).
- **Periodic 'check-ins'.** The app would ask users for feedback on how well it was working and if it was causing any problems. Any strongly negative reactions could be escalated, including a link to Yellow Card.
- **Monitoring.** If the app itself detected worrying patterns of behaviour (and some users were open to AI being used to monitor usage, though others had reservations).

Users also thought that, in support, information and awareness of DMHT safety and Yellow Card should be promoted through NHS contact-points such as GP surgeries and the NHS app.

Intermediaries did not generally see DMHT as risky. However, they did see social media, smartphones and other digital products as potentially very harmful. In some cases they would not recommend DMHT and might advise clients or patients to stop using it. Some had limited support in using DMHT with their clients or patients, such as access to lists of products specifically approved by or for their care setting. Others had to rely more on word of mouth and would welcome authoritative guidance and support, including on how to share concerns and with whom.

1. Introduction

1.1 Aims of the Research

The core aim of the research was to explore how the system for identifying and reporting harms arising from the use of digital mental health technology (DMHT) could be strengthened, including through integration with the Yellow Card scheme operated by the Medicines and Healthcare products Regulatory Agency (MHRA). This covered both current or potential users of DMHTs (including carers, family and friends) and intermediaries (such as healthcare professionals, therapists, mental health support workers and school safeguarding leads). Specific research aims included:

- The ways in which users and intermediaries understood the potential for harm posed by DMHT.
- How they might recognise the occurrence of harm to themselves or others.
- Potential barriers to reporting.
- How they could be encouraged and facilitated to report harm via the Yellow Card scheme, including through integrating reporting into apps and app stores.
- Specific differences or considerations relating to children and young people or to other groups of users.

This project builds on 'Digital Mental Health Technology: User and Public Perspectives' which reported on research carried out by Woodnewton and published by MHRA in April 2024. That previous research is cited at several points in this report.

1.2 Method

For the research, Woodnewton adopted a qualitative approach: that is, open and exploratory discussions in small groups or one-to-one interviews steered by a moderator or interviewer. This was best suited to elucidating people's perceptions and experiences, particularly as DMHT is a relatively new area of discussion and many participants would

not have direct experience of DMHT products and might not have thought about potential risks and benefits.

There were three groups of participants: current or potential adult users of DMHT, young people (aged between 13 and 17 years) and health, education and social care professionals who might recommend DMHT to those in their care or otherwise act as intermediaries.

In total, 200 participants took part in this research project and the detailed profile is set out below. 24 focus group discussions were held with adult users and potential users of DMHT and six focus groups were held with young people aged between 13 and 17. The intermediaries were engaged primarily through 1:1 depth interviews, with a small number of the discussions organised as paired depth interviews.

The focus groups and depth interviews both followed a semi-structured approach, in which the moderator or interviewer follows a 'topic guide' which sets out the broad themes and questions to be covered, but provides flexibility so that participants can raise points of their own and express themselves in their own words. The topic guides were informed by Woodnewton's previous work on DMHT for the MHRA and through discussions with the client to refine the questioning and ensure applicability to this particular area of enquiry.

The focus groups typically lasted 90 minutes for the adult groups and 60 minutes for the groups with young people. The depth interviews normally lasted between 30 and 45 minutes. Most of the focus groups were conducted online with the remainder in-person. The profile of the groups were designed so that we covered a breadth of different types of participants (for example by gender, age, whether they had a diagnosed mental health condition and prior DMHT usage).

The research used a grounded theory approach in which tools such as coding are used to identify themes and patterns within the fieldwork evidence, rather than gathering evidence to prove or disprove a pre-existing theory. This approach is widely used in social research and helps ensure the findings are rooted in participants' own experiences and interpretations. The analysis also used a dynamic theory of change model in which findings were structured and interpreted using a behavioural model covering people's awareness and understanding of the subject area, and their actual or likely behaviour in different circumstances. The model was used dynamically in the sense of being refined to reflect emerging findings as the fieldwork and analysis progressed.

The analysis was run in parallel with the fieldwork so that findings could be fed back into the fieldwork. For instance, we made two significant updates to the core topic guides throughout fieldwork (in discussion and agreement with the MHRA) to reflect emerging issues and

priorities. The change model evolved during the analysis including identifying and exploring factors which would either encourage or discourage change ('drivers' and 'barriers'). The analysis also considered the language used by participants, including comparisons and imagery, which could inform future communications and engagement.

1.3 Sample profile

Woodnewton utilised two channels to identify and recruit participants for this study, replicating a similar approach used for our previous research on DMHT. The majority of participants were recruited by a specialist qualitative recruitment agency, Roots Research, who have a database of around 500,000 UK residents who had previously indicated their willingness to take part in research. Demographic data is held about each participant so that research invites can be sent to specific groups who are then asked to complete a screening questionnaire before potentially being invited to take part. This enables the research team to target specific demographics and criteria.

To support the main recruitment channel, we also worked with a Multi-Academy Trust (MAT) to organise four in-person young people focus group sessions across two of its schools in England. These young people were recruited by their schools and were not recruited based on any screening of mental health conditions or concerns (although some did have and chose to articulate this in the group discussions).

Table 1 shows the profile of the adults who took part in the focus group discussions by different demographic criteria.

Table 1: Adult participant profile by demographic criteria

Category	Number
Male	53
Female	76
Non-binary	2
18 – 29 years	43
30 – 44 years	47
45+ years	41
White	79
Non-white	52
Based in England	111
Based outside England	20
Diagnosed with a mental health condition	93
Undiagnosed (self-reported) mental health condition	36
Had an adverse reaction to medicine / medical device	59
Parent / guardian of a child user of DMHT	10
Carer of an adult user of DMHT	6
Total	**131**

In addition, a total of 39 young people took part in the six focus group

discussions four held in person and two online). The in-person sessions were organised by individual schools within the MAT and the two online groups were recruited from the Roots database. Twenty-two of these participants were male and 16 female. All were aged between 13 and 17 years old.

Thirty intermediaries were also interviewed as part of this research. For this part of the sample, we aimed to cover a broad range of professionals involved in health, education and social care. The breakdown of the intermediary sample is set out in Table 2.

Table 2: Intermediary participant by profession or role

Category	Number
Children's social workers	5
Adult social workers	5
GPs	3
Psychological wellbeing practitioners	3
CBT therapists	3
Mental health nurses	3
School safeguarding practitioners	3
Principals / Vice Principals	2
SEND (Special Educational Needs and/or Disabilities) practitioner	1
Psychiatrist	1
Clinical psychologist	1
Total	**30**

1.4 Interpreting qualitative research

With qualitative research, there is always a question of the extent to which the findings from the sample of participants can be extrapolated to the wider population. For example, we cannot say that a certain percentage of the population hold a particular view or behave in a particular way. With this project, we have heard from a relatively large number of participants and these have been selected to provide a sample which is broadly representative of the UK population in terms of age, ethnicity, sex, social class and place of residence. This allows us to say that their views or behaviours are highly likely to reflect in broad terms those of the public or, in this case, those with some form of diagnosed or undiagnosed mental health condition.

In the report, we have used terms such as 'some' or 'many' as a guide to the prevalence of these views or behaviours amongst participants; and also, our judgement about the likely prevalence in the wider population. Similarly, we have included verbatim comments from participants where these are broadly representative of their experiences both within the research and in society more widely.

The focus of the report is on the perceptions held and expressed by participants. These may not be accurate: one of the main reasons for conducting this kind of research is to understand the differences between perceptions and an objective reality. This means that

the perceptions reported in this report should not be interpreted as providing a true and complete picture, for example in relation to the care provided by the health, care or education systems in the UK. In particular, they should not be seen as an endorsement or criticism of any individual product or service.

1.5 Ethics and Safeguarding

Adult participants were invited to take part on the basis that they had some form of mental health concern, but it was made clear to them that they were under no obligation to share any personal information if they did not feel comfortable doing so. They were also informed that they were free to end participation at any time if they wished. They were paid an incentive to take part, to ensure a more representative sample and to maximise inclusivity. This payment was not linked to completing the interview or focus group, so would not induce someone to continue to participate when they would rather not.

1.6 Theory of Change

To provide a framework for the research and analysis, we developed a simple behavioural change model (or theory of change), drawing on previous research. This posited a series of stages which would need to be completed for someone to report an adverse event relating to DMHT, along with a series of potential motivating factors, barriers and distractions. The theory of change was developed further during the course of the fieldwork and analysis. The main stages were:

- Understanding that DMHT had the potential to create an adverse event.
- Recognising that an individual might be experiencing or had experienced an adverse event.
- Knowing that there was a reporting mechanism.
- Feeling confident and motivated to report that event.

We also explored the frames of reference that users of DMHT might deploy when thinking about how to respond to any concerns. For example, they may have had concerns or complaints about other apps, or with healthcare professionals, or have heard from friends and family or through the media about how to raise concerns or make complaints in areas such as financial services or inline shopping. The more the expectations they bring to DMHT from the rest of their lives are understood, the more the reporting system for DMHT can be designed to facilitate the process.

Redress and the Public Interest

This also allowed us to probe a significant difference between the Yellow Card scheme and other mechanisms established to allow people to raise concerns or make a complaint, such as for financial services.

Our theory of change identified two core

motivations for those raising concerns or making complaints: to seek redress for themselves or those close to them, which may be support or compensation; and to help ensure that others do not experience the same harm in future. For some, there is also the desire that the individual or organisation seen to have done them harm would be held to account or punished, which could be seen as a form of redress and also contribute to the individual or organisation repeating the harm on others.

Most statutory complaints processes reflect this, with the complainant encouraged or actively required to use the complaints process of the service provider to secure redress. In such cases the regulator or ombudsman role is limited to oversight of the complaints process and stepping in if the process is not producing the right outcomes. That role also may include capturing complaints data, highlighting systemic failures and protecting the wider public interest including ensuring others do not experience the same harm. Everyday examples for consumers range from the ATOL Protection scheme for package tours to the Financial Conduct Authority. The approach is also common to professions with statutory standing such as lawyers and architects, and there are comparable private-sector examples such as Ebay and Amazon Marketplace.

In healthcare, where the complaint relates to a medicine or medical device, the complainant will usually need to seek redress from the company that holds the marketing authorisation that allows it to place the product on the market. The Yellow Card scheme provides a separate path for helping ensure information is gathered that could mean that others do not experience harm in future. Although originally designed to allow healthcare professionals to report adverse events amongst their own patients, patients, carers and members of the public can submit a report themselves.

Whether submitted by an individual or a healthcare professional, a Yellow Card report will not lead to any additional treatment or support or any redress or compensation. In this sense, the scheme is closer to a more altruistic process such as giving blood or taking part in medical research, compared to a 'classic' consumer complaints process.

This has two implications which were incorporated into the scope of the research: understanding more about frames of reference and expectations; and exploring what motivations for reporting through Yellow Card would help balance the lack of personal benefit from so doing.

1.7 Stimulus Material

Our previous research had shown a relatively low level of awareness of some of the more complex DMHT products or features now entering the market, such as those using remote monitoring or forms of Artificial Intelligence (AI). Participants were then given information

about a range of DMHT to illustrate some of the different ways in which the technology was being employed, the kinds of people who might be using it, and some of the design features and capabilities of the products. These included DMHT that:

- Provided secondary school-age children with advice and support to promote their mental well-being, including a moderated forum and access to trained counsellors.
- Used a camera-based device for mental health patients in a residential setting to allow their sleep and movement to be monitored at night, allowing staff to intervene when necessary instead of carrying out regular night-time in person observations.
- Integrated self-reported mood tracking with data from a smartwatch, medication data and patient records to give GPs an integrated picture of each patient, with prompts to alert them if there were signs that patients were struggling.
- Used a range of tools including self-reporting and CBT exercises to help people address disturbed sleep patterns.
- Offered self-diagnostic tests for a range of mental health conditions such as anxiety, Post-Traumatic Stress Disorder (PTSD) and Attention Deficit Hyperactivity Disorder (ADHD), with links to therapists who could offer a paid-for consultation and potentially follow-up treatment.

1.8 Terminology

The term DMHT covers a wide range of products and many of these, for example software used to process and prioritise information in an electronic health record, would not be encountered by members of the public. Although there was some discussion of attitudes towards these 'behind the scenes' products, most of the time participants talked about 'consumer DMHT' that they might encounter in their everyday lives or make choices about using.

Participants also tended to talk about mental health 'apps', as these were the DMHT products they were familiar with, and also to use 'apps' to cover a wider range of digital products, even if these might be accessed using a computer rather than a smartphone or tablet. To reflect this, we have used the term 'apps' in this report alongside DMHT as shorthand for 'mental health apps and other public-facing digital products'. Similarly, participants frequently used the term 'social media' to include content platforms such as YouTube and Reddit which do not rely on users to develop a social network.

1.9 Report Structure

This report has the following structure:

1 Introduction

2 The frames of reference that users of DMHT might apply to identifying or acting on concerns

3 Their perceptions of the potential risks of DMHT.

4 How they would go about raising a concern.

5 How participants perceive the Yellow Card scheme and its relevance to DMHT.

6 How the Yellow Card could be integrated into DMHT apps and be disseminated through other channels.

7 The perspectives of intermediaries and other professionals.

8 How the issues in the report relate specifically to children and young people and to other groups who may be particularly vulnerable or face specific challenges.

9 Conclusions and recommendations.

2. Frames of Reference

Key Findings	People are reluctant to complain about apps: they just uninstall them.
	Even if an app goes wrong, they often blame themselves.
	If they do complain, the main motivations are to seek redress, or to stop someone else having the same bad experience, or both.
	Lack of knowledge about routes for complaining are not a major barrier: if they want to complain, they will find out how to do it.

2.1 Acting on Problems with Apps

Our theory of change posited that users of DMHT would draw on their experience with other apps or digital technology, and this would extend to how they might act if they thought the apps were not functioning properly or had the potential to cause harm. We therefore explored with participants what experiences they had had with apps going wrong, and what if anything they had done in response.

