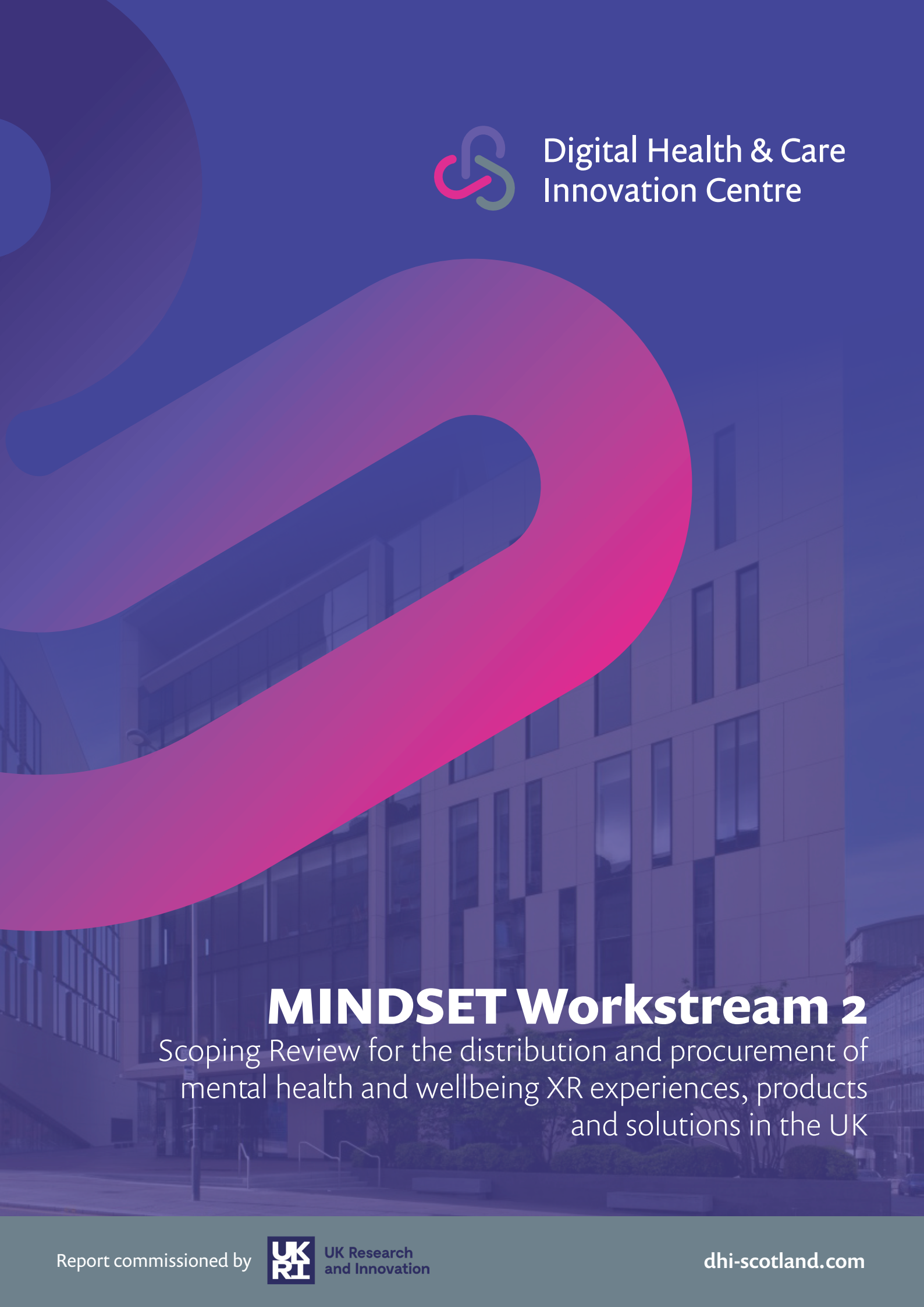


Digital Health & Care Innovation Centre

MINDSET Workstream 2

Scoping Review for the distribution and procurement of mental health and wellbeing XR experiences, products and solutions in the UK

Report commissioned by UK Research and Innovation

dhi-scotland.com

Authors
Written by Digital Health & Care Innovation Centre (DHI), with contributions from Fuzesi, Peter; Kendall, William; Mackenzie, Moira; McIntyre, Don; Rimpiläinen, Sanna; Savage, Jamie; Stoney, Charlotte.

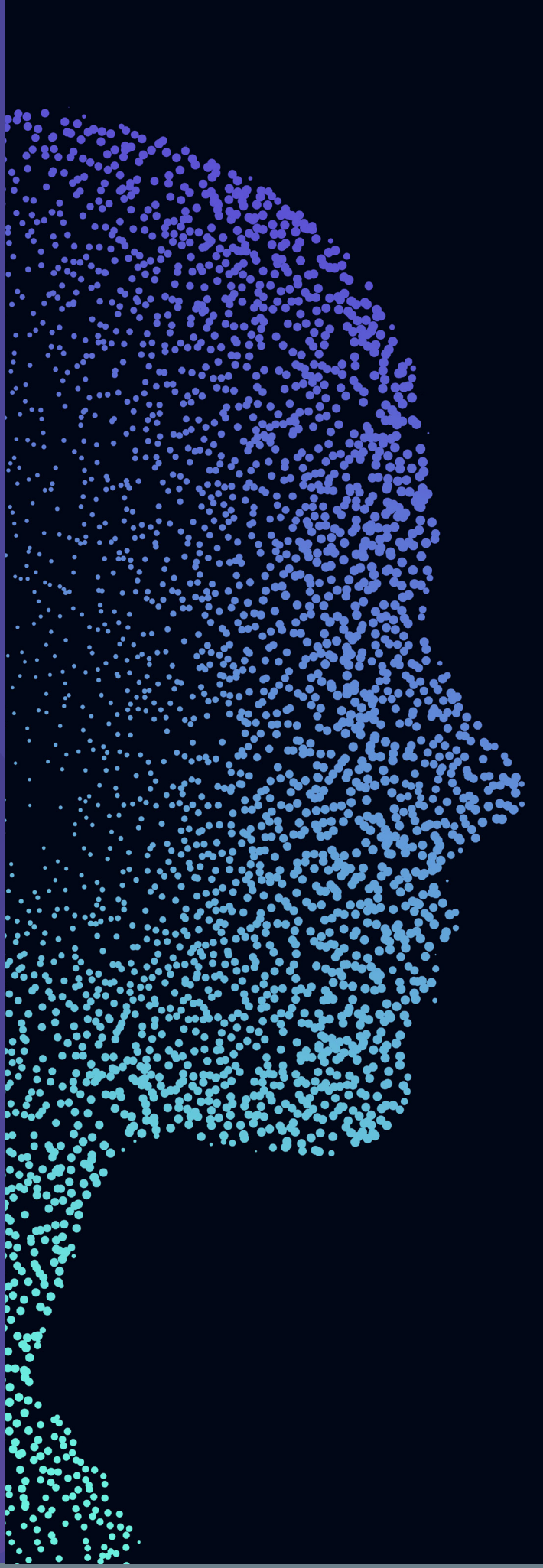
DOI
https://doi.org/10.17868/strath.00085575

Disclaimer
This document has been prepared in good faith using the information available at the date of publication without any independent verification.

Readers are responsible for assessing the relevance and accuracy of the content of this publication. University of Strathclyde, acting through the Digital Health & Care Innovation Centre, will not be liable for any loss, damage, cost or expense incurred or arising by reason of any person using or relying on information in this publication.

This document has been written and prepared by the Digital Health & Care Innovation Centre.

The DHI is a collaboration between the University of Strathclyde and the Glasgow School of Art and is part of the Scottish Funding Council's Innovation Centre Programme. DHI supports innovation between academia, the public and third sectors, and businesses in the area of health and care.



1 - Executive summary

The COVID-19 pandemic provided a sharp focus on mental health issues, especially among young people, with the UK and its devolved governments identifying improving mental health as a priority area[1] [2] [3] [4]. The pandemic also accelerated the digital transformation of health and social care service delivery, including mental health services. This has prompted a consideration of digital mental health market opportunities to help address the identified challenges.

In November 2022, DHI was commissioned by UKRI to inform Workstream 2 of the £20m MINDSET Programme, a "***test and trial a platform for the distribution and procurement of mental health and wellbeing XR experiences, products and solutions***". XR has been defined by UKRI as referring to "Extended Reality and covers Augmented Reality (AR), Mixed Reality (MR), Virtual Reality (VR), haptics, interfaces, platforms and software and will often be referred to as immersive technologies". DHI developed a three-stage approach to address questions posed by UKRI - Current State Mapping; Co-designing Future State; and Recommendations. The approach included a desktop and literature review, interviews, co-design workshops to inform the report recommendations.

Key Findings:

- Current mainstream procurement infrastructures offer poor support for XR health companies wishing to access healthcare markets, but there are a number of disparate mechanisms to support innovation that may help this emergent market to gain traction.

- Companies are not clear what they need to do to be in a state of readiness e.g., level of evidence to meet innovation procurement requirements. They tend to engage directly with individual clinicians to raise awareness and undertake trials; however, this is unlikely to provide significant market traction as the clinicians/trials tend not to be linked to procurement routes.

- The digital therapeutics market may gain traction from XR approaches for other healthcare related activities such as education and training, through which awareness and confidence could be increased.

- Although there are different approaches and requirements at national, regional and local levels, a route map containing high-level phases and requirements may help companies better pinpoint where they currently are and how to navigate forward. This could create a collaborative framework to address gaps e.g., common standards. An analysis of the desktop literature review and consultation materials elicited nine key elements that should be addressed to support XR technologies market penetration and would inform a route map.

- Some new procurement approaches are emerging for the procurement of XR technologies in England, which may support XR and digital mental health therapeutics.

Conclusion:

The broad scope of the brief allowed for a fuller exploration of the challenges and opportunities along the full route to market journey. The consultations and the User Stories proposed in the workshops reflect this, suggesting there is not a single solution but rather **a spectrum of capability requirements** from education and training, through clinical engagement and procurement to safe integration of XR technologies into care delivery.

The proposed solution space is therefore multi-faceted and needs to cater for pre-adoption activities (testing, piloting, formal trialling), plus support the transition stage where XR products are functionally ready for deployment but are not yet approved or fully compliant with all applicable standards and regulations. This would offer a **progression roadmap** for XR solutions to be tested by clinical teams and integrated into care pathways and subsequently made available as approved, mature solutions that can be procured and safely deployed in clinical settings.

The four workstreams currently being progressed by UKRI within the MINDSET Programme may address much of the capability requirements identified through this scoping review if progressed as a coordinated, flexible and mutually reinforcing set of activities, building on the findings of this report.

[1] https://www.england.nhs.uk/long-term-plan/
[2] Mental health - gov.scot (www.gov.scot)
[3] Levelling Up White Paper
[4] Call for evidence for new 10-year plan to improve mental health - GOV.UK (www.gov.uk)

Recommendations:

These are grouped into four key areas:

1. Test and Trial platform: to provide a set of core capabilities that when combined provide a focal point for supporting the introduction of XR technologies into mental health treatment.
2. Education: building expectation that technology-supported care should be a 'given' and not a 'gimmick'.
3. Funding and de-risking: options for de-risking XR introduction at scale.
4. Procurement: the development of a 'handbook' for market entrants.

Focusing specifically on the UKRI 'ask' relating to workstream 2, although the need for a test and trial platform was not directly articulated by the stakeholders engaged in this review, there was strong consensus on the salient challenges and opportunities. This suggests that a 'platform' type approach could offer an important and safe route for XR innovation introduction into healthcare settings.

The term 'platform' in this context is used to comprise a collection or federation of resources that together represent a suite of capabilities (see section 5.2.1/Diagram 3) for suppliers, clinicians, health and care organisations and procurers. This would offer benefits on multiple levels and could in time be adopted into procurement models and frameworks to accelerate the delivery of benefits and improve the assurance of product efficacy and equality of care.

The four key recommendations represent a broad palette of opportunities for positive, sustainable change along the full route to market and represent the distilled input from the stakeholders participating across the engagement exercises. There were strong, consistent messages indicating routes to assuring the development, integration, and exploitation of XR technology potential in mental health settings.

These areas and the specific recommendations under each offer strong candidates to progress the potential value of XR in mental health therapeutics for the benefit of patients, health and care professionals whilst assuring the future of innovation within a healthy, competitive market that delivers long term benefit and international credibility to the UK as a leader in digital health and care innovation.

2 - Introduction

DHI has been commissioned by UKRI to undertake this scoping review to inform the approach and scope of the proposed MINDSET Workstream 2, a ***"test and trial a platform for the distribution and procurement of mental health and wellbeing XR experiences, products and solutions".***

The COVID-19 pandemic provided a sharp focus on mental health issues, especially among young people. Research[5] found that 41% of previously healthy 18-24-year-olds reported a mental health condition in April 2020 which was more than double the 'normal' level (19%) in 2018-19, while 83% of young people with mental health needs agreed the COVID-19 pandemic had negatively impacted their mental health[6]. Most affected were young women aged 17-22[7] (or 20-24, according to ONS)[8].

The UK and its devolved governments have identified improving mental health as a priority area[9] [10] [11] [12]. The pandemic also accelerated the digital transformation of health and social care service delivery, including mental health services.

In May 2021, the "Growing Value of XR in Healthcare in the UK"[13]Report outlined the current state of XR[14] in healthcare in the UK and described how XR technologies could provide value to the healthcare system. XR has been defined by UKRI as referring to "Extended Reality and covers Augmented Reality (AR), Mixed Reality (MR), Virtual Reality (VR), haptics, interfaces, platforms and software and will often be referred to as immersive technologies".The benefits of XR in mental health were identified as including cost savings in delivering rehabilitation, cutting waiting times and improving surgical performance by as much as 230%.

Challenges to the realisation of these benefits were also identified, including the fragmented nature of the innovation ecosystem to support the development of XR technology, lack of opportunities for cross-sectoral collaboration and the absence of a marketplace for efficient distribution of XR solutions in health and care[15].

One of the recommendations of the report proposed the development of procurement frameworks: to create "a clear process to procure XR experiences into healthcare settings, including standard set criteria [commercial companies] must meet to qualify as a registered supplier, stated obligations and conditions needed to receive payment".

