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Digital health adoption: Looking beyond the role of technology

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Digital health adoption: Looking beyond the role of technology

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Editorial: Digital health adoption: Looking beyond the role of technology

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Editorial on the Research Topic
Digital health adoption: Looking beyond the role of technology

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Accelerating the adoption of proven digital health technologies and advancing their embedding into routine care operations has the potential to revolutionize human health by boosting efficacy, driving costs down, and increasing access to and capacity for care delivery (1). It can shape individuals' daily lifestyle choices, and advance population health management, thus improving life expectancy and quality of life worldwide (2). Nonetheless, the healthcare sector has been struggling to accelerate digital adoption. In line with recent insights in the literature (3, 4), the papers in this Research Topic illustrate that much of this frustration relates to challenges that lie beyond managing the technologies' technical core. We first introduce the papers and then reflect on key themes and implications.

Reflecting on adoption Shaw and Donia propose a broader socio-technical approach to the ethics of digital health, which spans domains from software, devices and supply chains to inter-personal relationships, organizational and government policies. They emphasize issues of social justice, the need to address inequalities in digital access and advocate anticipatory forms of governance to minimize potential negative consequences. Greenhalgh et al. discuss a conceptual framework—PERCS—used to evaluate remote healthcare consultation services in the UK. The authors focus attention on digital maturity and digital inclusion, examining seven inter-related domains, spanning from the reason for consultation, to patients, care delivery, home and family and the wider system. They identify tensions and contradictions along these domains and elaborate on related practical ethical issues. Shaw et al. analyze the accelerated implementation of video consulting during the COVID-19 pandemic. Using comparative and interpretive policy analysis, the authors identify key