Participants shared and discussed their experiences of apps or similar digital technology that had failed or otherwise let them down and caused them serious problems. We then explored what if anything they had done; and if they had not had direct experiences, what they thought they might do.

Participants made a clear distinction between three classes of apps and their likely actions:

- With the apps they **sourced themselves**, most participants thought that, in the majority of cases, they would be reluctant to take action, mainly on the basis that this would either take a lot of time and effort, or not achieve very much, or both. In most cases they would simply uninstall the app and put it down to experience.
- Where the app might have been **recommended by a third party**, such as a fitness app provided through a company wellness plan, some participants thought they would go first to that third party. Others thought they might contact the developer, or that the third party might direct them to the developer anyway.
- Where the app was part of a **wider service**, such as an app for online banking or buying railway tickers, participants said their first action would be to contact the customer services of that company. Some noted that this was a problem when the company's business model was to channel customer contacts through the app.

Participants felt that the actions they might take, if any, also depended on the seriousness of the impact or harm and the type of app or the role it played. If they had suffered a financial loss, for example, they were more likely to pursue it. If the app related to a sector that was perceived as being more closely regulated, such as financial services, they were again more likely to take some form of action.

Participants also distinguished between those they felt were responsible for the performance of the app; and those who might act on any concerns. For most, it was the developers who had the greatest responsibility. Then came those who might have provided or recommended an app, and this in turn ranged from those with only a light responsibility (for

example, a magazine article reviewing a number of apps) to those where their involvement and so responsibility was greater, such as a school or employer providing or recommending a specific app.

There was a feeling that app stores should have some responsibility for the effectiveness and reliability of the apps they sold, but that generally they would not exercise this responsibility. Similarly, some felt that government agencies ought to play a role but generally did not or could not, particularly given the international nature of apps and the internet. This reflected the low awareness amongst participants of the existing regulatory framework for DMHT both in the UK and internationally.

2.2 Physical Health App

To explore attitudes towards health apps in general, participants in the focus groups were presented with a hypothetical example in which they were to imagine they were using an app to guide their fitness regime in a gym, such as using weights, and this gave them the wrong advice, causing them a serious back injury.

Many participants said that they were unlikely to take any action beyond stopping using the app. They would assume that they themselves were at fault either in how they had used the app, or for relying on what was only some generic advice the app was providing. They did not see an app as offering advice or support that could or should be relied on to that extent.

This sense of the use of apps being a matter of personal responsibility could work on several levels:

- The user might genuinely have misused the app.
- They might believe or assume they had done so.
- They might expect to be told they had misused the app and so would not bother raising a concern.
- Any remedy would be excluded by the app's terms and conditions, which would be drafted to exclude any liability (and which users would have agreed likely without reading).

Some participants said they would take action, which would include contacting the app developer's customer services. If the app had been recommended by an individual or organisation who ought to be a reliable source of advice (in this case, the gym or a personal trainer), they might seek a remedy from them. They might also leave a bad review or warn their friends and family. Very few saw the app store as being responsible for the quality or safety of apps they hosted, though they might leave a bad review on the app store.

Where it could be demonstrated that the app was at fault, most participants felt that the priority would be to fix the

problem or improve the app. It would be unrealistic to expect the app to be withdrawn. Some felt that they could or should be a regulator or ombudsman providing some kind of oversight or remedy. Others felt there would not, and if there were it would have little impact, given the nature of digital technology. Overall, most participants felt that you used apps at your own risk, and if they went wrong there would be few effective routes to raise concerns or secure a remedy.

2.3 Common Frames

The six most common elements which would form frames of reference were:

- **Self-blame.** If an app went wrong, they would assume it was their fault.
- **Do nothing.** Even if they felt someone else was to blame, they did not think they would benefit from complaining, or any benefit would be outweighed by the cost in time, effort and stress.
- **Make a complaint.** They would seek redress from the manufacturer or supplier through customer services.
- **Tell others.** They would warn friends and family or (through online reviews or forums) warn the wider online community.
- **Report it.** They would either know of or assume they could find the relevant regulator or ombudsman. Those cited most frequently were the Advertising Standards Authority, ATOL and Ofcom.
- **Seek help.** They would turn to an organisation providing advice and support, such as Drinkaware or GambleAware.

These were not necessarily actions that participants had actually taken (for example, a majority of participants were familiar with GambleAware but none said they had used it), but that they could imagine accessing in different circumstances.

Significantly, participants did not say they would do nothing because they weren't already familiar with the processes for complaint or redress. They were generally confident that if they were motivated to act, then they could find out who to complain to or report it to, for example by asking friends and family or searching the internet.

3. DMHT: Perceptions of Risk

Key Findings	Few people (even HCPs) think DMHT can cause much or any harm.
	But most people (including HCPs) think social media and screen-time are doing them or others a lot of harm.
	The main concern about DMHT is it will worsen those harms – such as alienation, isolation, depression and low self-esteem.
	There are also concerns about self- or mis-diagnosis, forums and safeguarding.
	DMHT is currently seen as low-impact and low risk, but AI could make it much more of a potential threat.

3.1 Awareness

As in our 2024 research 'DMHT: User and Public Perspectives', there was little or no recognition of the term digital mental health technology amongst public participants. Almost all participants thought that there would be products used in medicine that would be regulated, such as x-ray machines or blood pressure monitors, and that these might involve digital technology; but they still felt that the kinds of products they might use, such as apps on their smartphones, were very unlikely to be covered by this term. Clearly it would be helpful to have a term which was readily understood by potential users, as this would make the task of encouraging awareness of DMHT and the potential to report adverse experiences via Yellow Card easier. The research did not aim to test out alternative terms in a formal way, but participants tended to use phrases such as 'health apps', 'mental health apps' or 'medical apps'.

Many participants had some experience of using DMHT, even if they were not aware of the term. The products they mentioned included products which would be classified as DMHT, and other products which would not, even though they were being used to address mental health conditions as well as more general mental wellness. Channels such as YouTube and TikTok were frequently used to provide mental health advice, and some channels used for this purpose were also supported by DMHT providers through advertising or sponsorship.

Participants also referenced the NHS app and other technology used to interact with their GP or other HCPs, including online booking systems, electronic consultations (including by video link as well as by phone), e-prescribing and e-dispensing.

In short, participants had a mental picture of a range of digital products or channels that might be relevant to their mental health, which were not divided clearly – if at all – into 'medical' and 'non-medical' or 'regulated' and 'unregulated'.

3.2 Recognising Risks

If users of DMHT are to report potential harmful effects, they or those around them need to be able to recognise those effects. Participants were asked about their general perceptions of the risks that DMHT might create. At this stage, most participants saw individual DMHT apps as generally low-risk and low-benefit. Users did not expect them to be transformative, but rather to offer some useful support, for example through features such as meditation or mindfulness. As a consequence, very few participants thought of DHMT as posing significant risks.

The three main concerns expressed at this stage were:

Screen Time. DMHT could encourage people to spend more time using phones or other digital devices, and less time interacting

with other humans in the real world, which would be bad for their mental health.

Profit Motive. The perception that apps were generally unregulated and developers were strongly motivated by the desire to make a profit and so would not have the same concern for users as, say, manufacturers of medicines.

The use of AI. In part, this related to users spending more time on their phones and the lack of direct professional input. It also reflected wider perceptions that AI was unreliable and also unproven, with the potential for hidden risks.

Participants were then given more information about a range of DMHT to illustrate current and potential functions and uses. In the following discussion, three further concerns emerged:

Use in Isolation. DMHT lacked the professional judgement provided by a clinician or therapist, who could provide more tailored help and also identify risks such as suicidal ideation. As a result, participants felt it would not be as safe or effective as human interventions.

Misdiagnosis. It allowed users to self-diagnose, which might be helpful in some cases but also risked misdiagnosis and over-diagnosis. This in turn meant users might miss out on the right treatment, and it could also undermine people's mental wellbeing or medicalise normal experiences or fluctuations in life.

Dependency. It could become intrusive or even addictive, particularly through features such as alerts, reminders and gamification, making users more anxious or stressed.

3.3 Screen Time

Many participants were concerned that encouraging people to use DMHT would divert them from spending more time in the 'real world', including interacting with other people. Physical activities such as swimming, spending time in nature or taking part in social activities were all known to improve people's mental health. DMHT needed to be seen in terms of an alternative source of support as well as on its own terms, and the convenience and potentially addictive nature of DMHT might mean people use it more, even when they would be better served using it less.

> *"It can feel like a connection, but it doesn't replace a human being. You might not notice this if you rely on it too much and then you might not search for help elsewhere."*

3.4 Profit Motive

Several participants were concerned that DMHT developers would be overly motivated by the wish to make a profit

and would therefore design apps that were not appropriate or they would not respond to criticism or feedback. This might make them less inclined to use the app, even if recommended by a healthcare professional, or to report a concern to the developer.

This extended to advertising and endorsements. Many participants said they were wary of specific DMHT products that were heavily advertised (including sponsoring content creators to endorse the product) and this 'hard sell' put them off. In contrast, authentic endorsement from those who genuinely used and benefitted from the products were generally seen as positive and helpful.

Similarly, participants expressed concerns that any terms and conditions associated with DMHT would not be intended to genuinely inform potential users of the risks and benefits, but more to provide some legal cover. This may have implications if terms and conditions were relied on to allow potential users to make informed decisions about using the technology or to make them aware of how they could provide feedback or raise concerns, including through the Yellow Card.

> *"Maybe there are some legal things they have to do, but this will be more about protecting themselves from being sued."*

Financial Exclusion

There was a strong concern among some participants that potential users would see the benefits of some apps for themselves or others (including their children) but be unable to afford the subscription. Two classes of apps were particularly prone to this: those that offered a diagnosis, particularly when this led to being offered the contact details of (paid-for) therapists; and where the app offered free trials, where users would have a positive experience but be unable to continue with the app once the free trial had expired.

> *"Not everybody can afford a therapist. So I think people would end up going straight to the bot, because I don't have the privilege of having the therapist alongside that."*

3.5 Use of AI

Participants had three main concerns about the use of AI in DMHT:

- Unreliability.
- Alienation.
- Feedback loops.

There was also a wider feeling that AI was a potential threat to society as a whole because it was very powerful, its likely impacts were not understood, and it was being driven by unaccountable corporations pursuing profits.

AI Unreliability

While many participants saw AI as being very powerful (and therefore potentially creating significant threats) they also saw it as very limited: in other words, it was both trying to replace humans and failing. Most participants felt that a human would do a better job than AI in providing mental health diagnosis and support, largely because AI interactions were less personal and did not genuinely replicate the experience of engaging with another human. This included both AI-generated content (such as a diagnosis) and AI "chatbot' interactions. The latter were sometimes treated with some scorn, and it may be that some participants were influenced by the experience of chatbots in other settings, such as banking or other customer service apps, being of poor quality and failing to understand their questions or find solutions.

Though some were open to the idea that mental health AI would improve, others doubted that it would ever be able to appreciate the nuances of human interactions, including both non-verbal cues and the idiosyncratic use of language.

> *"What if I might say 'we'll kill each other' and the AI takes it seriously and alerts someone."*

Alienation

Although this was a concern with DMHT as a whole, alienation was particularly associated with AI. Some participants were very worried that using AI could undermine people's connection to reality, particularly if this were a feature of their mental health condition. Where a mental health condition was seen essentially as a disconnect between perception and reality, an intervention based on a computer program pretending to be a human was fundamentally problematic. Conversely, if the AI did not create the perception that the user was interacting with a human, then the potential value of the interaction would be reduced: for example, a human could genuinely motivate and encourage someone to commit to a treatment path, while interactions that were obviously being generated by a computer were likely to be less effective.

Feedback Loops

Some participants were also concerned that where AI was learning about and from its users this could create negative feedback loops in which negative perceptions held by the individual about themselves or others would be amplified and played back to the user. This was seen as a very severe potential risk, particularly if the AI was not being supervised effectively, as the user drawn into such a feedback loop would by definition be unlikely to recognise the experience objectively and so seek help or report it.

AI: Positives and Mitigation

Although participants expressed significant concerns about AI, they also

saw some positive roles: for example, being used to provide ongoing support between regular therapy sessions or monitoring how someone is using DMHT and flagging up potentially harmful behaviours. Sometimes participants who were dubious about using AI themselves could see that others might benefit from it, reflecting the wider view that not everyone would have the same experiences with DMHT.

> *"See, I had a friend who was using a kind of AI bot thing to help her as she struggles with her mental health, and she said that she would ask it questions, or speak to it as if it was a person. And she said that they were quite good responses."*

Further, where participants had concerns, these were often reduced if the AI itself was being overseen by a healthcare professional: for example, if a GP could review the advice being given by AI to their patient and intervene if they thought it was inappropriate.

3.6 Use in Isolation

Participants were strongly of the view that DMHT would be of most value, and work most safely, when used as part of an integrated approach to mental health care. Involving a healthcare professional (HCP) would help ensure that people were using the right DMHT in the right way and were supported to stick with it.

> *"If I'm just trying things out like these apps and one doesn't work for me, then I'll just try something else. But if I have been recommended it by someone who knows a bit more about me, then I would [persist]."*

Interacting solely with DMHT could mean the user missing out on the benefit of constructive criticism or challenge from an HCP, for example in how well they were managing their condition.

> *"There's a risk of feeding the app to get the answers you want."*

> *"If you're face to face with your doctor, you'll be more truthful."*

They felt there was always a risk that when someone's state of mind deteriorated, it increased the risk of not engaging with the treatment, and this applied to medication or therapy sessions with a human. But in these cases, there would at least be a supervising HCP who could monitor the patient's progress. Relying on DMHT alone removed this safeguard.

> *"If you're feeling anxious it can be really hard to break out of it and use the app."*

It would also help ensure that if users were struggling with their condition, or with the DMHT itself, an HCP would be able to recognise this and intervene.