The Growing Value of XR Report informed UKRI's £20M Mindset Programme contains four key workstreams. It aims to transform UK Mental Health provision post-COVID through the development and scale-up of new digital delivery service models for Mental Health.

[5] The Resolution Foundation "Double trouble: Exploring the labour market and mental health impact of Covid-19 on young people"
[6] Young Minds. (n.d.). Mental Health Statistics UK | Young People. Young Minds.
[7] The Children's Society. (n.d.). Children's Mental Health Statistics | The Children's Society. https://www.childrenssociety.org.uk/what-we-do/our-work/well-being/mental-health-statistics
[8] Office for National Statistics. (2022, October 2). Young people's well-being in the UK - Office for National Statistics. https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/bulletins/youngpeopleswellbeingintheuk/2020
[9] https://www.england.nhs.uk/long-term-plan/
[10] Mental health - gov.scot
[11] Levelling Up White Paper https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1052060/Levelling_Up_White_Paper.pdf
[12] Call for evidence for new 10-year plan to improve mental health - GOV.UK (www.gov.uk)
[13] https://www.xrhealthuk.org/the-growing-value-of-xr-in-healthcare
[14] XR refers to Extended Reality and covers Augmented Reality (AR), Mixed Reality (MR) and Virtual Reality (VR), haptics, interfaces, platforms and software; XR may also be referred to as immersive technologies. (UKRI et al., 2021)
[15] UKRI et al. (2021). The Growing Value of XR in Healthcare. https://www.xrhealthuk.org/the-growing-value-of-xr-in-healthcare

2.1 – Requirements & Approach

DHI were asked by UKRI to address the following questions:

1. What is the innovation and procurement pathway to bring digital technologies to deliver mental health therapeutics?
2. What are the main barriers faced by innovators in bringing digital therapeutics to market? In addressing this question, the study should note the proposed scope of the other workstreams, including Workstreams 1 and 3 providing funding for early-stage R&D, and Workstreams 4 on knowledge sharing.
3. How can a further intervention through Workstream 2 add most value? In addressing this question, the review should not be confined to the existing statement of scope for the workstream and may consider other aspects such as regulatory approvals by MHRA, NICE/NHSX DTAC assessment and devolved nation equivalents.
4. If a test and trial platform is the most valuable intervention for Workstream 2:
   - An outline functional specification for a platform
   - Recommendations on the type of organization best placed to establish and operate a platform. In making recommendations the report should highlight where there is precedent for those types of organizations establishing such a platform and any learning from that experience.

To address these, DHI developed a three-stage approach as outlined below (Diagram 1) and further detailed in Appendix 1: Requirements and Approach.

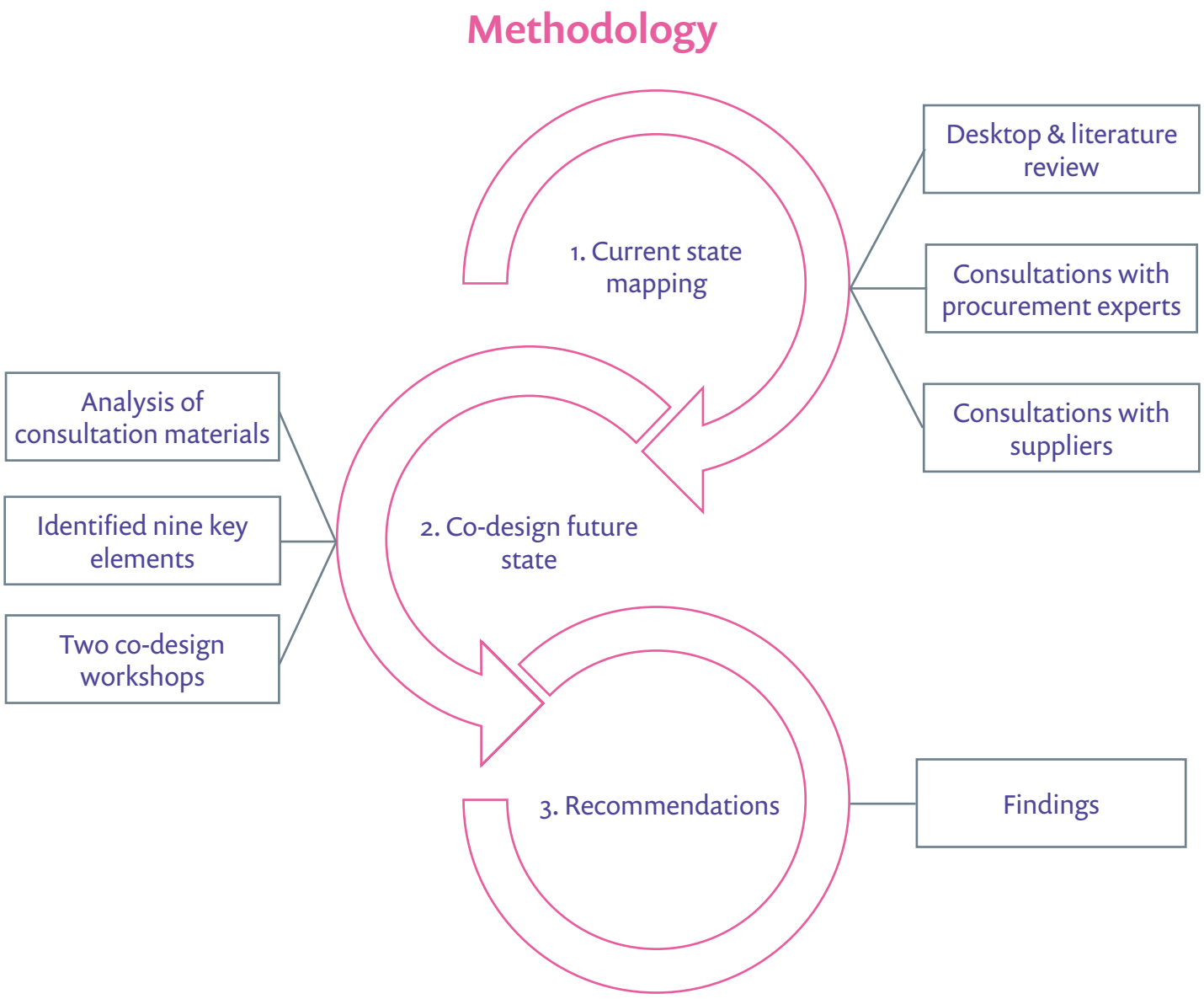


Diagram 1: Methodology

3 – Current State Mapping

3.1 - Desktop and Literature Review

Current state mapping initially involved a desktop and literature review which sought to analyse relevant market PULL factors from the commissioner's perspective, and market PUSH factors from the commercial supplier's perspective. This mapping considers the current procurement landscape across the four UK nations, provides examples of existing innovation support mechanisms, and summarises a short review of the current prevalence of XR mental health therapeutics in the UK.

3.1.1 – Current Public Sector Procurement Landscape in UK

The procurement-related functions of public sector bodies including the NHS, can be divided into three main aspects:

- Funding Distribution – top level funding distribution/procurement, directly by government or through another public body such as a health board/trust.
- Commissioning – assessing needs, planning, and monitoring services.
- Procurement – directly acquiring goods and services.

Responsibility for these functions is typically divided between national, regional and local organisations. Although this report refers to local councils as potential procurement bodies for mental health therapeutics (and this may also be true for third sector mental health organisations), for the purpose of this report, DHI has focused on the NHS to illustrate a potential large-scale public sector commissioner.

National

At the national level, commissioning and procurement are generally managed by separate bodies. The main organisations responsible for procurement in UK healthcare are NHS Supply Chain in England[16], NHS National Services Scotland in Scotland[17], NHS Wales Shared Services Partnership in Wales[18], and Procurement and Logistics Service in Northern Ireland[19] (See Table 1). Other procurement-related organisations typically focus on commissioning or business support. In addition, some services may be procured by national bodies which do not have procurement as their main function but have a procurement requirement e.g., devolved Governments, specialist health boards.

	Nation			
	England	Scotland	Wales	Northern Ireland
Government-level funding	Department of Health and Social Care	Scottish Government	Welsh Government	NI Department of Health
National Commissioning and Procurement Support	NHS England, NHS Supply Chain, NHS Shared Business Services (NHS SBS), NHS Central Commercial Function, Procurement Hubs	NHS National Services Scotland (NSS) Scotland Excel (Local Government)	National Collaborative Commissioning Unit, Welsh Health Specialised Services Committee, NHS Wales Shared Services Partnership, National Commissioning Board Wales	Health and Social Care Board, Strategic Planning and Performance Group (SPPG), Procurement and Logistics Service (PaLS); part of the Business Services Organisation (BSO), public health agency commissioning teams.
Local Commissioning and Procurement	42 Integrated Care Systems (ICSs), local governments	14 regional health boards	7 local health boards	5 Health and Social Care Trusts, 5 Local Commissioning Groups

Table 1: Summary of the Organisational Procurement Structure of the NHS across the 4 UK Nations

[16] *About NHS Supply Chain. (n.d.). NHS Supply Chain. Retrieved 16 December 2022, from https://www.supplychain.nhs.uk/about-us/*
[17] *How NSS works—Our aims. (n.d.). NHS National Services Scotland. Retrieved 9 January 2023, from https://www.nss.nhs.scot/how-nss-works/our-aims/*
[18] *About Procurement Services. (n.d.). NHS Wales Shared Services Partnership. Retrieved 31 March 2023, from https://nwssp.nhs.wales/ourservices/procurement-services/about-procurement-services/*
[19] *PaLS - Procurement and Logistics Service. (n.d.). HSC Business Services Organisation. Retrieved 12 December 2022, from https://hscbusiness.hscni.net/services/1878.htm*

Regional

At the regional level, there are 42 Integrated Care Systems (ICS) in England and 318 local councils; 14 territorial health boards in Scotland with 32 local councils; 7 local health boards in Wales with 22 local councils; and 5 Health and Social Care Trusts and Local Commissioning groups in Northern Ireland. These organisations tend to be responsible for both commissioning and procurement.

ICS's are composed of: Integrated Care Partnerships, which manage strategy through a committee of local authorities; and Integrated Care Boards, which fulfil the commissioning and procurement roles previously held by Clinical Commissioning Groups.[20]

In Northern Ireland, Local Commissioning Groups are separate bodies from their corresponding regional health and care trusts. [21] [22] NHS Scotland and Wales both use a similar structure of regional and specialist health boards. [23] [24] [25]

3.1.2 – Examples of UK Innovation Support Mechanisms

There are a number of innovation stages which can be supported by different mechanisms.

(a) Early-Stage Innovation

- **Evidence generation**

If a solution is at an early innovation stage, evidence generation will be necessary to show the value it can provide. Initially, evidence for innovations may focus on testing and implementing trials at a small-scale, local level – for example, by approaching individual clinicians or interested local services. This is important for early-stage evidence gathering and confidence building. Further routes for generating initial evidence include engaging with academia to conduct research studies, SBRI funded feasibility studies or working directly with third sector organisations or local authorities. [26]

- **Signposting, connection, and triage for trialling**

England's NHS Innovation Service, [27] [28] Scotland Innovates [29], and Digital Health Wales [30] provide portals to direct innovators towards the type of assistance that is most appropriate for the stage their innovation may be at. Each has connections with many organisations that can support innovation. Innovators submit a form detailing their innovation which is used to signpost, triage, and connect these appropriately for trialling.

- **Innovation challenge calls**

An innovation challenge call is where a procurer publishes a notice for all suppliers in a particular area. These calls typically highlight a specific area of need and an indicative contract value. They identify if they are focusing on feasibility studies or more advanced R&D. Suppliers apply detailing their innovations; the applications are evaluated, and the most promising innovations are offered further support, usually in the form of research and development (R&D) funding and guidance. Innovation challenges often take the form of pre-commercial procurement Small Business Research Initiatives (SBRIs). There are a number of organisations that issue these types of challenges including SBRI Healthcare [31], UKRI, Enterprise Agencies, and InnoScot Health [32].

[20] *NHS commissioning: Integrated care systems (ICSs). (n.d.). NHS England. Retrieved 7 February 2023, from https://www.england.nhs.uk/commissioning/who-commissions-nhs-services/ccg-ics/*
[21] *Local Commissioning Groups. (n.d.-b). DOH/HSCNI Strategic Planning and Performance Group (SPPG). Retrieved 30 March 2023, from https://online.hscni.net/in-your-area/lcgs/*
[22] *Health service structure. (n.d.). Belfast Health & Social Care Trust. Retrieved 30 March 2023, from https://belfasttrust.hscni.net/about/corporate-info/health-service-structure/*
[23] *Health Board Areas. (n.d.). NHSScotland Careers. Retrieved 9 February 2023, from https://www.careers.nhs.scot/careers/find-your-career/international-recruitment/nhsscotland-health-boards/*
[24] *NHS Wales health boards and trusts. (2023, February 3). Welsh Government. https://www.gov.wales/nhs-wales-health-boards-and-trusts*
[25] *Is healthcare in Wales really that different? (2019, October 21). Wales Centre for Public Policy. https://www.wcpp.org.uk/commentary/is-healthcare-in-wales-really-that-different/*
[26] *Interview with Scottish Government advisor (2023, Feb 23).*
[27] *About the service. (2022, August 3). NHS Innovation Service. https://innovation.nhs.uk/about-the-service*
[28] *How we use your information—Innovation Service. (n.d.). NHS England. Retrieved 24 February 2023, from https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/public-and-partners/innovation-service/*
[29] *Scotland Innovates—About. (n.d.). Scotland Innovates. Retrieved 14 December 2022, from https://innovator.scot/about*
[30] *Digital Health Wales. (n.d.). Digital Health Wales. Retrieved 30 January 2023, from https://digitalhealth.wales/digital-health-wales*
[31] *How we work—SBRI Healthcare. (n.d.-a). SBRI Healthcare. Retrieved 15 December 2022, from https://sbrihealthcare.co.uk/how-we-work/*
[32] *Who we are. (n.d.-a). InnoScot Health. Retrieved 16 January 2023, from https://innoscot.com/who-we-are*

(b) Developing and progressing innovations

- **Research and development (R&D)**

Innovations which have demonstrated feasibility are often further progressed through R&D funding. This may support planning, development of prototypes, regulatory approval, and testing. The innovation partnership procedure [33] is specifically designed to support R&D in a living lab type environment to further develop and refine the solution.