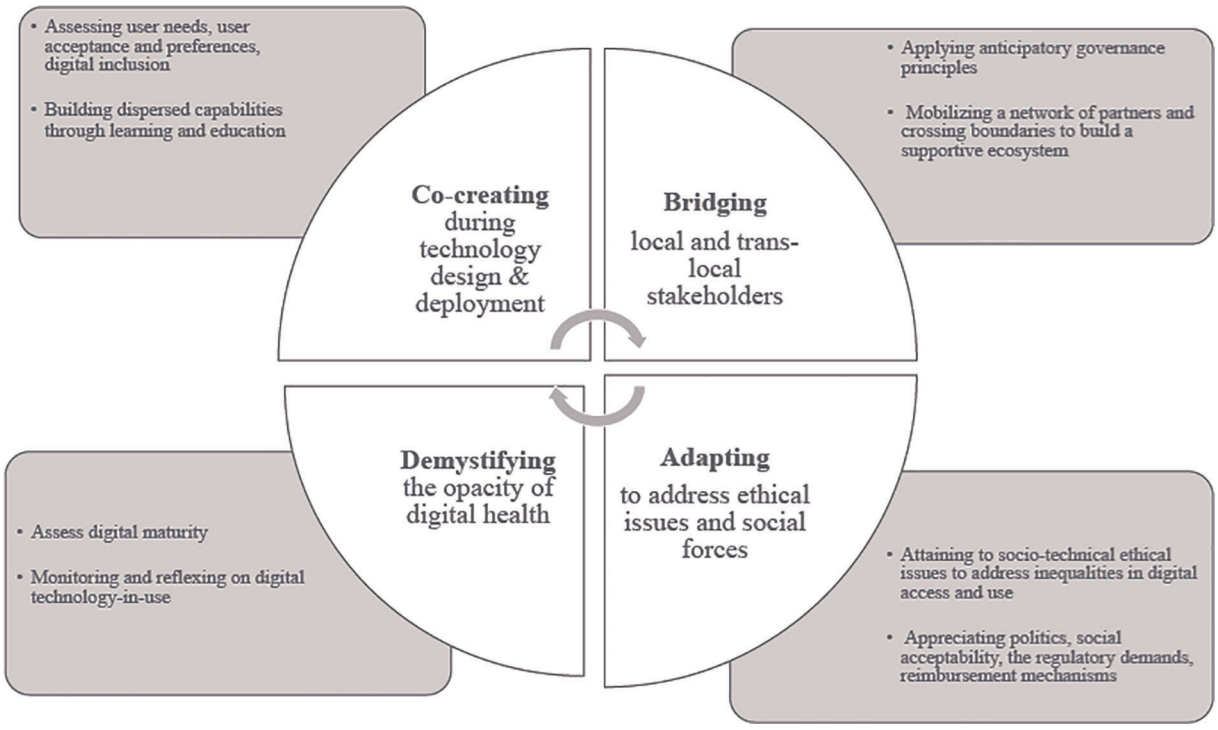

FIGURE 1
Themes on digital health adoption.

variations across the four UK health systems in terms of enabling and limiting conditions at both policy and delivery levels. The authors also caution against inequalities in accessing video consulting services.

Nantume et al. explore the commercialization of a wearable vital signs monitor in low resource settings and argue for a holistic implementation perspective, from idea and product design to market. They highlight implementation being intertwined with development and evaluation, involving local stakeholders as co-creators. The authors also stress the role of social dynamics, such as trust in regulatory authorities, and public misperceptions about the technology. Rainey et al. in their survey study explore perceptions of AI by UK radiographers for successful application and integration into clinical practice. The authors highlight important aspects of the professional roles of clinicians, and the need for learning, capability-building and de-mystification of the opacity of AI-in use. Bouabida et al. evaluated two platforms for remote patient monitoring following hospital discharge in the context of COVID-19 in Canada. The authors highlight issues of social acceptability by diverse stakeholders during adoption, maintaining human contact and balancing concerns for confidentiality and data security. They underline the need for user participation in technology development and deployment, also bringing to the fore organizational, social and ethical aspects.

Bennet et al. describe the experience of ID-Liver implementation and use in northern England for integrated, pro-active management of patients at risk of developing chronic liver disease. From setting up to piloting and using ID-Liver, the authors argue for the need to mobilize a network of collaborators including commercial partners, healthcare organizations and professionals. Yan et al. in their commentary on digital therapeutics raise the broader question of cost and reimbursement. The authors identify a set of dilemmas for policy-makers, which are related to the specificities of digital therapeutics including the ability of patients to afford and use technological devices and the possibility of reimbursing these therapeutics. Cripps and Scarbrough present a perspective on a sustainable approach to digital applications in the UK's NHS. The authors argue to shift the focus from the technology itself to considering the motivations of users and constraints within specific contexts. They advocate for a wider approach to change that incorporates clinical and behavioral insights, process engineering and knowledge management.

The papers' contribution can be grouped into four themes, which highlight key non-technology related aspects of digital health adoption (**Figure 1**): (a) *Co-creating* through digital inclusion and user engagement. (b) *Bridging local and trans-local stakeholders* including partners from the wider economy and the private sector. (c) *Adapting to ethical issues and social forces,*

beyond technical and clinical aspects, such as public (mis-) perceptions, professional and organizational dynamics, regulatory elements, as well as issues of cost and reimbursement. (d) *Demystifying the opacity* (clinical, operational) of digital health applications and assessing digital maturity in practice.

Reflecting on implications for policy and practice, the papers in this Research Topic highlight *five key levers* that can help drive more effective digital health technology adoption.