> *"If I wrote 'I'm suicidal' there is no-one there who is going to respond to it."*

Participants also expressed other concerns about DMHT being used in isolation or without the HCP being informed:

- People might decide to use DMHT alongside other interventions such as therapy and if the relevant HCP was not aware of this, it might create an unhelpful burden or undermine the effectiveness of the other treatment.
- They might use non-DHMT apps to support their mental health, and these might create risks – for example, someone with an eating disorder using a calorie-counting app, or someone using an AI bot to provide mental health advice.

> *"A friend used ChatGPT as her therapist. She asked it to 'act as my therapist' and then 'design an intervention for me'."*

Participants saw the risks of using apps to self-treat mental health conditions as further underlining the need for a healthcare professional to have overall responsibility for an individual's care. This would also allow HCPs to gain more insight into the risks posed by different products in different circumstances, and this in turn would help regulators to adapt regulatory requirements accordingly.

3.7 Misdiagnosis

Many participants were concerned that DMHT could lead to misdiagnosis. Some felt that no app could take the place of a healthcare professional in assessing a patient and reaching a reliable diagnosis; others felt that even if some apps could help with diagnosis, it would be important for an HCP to confirm the diagnosis independently. There were also concerns about the transparency of the assessment process and the quality of the diagnosis, including a perceived lack of consistency.

> *"I was doing a bunch of these tests and somehow they were all coming out with different results."*

This was an area where many participants had clear and often strong views. Many felt that apps should not attempt to diagnose mental health conditions, even if there were caveats about it only being a guide and users being encouraged to contact a healthcare professional.

> *"If an app claimed to be able to diagnose mental health conditions, I would delete it immediately."*

There was concern about the risk of over-medicalisation of situations such as sadness, stress or anxiety which were essentially part of the human condition. Participants tended to assume that if DMHT misdiagnosed, it would usually err towards giving people a diagnosis when this was not appropriate, rather than failing to diagnose an actual mental health condition. This shaded into a sense that many users of DMHT would be looking for a diagnosis and might,

consciously or otherwise, to give the app misleading information.

Some participants expressed concern that a diagnosis obtained through DMHT would not allow the user to contextualise what the diagnosis meant for them, or what forms of treatment or support might be available to them. Some sites provided a summary of different conditions and links to further advice or support, but this was not personalised and did not allow for the discussions with an HCP which would allow the user to make informed decisions.

> *"You arrive on this site thinking you might have depression and leave worrying you might be bipolar."*

The practice of including a disclaimer that the DMHT was not seeking to give a definitive diagnosis and that users should always consult an HCP was dismissed by many as taking an unrealistic view about why people would seek a diagnosis and what they would do with it. This said, there were a significant minority of participants who thought that online diagnostic tools could be valuable in helping people to explore and understand their symptoms or experiences and seek further support.

Participants were also concerned about what the user would do with their diagnosis. They thought there should be a pathway to discuss or review the diagnosis with an HCP, though they appreciated this might not be practical and were wary of apps that provided a diagnosis function and then suggested the user sign up for paid-for therapy through the same app or website.

> *"Is it pushing people to therapy when they don't need it?"*

In contrast, some felt that DMHT might delay people receiving the appropriate diagnosis or treatment. Some had themselves had this experience.

> *"It's a risk if this pushes you away from other support and it might just be another way to stop you seeing your GP. This could mask an underlying issue."*

In discussing their concerns about diagnosis through DMHT, a number of participants referred to similar negative experiences that they had had within non-digital healthcare. These included mis-diagnosis, over-diagnosis (include the medicalisation of normal emotions), and receiving a diagnosis without access to treatment or support (or having to wait months to receive this). It would also be possible to provide an HCP with misleading symptoms or other information, wittingly or otherwise, face-to-face, although there was a general view that an HCP would be more difficult to mislead than DMHT.

3.8 Anxiety and Dependency

Participants were concerned that some mental health apps might create a dependency that is not healthy for the individual: for example, a chat

bot might be viewed as an imaginary friend, displacing human relationships. Some reported having these kinds of experiences themselves, often associated with finding the app contributing to a feeling of being overwhelmed, with one participant comparing it to overdosing on a medicine. Some also said that paying for multiple apps could cause financial problems or anxiety.

> *"It's too much pressure. I turned the notifications off."*

Some users were also concerned about the amount of information DMHT could generate and the anxiety this could create, given that most people would struggle to interpret it.

> *"One of my friends had a ring which monitors your sleep, your heartbeat and everything else. That's a nightmare if you're going to start looking at it and trying to be figuring out what was going on."*

> *"He has addiction issues and stuff and I'm not massively sure it's going to be a constructive thing for him to be doing."*

Some participants described their experiences or concerns in terms of intrusion or distraction.

> *"I get lots of little prompts. It creates lots of stresses and anxiety."*

> *"Asking me to log-on every day became too intense for me. It became a burden."*

They also highlighted the potential dangers of using features such as rewards, prizes, competitions with other users or streaks (the expectation that they would use the app every day) to keep users engaged with the app. Some recognised that 'gamification' might be helpful for some users but could be harmful for others. Several compared it to the app Duolingo, and how being "pestered by a cartoon owl" was fine to encourage the learning of a language, gamification was much riskier when addressing mental health conditions, particularly when these might involve high levels of anxiety or obsessive or compulsive behaviours which the techniques could make worse.

3.9 Other Concerns

Participants raised a number of other areas of concerns. These sometimes overlapped with each other or with the risks listed above, but were also seen as distinct by at least some participants. These concerns include:

- Demotivation.
- Exacerbating symptoms.
- Forums.
- DMHT providing inappropriate treatment.
- DMHT being oversold in terms of its benefits and raising false expectations.
- DMHT being overused within the healthcare system.

- The quality of in-app support.
- The reliability of apps.

Demotivation

Participants expressed two concerns. First, using an inappropriate or ineffective DMHT product would lead to little or no progress, and so undermine the user's commitment to the DMHT or to making progress with their condition.

Second, the DMHT itself could undermine commitment by imposing targets or setting challenges which were inappropriate for the user. Inherently, some users will not meet the targets set by the app or which they set for themselves. This could be demotivating or even undermine people's self-confidence.

Exacerbating Symptoms

Participants saw two main ways in which DMHT could make symptoms worse.

The first, and most frequently suggested, was that the DMHT by its very nature could contribute to isolation from human interactions, whether it was healthcare professionals or friends and family. For those holding this view, a great deal of mental ill-health was caused by digital technology and applications such as social media, and the encouragement of negative behaviours such as constantly checking for notifications, doom scrolling or obsessing about personal presentation. DMHT may add to this, either because it would exacerbate those behaviours and effects, or because it would divert users from the things they needed to do, such as engaging with people in the real world or doing things that did not require the use of digital technology, such as interacting with animals or nature.
The second concern was that specific features of DMHT could make existing symptoms worse, as discussed above. For example, gamification features could undermine the user's self-esteem further if they failed to achieve the goals they had set themselves, or were set for them by the DMHT. Notifications designed to help ensure that users remained engaged with the DMHT and its associated treatment program could draw some users further into 'screen time' and away from beneficial human contact.

Forums

Participants had two main concerns about forums and similar features such as links to discussion groups. The first was ensuring that the personal information of users was protected, given the sensitivity of health data and the vulnerability of many users. The second was negative or malicious behaviour on the part of other users, particularly where the forums were anonymous or unsupervised, and where the technology did not require active and reliable verification of age and identity.

Some of the same effects might arise without a negative intention on the part of other forum users: for example, other users might share negative material in

good faith, without properly considering the impact on other users.

> *"In a forum with peers you could have anxiety and suicidal thoughts – it could turn dark. It would have to be monitored and moderated."*

Inappropriate Treatment

Some participants were concerned that DMHT might not provide appropriate treatment or support, either overall or in specific cases. For example, some DMHT might be designed to, or could be used to, explore a user's memories and past experiences: while this may be helpful for some, to explore trauma in an uncontrolled and unsupported way could be very dangerous. Similarly, cognitive behaviour therapy could be effective in some situations, but could pose risks if used unsupervised. This connected to a perception that DMHT lacked sufficient customisation for safe application in many more serious cases, and there was little confidence that algorithms could provide this.

Overselling and Managing Expectations

Participants commented that some apps made or implied bold claims for their impact, while users could also be looking for a product that would transform their lives and so be vulnerable to overselling. The fact that DHMT could be, and often was, heavily advertised, while medicines were barred from marketing to patients, was seen as a risk. It was also another way in which DMHT regulation did not resemble that for medicines.

There was some awareness of the role of the Advertising Standards Authority (and other references to Ofcom) which implied an awareness that there was a regime to ensure advertising was honest. Participants felt that it was particularly important that developers were not allowed to make claims that could not be backed up with robust evidence.

If users had high expectations and the DMHT could not match this, it could have a negative impact on their state of mind and also discourage them from continuing with the DMHT or seeking other forms of treatment. Negative experiences shared with others through forums, reviews or word of mouth might deter individuals from seeking other support channels and may discourage the use of similar apps more widely. User expectations could be managed by integrating warnings about potential issues into the product and ensuring users and HCPs had access to effective guidelines on using the product.

Overuse by the Healthcare System

Some participants were concerned that overstretched mental health services might come to rely too heavily on DMHT, and particularly AI-driven apps, using them as replacements rather than supplements to human care. These might be used to 'offload' patients or clear waiting lists rather than provide genuine support.

"I can see overstretched mental health departments or GPs fobbing people off on programs like that."

This would be inappropriate in itself and would also reduce people's choice. Some people preferred human interaction over using apps, while others lacked the skills to use or could not afford to pay for a DMHT. Apps should not be the only method of accessing services; reasonable alternatives should be available. Promoting choice in this way would also build buy-in and so make DMHT more likely to be effective.

"You are much more likely to engage if you are given a choice."

Quality of In-App Support

There were some concerns as to the effectiveness and reliability of app-based support. When shown a selection of DMHT products, participants frequently asked what support was available and how it could be accessed, and particularly how much there was a human element in that support. This may also be associated with widespread awareness of media criticisms of a specific DMHT platform that linked users with therapists.

Reliability

Some participants who had used DMHT commented on the need for them to be reliable, particularly if they were being used to provide on-going support. Many more participants spoke of the stress and frustration caused by technical issues such as apps freezing or crashing and felt this would be particularly unwelcome when someone is in a vulnerable state. There should be clear paths within apps for reporting technical faults and these should be taken seriously and acted on rapidly by the app developers.

"I have Type II diabetes meds linked to my mental health. I had an app for this but it dropped out very regularly and it left me feeling anxious and very annoyed."

User Error / Human Factors

There was some awareness of the risk that DMHT could be used in ways that made the DMHT less effective or potentially hazardous. This was particularly the case with diagnosis and monitoring features, where if users put in erroneous data, then the quality of diagnosis and support would suffer. This was not to blame the user: DMHT should be designed to minimise these risks and – given that errors would always arise – mitigate the consequences.

"I guess with medication, the outcomes are usually a bit more concrete. If you have a bad experience on an app, it might not be the app's problem."

3.10 Stopping Using DMHT

Participants had frequently stopped using DMHT for a variety of reasons of which the main ones offered were:

- **Moving on.** Users felt they had benefitted from the app but felt it had given them all it was likely to provide or had got bored with it and wanted to try something new.

"I had a free trial and I liked it. Deep breathing and habit trackers. I have ADHD and never stick with one thing for long, so I quickly lost interest."

- **Disappointment.** The app did not provide the expected benefits.
- **Frustration.** The app had features or ways of working that put users off, even if it also provided some benefits.

"It was good at first but then when I was having a bad day I found it annoying, so I just deleted it."

- **Cost.** A common theme was participants finding DMHT expensive to use. They often made use of a free trial but then discontinued use, even when they felt it was helping them. Others did so, or later stopped their subscription, because the apparent benefits were not sufficient to justify the cost, particularly when money was tight.

3.11 Information on Side Effects

There was some discussion about whether apps should inform users about potential adverse events, much as the patient information leaflet would for those taking medicines, and the risks this might create. There were two main views:

- If information was available on potential adverse events, it should be included as users had a right to make an informed choice whether to accept those risks or not. It would also help users to identify adverse events if they were to arise.
- Including potential adverse effects could make users anxious or even deter them from using the apps; or could sensitise them to the risk to the extent that they may come to believe that they are suffering from the adverse reaction, when they would not have done so without the warning.

Most participants recognised both views, even if they leaned towards one or the other, and thought the choice was a difficult one. Those who were clear that adverse events should be disclosed outnumbered those who were clear they should not. A majority felt that it would largely depend on how the potential for side effects were expressed. If it were 'scary' in the same way as a typical patient information leaflet, it could cause more problems. Something less formal, which placed potential adverse effects in

the context of the likely benefits of the DMHT, would be more appropriate. The text in Figure 1 below is based on the group discussions to illustrate the kind of content and tone that most participants would value.

Figure 1: Illustrative Text on Adverse Events

"Apps may not work for everyone and some may have poor experiences. For example, some people find the use of daily reminders and targets make them feel more anxious. If you feel the app is not working for you, or making things worse, please let us know at once. You can also share your experiences with the regulator for medical apps through the Yellow Card scheme. This will help us and the regulator understand how apps can be designed to avoid any bad experiences in the future."

3.12 Mitigating Risk

Reflecting on the discussion on using DMHT in isolation above, the main way that participants thought these risks could be mitigated was through integration of DMHT into wider mental health treatment and support. This integration might include:

- Combining human contact with features like journaling.
- Regular check-ins from professionals based on app data can provide a personal touch.
- Apps that allow users to log their feelings or health metrics and share this data with their GP can provide a more comprehensive view of their health.