Some R&D funding is also provided through pre-commercial procurement approaches (such as SBRI above). This is a competitive process where public procurers purchase R&D from several suppliers simultaneously. Suppliers compete during several phases, with the number of suppliers being successively reduced. Suppliers retain ownership of intellectual property, while procurers maintain some usage and licensing rights.[34]

- **Wider implementation and bidding on contracts**

Implementation-ready innovations with sufficient initial evidence can bid for public sector contracts where there is demand and funding available.

For innovations with limited evidence of impact or immature business models, smaller-scale local or regional procurements may be appropriate, while innovations with large-scale implementation evidence may be best suited for national procurements.

- Solutions with the least amount of evidence tend to be introduced and developed within a single service or local organisation e.g., unpaid trials via portals/individual contacts or applications to funded innovation challenge calls.
- Solutions which have sufficient small-scale evidence can be implemented across a wider range of organisations, or at a regional level e.g., R&D Procurements/Innovation Partnerships.
- Finally, solutions which have evidence of effectiveness from large-scale implementation can be rolled out on a multi-region/service basis or nationally where a contract is advertised.

(c) Innovation support organisations

Several organisations designed specifically for the procurement and development of innovations exist in the UK. Some of the main functions of these organisations include:

- Providing information/guidance on the innovation process and on selling to the public sector
- Connecting individuals or groups across businesses/suppliers, academia, and the public sector
- Regional coordination of innovation activities
- Running or funding competitions to identify innovations
- Supporting research and development
- Test and trial of innovations
- Accelerate the adoption of innovations.

The key innovation organisations with a focus on healthcare are listed in Appendix 2, broken down by UK nation.

3.1.3 - Upcoming XR procurements

The desktop and literature review suggests that the procurement of XR technologies appears to be in its infancy. However, there was evidence of some interesting and relevant procurement approaches emerging as outlined below.

Digital Productivity Programme

The NHS England Transformation directorate currently runs the Digital Productivity programme. This has stated aims of accelerating the adoption of digital tools into the NHS. Extended reality technologies are included among the programme's key projects. [35]

As part of this programme, research has been conducted into how XR technology is currently used within the NHS, generating insights for benefits and best practice. It was found that the top four areas in which XR is currently used are education and training, mental health and wellbeing, physiotherapy and rehabilitation, and pain management.

[33] *One of the regulated procurement procedures currently used in the UK.*
[34] *Pre-Commercial Procurement. (2022, June 7). European Commision. https://digital-strategy.ec.europa.eu/en/policies/pre-commercial-procurement*
[35] *Digital productivity—Welcome to the Digital Productivity programme. (n.d.). NHS Transformation Directorate. Retrieved 7 February 2023*

The transformation directorate has several XR-focused goals for 2022-23, including the development of a dynamic tool for finding evidence for XR technologies and a standardised benefits, risks, and costs evaluation framework. A key goal for 2023 onwards is to "Publish resource to support those developing, buying and selling XR in healthcare".

As part of this programme, the transformation directorate has also established the digital productivity fund, which is providing over £12 million funding to support the adoption of digital technologies.[36] This fund has invested £2 million into the adoption of XR technologies.

Dynamic Purchasing Systems (DPS) for XR

Dynamic purchasing systems that focus on the procurement of XR technologies are currently being established within NHS England, with the following examples evident.

HealthTech Innovation Gateway

On 12 December 2022, NHS SBS (Shared Corporate Solutions) published a prior information notice for a "HealthTech Innovation Gateway for the provision of Digital and Health Technology related Goods and Services".[37] This is to be based on a dynamic purchasing system (DPS) and stated an initial focus on artificial intelligence and extended reality technologies. It is estimated that the contract notice for the DPS will be published in Spring 2023.

This DPS has the potential capacity to include XR therapeutic technologies for use in mental health. XR technologies within the HealthTech Innovation Gateway will be classified according to NICE's Evidence standards framework for digital health technologies[38], which establishes three tiers: tier C covers devices which are used for treating and diagnosing medical conditions and are likely to be classified as medical devices; tier B describes devices which citizens can use to manage their own wellbeing; while tier A includes devices which are used to reduce costs or release staff time, without direct implications for patient health or care outcomes.

Digital mental health therapeutics are anticipated to fall under tiers B and C, requiring some degree of evidence, including that the technology "impacts on clinical management of the relevant condition, in a setting relevant to the UK health and social care system".[39]

Immersive Technology DPS

On 16 January 2023 Guy's and St Thomas' NHS Foundation Trust, which manages five hospitals in London[40] published a prior information notice for a dynamic purchasing system which would focus on XR technologies for use in teaching and training.[41]

This DPS is expected to include hardware, software, and content development services. Pre-market engagement was to be conducted in February, with a contract notice anticipated to be published in Spring 2023.

3.1.4 - Prevalence of XR mental health therapeutics in the UK

There currently appears very limited use of XR for mental health therapeutics in the NHS. Where immersive technology solutions are used, they are generally implemented in specialist clinical settings in particular geographic locations.

Consultation with experts indicated low awareness of XR solutions for mental health therapeutics outside academic circles, and any solutions identified appeared to be deployed in small pockets. Support for mental health therapeutics appears rare out with the current MINDSET R&D Workstream 1.

Several examples of the current use of XR in healthcare are provided in 'The Growing Value of XR in Healthcare in the United Kingdom' Report. Additionally, two specific examples of therapeutic[42] uses of XR in mental health have been identified as below.

[36] *Digital productivity fund. (n.d.). NHS Transformation Directorate. Retrieved 7 February 2023, from https://transform.england.nhs.uk/key-tools-and-info/digital-productivity/digital-productivity-fund/*
[37] *Future opportunity: Healthtech Innovation Gateway (10233). 2022/S 000-035125 (2022, December 12). Find a Tender. https://www.find-tender.service.gov.uk/Notice/035125-2022*
[38] *Evidence standards framework for digital health technologies: Section B: Classification of digital health technologies. (2022, August 9). NICE. https://www.nice.org.uk/corporate/ecd7/chapter/section-b-classification-of-digital-health-technologies*
[39] *Evidence standards framework for digital health technologies: How to meet the standards. (2022, August 9). NICE.*
[40] *Our organisation—Our hospitals and community services. (n.d.). Guy's and St Thomas' NHS Foundation Trust. Retrieved 7 February 2023, from https://www.guysandstthomas.nhs.uk/about-us/our-organisation/our-hospitals-and-community-services*
[41] *Immersive Technology DPS. 2023/S 000-001212 (2023, January 16). Find a Tender. https://www.find-tender.service.gov.uk/Notice/001212-2023*
[42] *UKRI et al. (2021). The Growing Value of XR in Healthcare. https://www.xrhealthuk.org/the-growing-value-of-xr-in-healthcare*

- **VR for phobia in autism spectrum disorder**

Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust has begun using virtual reality treatments for situation specific anxiety, fear, or phobia in young people aged 7-17 with autism spectrum disorder.[43] The treatment uses a form of cognitive behavioural therapy delivered in a specialised immersive VR environment using a 180-degree curved screen. It works through exposing young people to images specific to the individual's phobia or anxiety. Research indicates that this intervention could effectively treat phobia in both autistic children and adults.[44] [45]

- **VR for anxious social avoidance**

Oxford VR's Social Engagement uses cognitive behavioural therapy delivered through immersive virtual reality to treat anxious social avoidance.[46] [47] The program requires users to complete tasks that involve exposure to everyday social situations, such as shopping and taking a bus.

By completing virtual tasks, users become more confident in their ability to engage in real social situations. A key advantage is that the programme is fully automated and does not require a clinician to deliver the therapy. Social engagement is now available on the NHS via NHS Talking Therapies. In addition, following further randomised control trial evidence, Greater Manchester Mental Health NHS Foundation Trust is looking to integrate this solution into routine mental health care. [48]

It has been suggested that XR solutions have the potential to become widely used within the NHS over a relatively short timescale. If widespread acceptance was earned across clinical groups, it is estimated that adoption and implementation could be very fast e.g., 2-3 years. [49] This is dependent on the generation of strong and independently validated evidence of impact/cost-effectiveness within the context of mental health therapeutics. In addition, there appear to be ongoing developments on the use of Virtual Reality (VR) for teaching and training within NHS England.[50] [51] [52] The less stringent evidence requirements for these uses could be useful in increasing general acceptance and awareness of XR technology within public sector environments and could facilitate its adoption into other settings.

3.1.5 - Key observations

NHS Procurement

- Mainstream public sector procurements are generally focused on large contracts with experienced and known companies, where large % cost savings are most readily available/ identified.
- The entry route into the mainstream procurement system is challenging for small and medium companies (SME's) to gain traction and where they have limited evidence of impact.
- SME's may run many small pilots with clinicians but can often lack a long-term, financially viable business model to scale products/services.

Support for Innovation

- There are several routes through which public sector support is provided for innovation, but these are fragmented and not generally easy for innovators to find.
- Organisations focused on information for innovators and triage of innovations are being created and developed to help with this.
- There is no clear published pathway for innovators to navigate the complex health and care environment and signpost them to the most appropriate mechanism for the stage of development they may be at.

Digital Mental Health Therapeutics (DMHT)

- The sector appears "emergent" in terms of implementation and awareness by health and care professionals. Usage appears to be confined to localised specialist clinical interests in limited geographical areas.
- Some new procurement approaches are emerging for the procurement of XR technologies in England, which may support XR and digital mental health therapeutics.
- Increasing the usage and awareness of XR technologies in the health and care sectors for other uses such as workforce education and training, may increase confidence and acceptability for therapeutic purposes.

[43] *Virtual Reality—Information on Virtual Reality treatment for situation specific anxiety, phobia or fear.* (2022, July 12). Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust. https://www.cntw.nhs.uk/resource-library/virtual-reality/
[44] Maskey, M., McConachie, H., Rodgers, J., Grahame, V., Maxwell, J., Tavernor, L., & Parr, J. R. (2019). *An intervention for fears and phobias in young people with autism spectrum disorders using flat screen computer-delivered virtual reality and cognitive behaviour therapy. Research in Autism Spectrum Disorders, 59*, 58–67. https://doi.org/10.1016/j.rasd.2018.11.005
[45] Maskey, M., Rodgers, J., Ingham, B., Freeston, M., Evans, G., Labus, M., & Parr, J. R. (2019). Using Virtual Reality Environments to Augment Cognitive Behavioral Therapy for Fears and Phobias in Autistic Adults. *Autism in Adulthood*, 1(2), 134–145.
[46] *NHS offers new virtual reality treatment for patients with social anxiety.* (2020, March 13). Digital Health. https://www.digitalhealth.net/2020/03/nhs-offers-new-virtual-reality-treatment-for-patients-with-social-anxiety/
[47] *Oxford VR launch social engagement™—A first-in-class digital therapeutic using virtual reality technology to tackle anxious social avoidance in the NHS.* (2020). Oxford VR.
[48] Archer-Williams, A. (2023, March 7). Blog: Virtual therapists on how VR is changing mental health treatment. HTN. https://htn.co.uk/2023/03/07/blog-virtual-therapists-on-how-vr-is-changing-mental-health-treatment/
[49] *Interview with Scottish Government advisor* (2023, Feb 23).
[50] Mallik, R., Patel, M., Atkinson, B., & Kar, P. (2022). Exploring the Role of Virtual Reality to Support Clinical Diabetes Training-A Pilot Study. *Journal of Diabetes Science and Technology*, 16(4), 844–851.
[51] *Transforming Diabetes Education with VR Simulation. (n.d.). Oxford Medical Simulation. Retrieved 14 March 2023*
[52] *Junior doctors and medical students embrace innovative VR training. (2021, August 4). Somerset NHS Foundation Trust.*

3.2 - Consultations with Procurement Experts & Suppliers

Building on the findings from the desktop and literature review, a series of consultations were then conducted with commercial company suppliers and public sector procurement experts to explore the identified challenges and opportunities and elucidate ideas to support XR companies to target the mental health therapeutics market. The consultations were conducted over Microsoft Teams and lasted for approximately 60 minutes. A total of 13 consultations involving 18 interviewees were completed (See Appendix 1 for detail). Insights from these were harvested to inform the Co-Design Future State Workshops.

Findings from the consultations suggest that the emergent XR health market experiences are similar to those of the wider digital health landscape, and that although procurement is seen as part of the route to market, the current procurement infrastructures offer poor support for XR health companies attempting to access the NHS.

How do you get those technologies and innovations to market today? It's through hustle and resilience and outward investment to get you there. And of course, what we know is that a lot of technologies will die while they're waiting and won't make it to the sustainable position.	**Private Sector Support Organisation**
I haven't identified anything that isn't a challenge yet, to be quite honest with you.	**Private Sector Supplier**
So, the procurement process is easy. I think the difficulty is, as a company, getting yourself into a state of readiness to be able to meet those requirements.	**Public Sector Commissioner**
I don't think (access to the healthcare market) is about dismantling barriers. I think it's about enabling scale. If you think about it as kind of a series of villages which are all mapped together, …(but) don't interact with each other, and then somebody built the road and then, all of a sudden, they all travel to each other's villages and trade flourishes. There needs to be an infrastructure for this to happen.	**Private Sector Supplier**

Table 2: Illustrative Quotes from Procurement Expert & Supplier Consultations

The following key challenges were identified from the consultations with further detail noted in Tables 3 and 4:

1. The current healthcare system is not set up for procuring XR health interventions or evaluating their impact on clinical efficacy and service improvement.
2. The development, implementation, and evaluation of XR technologies takes place in a fragmented ecosystem.
3. The clinical market is risk averse, and developers face high compliance thresholds in terms of medical device, information governance and infection control regulations.