1. *Understanding and responding to the needs and preferences of diverse individuals and communities* is critical (e.g., Cripps and Scarbrough). A number of authors (e.g., Shaw and Donia; Greenhalgh et al.) highlight inequalities in digital health. While inequality is often considered at the point of care in terms of the ability of patients and clinicians to use technology, inequalities also arise when more marginalized groups are unable to voice their concerns and preferences upstream, and to influence the development and evaluation of digital innovations. Aptly, the question of *co-creation* underpins many papers in the collection.
2. *Early and active stakeholder engagement in both design and technology use* (e.g., Nantume et al.). This highlights the need to partner with and incentivize innovators (including the private sector) to bring in their technical expertise (e.g., Bennet et al.), as well as effective collaboration with patients, healthcare providers and commissioners.
3. *Building the capability and confidence of all actors to acknowledge and raise quality, privacy, security and safety concerns* relating to digital health care (e.g., Shaw et al. Bouabida et al.). Reskilling, learning and modifying professional roles play a vital role in adoption as the Rainey et al. paper illustrates.
4. *Adopting a holistic, rather than a piecemeal approach to build a supportive ecosystem*. This suggests the need for a long-term strategy, appreciating politics, the regulatory groundwork, reimbursement mechanisms, cost (Yan et al.).
5. *Considering seriously the wider ethical implications* of digital health (e.g., Shaw and Donia) to establish and maintain trust, transparency and accountability.

Author contributions

All authors provided substantial contributions to the conception and design of the work. YK drafted the final article and JLD, AB, HS revised it critically for important intellectual content. All authors provide approval for publication of the content and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors contributed to the article and approved the submitted version.

Conflict of interest

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The Impact of Digital Therapeutics on Current Health Technology Assessment Frameworks

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Historically healthcare has been delivered offline (e.g., physician consultations, mental health counseling services). It is widely understood that healthcare lags behind other industries (e.g., financial, transportation) whom have already incorporated digital technologies in their workflow. However, this is changing with the recent emergence of digital therapeutics (DTx) helping to bring healthcare services online. To promote adoption, healthcare providers need to be educated regarding the digital therapy to allow for proper prescribing. But of equal importance is affordability and many countries rely on reimbursement support from the government and insurance agencies. Here we briefly explore how national reimbursement agencies or non-profits across six countries (Canada, United States of America, United Kingdom, Germany, France, Australia) handle DTx submissions and describe the potential impact of digital therapeutics on current health technology assessment (HTA) frameworks. A targeted review to identify HTA submissions and guidelines from national reimbursement agencies or non-profits was conducted. We reviewed guidelines from the Institute for Clinical and Economic Review (ICER) in the USA, the Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada, the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK), the Institute for Quality and Efficiency in Health Care (IQWIG) in Germany, Haute Autorité de Santé (HAS) in France, and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia. Our review identified one set of guidelines developed by NICE in the UK. The guidelines by NICE outlined an evidence standards framework for digital health technologies (DHT). Depending on the organizational impact, financial commitment, and economic risk for the payer, different economic analyses are required. Economic analyses levels are separated into 3 categories, basic, low financial commitment, and high financial commitment. All economic analyses levels require a budget impact analysis. A cost-utility analysis is recommended for DHTs categorized in the high financial commitment category. Whereas, for DHTs that are in the low financial commitment category, a cost-consequence analysis is typically recommended. No HTA guidelines for DTx submissions were identified for the remaining countries (Canada, USA, Germany, France, and Australia)

Keywords: digital therapeutics, digital health, digital health technology, health technology assessment, reimbursement

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BACKGROUND

The majority of healthcare is currently delivered offline (e.g., physician consultations, pharmacy prescriptions, mental health counseling services). It is widely understood that healthcare lags behind other industries (e.g., financial, transportation) which have already incorporated digital technologies in their workflow (1). However, this is changing with the recent emergence of digital therapeutics (DTx) helping to bring healthcare services online. Digital therapeutics can be defined as a regulatory approved digital system or application that is prescribed to treat medical conditions, similar to that of new drug molecules or medical devices (2–6). As developers of digital therapeutics pass regulatory approval, the next step is to gain widespread adoption. To promote adoption, healthcare providers need to be educated regarding the digital therapy to allow for proper prescribing. But also, of equal importance is patient affordability of which a key determinant in many countries relies on reimbursement support from the government and insurance agencies. Transition to incorporate digital technologies into clinical practice have been slow due to strict regulations and the disparity between stakeholder views of this new change (7). If proven effective, with the introduction to virtual care, it will lead to great advances in convenience, accessibility, and potentially better outcomes for patients (8, 9). Moreover, it will allow for healthcare providers to conveniently monitor, educate, and adjust therapeutic regimens for an increased number of patients (8, 10). However, this will not be without challenges, including the need to prove value compared to current interventions and demonstrate potential cost savings for payers.