3.13 Heightened Vulnerability

Intermediaries and public participants both gave examples of groups they thought might be at heightened risk from DMHT or might face additional challenges in reporting harm. Chief of these was children and young people and the evidence and findings on that group is reported in Chapter 8. The other main vulnerable groups were:

- **Condition – specific users.** Those with more serious mental health conditions were seen as more vulnerable. In particular, several intermediaries thought that conditions or symptoms such as psychosis or dissociation could heighten the risks of DMHT. This was linked to conditions that made it harder to perceive reality or to relate to others.
- **Medication.** Where DMHT users were also taking medicines to treat a mental health condition, there was more chance that any negative effects would be masked by, or attributed to, the medication, or that the combination of DMHT

and medication could create additional risks.

- **Older people.** They tended to have a lower level of confidence and experience with digital technology and so might be more likely to stop using DMHT which might put them at greater risk.
- **Income.** There was considerable concern that many people would be unable to afford smartphones and DMHT app subscriptions, and this would leave them at a disadvantage, particularly if DMHT became a 'standard' part of providing mental health support.
- **Class.** There were fears that those from 'lower' socio-economic classes or with a lower level of education attainment might be disadvantaged in terms of access to DMHT and less confident in raising a concern if they suffered harm from DMHT.

4. Raising a Concern

Key Findings	People thought it would be very hard to recognise the occurrence of harm in yourself.
	They were much more confident healthcare professionals (HCPs) could identify harm.
	If the DMHT was recommended by an HCP or other intermediary, they would tell them about their concern.
	If they had sourced the DMHT themselves, they might contact the developer, leave a review or post on a forum – but probably wouldn't.
	They might in a very serious case try to find a regulator or professional body.

4.1 Recognising and Attributing Harm

Medicines were seen by participants as relatively predictable in terms of the physical conditions for which they were prescribed, and the expected benefit or outcome. Side effects would therefore be relatively easy to detect. In contrast, mental health was complex and varied considerably from individual to individual. It often fluctuated in line with internal and external factors such as relationship or workplace stress. Some participants described how they had been prescribed different medications for mental health conditions almost on a 'trial and error' basis until they and their healthcare professional found a medicine and dose that was effective.

For many, managing their mental health involved several overlapping interventions ranging from medication to therapy, potentially spanning many years. Further, it was hard for people to understand or track their own mood and behaviour 'from the inside'. There was also scope for an element of self-deception. Attributing the effects of DMHT – good or bad – was seen as correspondingly difficult, particularly as most participants thought of DMHT as 'low impact, low risk' compared to medication, where several participants reported having had severe side-effects.

Participants were also more likely to see DMHT 'not working' as a personal response, rather than necessarily indicating that the product was ineffective or likely to cause harm. This reflected the sense in which DMHT was making a small contribution to a complex and very personal condition.

> *"Different things work for different people, and just because they've recommended it to me and it hasn't worked doesn't mean it's a bad app. But it might work for someone else."*

Overall, participants thought that in most cases it would be very difficult for them to recognise harms caused by DMHT. There was a strong view that healthcare professionals would be better-placed to identify harm because they would have the required professional skills.

4.2 Risks and Benefits

The majority of participants thought that DMHT could make a positive contribution to supporting mental health in the right circumstances and with appropriate safeguards. There was near consensus that the risks would be minimised and the benefits maximised if DMHT was used within an integrated approach to care, with the limits of DMHT recognised and appropriate professional supervision in place.

The main benefits of DMHT suggested by participants were:

- There were no waiting lists, and you could benefit from it straight away (including while waiting for other treatment).

- It would be available to users 24/7, whenever they needed it, and the ability to carry the DMHT with you at all times would also be reassuring, even it was not used.
- It offered a lot of choice and so would be easier for users to try different DMHT products until they found one that worked for them.
- They might be more discreet than, for example, having a regular appointment for therapy or taking medication, which was significant given the ongoing stigma towards mental health conditions.

Participants did not think of DMHT or other potential interventions such as medication in isolation, but in terms of the costs and benefits of each, so that if there were an extended waiting time for access to a therapist, the perceived benefits of DMHT might become more attractive or the risks might be seen as more acceptable.

4.3 Initial Frames of Reference

At the start of discussions, participants tended to apply one or more of the elements of the common frames of references discussed in Chapter 2. The most popular response was that, if they thought a DMHT product might be causing them harm, they would simply stop using it and would probably delete it. If it had been recommended by an HCP or another professional (or they were being seen regularly by an HCP or counsellor) they might feed their experiences or concerns back to them. Otherwise, they were unlikely to take any further action. The more serious the perceived harm, or the more they felt responsible for other potential users (for example, children) the more likely they would be to take further action. This was most likely to be by leaving a negative review or posting a warning on relevant forums. In rare cases it might also include contacting the manufacturer or researching if there were an appropriate regulator or ombudsman.

As participants were presented with more information about DMHT and its potential uses, discussion moved to considering who were the responsible agents to whom they might pass on concerns. However, that discussion remained with the context that participants were still unlikely to take any action at all.

4.4 Responsible Agents

Participants discussed four possible routes through which they might raise a concern or make a complaint.

- The **developer** of the DMHT.
- A healthcare professional or other **intermediary** who had provided or recommended the DMHT.
- The **app store** from which the DMHT had been purchased.
- Some kind of **oversight body**

such as a regulator or an ombudsman, which might also involve a helpline.

Developer

Most participants felt that it would be hard to contact a developer and, even if they did, doubted whether they would act on their concerns. They assumed that the app would not have any contact details for feedback and that they might need to go elsewhere – such as an online discussion forum – to find those out. They also expected the process to be digital, rather than, say, a telephone helpline, and this too would be a disincentive for some users. They might also be required to provide evidence to support their concern, such as taking screenshots, and this would itself potentially form a barrier to following up on a bad experience. Participants were strongly of the view that those using apps to support their mental health were likely to find raising a concern very difficult, and trying and failing to make a complaint could leave the user worse off than if they had decided to do nothing.

> *"It would be a hard thing to do if you were in a bad place."*

In part, these negative expectations were based on experience of other apps, in part on the perception that app developers would not want to engage with negative feedback because this would require resources and so reduce their profits. Some participants were more positive about the potential to provide feedback, saying they would expect to find a channel for feedback in the app and that there would be a reasonable chance that the response would be satisfactory. These participants tended to be younger.

A few participants had contacted app developers in the past and in the main had been pleased with the response they received.

> *"I was using an app and suggested some changes to them. They actually replied and acted on it and I felt like I was dealing with a real person. It might have been different if it had been a bigger developer."*

HCP or Intermediary

There were mixed views as to whether someone would contact their GP or another HCP, but there was broad agreement they were much more likely to do so if it were the HCP who had recommended the app.

> *"If you get a recommendation from a professional for the app, you're going to go back to the doctor to make that report, that something isn't working."*

Either way, it would also depend on the individual patient and whether they were going through a mental health crisis at that point. Several felt it could be an ordeal to go back to the HCP, so it would also depend on whether they

had a one-off consultation with the HCP or if they were planning to have follow-up consultations. If the latter, they would be more likely to report problems. In addition, it would also depend on how the app had been recommended by the HCP.

> *"Would it be sort of 'give it a try' or would it be 'I want you to use this as part of your healthcare plan'?"*

Participants thought that if a GP or other HCP recommended an app, then that app should or would have been properly designed and tested or vetted in some way. Including some real-world testing. There was a strong expectation that the NHS would not recommend untested apps or ones that were not fit for purpose.

App Stores

Very few participants suggested contacting app stores, and there was generally a sense that the app stores would not want to act on any concerns raised.

> *"I think it's very difficult for an App Store to check an app around mental health when there are so many different facets to mental health."*

They could imagine that if it were an obvious and serious problem, then the app stores might act. This might be through a combination of individual feedback and concerns raised by healthcare professionals.

> *"Maybe complaining to an app store is something that a medical body would do if they'd had a lot of people coming back and saying this is harmful in some way. But I don't think as individuals it would be easy or would make the slightest bit of difference."*

Some felt that app store reviews would be helpful, while others felt they were too easy for developers to manipulate. There were mixed views on whether it was reasonable for the app stores to police the quality of the apps they hosted, or whether it would be better to have some kind of kitemark to indicate which apps met some kind of independent standard, which the app stores could then display on qualifying DMHT products.

Oversight Body

In most cases, participants thought in terms of a body which might intervene in relation to the nature of the harm. For example, if a DMHT product included a forum, and there were safeguarding concerns about its operation, then they would think in terms of contacting the police. If they used DMHT which was subject to a data breach, they might turn to the Information Commissioner's Office, while if they thought that DMHT was being advertised inappropriately, they might contact the Advertising Standards Authority. Some also said that

if the DMHT involved a therapist or other HCP, they might contact the relevant professional body.

> *"I'd assume individuals couldn't make any changes if it's a big enough app but you could report a mental health therapist."*

No participants spontaneously named the MHRA or the Yellow Card scheme as the most relevant oversight body or reporting route.

Some thought that there should be a helpline which anyone concerned about the use of DMHT could call to report the problem and access extra support. Some specifically cited the Drinkaware and GambleAware schemes as precedents. Although no-one mentioned using these themselves, they were widely seen as potentially providing an appropriate model for DMHT, perhaps because one of the main perceived risks of DMHT was addictive use.

> *"I think there's got to be like a like a government helpline that says "if ...you're suddenly feeling way worse than you did before you started using that, please give us a call". Or something along those lines."*

For some, an in-app reporting route, such as a chatbot, linked to the develop was seen as being the most convenient and appropriate. Others felt this might not always work well (or users may not be conformable using it, for example in relation to a data breach) and so an alternative route to a regulator or other oversight body would be needed. Some also suggested that if a chat function was used in the app, there should still be a route to escalate to an independent body. An independent helpline (including an in-app route) on the GambleAware model was also seen as closing the potential split between seeking help personally and reporting an adverse event on behalf of society. A helpline could do both.

Participants did not express much concern about not being aware of a specific route for raising concerns with an oversight body. Some clearly took the view that they could not imagine ever raising a concern, so it did not matter. For others, they were confident that if they needed to raise a concern, they would be able to find out the best route or would use a known route that felt appropriate – for example, writing to their MP.

Overall, participants tended to see a number of potential individuals or institutions with shared responsibility for DMHT safety.

Users

- Reporting any issues, stop using it if doing harm.
- Reporting abuse by other users if social forum aspect.
- Doing own research/making sure trusted website/app.

Developers

- Checking research/user testing.
- Ensuring they make responsible claims/advertise responsibly.
- Ensuring data security.

App stores

- Being transparent with ratings/ reviews.
- Ensuring app does what it says.
- Professionals.
- That it works if they are recommending it.

Government/regulators

- Duty of care/legal responsibility to keep people informed and safe.
- Ensuring any rules/regulations are followed.

5. The Yellow Card Scheme

Key Findings	The public (and non-HCP intermediaries) have very low awareness of Yellow Card or how medical products are regulated.
	When shown Yellow Card, they are very positive…
	…but think very strongly that reporting has to be integrated into DMHT, not solely a stand-alone site.
	They also want a kitemark scheme and/or more product information so they can make better informed choices on what good quality, effective and safe DMHT to use in a particular situation to avoid harm in the first place.

5.1 Awareness of the Medical Device Regulations

Most participants assumed that there would be a regulator overseeing products such as x-ray machines or blood pressure monitors, even if they could not name the regulator or were not familiar with the term 'medical device'. However, most participants did not think that the DMHT they had used, or been shown in the discussions, would be covered by those regulations.

Participants either assumed that DMHT would not be regulated or said they had not thought about it so did not know. Most felt that DMHT should be regulated, and that this was a gap in the regulatory landscape. Some suggested that it would be very difficult to regulate because of the international nature of the internet and variations in approaches to regulation in different countries. Some participants did suggest that therapists or other healthcare professionals operating online through apps would be regulated by their professional bodies. Most thought that if there were to be any accountability for developers, it would be through negative reviews or through litigation (though the latter might also be limited by companies operating internationally).

> *"There should be a reporting body - like you've got ombudsmen, you've got Ofcom, things that we're all aware of for other issues - but I don't know that I would know where to start with this."*

> *"I thought Ofcom regulated things like that [DMHT] but I don't know what power they have."*

> *"I think there has to be a system in place, there perhaps is, that you cannot set up a medical app purporting to give medical advice without it being signed off by a medical body and being backed by medical professionals, you know?"*

5.2 Awareness of Yellow Card

Awareness of the Yellow Card scheme amongst participants was low, even though the profile of participants was weighted towards those with pre-existing conditions who might be expected to have taken more medication than the average person, and so have had more chance of hearing about the Yellow Card scheme or even of having had an adverse reaction. This reflects unpublished research carried out by Woodnewton for the MHRA in 2024 in which 14% of the public felt they knew either 'a little' or 'a lot' about the Yellow Card scheme.

Most of those who had some awareness of the Yellow Card scheme did not have a clear picture of who ran it, who could complete reports, what would happen to those reports after submission or what data was published.

5.3 The Yellow Card Site

When shown the Yellow Card reporting website, almost all participants were impressed. Some who had experienced adverse reactions with medicines said they wished they had known about it, while most participants said they would consider using it in the future, now they knew about it, if they had one. A common frustration was that something so important and useful was not better-known.

> *"I am amazed this exists. I know about the FDA[1] and I don't know about this! They need to up their game!"*

There were some criticisms. Some participants felt the site did not explain clearly or forcefully enough the benefits to others that would come from making a report, or make clear what would be done with the reports once submitted.

> *"It's like a black box. What happens next? Do they reply? It doesn't feel like they are there to help you."*

Some participants commented that the site looked 'dull' or 'clunky', but this was not generally seen as a drawback as there were advantages in being "reassuringly boring". It did not need to be 'slick', and this might even put some people off: it was more important to make clear it was serious and trustworthy, and there were plenty of visual cues that this was an official or government site.

> *"It looks a bit like DVLA[2]. And that's a positive!"*

Some commented that it should have more of a 'call to action', with testimonials or other ways to demonstrate the value of making a report, although some felt this was not essential.