Systems of Evaluation and Procurement	
Mismatch with the purpose and scale of procurement systems	Historically, procurement systems have been set up to evaluate large scale commissions and projects that operate very differently from the current stage of XR health interventions.
Lengthy and laborious route to market	Healthcare procurement systems are designed for more established companies, who have more resources at their disposal. Submitting procurement bids in a system designed for generally large-scale procurement places significant burden of work on XR health SMEs, and long waiting periods do not support their operating models.
Running pilots with multiple clinical teams	In addition to lengthy procurement processes, XR companies spend long pre-sales periods in building and maintaining relationships with clinicians. Engagement with clinicians was seen as crucial both for developing, specifying and implementing products to fit specific clinical workflows, and for generating evidence of the efficacy of XR interventions in clinical contexts. The importance of building direct relationships with clinicians is heightened in a context where there is a relative dearth of XR mental health therapeutic-specific procurement contracts. Hence, XR suppliers reported almost exclusively that they took a grass-roots approach, running multiple trials with different clinical teams in different hospitals.
Mismatch in standards of evidence of clinical efficacy	Some of the problems XR companies face are characteristic of the wider digital health sector. The clinical efficacy and benefit to the health service of these technologies materialises differently from established healthcare interventions and are often on more individual and multifaceted levels. As has been evidenced previously, the benefits of these technologies require different evaluation methods.
Ambiguity about the level of required evidence	While procurement experts are clear on the need for establishing stronger evidence base for XR products, suppliers pointed out that there is lack of clarity on the required level of evidence.
Accommodating different clinical teams	Procurement experts also emphasised the need for XR companies to tailor their products to the needs of diverse clinical teams to accommodate their needs, build 'reputation' and generate buy-in. This is often a long-term investment, and it might be a relatively high threshold and limiting factor for SMEs.
Demonstrating service improvement	Both suppliers and procurement experts emphasised that XR pilots and trials need to go beyond proving clinical efficacy; technologies integrated in different clinical workflows need to demonstrate positive service change and improvements.
Limited resources – labour and cost	Running clinical pilots of XR technologies places a considerable financial strain on XR SMEs and is dependent on the labour and buy-in of clinical staff.

Table 3: Summary of Consultation Comments on Systems of Evaluation & Procurement

Fragmented ecosystem	
Lack of a single 'front door' to the healthcare system	Suppliers and procurement experts reported both functional and regional fragmentation. Decisions were not taken centrally or by a single agency; there is no centralised 'front door' to enter the healthcare market. This has led to the companies having to engage directly with clinicians.
Disjointed decision-making	Conversely, while healthcare professionals were able to assess the clinical efficacy and service impact of piloted XR technologies, they appeared to have no insight into the available funds, processes and funding structures for healthcare procurement. Given the pressures on NHS funding, several suppliers reported that they have accessed funds from charities to provide clinical devices which often have simpler access requirements.
Regional fragmentation	There are significant regional differences between healthcare organisations in the operation and interpretation of standards and regulations (including Medical Device Regulations, information governance, etc.), and in how different clinical care pathways are organised. This not only increases XR health companies' workload when entering these markets, but also creates additional uncertainties, e.g., relating to finances and business survival.
Regional opportunities	There are differences in the way regional and local services are organised within the UK. For example, in Scotland a more unified approach is promoted which emphasises equity of care while embracing solution choice where practicable.
High compliance threshold for clinical interventions	Some procurement experts suggested that while compliance with the different types of regulations is a significant barrier, this could be addressed by improving companies' understanding on these, and there are already some initiatives in this space to inform SMEs of the different regulations. In addition, while clinical practices are more risk-averse and have a higher compliance threshold, non-therapeutic or non-medical applications of XR could be used to evidence and strengthen the company's position within the XR health market. Some interviewees noted that XR applications that enter healthcare education and workforce development markets do not have to deal with the same compliance threshold as clinical applications. As these technologies enter clinical education, future professionals will be more familiar and confident using XR technologies.
Calls for transparency and a targeted procurement framework	Many suppliers and procurers highlighted the need for a more targeted approach to support XR health companies' route to clinical markets and could provide mutual benefits by informing and setting standards.

Table 4: Summary of Consultation Comments on Fragmented Ecosystem

3.2.1 - Key observations

Many of the observations from the consultations reinforced the challenges highlighted within the desktop and literature review including:

- Current mainstream procurement infrastructures offer poor support for XR health companies wishing to access healthcare markets, but there are a number of disparate mechanisms to support innovation that may help an emerging market to gain traction.
- Companies are not clear what they need to do to be in a state of readiness e.g., level of evidence, to meet procurement requirements. They tend to engage directly with individual clinicians to raise awareness and undertake trials; however, this is unlikely to provide significant market traction as the clinicians/trials tend not to be linked to procurement routes.
- Although there are different approaches and requirements at national, regional and local levels, a route map containing high-level phases and requirements may help companies better pinpoint where they are and how to navigate forward, and create a collaborative framework to address gaps e.g., common standards.
- The digital therapeutics market may gain traction from XR approaches for other healthcare related activities such as education and training, where awareness and confidence could be increased.

An analysis of the desktop, literature review and consultation materials elicited nine key elements that must be addressed to support XR technologies market penetration. These were used to inform the mapping of a co-designed future state.

1. **Clinical community**
2. **Evidence**
3. **Funding and payment models**
4. **Market intelligence**
5. **Policy**
6. **Procurement**
7. **Technology Familiarity**
8. **Standards (including compliance with medical device, information governance and infection control regulations)**
9. **XR supplier market**

Diagram 2: Nine key elements

4 – Co-designing a Future State

4.1 - Problem Space & Solution Space

Following the current state mapping activities, two co-design workshops were developed and scheduled in mid-March to review the challenges identified and consider opportunities for a future, preferable state, i.e establishing the 'problem space' and the 'solution space'.

The workshops had the following goals:

1. To create a virtual multi-stakeholder environment, where insights and observations gathered from the interviews could be reviewed, discussed, and verified in a shared, collaborative, and open context.
2. Through a series of facilitated interactive activities (designed to be incrementally and more definitive) increase understanding of the barriers faced by innovators in bringing digital therapeutics to market.
3. Validate the need for a test and trial platform, and if so, provide a sense of how such a platform should function and the benefits for each stakeholder group.
4. Using insights derived from preceding consultation activity, stimulate opinion, and reveal opportunities.
5. Define the key Business Requirements and objectives of either a high-level navigation pathway or outline pathway specification.

Further details of the workshops are available in Appendix 1.

4.2 - Overview of Opportunities

Activities undertaken as part of the two design workshops identified opportunities that could be associated with all four Mindset Programme workstreams. Those considered to be a priority, and which were endorsed and highlighted by the range of stakeholders involved in the workshops are listed below.

Clinical community

- There is a need for an accredited products and technologies set that clinicians and commissioning bodies can choose from.
- There is an opportunity to create a centralised, UK-wide, procurement and distribution system instead of taking a (health) board-by-board approach. This would offer efficiency on multiple levels including addressing the issue of developers engaging with individual health boards and developing solutions that may only be relevant to (and have the approval of) a single geographical region.

Evidence

- There is a need for multiple repeated studies to show efficacy and impact of XR in a clinical mental health setting.
- A more holistic approach to evidence is required to facilitate cooperation between industry and the NHS, with consideration given to how solutions can be deployed.

Funding and payment models

- For XR to develop and be seen to be successful in a clinical setting, it is vital that companies are supported in the development of compelling, evidence-based economic value propositions.
- XR should be supported so that it is viewed as a viable, effective alternative and complement to current treatment methods as opposed to an 'indulgent gimmick'.

Market intelligence

- A database / resource of existing solutions alongside related product information and evidence is needed.

Policy

- Evidence-based case studies could be integrated into key policy documents related to the use of immersive technologies in a mental health context.

Procurement

- Develop, test and validate XR innovation within centres of excellence that already have a strong understanding of XR - and then support scaling across the UK.
- There are opportunities to overlap with social prescribing initiatives and national strategies aligned with preventative care.

Technology familiarity

- The expectation of appropriate technology-supported care pathways in mental health care delivery settings should be embedded early within the education and training routes for clinicians and support teams. This normalises the expectations of digitally supported care as a default for new entrants to the workplace.
- Showcase early adopters through case studies and industry events to support knowledge sharing, networking, and technology orientation.

Standards

- There was overwhelming support across those involved for the creation of a working group to define and communicate standards associated with the development and deployment of XR digital therapies.

XR supplier market

- Trusted digital technology assessment and distribution organisations (e.g., ORCHA) and professional bodies such as the Association of Clinical Psychologists UK (ACP-UK) and the Heads of Psychology Scotland (HOPS) could help define integration test methodologies and support an approval service for XR-supported care pathways at national level.

4.3 - User Stories

A User Story simply describes something that a stakeholder ('user') wants in order to help them overcome a problem or difficulty so they can achieve a specific goal.

Typically expressed in a three- or four-part standardised format (role/title, functional context, need/want, outcome), User Stories are a useful way to help elicit and capture requirements quickly using natural language expression.

The standardised format helps to generate more detailed solution requirements that can be fed back to the stakeholders for validation and prioritisation. In aggregate, the workshops identified around two dozen User Stories, which have been distilled into summaries across three key stakeholder perspectives - mental health clinician, commissioner of services in the NHS, and XR technology supplier as outlined below.

Mental Health Clinician

- Someone in this role would require access to training and professional accreditation in order to understand how to get the most value from XR technologies. In doing so, patient safety can be assured and the best value for money is delivered to operational managers and the NHSE.

Commissioner of Services in the NHS

- As the individual responsible for commissioning technological solutions there would be a requirement for evidence of cost-effectiveness and a demonstrable understanding of what is involved with respect to implementation. This would provide a guarantee that the deployment of XR in a mental health context is a worthwhile investment that will deliver value throughout the lifespan of a project.

XR technology supplier

- Promotion and support of the introduction of XR through direct engagement with clinicians providing a clear forward view of demand at a national level, so businesses can be more efficient and effective with an ability to plan for the future.
- Clear definition from healthcare providers outlining the challenges and any detailed requirements to be addressed by any XR system, technology or service. This will support the project development lifecycle, particularly implementation and help galvanize the relationship between supplier, procurers, and clinicians.
- Establishment of long-term partnerships with academic/healthcare partners that have XR knowledge that will support evidence gathering, allowing products to be developed and scaled in an informed context.
- To support commercialisation of products, clearer guidance on IP generation with clinical partners would be preferable. This is particularly relevant bearing in mind the number of hospitals willing and keen to co-own IP.
- Funding support and access to partners to enable better approaches to co-design applications and services, ensuring products are meaningful and effective for a range of communities and stakeholders with different user needs.

5 – Conclusion and Recommendations

5.1 - Conclusion

Beyond the core focus of informing Workstream 2 (i.e., evaluating the need for a test and trial platform and to outline its key functional requirements), the broader scope of the brief allowed for a fuller exploration of the challenges and opportunities along the full route to market journey. The consultations and the User Stories proposed in the workshops reflect this, suggesting there is not a single solution but rather ***a spectrum of capability requirements.***

These extend from education and training, through clinical engagement and procurement to safe integration of XR technologies into care delivery and assuring equity of care. The solution space, therefore, is multi-faceted, albeit with a core focus on the coordination of evidence and testing, clearer standards and compliance, and ultimately the safe adoption of effective XR technologies into mental health care delivery.

The desktop and literature review, stakeholder consultations and the future state mapping workshops surfaced over twenty opportunities and a similar number of requirements expressed as User Stories. As might be expected, these addressed a broad range of systemic and DMH-specific issues faced by clinicians, suppliers, NHS commissioners and procurement professionals.

The solution space must cater for pre-adoption activities (testing, piloting, formal trialing), plus the transition stage where XR products are functionally ready for deployment but are not yet approved or fully compliant with all applicable standards and regulations. This offers a progression roadmap for XR solutions to be tested by clinical teams and integrated into care pathways and subsequently made available as approved, mature solutions that can be procured and safely deployed in clinical settings.

The solutions and recommendations resulting from this scoping review therefore represent the spectrum from initial engagement through to embedding XR technologies into business-as-usual healthcare practice.

The four workstreams currently being progressed by UKRI within the MINDSET Programme may address much of the capability requirements identified through this scoping review if progressed in a coordinated, flexible and mutually reinforcing set of activities building on the learning from this report.

5.2 - Recommendations

5.2.1 - Test and trial platform

The need for a test and trial platform was not directly articulated by the stakeholders engaged in this review, but strong consensus emerged on salient challenges and opportunities suggesting that a 'platform' type approach could offer an important and safe route for XR innovation introduction into healthcare settings. This could help extend activity from R&D stages and structured evidence collection, through to approved solutions that clinicians can adopt into their practice.

It is important to avoid overloading the platform concept with capabilities that might best be delivered through other channels. The recommendation therefore assumes in the first instance that the term 'platform' could comprise a collection or federation of resources that together represent a suite of capabilities for suppliers, clinicians, health and care organisations and procurers.

Adopting this perspective would allow for the staged introduction and early benefit realisation of the key capabilities identified:

- National platform 'storefront' with clear product accreditation and compliance status
- Prescription model for approved products
- Two-tier model of solution curation and subscription
- Roadmaps:
  - Vendor technology and capability forward view (NDA, IP-managed service)
  - Consumer demand, including forward view of regional/national procurements
- National evidence base, and model for contributing to this
- Accreditation model for suppliers and products, with progression roadmap for technologies to advance from 'test and trial' to 'approved for deployment'

- Guidance and route-map of compliance for suppliers and clinical consumers
- Collaboration hub between clinical standards-setting groups and industry to maintain product-independent efficacy evidence standards and exemplar care pathways
- A range of technology-enabled care pathways that clinicians can safely adopt or use as a base for piloting new solutions
- Subject matter expert support through a collaboration hub.