There has been doubt to whether cost savings can truly be achieved when using DTx (11). Experts have argued that if these DTx were proven to be cost-effective, it would likely result in a net overall increase in healthcare spending (12). Governments are exploring to introduce additional billing codes to support digital care monitoring which can potentially lead to increased spending (9). Moving forward, as a DTx software evolves when incorporating more data, this may impact current and future HTA submission recommendations. Here we explore how health technology assessment (HTA) agencies handle DTx submissions. We conducted a targeted review to identify HTA submissions and guidelines from national reimbursement agencies or non-profits across six countries (Canada, USA, United Kingdom, Germany, France, Australia). The following agencies were reviewed: the Institute for Clinical and Economic Review (ICER) in the USA, the Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada, the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK), the Institute for Quality and Efficiency in Health Care (IQWIG) in Germany, Haute Autorité de Santé (HAS) in France, and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia.

PHARMACEUTICAL DRUGS VS. DIGITAL THERAPEUTICS

Unlike pharmaceuticals whereby a drug is administered into the body, a DTx relies on extraneous factors such as a stable internet connection, complimentary cellular device, or proficient user interaction. When conducting a health technology assessment and determining parameters such as epidemiology estimates of the disease and the associated economic costs for implementing a DTx intervention, a stakeholder must consider if the end user (i.e., patient) has the adequate technology and/or user ability to operate the technology. Due to the nature of DTx, only patients who can operate and afford technological hardware may benefit leading to potential bias. Studies have shown individuals of higher socioeconomic and education status tend to be healthier and have healthier behaviors (13–15). Age is also an important factor as older individuals may not own or be familiar using smart technologies (i.e., smartphones, tablets) (16). Moreover, other identified barriers for older individuals include the complexity and lack of guidance when using these technologies (16). The elderly may also not be interested in learning how to use new DTx interventions even if this could potentially be the population that would receive the largest benefit (17). These older individuals would not need to physically visit their physician's office for every appointment and could use remote monitoring as a tool to improve overall health.

Age and socioeconomic factors need to be examined (e.g., education level, family income) as these digital interventions require the necessary user ability and hardware to function. Thus, when DTx are indirectly compared to pharmacologic treatments for HTA purposes, baseline characteristics may potentially need to be adjusted more heavily for socioeconomic factors. Unlike pharmacological drugs whereby it impacts a biological mechanism (e.g., SGLT2 inhibitor for diabetes or antiplatelet agents to prevent cardiovascular events), DTx heavily relies on an individual's behavior and attitudes toward health. Contrary to pharmaceutical drugs whereby consideration for human biological factors is necessary to assess for potential therapeutic effectiveness (e.g., ancestry, genetics), in digital therapeutics technology literacy, age and other socioeconomic factors (e.g., income, nationality) may potentially play a larger role when conducting reimbursement decisions.

As DTx is implemented and evolve with capabilities, will payers be expected to pay for initial and future training and operation costs associated with these technologies? Moreover, as the technology accumulates increasingly more data, the evidence will also need to be consistently updated. Assuming the technology evolves, this may impact prior HTA results, potentially making the intervention more or less cost-effective. In contrast, with pharmaceutical drugs, the effectiveness of the drug does not change. A potential solution would be incorporating dynamic HTAs whereby the evidence is consistently updated throughout predetermined time intervals as a part of post-market surveillance. However, challenges to this include accurately isolating therapeutic effectiveness as a result of the intervention's technology or other associated factors.