> *"If you go to the bother of finding the website, then you're going to report it anyway."*

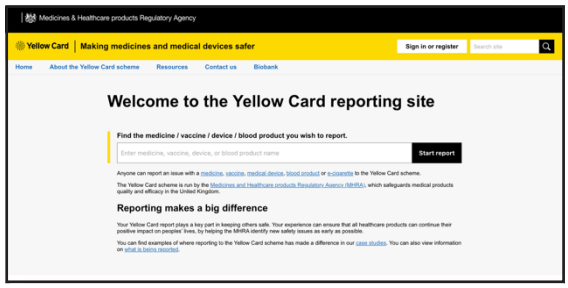
The main criticism was that it was very unclear that it was possible to report an adverse experience with DMHT. There was nothing on the front page to suggest this, either directly or through imagery, and subsequent pages still failed to communicate this effectively. Even if a potential user followed the 'medical device' link, the definition and examples of medical devices given did not mention DMHT. The consensus was that this could be put right easily with a clear statement of the scope of the Yellow Card scheme on the front page. More information and examples of the types of issues that should be reported about DMHT would also be needed.

5.4 Confidence in Yellow Card

In general, participants thought the site felt authoritative and trustworthy. There was considerable surprise at the wealth of information about

1 The US Food and Drugs Administration.

2 The UK Driver and Vehicle Licensing Agency.



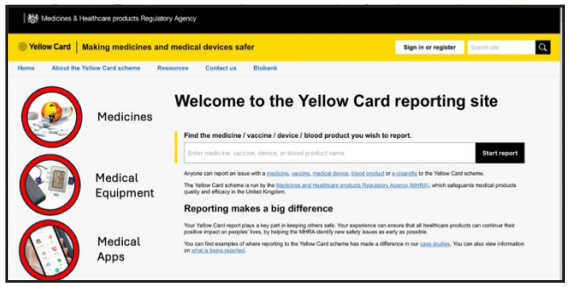


Figure 2. (Example of how DMHT could be made more prominent, based on participant feedback: current screen above, amended screen below.)

individual medicines and a sense that some participants were revisiting their assumptions about the secrecy of the pharmaceutical industry or a lack of transparency on the part of the regulator.

5.5 Yellow Card and DMHT

Although participants were positive about the Yellow Card scheme and also believed that it could be marketed more widely, most were not convinced that this would on its own ensure that users of DMHT would know how to raise a concern or would choose to do so. There was a strong consensus that apps themselves needed to support users in identifying and reporting potential harm. This meant that the integration of DMHT and Yellow Card was seen as more important overall than the design, or even marketing, of the channels for making Yellow Card reports directly.

Barriers to Yellow Card Reporting

Participants saw a range of barriers that might stop them or others from making a report. These included a lack of awareness of the Yellow Card scheme, a lack of confidence that their concerns would be taken seriously or acted on, and the challenge of making a report while also dealing with a mental health condition (particularly if this has been exacerbated by the use of DMHT):

- **Attribution.** Users would not see harm as stemming from the use of the app, because of all the other potential factors influencing their mental health.

"Mental health is so complex anyway, that people need an array of different treatments. And what works for one person would absolutely not work for someone else. I think it's more a case of not that it's not working, just that it's not for you. And then maybe you need to try something else."

- **Entitlement.** People would still be prone to blame themselves, particularly where their underlying mental health condition involved a lack of confidence or self-esteem, or where previous experiences had led them to believe that complaining would not lead

anywhere. This linked strongly to social class and discrimination.

"No matter whether there was a button or not, if it's a free app or a free service, I'm just not going to complain. Because you just don't feel like you're entitled to anything because you've got this for free… I would just delete the service and move on to something else."

- **Confidence.** Users would need to feel confident that there would be effective enforcement or other follow-up (and some participants commented that the Yellow Card website did not have any examples of the consequences of making reports about DMHT). Most participants did not think the regulator would have powers to compel developers to remedy issues with their products or to take products off the market. There were also some doubts about whether the regulator was truly independent.

"It takes a lot of people to die for some medications to be taken off the market. So I think I'd probably be less inclined to report something just because … it's not really taken seriously."

"I would be a bit sceptical about reporting because I wouldn't really know what [action] that would lead to."

- **International.** There were questions about how such a system could cover apps based in other jurisdictions.

"I know somebody who used [XXX] and actually alarm bells were going for a lot of people in their life about the type of advice that they were receiving. But because the therapist was based in a different country and it's through an app …it's not easy to report."

A further issue is that the Yellow Card Scheme was originally designed for medicines rather than medical devices or DMHT, and where it is known at all, it is usually viewed as part of a wider system for the post-market surveillance of medicines. Most public participants were not aware of Yellow Card, but those that were thought of it in terms of medicines. Even amongst healthcare professionals, where awareness was much higher, there was a widespread view that using Yellow Card to provide feedback on DMHT was not an obvious step. Neither the public nor intermediaries saw DMHT as fitting into a medicines frame of reference. While they were not necessarily against using Yellow Card for reporting, they were more conscious of the differences between prescribed medicines and DMHT post-market surveillance than the similarities.

6. Integration into DMHT

Key Findings	The public felt strongly that in-app reporting should cover both positive and negative experiences in a single channel.
	Serious negative experiences could then generate or lead to appropriate notification or alert.
	DMHT should have a 'patient information leaflet' for users to review at first use to cover potential side-effects and how to report.
	There should also be in-app prompts to give feedback and digital phenotyping to spot worrying in-app behaviour.
	Awareness of DMHT risks and Yellow Card reporting should be raised through app stores, NHS touch-points, social media content creators, forums and reviews.

6.1 Integration

There was consensus amongst participants that adult users of DMHT had a right to be informed of the potential for adverse events and how they could raise concerns, including through the Yellow Card scheme. This right might vary according to the nature of the app, and particularly their risk profile. Although participants did not refer to the medical device regulations for DMHT, they felt that apps providing or substituting for a medical role, such as diagnosis, monitoring or treatment would have a greater duty to inform users about adverse events and Yellow Card reporting.

Participants also thought that other channels should be used to promote awareness of the Yellow Card scheme generally and in relation to DMHT; and the potential risks posed by DMHT. These channels ranged from including information in the app stores to ensuring healthcare professionals and others working with potential DMHT users were themselves aware of the risks and reporting channels. Although these are discussed separately in the next chapter, participants saw the two approaches as mutually supportive.

6.2 Green and Yellow Cards

As discussed above in Chapter 4, participants strongly believed that it would be a mistake to have a channel for reporting harm or raising concerns which was entirely separate from channels seeking feedback on users' satisfaction with the DMHT product. This single route might lead to a range of options. One of these could be a dedicated reporting route of adverse events such as Yellow Card. If so, there should still be a common entry-point or pathway. This would also ensure that users were provided with all relevant options and guidance and could make informed decisions about what kind of feedback they wanted to provide.

Many participants felt that it was just as important to understand the extent to which DMHT benefitted users, including for different conditions or different types of user, as efficacy was important in itself and in making judgements about whether the potential drawbacks of a DMHT were outweighed by the potential benefits.

Some participants saw it as essential that DMHT encouraged feedback as much as possible, and acted on it, given how important they were likely to become in people's treatment.

> *"If this is the way forward, and it seems to be, there has to be some kind of way to ensure that it's constantly improving, and that you've got an area dedicated to feedback, because how else are they going to improve?"*

6.3 Stages of Integration

There were four main ways that participants thought that information about adverse events and the Yellow Card scheme could be integrated into apps and other DMHT:

- **Product Information.** Provided when the user first downloads or signs up to the app, much like a patient information leaflet for medicines, including information on possible negative experiences and routes for reporting these.
- **Passive Feedback.** Providing routes in the product's customer service functions to allow users to provide feedback or raise concerns.
- **Active Feedback.** Prompting users periodically to report on their experiences with the app during the use of the app.
- **Monitoring.** Prompting for feedback when the user displayed potentially worrying patterns of use.

6.4 Product Information

Most participants thought that if a developer or other relevant body were aware of actual or potential risks from the use of DMHT, this ought to be passed on to users so they could make an informed choice about whether to use the DMHT and be alert if they themselves experienced those adverse effects. The clear frame of reference was the list of side effects provided in the patient information leaflet supplied with medicines. They also felt that the app should provide guidance on how to use it safely, which would address the human factor risks, and again was parallelled in the guidance on how to take medicines safely (for example, not on an empty stomach or when operating machinery) included in the PIL. Also, users should be advised to seek independent advice and support from professionals if they had not already done so, or if they felt their condition was not improving over time, or was deteriorating.

> *"Apps need to be open and transparent and straight to the point and say: these are the shortcomings, these are the positives … make up your own mind or seek independent advice."*

Participants recognised the risk that this information might discourage people from using the app, so missing out on its benefits. They also recognised that in some circumstances, being aware of a potential side effect might sensitise users to this risk, so that they begin to experience the negative impact in a way they would have otherwise not have done. But the strong view was that transparency was more important.

> *"It's still better to have the information, even if some people are discouraged."*

Although participants referenced the PIL as a precedent, they felt strongly that the information in the app should be much more accessible and user-friendly. It should be frank about the risks but written so as not to worry people unnecessarily. This meant it would need to be very clearly written, avoiding complex terms which potential users might not recognise, and also not 'hidden' in the DMHT product's terms and conditions, as was common with other apps, where almost all users would not read them. It was also suggested that a short video or animation would be more inclusive. Some suggested that people should not be able to use the app until they had confirmed they had read this information.

Some commented that this user information should not be used to limit people's rights to raise a concern or seek redress if the app did not work as expected. This played into the view some held that terms and conditions were created to limit legal liability or otherwise to suit the developer (or for PILs, the drug manufacturer), not the user.

> *"No-one reads the leaflet. It's just arse-covering."*

In contrast, a clear and honest statement of what the app could achieve, its limitations and any potential risks ought to give users more confidence to use it, as well as managing expectations. This could highlight the approach to securing customer feedback. Users are more likely to trust and use apps that demonstrate a commitment to their well-being and continuous improvement.

> *"If there is an issue, that should be made clear in the app. That would give you more confidence."*

6.5 Passive Feedback

There was consensus amongst participants that DMHT should provide clear and easy routes to report concerns within the app. This would help developers identify and address issues promptly, improving overall app quality. It would also potentially make users feel heard and valued, which would be particularly valuable given that many users might be vulnerable to feelings of being ignored. Most participants compared this to feedback or reporting channels they knew from other classes of digital products which involved an element of risk, notably gambling and dating sites, financial services apps, social media networks and forums.

> *"It should have a report button, similar to what you have on dating apps."*

Given these frames of reference, participants did not tend to suggest that this reporting process should start with Yellow Card. It was more appropriate if, in the first instance, reports went to the developers, who (in most cases) were the ones who would be best placed to act on it quickly and effectively. This was despite there being some concern

that some developers would not act on feedback, particularly if it meant incurring significant costs or making their products less attractive. Nevertheless, the prevailing view was that developers should at least be given the opportunity to put things right before a regulator became involved.

Several factors helped form this view.

- Most participants thought that there should be a single path to provide both positive and negative feedback, which precluded including the Yellow Card as a completely separate path.
- Many also thought that the single path should initially cover both reporting a concern and seeking advice, support or even redress, whereas the Yellow Card scheme was only about raising a concern.
- Many of the frames of reference required that users use the internal process for raising concerns or making complaints before escalating these to the regulator or ombudsman.

6.6 Active Feedback

Many participants thought that the most straightforward and effective way for users to be made aware of the risks of adverse events and how to report these would be through the use of in-app prompts. As with the equivalent of the patient information leaflet, this was seen as needing to be short and clear, and not needlessly raise concerns or put people off using the app. There was also a strong view that such prompts should cover both positive and negative experiences, being framed as *'how is it going for you?' or simply a thumbs up or down*. This would have several benefits:

- It would give a more comprehensive overall picture of the impact of the app, including the positives.
- More users would be likely to engage with it.
- It would be less likely to worry users compared to focusing only on negative.

The design of the prompt might vary from app to app, taking account of different functions and also different types of users. It could include a simple scaled question about how much the app was helping the user: if the user gave the lowest score, this could lead to a further question about whether the app might be causing them any harm, and this in turn could lead to a link to the Yellow Card scheme. The prompt might also include one or more open questions including one on how the app could be improved. This could be reviewed to identify any users where the suggested improvements indicated that they might have experienced an adverse event.

Some participants commented that the design of the feedback process would make a great difference to how well it worked and how much weight could be put on its findings. While simple

scoring might form part of it, there was also a need to allow people to express themselves in their own words – otherwise, nuances would be missed and vulnerable people would not feel heard.

> *"I don't think you can use this kind of star system for something as complex as mental health. But I suppose, like, you say, 'do we feel like we're getting somewhere? Does this feel like the right direction?'"*

6.7 Digital Phenotyping

Digital phenotyping allows data to be accessed in real time from smartphones, watches and other digital devices and enables monitoring and assessment of a user's physical or mental health. Although participants did not use this term themselves, there was a widespread view that DMHT ought to monitor how people used the app and intervene in a variety of ways if that behaviour showed a pattern of risk either to the user or others. Some mentioned Apple's approach of providing a weekly report on a user's screen time as an example.

Some participants did note that some potential users might find the idea of being monitored off-putting or could even exacerbate some mental health symptoms such as anxiety or paranoia, and that as a consequence monitoring would have to be by user consent, and it would also add to the risk if there were a data breach or leak of personal information; but they were overall supportive of the idea of monitoring. This was even the case when that monitoring was linked to AI, which was otherwise generally treated with caution or rejected outright.

> *"Maybe the AI could be trained to prompt for any problems if it sees there's a problem from the way the app is being used. Like someone using it less."*

It may be relevant that some of the cited frames of reference – notably online gambling – either used some form of monitoring, or there was public debate about whether monitoring should be introduced or enhanced. This was seen to provide a level of safeguarding which would be particularly valuable in identifying ideation on suicide or self-harm, or where other users might misuse chat forums.