Test and Trial Stack Concept View

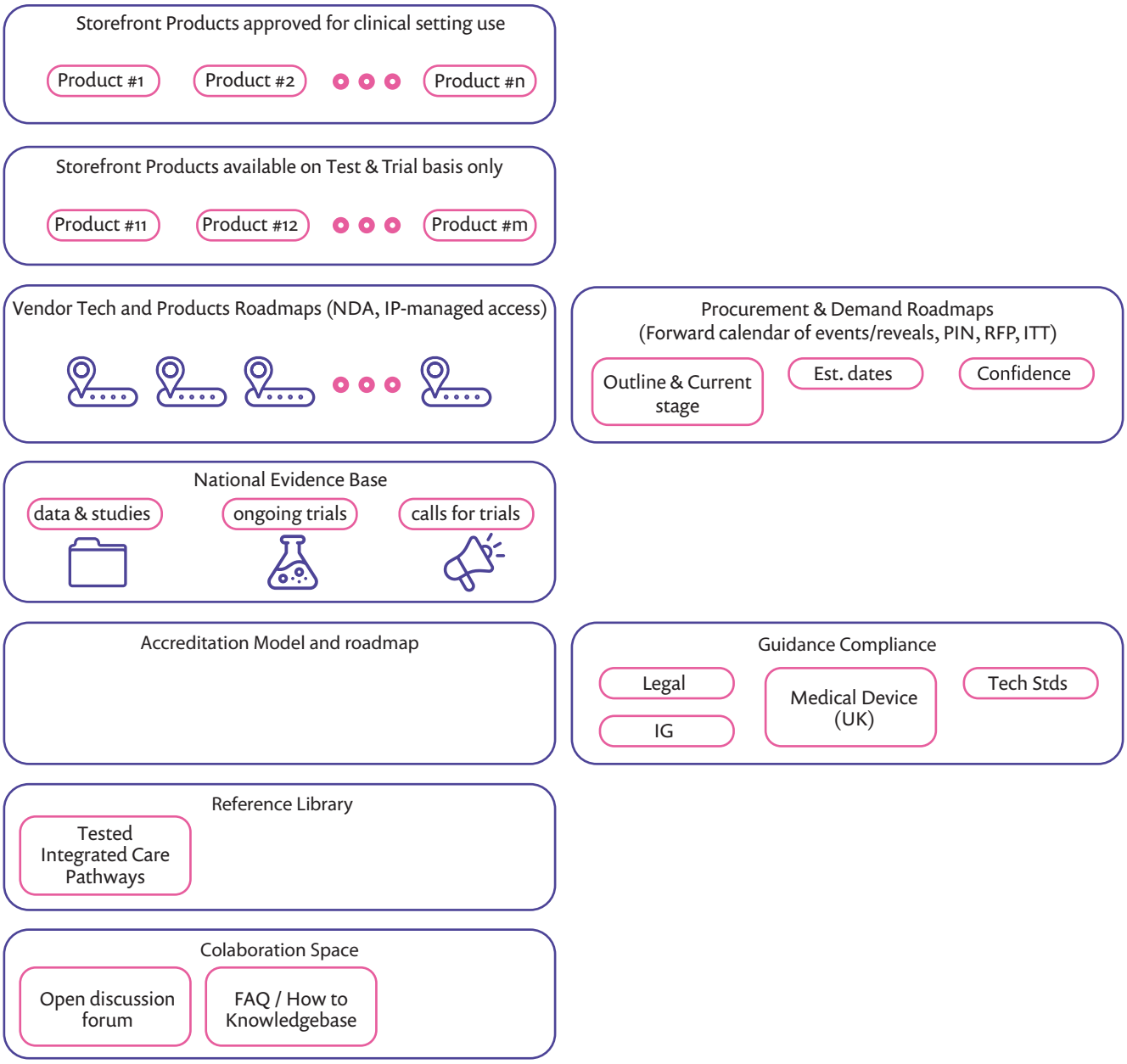


Diagram 3: Test & Trial Concept Stack

The test and trial platform concept parallels the trajectory of work currently being progressed by ORCHA https://orchahealth.com/ and SyncVR https://www.syncvr.tech/ , which is building additional tiers of technical, data and roadmap capability into the SyncVR platform under the well-established ORCHA testing and accreditation model. A collaboration with appropriate mental health professional bodies would further strengthen the platform approach by providing a means to approve/accredit XR solutions that have been successfully integrated into care pathways, offering clinical teams an assured source of template pathways that can be quickly adopted. For clinical innovators, the model would offer a route for structured testing and evidence collection and routes to promote tested combinations of technology and interventions and pathways as candidate templates for broad adoption.

The XR companies are responsible for complying with applicable legislation within the jurisdiction they are selling into, but it would be helpful if the core compliance requirements were clearly set out for them, as well as accreditation requirements for deploying product into clinical settings and pathways.

Combining the guidance and compliance (and accreditation) thresholds with a platform that curates and offers accredited solutions to the market would be a strong play. This would benefit suppliers as they will know what they are aiming at, and it will benefit clinicians as they can be confident that by using the platform, they will be procuring products with a known level of compliance and approval for use in their intended pathway.

For products that are emerging, but which have yet to be proven in healthcare settings, clinician innovators could see the evidence base via the platform, selecting products to use in their clinics as part of a pilot or possibly formal trial, allowing innovations to be introduced into the appropriate health and care settings while further contributing to the evidence base.

The test and trial platform concept, therefore, offers benefit on multiple levels, and could in time be adopted into procurement models and frameworks to facilitate accelerated benefits delivery and improved assurance of product efficacy and equality of care delivery.

5.2.2 - Education

An important recommendation emerging from consultations is that adoption and effective use of digital technologies – particularly immersive technology in mental health applications - must be embedded in pre-workplace and in-service education and training for clinicians, health and care professionals.

- Digital technologies as part of clinical practice should generally be added to the medical school curricula and extended into other health and care education pathways in universities and colleges.
- The consultations suggested that the fastest way to change culture and attitudes, and to create a market for immersive technologies in healthcare, is to introduce future professionals to it during their training. This will create an expectation within the workforce that they will work with these technologies as part of their practice, as well as supporting the specific use of digital technologies for the treatment of mental health conditions.

5.2.3 - Funding and De-risking

The custom in health and care of biasing risk towards suppliers can challenge business viability in the current XR therapeutics landscape in the UK, where small suppliers routinely engage in multiple free-of-charge pilot projects directly with clinical teams.

This approach does help raise awareness and familiarity of XR technology, but at an ongoing cost to the supplier, often with no identified route to a procurement on successful conclusion of the pilot work. This frustrates both the supplier and clinical innovators seeking to move beyond pilots, and in turn discourages innovation and inhibits formal evidence collection due to uncertainty around return on investment. Such challenges are not unique to XR, mental health or digital health innovation introduction in general, but the fragility of the XR therapeutics space is especially concerning given the potential scale of benefits.

Initiatives are in place to support digital technology adoption, e.g., the NHS England Digital Productivity Fund, and these offer important routes for establishing projects and test beds. Against this backdrop, several funding and financial de-risking approaches were advanced during the consultations that would merit deeper exploration and quantification to test their validity and value.

Some of these are summarised below.

- Aside from charity-sourced funding, clinicians typically do not have ready access to funds that have not been identified and provided for in their Board/Trust budget cycle, and discretionary provision in-year is under constant downward pressure. An approach used in the Netherlands sets aside identified small 'pots' (c.€10k) within hospitals for discretionary spend, and there are equivalent Government sums that can be applied for. The UK does have funding options beyond the NHS budgets, but the routes to accessing these could be made clearer, and possibly formally segmented to key emerging treatment areas.
- Concerns were raised around VR hardware purchases, with early obsolescence being cited as a risk as software demands on hardware specifications change rapidly. A programme of centralised bulk purchase, or possibly hardware leasing, could be used to mitigate potential impairment write-off concerns raised by individual NHS departments or Boards/Trusts. If combined with a broader XR strategy in health and care the scale benefits may make a centralised 'call off' hardware model viable.
- The fragmented evidence landscape remains a barrier to adopting XR therapeutics solutions in mental health, and commissioners need evidence to de-risk their investment. One solution would be to adopt evidence-linked pricing models where the price of the solution is mapped to a benefits realisation model agreed by the commissioner and the supplier. This would help de-risk the NHS investment costs while incentivising long-term evidence collection and support for formal trials. At the macro level, this could have potential for assuring the health of the XR industry itself in the UK as well as accelerating the route to delivering benefit to patients.

5.2.4 - UK Procurement

The consultation also highlighted the variation in procurement routes across the four nations. While welcoming ongoing changes to support digital health solution procurement, some stakeholders suggested further convergence of the formal procurement 'front doors' across the UK, or at least a centralised signposting resource that could be more easily navigated by new entrants to the XR therapeutics marketplace.

The latter 'signposting' approach may be more practicable than making structural changes to national procurement mechanisms and could be implemented as part of the construction of a test and trial capability, effectively forming a part of a business handbook for suppliers and health and care innovators alike.

The four key recommendations represent a broad palette of opportunities for positive, sustainable change along the full route to market. These areas and the specific recommendations under each offer strong candidates to progress the potential value of XR in mental health therapeutics for the benefit of patients and healthcare professionals while supporting a vibrant and innovative supplier marketplace.

However, while practical aspects of delivery and implementation costs have shaped the solution space set out in this report, the constraints of the workstream 2 engagement have limited the depth to which details of cost, complexity and risk to implement could be explored.

6 – Bibliography

About NHS Supply Chain. (n.d.). NHS Supply Chain. Retrieved 16 December 2022, from https://www.supplychain.nhs.uk/about-us/

About Procurement Services. (n.d.). NHS Wales Shared Services Partnership. Retrieved 31 March 2023, from https://nwssp.nhs.wales/ourservices/procurement-services/about-procurement-services/

About the service. (2022, August 3). NHS Innovation Service. https://innovation.nhs.uk/about-the-service

About Us. (n.d.). Welsh Health Specialised Services Committee. Retrieved 30 March 2023, from https://whssc.nhs.wales/about-us/

Archer-Williams, A. (2023, March 7). Blog: Virtual therapists on how VR is changing mental health treatment. HTN. https://htn.co.uk/2023/03/07/blog-virtual-therapists-on-how-vr-is-changing-mental-health-treatment/

Commissioning teams. (n.d.). HSC Public Health Agency. Retrieved 31 March 2023, from https://www.publichealth.hscni.net/directorate-public-health/service-development-and-screening/commissioning-teams

Department of Health and Social Care. (2022, April 12). Call for evidence for new 10-year plan to improve mental health. GOV.UK. https://www.gov.uk/government/news/call-for-evidence-for-new-10-year-plan-to-improve-mental-health

Digital productivity—Welcome to the Digital Productivity programme. (n.d.). NHS Transformation Directorate. Retrieved 7 February 2023, from https://transform.england.nhs.uk/key-tools-and-info/digital-productivity/

Digital productivity fund. (n.d.). NHS Transformation Directorate. Retrieved 7 February 2023, from https://transform.england.nhs.uk/key-tools-and-info/digital-productivity/digital-productivity-fund/

Evidence standards framework for digital health technologies: Section B: Classification of digital health technologies. (2022, August 9). NICE. https://www.nice.org.uk/corporate/ecd7/chapter/section-b-classification-of-digital-health-technologies

Evidence standards framework for digital health technologies: How to meet the standards. (2022, August 9). NICE. https://www.nice.org.uk/corporate/ecd7/chapter/how-to-meet-the-standards#standard-14-provide-evidence-of-the-dhts-effectiveness-to-support-its-claimed-benefits

Future opportunity: Healthtech Innovation Gateway (10233). 2022/S 000-035125 (2022, December 12). Find a Tender. https://www.find-tender.service.gov.uk/Notice/035125-2022

Government of UK. (2022). Levelling Up the United Kingdom (No. CP604). UK Government. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1052708/Levelling_up_the_UK_white_paper.pdf

Health Board Areas. (n.d.). NHSScotland Careers. Retrieved 9 February 2023, from https://www.careers.nhs.scot/careers/find-your-career/international-recruitment/nhsscotland-health-boards/

Health service structure. (n.d.). Belfast Health & Social Care Trust. Retrieved 30 March 2023, from https://belfasttrust.hscni.net/about/corporate-info/health-service-structure/

How NSS works—Our aims. (n.d.-a). NHS National Services Scotland. Retrieved 9 January 2023, from https://www.nss.nhs.scot/how-nss-works/our-aims/

How we use your information—Innovation Service. (n.d.). NHS England. Retrieved 24 February 2023, from https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/public-and-partners/innovation-service/

How we work—SBRI Healthcare. (n.d.-a). SBRI Healthcare. Retrieved 15 December 2022, from https://sbrihealthcare.co.uk/how-we-work/

Immersive Technology DPS. 2023/S 000-001212 (2023, January 16). Find a Tender. https://www.find-tender.service.gov.uk/Notice/001212-2023

Is healthcare in Wales really that different? (2019, October 21). Wales Centre for Public Policy. https://www.wcpp.org.uk/commentary/is-healthcare-in-wales-really-that-different/

Junior doctors and medical students embrace innovative VR training. (2021, August 4). Somerset NHS Foundation Trust. https://www.somersetft.nhs.uk/?news=junior-doctors-and-medical-students-embrace-innovative-vr-training

Learn More About Us. (n.d.-a). NHS SBS. Retrieved 19 January 2023, from https://www.sbs.nhs.uk/nhs-sbs-about-us

Local Commissioning Groups. (n.d.). DOH/HSCNI Strategic Planning and Performance Group (SPPG). Retrieved 30 March 2023, from https://online.hscni.net/in-your-area/lcgs/

Mallik, R., Patel, M., Atkinson, B., & Kar, P. (2022). Exploring the Role of Virtual Reality to Support Clinical Diabetes Training-A Pilot Study. Journal of Diabetes Science and Technology, 16(4), 844–851. https://doi.org/10.1177/19322968211027847

Maskey, M., McConachie, H., Rodgers, J., Grahame, V., Maxwell, J., Tavernor, L., & Parr, J. R. (2019). An intervention for fears and phobias in young people with autism spectrum disorders using flat screen computer-delivered virtual reality and cognitive behaviour therapy. Research in Autism Spectrum Disorders, 59, 58–67. https://doi.org/10.1016/j.rasd.2018.11.005

Maskey, M., Rodgers, J., Ingham, B., Freeston, M., Evans, G., Labus, M., & Parr, J. R. (2019). Using Virtual Reality Environments to Augment Cognitive Behavioral Therapy for Fears and Phobias in Autistic Adults. Autism in Adulthood, 1(2), 134–145. https://doi.org/10.1089/aut.2018.0019

National Commissioning Board Wales. (n.d.). Welsh Local Government Association. Retrieved 31 March 2023, from https://www.wlga.wales/national-commissioning-board-wales

National Procurement and Logistics—What we do. (2022, June 27). National Services Scotland. https://www.nss.nhs.scot/departments/national-procurement-and-logistics/