Participants thought that if a user chose to cancel their subscription or uninstall the app, it might indicate they'd had a bad experience and this would be a good moment to ask the user for feedback. This could include a link to the Yellow Card scheme if the feedback from the user showed they might have suffered an adverse experience. They also appreciated than in most cases the user would not respond, whether or not their reason for stopping using the app involved a bad experience, but that it was still appropriate to seek this feedback.

6.8 Third Parties

Participants saw benefits in allowing HCPs and family members/carers to report on behalf of users with serious mental health conditions. They could assess the user's progress and the impact of the DMHT more objectively and in the case of HCPs, would also have their professional training and experience to draw on. There was a strong expectation that this would require the consent of the DMHT user.

Some users commented that if they had concerns about someone they knew using a DMHT app, they would get the app themselves and see how it worked. This would help them decide if some kind of intervention was needed. There was also a feeling that friends and family would find it easier to raise concerns if the user themselves invited them to help judge how much benefit the DMHT was providing. One suggestion was that the app could recommend to the user that they consider asking a friend or family member or someone else with a similar condition to provide them with informal support using the app, as with some apps for physical health.

6.9 Kite-Mark

Participants felt it was important to test DMHT as rigorously as possible before they were put onto the market, after which it would display a familiar symbol used to reassure them that the product had been properly tested, as with the British Standards Kitemark. They felt this would provide a strong safeguard and be more familiar to potential users and could make people more likely to use and benefit from DMHT.

> *"If an app shares that it's regulated by X government body then I would feel happier… safer."*

Some went further, saying that, to them, pre-market testing was more important than optimising a system to allow users to report problems once the products were on the market. However, as explored in Chapter 3, participants had little or no awareness of the current regulatory regime for Software as a Medical Device, which does in fact require these products to be tested prior to being placed on the market and thereafter sets a framework for them to be monitored continuously in use for safety and efficacy. (This regime is intended to allow more products to enter the market and benefit patients by ensuring that, if products do reveal problems in real-world use, these are quickly identified and resolved. If participants were more familiar with the current regulatory regime, they might not place this level of emphasis on pre-market testing compared to post-market surveillance.)

Participants generally had a lot of confidence in any product endorsed by the NHS, though this tended to be higher in assurance that it was safe to use than that it would be the best on the market.

> *"If it says it's by the NHS you*

know you're probably not going to get scammed out of money."

"I haven't always had the best experiences with the stuff that the NHS have sent me or suggested to me for self-help."

The kitemark could be displayed on apps and within app stores. It could also be used more widely in marketing or other routes to build awareness of the regulatory framework, including the Yellow Card scheme, in relation to DMHT.

6.10 Marketing Yellow Card outside DMHT

Participants were very keen that the Yellow Card scheme should be marketed more widely, and suggestions ranged from posters in GP surgeries to TV advertising or public information campaigns. The main discussion focused on routes that were more closely integrated with DMHT itself, or the points at which users might interact with the health system.

On the App Stores

Participants suggested that the app stores could or should inform users of DMHT about the possibility of having a negative experience and the option of reporting it via the Yellow Card scheme. They also thought that if a user gave a one-star review, they should be prompted to consider making a Yellow Card report if they felt the DMHT's performance had caused them harm.

At 'Prescription' or Recommendation

Some participants suggested that when DMHT was being recommended by a HCP or other responsible person, such as a teacher or social worker, they should also explain to the user the possibility of having a negative experience and the option of reporting this via the Yellow Card scheme. This could be done directly if the recommendation was personal. If the recommendation was more general, such as through inclusion of a list of approved DMHT, then the website or leaflet listing the DMHT could itself include the explanation. This links to the view expressed by a number of intermediaries (see Chapter 7) that they would like to have more information about DMHT to share with patients or clients or so they could recommend it with more confidence.

NHS Touch-Points

Participants suggested a number of ways in which the healthcare system could inform or remind people to give feedback on DMHT, including Yellow Card reports. These included:

- The NHS App (including a strong view that the Yellow Card site should be integrated with the NHS App).
- The NHS website.
- In emails or other messages from

HCPs, such as appointment reminders.

- An insert or other information added to prescription medicines (which could also be linked to prescriptions issued for specific mental health conditions).

Social Networks and Internet Channels

Participants often turned to channels such as TikTok, Instagram and YouTube to gain information or guidance about their mental health conditions and how to manage it. This often involved finding trusted sources of information. These could be categorised as:

- **Mental health content providers[3]:** those specialising in information and guidance relevant to mental health, either because they had a professional interest or role or as a source of income (or both). These would include qualified healthcare professionals or counsellors.
- **Other content providers:** those specialising in non-mental health content who might be sponsored by a DMHT provider and include a personal endorsement in their content.

As with any media outlet, content providers are likely to be interested in free content (including interviewing experts) that will be of interest to their followers, or being paid to run content. This forms an opportunity to provide content providers with more information about DMHT, the regulatory regime and the Yellow Card scheme which is closely matched to audience interests either directly or through specialist agencies.

> *"They should publicise it through TikTok and Facebook using HCPs with followings."*

Forums

Several participants said that forums were a valuable resource for understanding mental health conditions and the resources available for support including discussion on various apps. These included specialist mental health forums and other sites and forums that have a different focus (such as parenthood) but which host discussions related to mental health. It would be very helpful if these could include authoritative content (or at least links to such content) and links to other sources of advice and support, which would naturally include reporting via the Yellow Card scheme.

> *"I find Reddit's quite good with these kinds of things. If something's terrible or is a scam or fraud or whatever, then it can push you to the right agencies, government agencies or independent agencies that can help deal with that."*

3. Content providers build their audiences through a mix of the content or information they provide and their own personality and connection to their audience. Where the latter is stronger, the term 'influencer' may be used, but it is also down to the preference of the individual content provider.

Some participants had experienced sites where government accounts would be used to post information and links from time to time, or even to intervene in discussion threads to provide information or respond to questions. This was seen very positively and did not need to respond to every question or every posting.

Reviews

Some participants said they might leave a review of a DMHT product that did not meet their expectations or even caused them harm, though most thought they would not, particularly as the moment for leaving a review might well coincide with additional mental health challenges. There was considerable suspicion about reviews, and most participants thought they would not rely too much on them.

> *"I don't think people necessarily trust an in-app rating system. I think they like a kind of outside of the app system of being like, 'oh, this is good' or 'this isn't'."*

> *"Maybe you could leave a bad review – but this might identify you."*

There was some concern that negative reviews/reports could lead to apps being removed from app stores, potentially affecting users who benefit from them. Users should consider the broader impact of their reviews on others.

7. Professional Perspectives

Key Findings	Most intermediaries (including some HCPs) had low or no awareness of the risks of DMHT or the role of Yellow Card in reporting concerns
	Intermediaries working with people with serious mental health conditions often had very deep concerns about the wider impact of digital tech and social media
	They also saw considerable risks in the excessive or inappropriate use of DMHT leading to alienation, paranoia and addiction
	All intermediaries felt the need for authoritative guidance on effective DMHT products and potential risks, including alerts for new concerns

7.1 The Role of Intermediaries

There are several groups of professionals who may through their work either provide people with DMHTs or recommend them; or who have people in their care who are using or thinking of using DMHTs. The main classes of intermediaries are:

- Healthcare professionals, including GPs and also specialists such as psychiatrists, psychologists and mental health nurses and those such as therapists with specialist mental health training.
- Other professionals providing care and support to those with mental health conditions, such as social workers or mental health support workers, but who do not necessarily have a medical qualification.
- Counsellors in private practice or employed in schools, colleges or workplaces; or others providing advice and support who do not necessarily have a medical qualification.
- Teachers or school safeguarding staff or wellbeing practitioners who might administer DMHT resources (such as a school web page) or recommend DMHT products to students in schools and colleges.
- Human resource managers who administer DMHT resources (such as employee mental health and wellbeing schemes).

Intermediaries can also be divided into HCPs and non-HCPs. The former are more likely to have training and/or experience in recognising and managing mental health conditions. They should also have a developed understanding of relevant concepts such as adverse events and may have had direct experience of reporting through the Yellow Card scheme. The latter may have no more knowledge or experience of adverse events or the Yellow Card scheme than the general population and may also have variable skills in understanding and engaging with those with mental health conditions.

7.2 Awareness and perceptions of DMHT

In general, intermediaries were aware of individual DMHT products and may have provided or recommended them, but they did not in general recognise the term DMHT. Some saw the DMHT products with which they were familiar as being 'resources' that were potentially beneficial but similar in terms of risk and efficacy with other more traditional resources, such as websites, self-help books or videos. There was no expectation or reliance that they would make a significant or measurable difference. Others saw them more like 'interventions', in which the DMHT was intended to provide a specific benefit, such as providing CBT therapy, helping the user to improve their sleep patterns or manage their anxiety.

In both cases, intermediaries either made use of one or more sources of guidance or recommendations on DMHTs (usually

developed regionally or for individual care settings) or wished that they had access to such resources. There was a general view that DMHT were going to be increasingly important, and potentially increasingly more central to diagnosis and treatment, and so they wanted to know more about what was available and how to use it effectively. These sources were also valuable because intermediaries felt they did not have the time – or skills – to assess the value or safety of each DMHT themselves.

> *"It's accredited by our health board so that gives us confidence."*

> *"As a clinician I would struggle to really assess how much to trust the app."*

This extended to intermediaries actively seeking out advice and guidance.

> *"If no one in the team has used something we would do some research. We recently found a new one and contacted NHS to see if they recommended it or not."*

Intermediaries spoke about seeking out products that felt appropriate for their patient or client group or speciality, or even for individual patients and clients. They might be reassured that mental health professionals had been closely involved in developing or evaluating the product. It also helped if the DMHT was already being used successfully within the NHS or other care settings.

Some intermediaries indicated that, as with other medical devices, there could be a significant risk arising from 'human factors': how people used them, and how the design of the product could manage or exacerbate those risks.

Intermediaries tended to see most DMHT as low-risk, low impact, where if it did not work, then no harm would be done and users could simply stop using it. There were four overlapping factors that affected people's views about the extent to which DMHT might pose some kind of risk to its users:

- The nature and seriousness of their mental health condition: the more serious, the more that it was important that a DMHT worked as intended.
- The vulnerability of the user: for example, children or young people in or leaving care.
- The relationship between the intermediary and the user: particularly where an intermediary was directly responsible for someone's care (usually an HCP, but this might also include mental health support workers).
- The task the DMHT was aiming to perform. Products offering diagnosis or therapy were seen as higher risk.

Some intermediaries also commented that they would rely on recommendations from colleagues in other disciplines or agencies, which is significant given the prevalence of inter-agency working in delivering mental health care and

support. This could extend to presuming that if a colleague was recommending a DMHT product, then they could safely do the same – though on reflection, they recognised this might not always be a robust approach.

> *"I always just ask other professionals what has worked for them – a lot of word of mouth is important." (Children's Social Worker)*

Different classes of intermediaries also had different perspectives on their role. For example, teachers might be particularly focused on safeguarding and on the relationship between a student and that student's peers. HCPs would be more likely to bring a medical framework to bear, while a counsellor might focus on the root causes of anxiety or PTSD, rather than managing symptoms. This also meant that the boundaries between DMHT and other digital products that might be relevant to managing or supporting mental health would look different to each group of intermediaries.

Overall, a majority of intermediaries had a low awareness of the potential issues arising from the use of DMHT products in their professional lives. Many said they thought they should know more and some said they would raise it with colleagues and ensure that they had more information and explored any specific risks for their patients or clients.

Some were already more conscious of the risks. Sometimes this was because their workplace had put in place training and systems to identify and manage risks, such as ensuring practitioners only recommended DMHT that had been approved for use in their care setting. In other cases, it was that they had applied their own professional judgement and sense of responsibility to their patients or clients.

> *"It's also important that staff know how to use an app if they recommend it. I would want to download the app to show people myself." (Mental Health Nurse)*

7.3 Recommending DMHT

The main reasons given by intermediaries for recommending DMHT products were:

- The patient or user might not engage with face-to-face treatment or support.
- They could access support faster, either by avoiding a waiting list or using it while on a waiting list.

> *"I would only offer DMHT as part of a care plan… say, to tide them over to see a psychiatrist. In my mind, it's an extra tool in the toolbox." (GP)*

- It provided additional support to those in treatment, such as providing an immediate and 24/7 resource for patients to manage their thoughts of self-harm or suicide.

The main reasons given for **not** recommending DMHT products when this might be relevant were:

- It was not appropriate given the patient or client's situation and the nature of their challenges. Some participants wanted to avoid a patient or client feeling they were being 'fobbed off' with an app that did not provide the depth of support that reflected the seriousness of their condition.

"If they're really not in a good place and they're feeling maybe particularly vulnerable, I would avoid the on-line world." (Psychological Wellbeing Support Worker)

"Generic tools such as compiling a playlist of music that supported a positive mood will likely to be seen as not taking their situation seriously, or would be something they had tried or were already using." (Social Worker)

- There were some conditions or symptoms where HCPs in particular thought they would be very cautious about recommending DMHT. These included psychosis, and personality disorders particularly where it was not clear that the apps had been designed or developed for these conditions.

"It could play into their delusions and make things worse. Often with those patients it's about reducing stimulus not giving them more." (Mental Health Nurse)

- The patient or client might not have the necessary skills to engage with the technology, or didn't own a suitable smartphone.

"The people I work with are very vulnerable, maybe have learning needs. So I'd be looking at the level of understanding that was needed. Would the tech be appropriate for them? The last thing I want to do is cause even more worry for someone." (Mental Health Nurse)

- There might be a confidentiality or safeguarding risk, for example if their partner had access to their phone.
- They couldn't afford the DMHT products.

"I signpost people towards different apps and website. The biggest problem is a lot of them you have to pay for them." (Psychological Wellbeing Practitioner)

Various factors would also influence their choice of specific DMHT products.

"Some of my clients have disabilities, cognitive impairments, which make a lot of things really hard for them. So I would be looking at how easy it is to use." (Psychological Wellbeing Practitioner)

Some intermediaries also reported being asked for recommendations by patients or clients, including both asking their views about a particular product they

were already using.

> *"People are more and more asking what resources there are, because people [are] not getting so much face-to-face time." (Mental Health Nurse)*

Most intermediaries were cautious about what DMHT products they recommended, and either took them from an approved list or had used them themselves to check they were appropriate, or both. Some said they asked their clients or patients about their experiences with different apps to see what worked well and for whom, and this was definitely valuable, though none suggested they would rely solely on this feedback.

> *"I wouldn't recommend anything that wasn't approve by NHS and our organisation. I wouldn't find something independently." (Psychological Wellbeing Practitioner)*

7.4 Harm

Intermediaries reported few or no experiences of DMHT products appearing to cause harm. It was much more common for products not to provide any benefit, but this was what they expected and they would not think this needed to be reported formally, for example to a regulator, although they might feed this back to colleagues to help them understand which products worked best in which circumstances.

Some intermediaries provided examples of harm or risk spontaneously.

> *"A young person I worked with – she brought to me that she was using an app to track how many days she'd been self-harm free. I'd heard of this app before and I know it has bad components to it. With this app, if you're just tracking how many days you're free from self-harm that's just about ok, but there are also chat rooms and group chats, and it creates a triggering culture – people posting messages and images of self-harm. So when she shared that with me, I suggested she deleted the app." (Psychological Wellbeing Practitioner)*

> *"I've come across children using ChatGPT to create a friend. That's concerning. It can spit out the words, but the empathy really isn't there." (Psychiatrist)*

As with public participants, there was a strong view that DMHT that might work for one user, could be ineffective or even harmful for another. A common example was the risk of an app using common features such as challenges or push notifications which added to the user's stress or anxiety, or distracted them from more positive activities, or added to a general sense of being overwhelmed. In many cases intermediaries would be much better placed to make the judgement about these risks than potential users.

After an initial discussion on risk and harm, some intermediaries identified further concerns. For example, one GP regularly recommended an app that encouraged participants to upload positive memories to help them push back against suicide and self-harm ideation, and he found it very effective. But he mentioned a former patient who – had they been recommended the app – would probably have used it to upload negative memories and this would have encouraged self-harm, not prevented it.

As with patient participants, the main concern about DMHT amongst intermediaries was that young people in particular already spent too much time using digital technology, and this was a major cause of mental ill-health. One of the most powerful ways to treat or manage mental health conditions was for young people to spend more time taking part in real-world activities, including socialising with friends and staying fit and active. Some intermediaries even recommended using non-digital tools such as journaling on paper in place of digital alternatives.

> *"The only problem with digital is younger people over-using their phones. And it is so hard to get them out of this social media negativity." (Mental Health Nurse)*

> *"I suppose the internet and social media causes our kids to stay up all night and can physically make them ill. Just being online in general can be harmful. Doesn't stop and no shut off." (SEND Practitioner)*

Apart from this concern, very few intermediaries saw DMHT as likely to cause harm. If it did, they expected that users would just stop using it.

> *"If an app is causing someone distress then I would expect them to just not log on or not engage with it." (Mental Health Nurse)*

The main concerns they voiced were;

- Misdiagnosis.
- Isolation.
- Chat-rooms and forums.
- Dependency.
- Worsening symptoms.
- Reliability.

Self-diagnosis

Intermediaries voiced concerns about self-diagnosis, though as with public participants this risk included using self-diagnosis guides or quizzes published on social media platforms and diagnostic advice from content providers.

> *"Self-diagnosis is a big problem … people will take 2-3 symptoms and decide they have something and all the ramifications with that are worrying." (GP)*

> *"I think the whole self-diagnosis is quite an evil. But it's not just in those apps, it's everywhere. I think it's not a good thing to do full stop." (Psychological Wellbeing Practitioner)*

Isolation

Partly reflecting wider concerns about screen time, intermediaries voiced concern about DMHT making users more isolated, and the potential for this to exacerbate problems with perceiving the real world clearly and engaging with it fully.

> *"Another risk is some kind of disconnection from reality – loneliness from people you're with in your real world. On-line can be a safe space for people who [feel they] don't fit in or have a social network. But it makes them even more isolated." (Psychological Wellbeing Practitioner)*

> *"The risk is that knowing it is a machine is alienating. I've been asked at the start of type therapy when exchanging emails if I'm a real person or a bot." (Psychiatrist)*

Chat Rooms

Some intermediaries said they would not recommend or direct patients to chat rooms or online groups as there was a considerable risk of harm if they were not properly moderated. They also voiced concerns that many apps – including some DMHT – did not require proper registration or age checks, and this was of particular concern for safeguarding young or vulnerable people.

Less commonly, intermediaries were concerned that their patients or clients might be tempted themselves to make use of chat rooms and other anonymous spaces inappropriately.

> *"One pupil has borderline schizophrenia – she lies about things constantly and can be manipulative in her behaviour. If she was on apps and chat groups, that might feed into her problems." (SEND Practitioner)*

Substitution

Intermediaries were concerned that DMHT could provide a less effective solution for users who really needed more tailored or structured support.

> *"It can stop them getting help from professionals at school or parents. They talk about it on the app and then don't open up to people who can help them." (SEND Practitioner)*

Dependency

Some intermediaries felt that users could come to rely on DMHT to the extent that it would shape their self-perception in unhelpful ways, including where the user may have used DMHT to self-diagnose their condition. Users prone to addictive behaviours would be particularly vulnerable. Some intermediaries questioned whether some developers might want users to come to rely on their products, as this would mean they would continue to subscribe.

"There's a worry that people might start labelling themselves. I don't want people to start thinking they have something unmanageable, or that isn't solvable." (Children's Social Worker)

Reliability

Reflecting the high level of risk for many of those with serious mental health conditions, some intermediaries were concerned about relying too heavily on DMHT. For example, if someone lost their medication, there was an emergency process. If an app failed, or they lost their smartphone, this could create an additional risk and no obvious remedy.

"Technology is good until the point it's not working. I don't want someone to be in a crisis, relying on an app, and it's not working or updating or something in that moment where they need to look at their safety plan or get a contact number." (Mental Health Nurse)

Commitment

Managing or treating mental health conditions could demand a great deal of commitment and hard work from patients. DMHT could not replace this and would not be effective if presented as an easy option. This might in turn make users less likely to pursue other treatments, be more self-critical and feel demoralised.

"You have to put in the work! There's no instant gratification, like on TikTok. I have to educate my patients about this." (GP)

7.5 Raising Concerns

Most assumed that they would raise concerns with colleagues or managers, particularly if a team member had a higher level of relevant knowledge or, in the case of non-medical professionals, a health qualification. Some were aware of a formal or semi-formal process, but for most it was more a matter of using the channels to share concerns they would for any other part of their workplace responsibilities. Some also mentioned that they might try and identify a specialist in IT or DMHT within their organisation, or contact the body that provided or recommended DMHT.

"I'm not sure. Maybe there is some digital tech adviser somewhere? I'd probably raise it with colleagues and we would probably have a confused discussion!" (GP)

Where there was a clear route to raise concerns within their team, most felt this would be sufficient, even if just meant limiting or ending the use of the app within their organisation. Some also felt that they would like to know that those concerns had registered with the developer of the app, so the risks were reduced for other users outside their organisation. But there was also realism

about finding the time for this.

> *"If I'm really honest, I would then just leave it – but I think where my job and our lives are so busy, do I have time to start emailing a company about an app? No. But my moral compass says you should do something." (Psychological Wellbeing Practitioner)*

> *"I imagine there's not going to be an option to contact the people who built the app, but if there was I would want to do that." (Mental Health Nurse)*

Some saw the concerns as falling within 'safeguarding', which provided a clear process, at least for young people.

> *"It would be easier if they are under 18, as raising child protection flags is very clear cut. For over 18s, you could raise vulnerable adult flags. Then social services and my boss would get a copy." (GP)*

For children and young people, and potentially for adults receiving care and support, there was also a role for others to help monitor the use of DMHT.

> *"There could be something that comes up for parents if they're tracking the apps their children are using. Especially neurodiverse young people … or a younger person. The parents need to know what's going on." (Psychological Wellbeing Practitioner)*

After discussing harm and risk, a number of intermediaries voiced concern that they were not aware of a helpline or other route for raising concerns that did not depend on contacting an HCP, as with GambleAware and Drinkaware.

> *"GPs are not going to do anything with that. Where do you go when it's damaging? Is there something like with a gambling app?" (GP)*

7.6 Yellow Card Scheme

Most HCP intermediaries were familiar with the Yellow Card scheme and some had used it to report medicines and, more rarely, medical devices. Most non-HCP intermediaries were not aware of it.

When shown the Yellow Card scheme website for the first time, most intermediaries were positive about it and thought it could be used for DMHT reporting, though to some extent this positive reaction was about the perceived need for a reporting channel, rather than Yellow Card itself being the ideal channel.

> *"I'm aware of Yellow Card, but I would not have thought about this for DMHT. But after considering it, then it makes sense." (GP)*

There was a general view that the site needed to be updated to reflect the scope for reporting DMHT and also some explanation of what would happen. It should also allow the frequency and nature of reports on DMHT products to be viewed, just as with medicines. But there was consensus that the Yellow Card site on its own would not be enough.

> *"As soon as people have to go elsewhere and look for something, they won't do it." (Mental Health Nurse)*

Reporting needed to be integrated into the apps themselves; and intermediaries needed to be given guidance and support to help ensure their patients and clients were using the right apps in the right way and were aware of the risks of harm and how to report them.

Reporting

Reporting was seen as important both for safety and for the continual improvement of the DMHT products themselves. Developers should welcome this from users, intermediaries and from academia.

> *"You'd want to see it evolve and change. To be updated and reflect latest research. You'd need to feed that back to the product itself. Not everything gets it right straight away, so there's probably room for correction." (Child Social Worker)*

Intermediaries thought that there needed to be multiple points at which users were given the opportunity to be informed about risks and given the opportunity to report. Their views were very close to those of public participants described above and included:

- In the app stores.
- At download / registration.
- In regular 'how is it going?' check-ins.
- Flags for concerning behaviour / use such as excessive hours.
- Through a simple and prominent alert button that would access help and support, including the option of reporting concerns or harm.

Those working with young people were particularly conscious that this group were very likely to ignore pop-ups or click through terms and conditions, so techniques such as being prevented from using the app without active evidence of having read the guidance on safe use might be appropriate.

Regulation

Intermediaries generally felt that given the difficulty of identifying any harms that DMHT could cause, it was very important that products were properly tested or evaluated before being put on the market. Some thought that the developers of DMHT should have a shared interest in making sure their products worked well and any risks were fully understood, though some took a more cynical view and thought it would

be all too easy for someone to develop and launch a product with little or no interest in patient outcomes – which only underlined the need for regulation.

Intermediaries tended to see a greater role for the app stores both in preventing users from accessing inappropriate DMHT and in restricting or removing DMHT that could be causing harm. But few had a clear idea how to raise concerns with the app stores, and some thought it unlikely that the app stores would act.

> *"An app store can remove it if it breaks their rules, but I wouldn't have a clue what rules they'd have to break in order to be removed." (Psychological Wellbeing Practitioner)*

Some felt that DMHT products should have a kitemark or a scoring system to help users and also parents or carers to identify which products were safe and effective.

> *"There could be something like a traffic light system that says this has been checked so it gets a green. This would also help parents if they were able to also look up different apps to help guide their children in what to use." (GP)*

Intermediaries identified a number of tasks that might fall to a regulator, given their general view that many DMHT products were developed to turn a profit rather than prioritise user wellbeing and regulation was needed to tackle this (and also protect developers who were adhering to higher standards from being undermined). These potential interventions included:

- Apps should alert users to potential risks and advise how to use the app safely before they start to use it. This would include how to identify potential harms and what to do, both in seeking advice and support and reporting concerns to the authorities.
- Apps that pose significant risk should not be available to anyone on the app stores without some kind of age validation, if at all.
- There should be multiple channels for publicising the ability to report concerns, including within each DMHT product.
- Those recommending or providing apps should have access to the best possible advice, guidance and if necessary training on which apps to use in different circumstances, to avoid harm in the first place. This might involve professional bodies and educational institutions.

Safety Alerts

Some intermediaries commented that there would need to be a system for alerting themselves, and app users, about any emerging risks with individual DMHT products. These would fulfil the roles of safety bulletins, Direct Healthcare Professional Communications

and product recalls for medicines and medical devices. These would need to be integrated into the apps and also through a separate process so intermediaries who were not themselves using the products would still be alerted. It was also suggested that warnings might be more effective if they were sent via an official NHS email as this tended to have more impact.

Professional Perspectives on Regulation

As professionals working in health, social and educational care, the intermediaries were well-placed to step back and consider the practical implications of trying to improve the safety of DMHT including the use of Yellow Card within the context of limited resources and multiple demands on their time, including alternative ways to protect and support their patients and clients. Against this background, it was striking that there was a broad consensus amongst intermediaries that:

- There was a critical and largely negative relationship between digital products and mental health and well-being.
- DMHT might help; but it also brought considerable risks which needed to be better understood. There was an urgent need to sensitise intermediaries to these risks, particularly those working with the most vulnerable patients and clients.

"Until today, it never entered my head that an app could cause problems." (GP)

- Practitioners needed more authoritative guidance and support, including on identifying harm, managing risk and reporting concerns – and the latter should include building a global picture of potential harm as well as limiting the use of apps within individual frontline organisations. This would involve using precious professional time and other resources, but this was necessary.

"If you can regulate them and make some kind of library system for professionals, that would be really good. We're busy, so it would help us a lot." (Psychological Wellbeing Practitioner)

- The task facing the MHRA was difficult, but vital.