National Services Division: A guide to Scotland's national specialist commissioner. (2022). National Services Scotland. https://www.nss.nhs.scot/media/2384/nsd-service-guide.pdf

NHS commissioning: Integrated care systems (ICSs). (n.d.). NHS England. Retrieved 7 February 2023, from https://www.england.nhs.uk/commissioning/who-commissions-nhs-services/ccg-ics/

NHS commissioning—NHS England. (n.d.). NHS England. Retrieved 8 February 2023, from https://www.england.nhs.uk/commissioning/who-commissions-nhs-services/nhs-england/

NHS commissioning: Integrated care systems (ICSs). (n.d.). NHS England. Retrieved 7 February 2023, from https://www.england.nhs.uk/commissioning/who-commissions-nhs-services/ccg-ics/

NHS England Board meeting: New commercial strategy for the NHS. (2022). NHS England. https://www.england.nhs.uk/wp-content/uploads/2022/07/BM2227-new-commercial-strategy-for-the-NHS-7-july.pdf

NHS England. (n.d.). NHS England » NHS Long Term Plan. NHS Long Term Plan. https://www.england.nhs.uk/long-term-plan/ (accessed 17th April 2023)

NHS offers new virtual reality treatment for patients with social anxiety. (2020, March 13). Digital Health. https://www.digitalhealth.net/2020/03/nhs-offers-new-virtual-reality-treatment-for-patients-with-social-anxiety/

NHS Procurement in Partnership. (n.d.). NHS Commercial Solutions. Retrieved 31 March 2023, from https://www.commercialsolutions-sec.nhs.uk/pages/procurement-in-partnership

NHS Shared Business Services. (n.d.). HCSA. Retrieved 23 January 2023, from https://www.nhsprocurement.org.uk/partners/nhs-shared-business-services

NHS Wales health boards and trusts. (2023, February 3). Welsh Government. https://www.gov.wales/nhs-wales-health-boards-and-trusts

O Brien, R., Ticho, S., & Kilkenny, F. (2021). The Growing Value of XR in Healthcare. https://www.xrhealthuk.org/the-growing-value-of-xr-in-healthcare

Office for National Statistics. (2020, October 2). Young people's well-being in the UK - Office for National Statistics. https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/bulletins/youngpeopleswellbeingintheuk/2020

Our organisation—Our hospitals and community services. (n.d.). Guy's and St Thomas' NHS Foundation Trust. Retrieved 7 February 2023, from https://www.guysandstthomas.nhs.uk/about-us/our-organisation/our-hospitals-and-community-services

Oxford VR launch social engagement™—A first-in-class digital therapeutic using virtual reality technology to tackle anxious social avoidance in the NHS. (2020). Oxford VR. https://www.oxfordvr.co/wp-content/uploads/2020/03/Oxford-VR-social-engagement-VR-therapy-announcement-UK-press-release-.pdf

Ozsevim, I. (2023, February 3). NHS England: Building a Commercial Community. SupplyChain. https://supplychaindigital.com/company-reports/nhs-england-building-a-commercial-community

PaLS - Procurement and Logistics Service. (n.d.). HSC Business Services Organisation. Retrieved 12 December 2022, from https://hscbusiness.hscni.net/services/1878.htm

Planning and Commissioning. (n.d.). DOH/HSCNI Strategic Planning and Performance Group (SPPG). Retrieved 31 March 2023, from https://online.hscni.net/about-us/commissioning-directorate/

Powell, T., Harker, R., & Parkin, E. (2020). The structure of the NHS in England (CBP 07206). House of Commons Library. https://researchbriefings.files.parliament.uk/documents/CBP-7206/CBP-7206.pdf

Scotland Innovates—About. (n.d.). Scotland Innovates. Retrieved 14 December 2022, from https://innovator.scot/about

Scottish Government. (n.d.). Mental health. Policy: Mental Health. https://www.gov.scot/policies/mental-health/ (accessed 17th April 2023)

Scottish Health and Industry Partnership Group. (n.d.). Scottish Government. Retrieved 8 March 2023, from https://www.gov.scot/groups/scottish-health-and-industry-partnership-group/

Sehmi, R., & Slaughter, H. (2021). Double Trouble. The Health Foundation and Resolution Foundation. https://www.resolutionfoundation.org/app/uploads/2021/05/Double-trouble.pdf

Step 5: Commissioning and adoption (Advanced Guide). (2023, January 5). NHS Innovation Service. https://innovation.nhs.uk/innovation-guides/advanced-innovation-guide/step-5-commissioning-and-adoption

The Children's Society. (2023, April 5). Children's Mental Health Statistics | The Children's Society. https://www.childrenssociety.org.uk/what-we-do/our-work/well-being/mental-health-statistics

The CivTech Process. (n.d.). CivTech. Retrieved 10 January 2023, from https://www.civtech.scot/process

Transforming Diabetes Education with VR Simulation. (n.d.). Oxford Medical Simulation. Retrieved 14 March 2023, from https://oxfordmedicalsimulation.com/wp-content/uploads/2020/01/Case-Study-NHS-Diabetes.pdf

Transforming the NHS procurement landscape. (2018, July 4). National Health Executive. https://www.nationalhealthexecutive.com/Comment/transforming-the-nhs-procurement-landscape-

Virtual Reality—Information on Virtual Reality treatment for situation specific anxiety, phobia or fear. (2022, July 12). Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust. https://www.cntw.nhs.uk/resource-library/virtual-reality/

Welcome to the National Collaborative Commissioning Unit. (n.d.). National Collaborative Commissioning Unit. Retrieved 30 March 2023, from https://nccu.nhs.wales/

What is commissioning and how is it changing? (2019, September 19). The King's Fund. https://www.kingsfund.org.uk/publications/what-commissioning-and-how-it-changing

Who we are. (n.d.). InnoScot Health. Retrieved 16 January 2023, from https://innoscot.com/who-we-are
One of the mandatory procurement procedures currently used in the UK.

Pre-Commercial Procurement. (2022, June 7). European Commision. https://digital-strategy.ec.europa.eu/en/policies/pre-commercial-procurement

Appendices

Appendix 1: Requirements and Approach

This appendix lays out DHI's research and co-design methodology.

Questions	Methodology
-What is the innovation and procurement pathway to bring digital technologies to deliver mental health therapeutics?	• Literature review • Consultations with procurement experts The review has identified key customers for XR mental health therapeutics and their current purchasing routes, including current general requirements or standard criteria for inclusion in public sector frameworks designed to support innovation, as well as those of particular relevance to the emerging XR therapeutics marketplace. The review has also considered Medical Devices Regulations, Clinical and Information Governance requirements (e.g., NICE, SIGN, DTAC, NHSX).
- What are the main barriers faced by innovators in bringing digital therapeutics to market? In addressing this question, the study should note the proposed scope of the other workstreams, including Workstreams 1 and 3 providing funding for early-stage R&D, and Workstreams 4 & 5 on knowledge sharing.	• Literature review • Consultations with procurement experts • Consultations with XR providers Based on the desktop review, DHI developed interview schedules for engaging procurement experts, XR providers and clinicians. 13 consultations with 18 key stakeholders were carried out, transcribed, and analysed. *Limitations to the study:* Despite numerous efforts to engage clinicians in interviews, the review was not successful in securing their participation. The consultations with other parties refer to clinicians and their involvement in XR projects, but the lack of first hand input from clinicians may be taken as a limitation in the scoping review.
- How can a further intervention through Workstream 2 add most value? In addressing this question, the review should not be confined to the existing statement of scope for the workstream and may consider other aspects such as regulatory approvals by MHRA, NICE/NHSX DTAC assessment and devolved nation equivalents.	• Analysis of consultation materials • Co-design workshops with key stakeholders Informed by the findings from consultations on procurement push and pull factors, as well as barriers and opportunities to getting XR innovations to healthcare markets, co-design workshops were developed and ran to map out initial requirements for either a High-Level Market Navigation pathway or outline platform specification for the procurement of XR mental health therapeutics for the NHS.
- If a test and trial platform is the most valuable intervention for Workstream 2: An outline functional specification for a platform Recommendations on the type of organization best placed to establish and operate a platform. In making recommendations the report should highlight where there is precedent for those types of organizations establishing such a platform and any learning from that experience.	• Analysis of the co-design workshop outputs • Bringing together findings from all three stages of the study to produce recommendations. Drawing from the challenges and opportunities distilled from the interviews, and combining with workshop participant 'User Stories' articulating needs from the stakeholder viewpoints (clinician, supplier, commissioner, procurement), a combined set of 'stories' was distilled which represent an outline functional requirements specification framed in natural language. Additional grouping of the material allows requirements to be expressed as capabilities that could be combined into a technical service 'platform' model, set in the context of a wider solution opportunities space that suggests options for e.g, organisational risk mitigation.

Table 1: DHI's research and co-design methodology.

Ethics

DHI has a 4-year blanket ethical clearance from the University of Strathclyde for carrying out consultations, when the research participants act as spokespersons for their organisations.

Consultations

The consultations were carried out over Microsoft Teams with 18 interviewees during 13 separate interviews; 11 of these were recorded, with transcripts produced by AI, checked and corrected by members of the research team before carrying out a thematic analysis. The emergent themes, which focussed on procurement push and pull factors and procurement barriers and opportunities, were used to inform the development of the co-design workshop. Some interviewees asked not to be named. Hence, we have only named the organisations that were engaged in the consultations.

- Six participants represented procurement side, eleven supplier side, with one representative for clinicians (several clinicians were approached, but no other had the time to attend an interview or a workshop).
- Three participants were from the public sector (all Scotland; UK/England public sector procurement representatives that we approached declined participation due to the pending new procurement legislation was not out yet); thirteen from the private sector and two were classed as "other" type of organisation.
- Four participants represented England, one Wales, five Scotland, eight UK. No suitable representatives from Northern Ireland could be identified for this study in the available time.

	Interviewee	Type of contact	Organisation	Sector	Region
1	Male	Procurement	NHS	Public	Scotland
2	Male	Procurement	Scottish Government	Public	Scotland
3	Female	Procurement	ORCHA	Private	UK
4	Male	Procurement	ORCHA	Private	UK
5	Male	Supplier	XR Therapeutics	Private	England
6	Female	Supplier	XR Therapeutics	Private	England
7	Female	Supplier	SyncVR Medical	Private	International
8	Male	Procurement	SyncVR Medical	Private	International
9	Male	Supplier	Rescape VR	Private	Wales
10	Male	Supplier	The VR Hive	Private	Scotland
11	Female	Supplier	XR Health Alliance	Other	UK
12	Male	Supplier	Sim-Viz	Private	Scotland
13	Female	Clinician	British Psychological Society	Other	UK
14	Female	Supplier	ORCHA	Private	UK
15	Male	Supplier	ORCHA	Private	UK
16	Male	Advisor Procurement	Scottish Government	Public	Scotland
17	Male	Supplier	VIVE	Private	UK
18	Male	Supplier	ReScape VR	Private	UK

Table 2: breakdown of consultation participants

Design Workshops - approach

The workshops, held on the 17th and 25th March 2023 respectively, had the following goals:

1. To create a virtual multi-stakeholder environment, where insights and observations gathered from the interviews could be played back, discussed and verified in a shared, collaborative and open context.

2. Through a series of facilitated interactive activities, which were designed to be incrementally more definitive, develop meaningful conversations that supported the objective of understanding more about the barriers faced by innovators in bringing digital therapeutics to market.

3. Validate the need for a test and trial platform, and if so, provide a sense of how such a platform should function and the benefits for each stakeholder group.

4. Using insights derived from preceding consultation activity, stimulate opinion and reveal opportunities.

5. Define, at Business Requirement level, the key requirements and objective of either a high-level navigation pathway or outline pathway specification.

The environment used for the Workshops, Miro, was familiar to most workshop participants who represented the range of sectors relevant to the Mindset project. The workshops were organised with a short lead-up time, which unfortunately had an impact on the availability of participants. The first workshop had six participants, with emphasis on private sector presence. Representatives came from Rescape Innovation Ltd, XRHA, XR Therapeutics, and UKRI. The second workshop was dominated by the public sector and procurement representatives, with two further suppliers present. The organisations represented were the NHS, Scottish Government, University of Strathclyde, Mental Health Foundation, Synch VR, SimViz and UKRI.

The workshop approach:

Activities

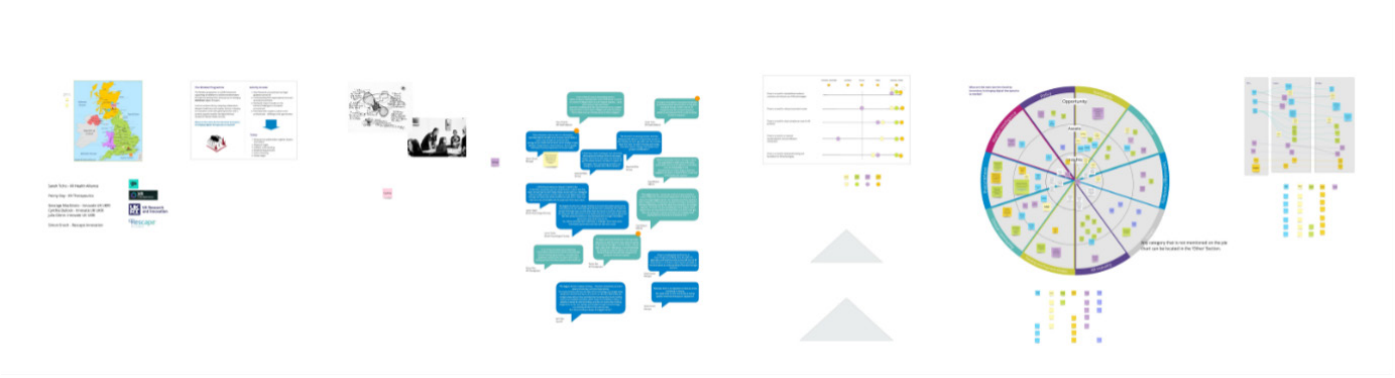
1. Following an initial 'icebreaker' activity designed to familiarise users with Miro, participants were provided with background and objectives of the Mindset Programme and introduced to the design driven approach to be taken during the workshops.

2. A number of quotations elicited from participants during the consultation stage of the project and identified by the DHI research team as particularly relevant were used as a basis for deeper discussion and scene setting.