"Absolute minefield. I don't envy them as I think it's impossible to do what they are trying to do." (GP)

"Government has a big role to play – not least so ensure that those who are making money off this are holding to their standards." (Psychological Wellbeing Practitioner)

8. Children and Young People

Key Findings	Young people were very aware of the risks of social media and other digital products – inappropriate content, alienation, bullying, grooming and addiction
	DMHT might work well for those reluctant to seek help from an adult
	But it might conflict with their limiting screen time to avoid digital harms
	They thought it very unlikely they would 'report' DMHT but might give feedback to an intermediary or via in-app feedback
	Intermediaries shared concerns about using DMHT to deal with what were often digitally-created or enabled problems facing children and young people – for example, if students were relying on DMHT but a school wanted to ban mobiles

8.1 Young People

Young people have a distinct relationship with digital media and also a different profile in terms of risk and safeguarding. We therefore ran six focus groups with young people to explore their attitudes towards DMHT, again taking in the wider context of their perceptions of, and use of, social media and other digital channels. This was supplemented by discussions with parents in the adult focus groups and with interviews with intermediaries who had direct experience of supporting young people with their mental health, including healthcare professionals, mental health support workers and social workers.

8.2 Social Media and Mental Health

Young people are 'social media natives' who only know a world in which entertainment and networking with friends can largely be conducted on social media platforms such as Snapchat and TikTok. There was no sense that participants 'chose' to use social media, any more than they 'chose' to live in a world with cars or schools.

Some even spoke about how difficult it was to limit their use or to step away, even temporarily, from digital technology. Further, the technology itself might prevent them from changing their pattern of use. For example, if they were being bullied on a social media platform group and they left it, then any other user could add them to the group again without their permission. To stop this, they would have to individually block every other user in that particular group.

They had little confidence in the protections supposedly put in place for their wellbeing. If enough people complained, then a social media platfkrm might take down an offensive video, though the assumption is that a single video being used to bully an individual might not qualify as there would only be a small number of complaints compared to a more widely-circulated video that breached a platform's community guidelines. Similarly, some young people commented that there was 'no point' complaining about other users to the platform because, even if they were banned, they could just get another e-mail address and rejoin.

Unlike the adult participants, young people did not see simply uninstalling apps as a way to avoid harm. Although many young people participants had experienced online harm, most had not stopped using those apps and amongst those who had, several had reinstalled them.

This was particularly significant given how strongly young people made a connection between social media and mental health. All participants had seen age-inappropriate content and this included self-harm. The apps themselves could be isolating and addictive.

> *"TikTok is very addictive and you end up spending so much*

time on it you don't get enough sleep, and then you feel tired and irritated the next day." (Year 10)

8.3 Perceptions of Risk and Benefits

Young people had low awareness of DMHT and only a few participants had used apps to try to support their mental health, for example by reaching out to friends through social media, journaling on their smartphone or watching videos about depression. But in general, they thought it would be better to speak to someone in real life, such as a trusted teacher.

Some found it hard to imagine how an app designed to help with their mental health could pose any risks. In general, they saw DMHT as 'low risk, low reward'. They did raise some concerns, based on their wider experience with digital technology:

- **Content.** While some young people were very positive about being able to talk to peers and those with similar mental health concerns, forums or other interactions with other users could lead to amplifying negative thoughts and/or poor advice, particularly if these were unmoderated or anonymous.
- **Safeguarding.** Participants also reported being contacted on social media by people they did not know and were aware of the risks of catfishing and grooming. They felt this could also happen with some DMHT if those using the products were not verified. All young people participants had taken part in online safety awareness programmes.
- **Privacy.** Having mental health content on a smartphone could be perceived as embarrassing if, for example, a parent asked to check their phone. Also, smartphones were vulnerable to being hacked or taken and misused by others, for example leading to bullying.

Some also questioned how **effective** such products would be, and in particular that generic content would not reflect the serious nature of mental health conditions. Linked to this, there was considerable scepticism that DMHT that relied on AI (rather than interactions with real people) could be effective as they would lack emotional intelligence.

"If you're having a panic attack, the last thing you need is a passive/aggressive cartoon telling you how to breathe."

Perhaps more so than with adults generally, several young people saw the main potential benefit of DMHT as the ability to get support without having to speak to an adult. This was seen as being very important for some young people and although they acknowledged that it would be better to speak to a real person, having some digital support is

better than nothing. At the same time, these participants also felt it was important for DMHT to highlight to users that using digital technology to support one's mental health should not be as a replacement to seeking support from a trusted adult or professional.

Another potential benefit of DMHT was having access to digital mental health support 24/7, particularly outside school times when in-person support would not be available.

There were mixed views about DMHT and diagnosis. Some felt that there was a risk that young people would use it to understand more about symptoms and then game the system to gain a 'badge of honour' which would also give them access to extra consideration or support at school. A few young people and other intermediaries felt it would be a valuable way for someone to explore their mental state and understand more about their symptoms or behaviour, which might also lead them to have more confidence to seek help or support.

8.4 Reporting Harm

These participants had experienced first-hand, or heard from friends, the harm that social media can bring. They therefore tended to view DMHT in this context. These young participants generally felt that harm would have to be very significant before they would think of reporting it. The most likely reporting route would be to a teacher or other trusted adult, but they also would expect there to be a safeguard and reporting route within the app. It was extremely unlikely they would report through a separate online channel.

8.5 Parent Perspectives

Parents felt they had both a right and a duty to know that their children were 'ok' both in terms of how they used smartphones or other digital channels and their mental health. They were very concerned about the potential for harm posed by social media, including seeing inappropriate content (including self-harm and other content related to mental health), bullying and online grooming. Smartphone content (games and videos) could also be addictive and distracting.

But they also appreciated that young people could not be supervised the whole time and needed to develop skills in managing their own lives, and that others – including schools and the health and care system – had roles to play. They also felt that simply preventing their children from having access to digital channels was unrealistic. Some were open that their children had far more digital competence than they did, which made supervision or control hard to implement.

There was a general sense that parents were not sure how best to act, and would welcome more guidance and information, so long as it was not prescriptive or unrealistic: they could not fight

social media on their own. This could come direct or through schools or other intermediaries.

8.6 Intermediary Perspectives

The participating intermediaries tended to work with young people with more serious mental health conditions, and so had a different perspective than parents or young people themselves. Intermediaries were open to the idea of DMHT providing valuable support for young people, though they saw this as part of a wider treatment program involving professional oversight. They were also concerned that many young people were already over-dependent on social media and digital technology and that this created serious harms and vulnerabilities. Some felt that young people could become over-confident in using technology because they were so familiar with it, notably on forums and peer-to-peer support, and so would potentially underestimate the risks posed by the technology or other users.

Their main concern was to have access to reliable and comprehensive guidance on DMHT for young people, including risks and efficacy and when they should consider using or recommending DMHT products, much as they would for any other treatment or approach. As with parents, some commented that they did not themselves have the same level of digital competence or experience as the young people they worked with, and often turned to them to understand more. This included asking what DMHT or other digital products they were using to help manage their mental health.

There was a strong view that social media could be very harmful to young people and in some cases the intermediaries would limit access to smartphones to try and manage this, particularly in residential settings. For schools, there was a particular challenge with DMHT in that many were moving to limit access to smartphones while on school premises: if a student was using DMHT to support their mental health, and so wanted to have access to their smartphone at all times, this could make enforcing controls more widely very difficult.

Some intermediaries said that they were very open to working with developers to try and ensure DMHT products were as robust and beneficial as possible, and one had taken part in such a trial and seen it as a valuable experience on all sides.

9. Conclusions and Recommendations

Key Findings	Most people do not think DMHT is likely to harm them. If they had bad experiences, they would simply stop using it, not report it.
	They are more concerned about others, particularly young people, as smartphones and social media are a major driver of mental health conditions.
	They are also worried about DMHT using AI because it could worsen existing mental health conditions such as anxiety, alienation and psychosis.
	Users would find it hard to identify harm to themselves. More complex DMHT needed to be supervised by a healthcare professional and integrated into non-digital treatment.
	Reporting and analysis of user experience should be integrated into DMHT with serious concerns linked to Yellow Card reporting.
	Intermediaries should have access to authoritative guidance on the risks and benefits of DMHT including for different user groups

9.1 Main Findings

The research has shown that most **users** or potential users of DMHT think:

- These are not high-risk products, except potentially where they employ AI or are being used by children or other more vulnerable groups.
- The specific risks with DMHT, such as self-diagnosis, inappropriate advice, excessive screen time, addiction, harmful forums, are prevalent in the wider digital space.
- Digital technology is already contributing to higher levels of mental illness by generating isolation and anxiety, and there is a risk that DMHT might make this worse.
- DMHT should generally be used as part of a care plan and under the supervision of a mental health professional: otherwise, the risks are increased and the potential benefits reduced.
- There should be a way of reporting concerns or harm, but that this should be part of a wider feedback channel for user experience that also covers the benefits.
- Yellow Card could be developed to fulfil this role, but reporting has to be integrated into each app and made very straightforward.
- Awareness of Yellow Card and reporting needed to be part of a wider approach to DMHT safety.
- DMHT should ensure users are aware of potential adverse effects prior to use, so they can make informed consent.

Most **intermediaries** share some or all of these views, and also think there should be more guidance available to HCPs and other intermediaries to support how the choose and recommend DMHT, including identifying and managing risks and reporting adverse events.

Perceptions of Risk

In general, participants did not think DMHT posed much if any risk. If an app did not work, they would just stop using it. They were much more concerned about the wider problems caused by social media and other digital technologies, including causing or contributing to isolation, anxiety, depression and self-harm.

Some did have specific concerns, and these were also shared by intermediaries:

- Screen time. It would contribute to excessive screen time and could make conditions or symptoms such as isolation or alienation worse.
- Financial exclusion. The apps were developed more to make money than to help users, and those who could not afford the apps would be disadvantaged.

- Use of AI. Where AI was being used to replace human treatment and support, this would in many cases make problems worse.
- Self-treatment. Using DMHT in isolation from professional support would exacerbate risks such as misdiagnosis or managing suicidal ideation.
- Misdiagnosis. DMHT could provide false or misleading diagnoses, and this might prevent users from seeking appropriate help or reinforce negative self-image or behaviours.
- Addiction and isolation. As with other digital technologies, DMHT could be addictive and divert users from developing human connections or undertaking real-world activities.

Participants recognised that these risks would be hard for users to recognise for themselves, which underlined the need for DMHT to be used in a supervised way and ideally as part of a care plan supported by healthcare and other professionals and by family and friends. DMHT itself could support this by allowing HCPs or others to access data on how patients or clients were using it or for the app to monitor and 'check in' with users who were displaying concerning behaviour.

Potential for Harm

The main ways in which users and intermediaries understood the potential for harm posed by DMHT were:

- Giving them a misleading diagnosis which might negatively influence their sense of self or lead them to pursue the wrong, or no, treatment.
- Making their symptoms worse, for example by deepening the user's sense of isolation or undermining their sense of self-worth.
- Diverting them from seeking effective support from others, including healthcare professionals.
- Exposing them to harmful content or misleading information from other users, for example in chatrooms.

Behind each of these was the risk of people using DMHT in isolation, and this could be mitigated by integrating DMHT into wider care and support for users, including oversight by HCPs or other intermediaries.

Recognising Harm

In most cases harms would be hard for users to recognise because mental health was both complex and individual. It also fluctuates with internal and external factors, including the use of digital products and platforms. As a result, it would always be hard to attribute either positive or negative impacts to DMHT, particular for individual users.

There was much more confidence that HCPs would identify harm, and openness

to the idea that apps themselves could identify risk and harm and act on it. There was also potentially some role for friends and family in assessing impact or monitoring progress.

Reporting Harm

Most users said that, even if they recognised or suspected harm from using DMHT, they would not make a report or provide feedback because they would not know how, or would expect it would make no difference, or it would be hard to do while also struggling with their mental health condition. The one exception was if the DMHT had been provided or recommended by a healthcare professional or other intermediary, in which case they were likely to inform them directly. However, this was limited to cases where they were receiving ongoing care and support: for example, they were unlikely to make an appointment with their GP just to report a bad experience with DMHT.

Users felt that if there was a simple and reliable way to provide feedback, they might do so. Some felt feedback should go direct to developers, but others thought there needed to be an independent body, similar to an ombudsman or regulator.

9.2 Integrating Yellow Card

Few users had heard of the Yellow Card scheme. None – including HCPs and other intermediaries – spontaneously linked the need for a reporting route for harms arising from DMHT to Yellow Card. But almost all thought that if Yellow Card were the appropriate route, then all DMHT users should know about it and be able to access it easily. However, there was a strong view that there should be a single feedback channel covering both positives and negatives, which could then link on to Yellow Card. This could also lead to advice and support (as with campaigns such as Drinkaware).

Information on risks and reporting should not rely on a single channel but could include:

- **First use.** When users first signed up for or downloaded an app (similar to a patient information leaflet for medicine, but much shorter and clearer)
- **Periodic 'check-ins'.** The app would ask users for feedback on how well it was working and if it was causing any problems. Any strongly negative reactions could be escalated, including a link to Yellow Card.
- **Monitoring.** If the app itself detected worrying patterns of behaviour (and some users were open to AI being used to monitor usage, though others had reservations).

Users also thought that, in support, information and awareness of DMHT safety and Yellow Card should be

promoted through NHS contact-points such as GP surgeries and the NHS app.

Intermediaries did not generally see DMHT as risky. However, they did see social media, smartphones and other digital products as potentially very harmful and because of this, in some cases they would not recommend DMHT and might advise clients or patients to stop using DMHT. Some intermediaries had limited guidance and support in using DMHT with their clients or patients, such as access to lists of products specifically approved by or for their care setting. Others had to rely more on word of mouth and would welcome authoritative guidance and support, including on how to share concerns and with whom.