3. The research activity allowed the formulation of provocation statements against which participants were asked to register a degree of concurrence through the placing of a coloured 'dot' on a horizontal scale. The resulting conversation and discussion helped build consensus and insight.

4. By placing the themes outlined earlier in a circular 'pie' type layout, the groups were asked to consider the insights, assets and opportunities associated with each area. To help 'kick start' the process, some Insight items were added to the figure.

5. The final activity was structured in 'Use Case' format (Stakeholder/Need/Output) and included with view to defining requirements associated with a procurement process or platform.



With a view to addressing the project objectives (outlined in table 1 above), particularly with respect to understanding more about the challenges and opportunities associated with the innovation pathway, insights, assets and opportunities associated with each of the nine elements (outlined above) were mapped and distilled through thematic analysis into key problem-and-need messages and corresponding solution opportunities.

A tenth 'other' category was added to the nine segments on the pie template to allow participants to propose any new theme that the consultation analysis had not highlighted. This exercise showed there was consensus on the nine themes and no adjustment to the chart was needed. Findings around challenges and opportunities were placed within the relevant segment.

These were further cross-referenced with the consultation transcripts and key messages for consistency and completeness. The table below shows the combined summary of the key themes and opportunities, which were used to inform the solution space and recommendations of the review:

Questions	Methodology
Clinical Commmunity	
• In the case of XR, as with other areas of health and care related procurement, influential clinicians often have significant impact on which technologies are introduced and adopted in a clinical setting.	• There is a need for accredited products that clinicians and commissioning bodies can choose from. • There is an opportunity to create a centralised, UK-wide, procurement and distribution system instead of taking a (health board)-by-board approach. This would offer efficiency on multiple levels including addressing the issue of developers engaging with individual health boards and developing solutions that may only be relevant to (and have the approval of) a single geographical region. • Developing, testing, and scaling within centers of excellence that already have a strong understanding of XR - and then scaling across the UK. • There are opportunities to overlap with social prescribing initiatives and national strategies aligned with preventative care. For example, the National Academy for Social Prescribing has an Accelerating Innovation https://socialprescribingacademy.org.uk/our-work/our-workaccelerating-innovation/
Evidence	
• Need for standardised evidence collection and a clear procurement route—albeit this could be a very expensive and time-consuming exercise. • The benefits and savings of using XR technologies are difficult to measure on an individual level and that evidence regimes are not designed with XR interventions in mind. • Examples of evidence frameworks from NHS England were brought forth. However, in some cases standardization had led to inflexibility within the process resulting in the exclusion of some developers from the framework.	• There is a need for multiple repeated studies to show efficacy and impact of VR in a clinical mental health setting. • A more holistic approach to evidence is needed to facilitate cooperation between industry and the NHS, with particular consideration given to how solutions can be deployed. • The is an opportunity for research students to work alongside companies in a knowledge exchange style arrangement, allowing academia to focus on RCT (randomised controlled trials) and research collection, whilst a product is in development. • There may be scope to partner with organisations such as the NIHR (National Institute for Health and Care Research) to develop proof of concept clinical trials.
Funding and payment models	
• Need for dedicated funding and facilitation for XR technology development; funding should be driven by the problem, not a predefined solution. 'We need to encourage innovation and make sure XR is the correct solution.' • Developing pathways into the NHS will encourage further industry investment into VR in a clinical setting. XR developers do not have the resources to build an evidence-base to develop a 'Value proposition' that is compelling enough, in terms of health economics, for the NHS. There is an opportunity to support developers in this regard. • The NHS has a budget for mental health and tech solutions but this is always allocated based on predefined priority. The question is how do we get to the stage where this is seen as a priority? • Charity funds often the only route readily available to the clinicians whom XR therapeutics suppliers rely on to purchase products following successful pilots. Such routes are expedient and often appropriate for tactical purchases, but the approach lacks the consistency and scalability offered through structured NHS procurement models.	• For XR to develop and be seen to be successful in a clinical setting, it is vital that companies are supported in the development of compelling, evidence-based economic value propositions. • To promote XR so that it is viewed as a viable, effective alternative and complement to current treatment methods as opposed to an indulgent gimmick. • The goal with respect to funding and payment models should be the establishment of dedicated funding approaches for XR technologies AND the associated service innovation. • Mitigating financial exposure—particularly impairment write-off risks - for Boards and Trusts through centralised capital and leasing options for XR hardware would offer scale cost efficiencies and reduced local risk. • There are opportunities to co-fund via investment from Creative Industries, including Unity for Humanity, Microsoft, Epic Megagrants https://www.unrealengine.com/en-US/megagrants • Exploring opportunities in Care and Education may be an easier way into the NHS.

Market Intelligence	
Providing a quicker route into the NHS will encourage manufacturers to drive more development in healthcare settings. Currently, most development is in a gaming setting, where developers have a direct route to market	• A database / resource of existing solutions alongside related product information and evidence is needed. • A cross-industry network with the purpose of facilitating connections and sharing insight between VR related sectors such as gaming, the creative industries, SMEs academics and policy makers could be created.

Policy	
• Setting out a clear regulatory and standards compliance framework for XR therapeutic solutions in mental health will ensure rigor and robustness which will have the effect of reassuring partners and 'validating' the provision of immersive technologies as a credible technology solution in a clinical setting. • Although standards could introduce a degree of stagnation with respect to innovation, the benefits to the industry outweigh any disadvantage.	• Integrate evidence-based case studies into key policy documents related to the use of immersive technologies in a mental health context

Procurement	
• Suppliers see multiple procurement routes, which place different demands on XR companies who have limited resources. • The aggregate time to market is very long and this can pose a risk to the viability of the XR therapeutics market. • While the need for a clear, concise and informative procurement platform, it was generally felt that this wouldn't be straightforward to implement across different Boards.	• There is a need for accredited products that clinicians and commissioning bodies can choose from. • There is an opportunity to create a centralised, UK-wide, procurement and distribution system instead of taking a (health board)-by-board approach. This would offer efficiency on multiple levels including addressing the issue of developers engaging with individual health boards and developing solutions that may only be relevant to (and have the approval of) a single geographical region. • Developing, testing, and scaling within centers of excellence that already have a strong understanding of XR - and then scaling across the UK. • There are opportunities to overlap with social prescribing initiatives and national strategies aligned with preventative care. For example, the National Academy for Social Prescribing has an Accelerating Innovation https://socialprescribingacademy.org.uk/our-work/our-workaccelerating-innovation/
• If a test and trial platform is the most valuable intervention for Workstream 2: An outline functional specification for a platform Recommendations on the type of organization best placed to establish and operate a platform. In making recommendations the report should highlight where there is precedent for those types of organizations establishing such a platform and any learning from that experience.	• Analysis of the co-design workshop outputs • Bringing together findings from all three stages of the study to produce recommendations. Drawing from the challenges and opportunities distilled from the interviews, and combining with workshop participant 'User Stories' articulating needs from the stakeholder viewpoints (clinician, supplier, commissioner, procurement), a combined set of 'stories' was distilled which represent an outline functional requirements specification framed in natural language. Additional grouping of the material allows requirements to be expressed as capabilities that could be combined into a technical service 'platform' model, set in the context of a wider solution opportunities space that suggests options for e.g, organisational risk mitigation.

Technology Familiarity	
• NHS Staff can be tech averse and see new tech as adding to their already significant workload, particularly if training is required. • Uncertainty of available tech and their quality. • Gaining clinical acceptance can be a challenge if VR is considered a gimmick, which will continue to be the case until evidence-based standards are established. • Standards need to be introduced in relation to the integration and operational deployment of VR technologies in a clinical context. • There is low clarity and understanding with respect to regulatory compliance. • An observation: where in the innovation process is there an appropriate point to implement standards and for them to become legislation? Doing this at too early a stage may impede the innovation process.	• Showcase early adopters through case studies and industry events to support knowledge sharing, networking, and technology orientation (which could go some way to addressing the 'gimmick' association). • The expectation of appropriate technology-supported care pathways in mental health care delivery settings should be embedded early through the education and training routes for clinicians and support teams. This normalises the expectations of digitally-supported care as a default for new entrants to the workplace. • Overwhelming support for the creation of a working group to define and communicate standards associated with the development and deployment of XR digital therapies
XR industry	
• A need for relevant bodies to support XR industry to engage with clinical innovation pathways and to ensure there are sufficient resources to support the entire procurement journey. • No standard way in which companies engage with clinicians, which leads to variable insight and information exchange. • Many companies in the XR domain cannot endure lengthy, protracted engagements with centralised procurement frameworks.	• There is the potential for collaboration with providers such as Unity and Unreal, both of whom run relevant programmes: https://unity.com/humanity https://www.unrealengine.com/en-US/educators • Trusted digital technology assessment and distribution organisations (ORCHA being the leading player) and professional bodies such as the Association of Clinical Psychologists UK (ACP-UK) and the Heads of Psychology Scotland (HOPS) could define integration test methodologies and an approval service for XR-supported care pathways at national level.

Table 3: Challenges and opportunities identified in the co-design workshops mapped across the nine key elements.

Appendix 2: List of Key Innovation Organisations across the UK

Organisation	Function
Accelerated Access Collaborative (AAC)	High level strategy, works with other organisations and establishes new routes.
NHS Innovation Service	Provides information and connects innovators with other organisations.
Academic Health Science Networks (AHSNs)	There are 15 regional AHSNs, and offerings may vary by region. Key goals include horizon scanning, supporting development, and increasing uptake of innovations.
Academic Health Science Centres (AHSCs)	Accelerate innovation through early-stage research.
NHS test beds	Test innovations, providing evidence of how they function in a real-world setting.
SBRI Healthcare	Runs small business research initiative competitions for innovative healthcare solutions, providing funding for feasibility testing, development, and implementation.

Table 1: key innovation organisations in England

Organisation	Function
Scotland Innovates	Provides advice and connects suppliers with relevant public sector organisations.
Accelerated National Innovation Adoption Pathway (ANIA)	Fast-tracks the adoption of particularly impactful innovations.
CivTech	Issues challenges, providing R&D funding and helping with adoption.
InnoScot Health	Accepts submissions from innovators, offering funding and support with R&D, testing, regulatory approval, and commercialisation. Targeted towards NHS Health & Care professionals.
Innovation centres	Scotland's 7 innovation centres each focus on a different domain. They enable innovation through collaborations between industry, academia, and the public sector.
NHS test beds	Accelerate adoption of innovations through testing in a real-world environment.
Scottish Health and Industry Partnership Group (SHIP)	Advances early-stage innovation by building on research and encourages collaboration.

Table 2: key innovation organisations in Scotland

Organisation	Function
Digital Health Wales	'One-stop-shop', collates resources relevant to innovation development.
Life Sciences Hub Wales	Accelerates innovation adoption and development through collaborations with industry, academia, and healthcare, and encourages economic development in the life sciences sector. A body of the Welsh government.
Digital Health Ecosystem Wales (DHEW)	Provides guidance to industry on how to sell digital healthcare products and services to the NHS, and encourages industry/ academia/healthcare partnerships. A collaboration between Life Sciences Hub Wales and Digital Health and Care Wales.
SBRI Centre of Excellence	Supports the Small Business Research Initiative in Wales.
Business Wales	A body of the Welsh government which provides business support services. Runs the Expertise Wales portal, and manages the small business research initiative in Wales.
Expertise Wales	Runs a series of 'SMART' innovation support programs, and provides a platform for viewing industry and academia opportunities. Also runs a network of local innovation specialists. Part of Business Wales
SMARTInnovation	Offers support to Welsh businesses via IP advice, design consultancy, support with technical collaborations, support with commercialisation, and assistance with R&D funding access. Programme of expertise Wales
Bevan Commission	Runs the Bevan Exemplars Programme, which supports health and care professionals to develop healthcare innovations through a 12-month programme, and the Adopt and Spread Programme, which helps to scale up these innovations.
Wales Regional Innovation Coordination (RIC) Hub Network	Seven regional innovation hubs coordinate local innovation activity.

Table 3: key innovation organisations in Wales

Organisation	Function
Innovate NI	Provides detailed information to businesses on how to develop their innovations, and an Innovation Assessment for evaluating needs and delivering targeted advice. Delivered by the Invest Northern Ireland regional economic development agency and the government's Department for the Economy.
Invest Northern Ireland	The regional business development agency for Northern Ireland. Offers R&D grants and expert knowledge support to companies who intend to sell outside Northern Ireland. Also runs NI business Info, an online resource for business advice including innovation support.
InterTradeIreland	Offers R&D funding and a programme of free innovation lectures and classes to businesses in Ireland and Northern Ireland.
The Northern Ireland Connected Health Innovation Centre (CHIC)	Focused on business led research. Supports innovative healthcare businesses in various ways, including intellectual property services, prototyping and design, collaboration opportunities, and information on funding sources.
HSC Innovations	Offers intellectual property and innovation development services for health and care staff in Northern Ireland.
Health Innovation Research Alliance Northern Ireland (HIRANI)	A cluster organisation of universities and health organisations including Invest NI, Public Health Agency, HSC Research & Development Office, and government departments. Focused on collaboration across business, academia, and healthcare and providing easier access to innovation resources.

Table 4: key innovation organisations in Northern Island

Appendix 3: Interview quotes

REFERRING TO CHAPTER 3.2: SYSTEMS OF EVALUATION AND PROCUREMENT & FRAGMENTED ECOSYSTEM

Quotes 1.1 - 1.8 in this appendix relate to table 3 - "Summary of Consultation Comments on Systems of Evaluation and Procurement"; and quotes 2.1 – 2.6 to table 4 - "Summary of Consultation Comments on Fragmented Ecosystem".

1.1 - Mismatch with the purpose and scale of procurement systems

Historically, procurement systems have been set up to evaluate large scale commissions and projects that operate very differently from XR health interventions.

- ***What's historically happened is health systems have implemented digital technologies in the same way as Electronic Patient Record systems and other monolithic IT projects. (We have to) make people think about digital health interventions, patient-facing digital health interventions, stop thinking about Electronic Patient Record. Just think about these as a form about health intervention and have a strategy for that, that lines up with your strategies to support your patient groups. The digital component in that strategy should deploy low complexity digital solutions.*** ORCHA

1.2 - Lengthy and laborious route to market

Healthcare procurement systems are set up to meet the general requirements for companies, who might have more resources at their disposal. These parameters can disadvantage XR health SMEs in multiple ways.

- ***[The NHS is] quite difficult to integrate into and it's quite a difficult system because there's so much variability across the different areas. So, I think there'll be logistical issues that you'd have to address across that.*** Scottish Government

- ***The procurement process is, it's slightly laborious and pretty simple. Well-established. Everybody knows what you need to do. You know the stages you go through. There's nothing, there's nothing new about procurement process and it can be run quickly or slowly.*** ORCHA

XR suppliers also indicated that submitting procurement bids can place significant burden of work on them, and long waiting periods do not support their operating models.

- ***We shouldn't be winning tenders and then being worried about it. It's great that we won it. But actually, we don't get paid until nine months down the road, but we're starting work today. That does need to change, that needs to be greater consideration***. VR hive

- So, we worked a lot with public sector funding, and I think that the ASK is not clear enough, you're still getting tons of emails and newsletters for opportunities that actually, when you look into it, really wouldn't be relevant for your organization. So, I think if you could find a way that you could filter out those opportunities, and so maybe someone was getting a weekly email with the relevant opportunities

1.3 - Running pilots with multiple clinical teams

While the procurement process itself can be lengthy and laborious, XR companies had to spend long pre-sales periods in building and maintaining relationships with clinicians. Engagement with clinicians was seen as crucial both for specifying and implementing products, and for generating evidence of the efficacy of XR interventions in clinical contexts. This process enabled healthcare teams and XR health suppliers to safely embed XR technologies in clinical practice, and to tailor them into specific workflows.

Building direct relationships with clinicians was even more important because of the relative dearth of XR mental health therapeutic-specific procurement contracts. Hence, XR suppliers reported almost exclusively that they took took a grass-roots approach, running multiple trials with different clinical teams in different hospitals.

- ***Our predominant method, if you like, is actually has just been outreach and just, and demoing the technology, and maybe starting with some feasibility type trials or projects in which we can gather some real-world validation in terms of clinical use.*** -SyncVR

For suppliers, the purpose of these local trials is to familiarise clinicians with the technologies and generate evidence about clinical efficacy and impact on the service.

- ***We try to make it formal on the tablets. You can collect pain and anxiety scores before and after the experience. We also have the ability to create a questionnaire so we can personalise, know if there's certain things that somebody wants to find out, we can do that.*** - Rescape

- ***(Q: Do you collect evidence through each of these trials?) So, we have evaluation forms, then they can fill them out either on paper and sort of present that evidence to us during our biweekly evaluations or they can actually do it through our tablets. ... we have studies that we've run as well. So, there's like a randomized control trial that we did for example.*** - SyncVR

Procurement experts, on the other hand, emphasised the importance of cooperation with clinicians and NHS structures from the developmental phase.

- ***Being developed in partnership with the NHS and partnership with the clinical structures, because I think that will be key to getting that kind of ownership of the technology within clinical settings and ultimately clinical acceptance.*** -Scottish Government

1.4 - Mismatch in standards of required evidence

Some of the problems XR companies face are characteristic to the wider digital health sector insofar as the clinical efficacy and benefit to the health service of these technologies materialises differently from established healthcare interventions, often on a more individual level. Hence, the benefits of these technologies cannot be fully evaluated using the same methods.

- ***(if) you build a business case around is that macro deployment strategy. And we've done the economic modelling around all these little incremental benefits on the population. And when you do that (on) scale, you know, deploying technologies to scale, to high impacts of populations, the paybacks are phenomenal. But if you try to come back to relying on commissioning one product, you've got no hope.*** - ORCHA

It was highlighted that unlike other healthcare interventions, digital mental health interventions benefit patients in diverse ways; and different patients within population can improve their health using a diverse set of healthcare interventions.

- ***The kind of strategy around digital tends to be what I describe as a silver bullet strategy. This is the product that will solve that problem. We know from research and from patient engagement and from professional engagement the particularly in in those chronic condition management areas-- (If we) implement 10 or 15 (digital technologies) at a time, because that's where you'll get the benefit. The holistic effect, let's say on a community of people such as long-term condition sufferers, where you, you, you deploy a range of technologies and for one person with diabetes, it will be the weight management. That's really helpful and for another person it'll be distress and anxiety management. And for the third person, it would be something that's much more directly associated with their diabetes.*** - ORCHA

1.5 - Ambiguity about the level of required evidence

There was some difference in views of levels of required evidence: while procurement experts emphasised the need for establishing stronger evidence base for XR products, suppliers pointed out that it is not clear what level of evidence is required.

- ***I think the first, probably the biggest one, is around clinical acceptance. So, we know the digital therapies that we use for example, have very strong evidence that sit behind them. So randomized control trials, NICE guidance, recommendations and so on and so forth. I think virtual reality is just a wee bit too early and it's kind of evidence gathering phase to really have enough to get that clinical acceptance.*** -Scottish Government

- ***A simple entry platform (would be beneficial). So, knowing exactly what evidence is required, and good enough, I think I see lots of companies that do not have very good evidence, but because there's a lack of clarity of what is required.*** - XR Health Alliance

1.6 - Accommodating different clinical teams

Procurement experts also emphasised the need for XR companies to tailor their products to the needs of diverse clinical teams.

- ***To be able to integrate it into health and you have to get the buy-in of the health board and each of the different clinical services that are trying to introduce it. I think the difficulty for a lot of companies is how do you maintain a level of technical agility. So, you're kind of moulding the service and the technology into the new technologies like VR for example, and also then still building up the kind of clinical evidence and the clinical impact…*** -Scottish Government

One procurement expert noted how entering the clinical market requires not only producing evidence, but XR companies also need to work with different health teams to accommodate their needs, build 'reputation' and generate buy-in. This is often a long-term investment, and it might be a relatively high threshold and limiting factor for SMEs.

- ***The companies that are more successful, particularly in digital mental health, are those companies that have built up their reputation slowly, but built up in the right way. So, a lot of clinical inputs, a lot of cooperation and collaboration with health care services, the ability to be flexible in how they deliver is really the key. And if we're getting to mould their technologies into the existing clinical practices that's a huge plus now for us, so they needed to have all of that before they'll get to the stage where they have a big opportunity.*** -Scottish Government

1.7 - Demonstrating service improvement

Both suppliers and procurement experts emphasised that these trials need to go beyond proving clinical efficacy; technologies need to be integrated in different clinical workflows and have a positive impact on the service level.

- ***But I think there's still a heavy reliance on being able to prove the case and not just showing value from a clinical perspective but showing value from a service delivery perspective and showing impact.*** - Scottish Government

- ***If you're not solving a problem for someone, why would they want to purchase it? - - They will embrace it because they know the patient gets the benefit and they get the benefit. - - We need to do a selling job on your team.*** -Rescape

1.8 - Limited resources - labour and cost

Running clinical pilots of XR technologies is dependent on the clinical staff's labour and buy in.

- ***So about 25% of our trials, the reason healthcare professionals haven't taken it up as they said we loved it, but we just don't have the capacity to someone to be able to deploy the time.*** -Rescape

Running the trials can also place considerable financial strain on XR SMEs.

- ***Time is always a factor. I think if we can start to limit these, once we have generated so much use case data and evidence. Now we're working with 15 NHS Trusts and hopefully that all will hopefully start to convince more people to direct route to purchase and sort of just going down that pilot trial route. As you probably are aware, we can't offer free trials forever unfortunately. So as a startup we do have to consider that.*** -SyncVR

2 - Fragmented ecosystem

This chapter discusses XR health companies' difficulties of engaging with a complex healthcare system, and how this places additional work and resource constraints on these relatively small companies.

2.1 - Lack of a single 'front door' to the health system

Suppliers and procurement experts reported both functional and regional fragmentation. Decisions were not taken centrally or by a single agency. There is no centralised 'front door' to enter the healthcare market.

- ***We're able to sort of compare across different countries and it does seem that the process in the UK is a bit more sort of complex than it may be and some of the other countries that we work in.*** -SyncVR

Hence, most suppliers found targeting clinicians directly a more viable method for engaging with the sector.

- ***So again, we've, we did try kind of the top-down approach as well. But even then, when we spoke to operational managers, the first thing is they go, yeah, yeah, that's really good. It sounds amazing, but actually you need to speak to the clinicians because they are the ones that are going to be giving the treatment anyway.*** -XR Therapeutics

- ***It's mainly the clinicians themselves. So, we we've tried to, a broader strategy to contact departments, but we found actually, we've had more success by individuals. But it's like trying to find needles in the haystack.*** -Rescape

2.2 - Disjointed decision-making

Conversely, while healthcare professionals were able to assess the clinical efficacy and service impact of technologies, they have no insight into the available funds, processes and funding structures within healthcare organisations.

- ***The biggest barrier is always funding and the, and not necessarily the actual funding. Clinicians aren't aware of how they can fund these devices. Some clinicians will love the idea of the technology, but say no we can't afford that without knowing what funds funding sources are available.*** -SyncVR

- ***So, funding and reimbursement models that, that's a massive challenge. We finance our system on a lease basis. And I'm not sure that's the best way to do it for the NHS. We need to work with the NHS to understand what reimbursement model would work for them best, obviously how do we have access to funds? How do you create a pot of money that is directly for XR?*** -Rescape

Given the lack of NHS funding, several suppliers reported that they access funds from charities to provide clinical devices. It is likely that charitable funding plays an especially important role because it is not subject to the annual budgeting constraints, and it can be available for developing the service.

- ***I'd say 80% of, probably, purchases have been made -- through charity bids, and so charity funding for these devices following successful pilots or successful feasibility project.*** -SyncVR

2.3 - Regional fragmentation

Beyond disjointed decision-making, there are significant regional differences between healthcare organisations. These discrepancies are rooted both between different clinical care pathways, and disparities in the way regional and local health boards and trusts operate and interpret standards.

This not only increases XR health companies' workload when entering these markets, to which SMEs can be sensitive to but also creates additional uncertainties.

- ***(More transparency would help because) it took me so long to really understand and I know each department and different trusts are different because they are given different budgets, but even just to understand what the actual cost is to the NHS, for someone to go through the process of having cognitive behavioural therapy isn't something that's particularly open and spoken about. So again, that would have saved a lot of conversations with different clinicians of kind of going back and forth, going, that is quite expensive.*** -XR therapeutics

- ***What is absolutely critical is the way in which two organizations might look at the same information and come to different conclusions as to its acceptability or not. And that acts as a major drag on both the suppliers, but also is a wasted effort on the half of the healthcare systems.*** -ORCHA

The suppliers echoed similar duplication of effort within the current system. It does not help that there is ambiguity about how medical device regulation applies to XR technologies.

- ***They're insisting that we fill forms in, even though we're filling every box with 'not applicable', and they'll be back, but we still have to fill those forms in. So, there's a bit of work that needs to be done about an understanding of how (technology) interacts.*** -Rescape

Besides medical device regulation and legal compliance, information governance processes create additional workload on companies.

- ***The biggest hurdle we're always finding is the local information governance. And because we can nationally agree and procure something, but unless we can get it through every local IG area, then that starts to become a flow issue. Some information governance process can take over a year.*** -British Psychological Society

2.4 - Regional opportunities

There are differences in the way regional and local services are organised within the UK. For example, in Scotland a more unified approach is promoted which emphasises equity of care while embracing solution choice where practicable:

- ***Everything's coordinated so strategically in Scotland that we take our whole systems approach to delivery, and we try very hard to have an approach of equity and whole systems approach. So, for example, we're launching a national Psychological Therapies specification, it includes digital in there on how psychological care should be delivered throughout Scotland.*** -British Psychological Society

2.5 - High compliance threshold for clinical interventions

Some procurement experts suggested that while compliance with the different types of regulations is a significant barrier, but this could be dismantled by improving companies' understanding on these.

- ***I think regulations are really significant, and simply because of the limited understanding of what you need to do to achieve it - - If [companies] did appreciate them, then I think they'd spend more time on them, and if they spent more time on them, it's probably not that big a barrier.*** -Scottish Government

At the same time, there are initiatives in this space to inform SMEs of the different regulations.

- What we're able to do for, an even very fledgling organizations, is to provide them with a To Do List, a checklist of all the things you need to worry about. And some of that's hard compliance like medical device and GDPR and a lot of it is soft. It's what evidence stands, you know, what's the evidence. -ORCHA

In addition, while clinical practices are more risk-averse and have a higher compliance threshold, non-therapeutic or non-medical applications can be used to collect evidence and strengthen the company's position within the XR health market.

- ***I don't think [third sector] have the same barriers that we have within NHS and social care type settings - - So, there's lots of opportunities, and I think that commercial companies are looking to build evidence and it's perhaps an easier route to get into that sector.*** -Scottish Government

Some interviewees also noted that XR applications that enter education and workforce development markets do not have to deal with the same compliance threshold as clinical applications. As these technologies enter clinical education, future professionals will be more familiar and confident using XR technologies.

- ***Integrating (educational XR applications) into workforce, and workforce training - - will increase acceptance of VR across clinical settings. And then I think what will happen as a consequence is it will be accepted within clinical situations for patients. So, I think it will be workforce and education first.*** -Scottish Government

2.6 - Calls for transparency and a targeted procurement framework

When asked about how a targeted procurement framework could improve the current situation, suppliers overwhelmingly welcomed this idea.

- ***Yes, I think if there could be like a general mental health procurement framework, I think it would be a lot easier.*** -SyncVR

Many interviewees, both suppliers and procurers, highlighted the need for a more targeted approach to support XH health companies' route to clinical markets.

- ***I think it would give people sort of a comparative site as well. So, people would understand what they were doing and give them a better idea of what is in the market at the moment. We would see it as credibility if we're on an NHS endorsed website. To say that we are an approved supplier, we think that would be a really positive thing.*** -Rescape

- ***So, we are massive fans of coordinated national repositories of tried and tested and evaluated innovations that can be picked and then go through an open procurement framework, because there will be competition in that landscape.*** -ORCHA

Some suppliers also indicated that a targeted approach would benefit both suppliers, clients and procurers by setting standards.

- ***Basically, there is no regulation so that you know everything is missing. We really need to have a think about having specific immersive therapeutic regulations.*** -Rescape