DIGITAL THERAPEUTICS AND HEALTH TECHNOLOGY ASSESSMENT

Our review identified one set of guidelines developed by NICE in the UK (18). NICE has outlined an evidence

standards framework for digital health technologies (DHT) and has compartmentalized DHTs into functional groups. These functional classes are grouped into evidence tiers and are intended to capture the level of clinical risk associated with the DHT. There are three evidence tiers; Tier A: system impact, Tier B: understanding and communicating, and Tier C: interventions. Tier A includes DHTs which focus on system services and have no measurable impact on patient outcomes (ex. electronic prescribing systems). Tier B DHTs focus on information, communication, and simple monitoring (ex. cognitive behavioral programmes, healthy lifestyle applications). Tier C DHTs focuses on diagnosis, treatment, and active monitoring. Examples of Tier C technologies may include DHTs that use data to assist in disease diagnosis or DHTs for treating and monitoring chronic conditions (e.g., diabetes).

Depending on the organizational impact, financial commitment, and economic risk for the payer, different economic analyses are required. Economic analyses levels are separated into 3 categories, basic, low financial commitment, and high financial commitment. All economic analyses levels require a budget impact analysis. A cost-utility analysis is recommended for DHTs categorized in the high financial commitment category. These include DHTs that obtain funding by the government for health and non-health outcomes. A cost-consequence analysis can also be conducted if evidence is not sufficient for conducting a cost-utility analysis, however, this appears to be evaluated on a case by case basis. Cost consequence analysis are also a minimum requirement for DHTs that are in the low financial commitment category (18). These evidence requirements are only directed toward digital technologies seeking public reimbursement and do not apply to unpaid interventions. It is unfortunate that no other HTA agencies we reviewed have as of yet outlined any public recommendations to guide digital health technology submissions as many DTxs have already been approved by multiple regulatory agencies. Reports and case studies evaluating existing DTx have been conducted by NICE and CADTH (19, 20). It appears the assessments and evaluations that have been conducted attempt to fit the mold of existing frameworks for pharmaceutical and medical devices. However, DTx is unique in that it is unlike traditional drugs and devices.

The issue of potential changes in effectiveness due to DTx software updates and how that will impact previous HTA assessments requires clarification. Assuming changes in effectiveness, will companies be expected to alter pricing according to local willingness to pay thresholds? A potential solution can be requiring original manufacturer model submissions to include larger variances in their sensitivity analysis, thereby accounting for a wider fluctuation in input parameters. Non-adherence to DTx needs to also be accounted for in economic evaluations and its potential impact on costs and effectiveness. Non-adherence to traditional pharmaceutical drugs is already a common issue contributing costs upwards of $50,000 per patient per year (21). Compounding the complexity from simply taking a pill to be added or replaced with navigating through a smartphone application, meanwhile, answering questions and communicating results with healthcare practitioners will most likely lead to a greater depreciation in adherence.

Traditionally, patients are prescribed and dispensed medication without knowledge of their adherence history. Revoking reimbursement privileges due to non-adherence is an ethical issue and patients should not be unnecessarily penalized for occasionally being non-adherent when they could possibly be overwhelmed with other parts of their life. Due to the technological nature and potential ability to track software usage, it is possible to restructure contemporary reimbursement strategies. Reimbursement agencies can potentially pay per active DTx use whereby the patient successfully finishes the instructions provided by the physician. In this scenario in events that the patient is non-adherent, it does not penalize the patient nor the reimbursing party. Moreover, this can complement traditional healthcare whereby non-adherent patients can be easily identified and early alternative interventions can be discussed to promote more personalized healthcare services. Nonetheless, when establishing criteria for linking reimbursement to adherence, it can create both opportunities and challenges for decision makers.

If tracking health outcomes can also be possible in real time, is it also possible that payers require certain incremental levels of health benefit for continuing reimbursement support? Similar to pharmacological therapy, patients are switched to alternative drug therapies if the initial treatment did not demonstrate adequate effectiveness (e.g., blood glucose and A1C levels in diabetes patients). However, the criteria for health benefit will need to be adequately defined to prevent removing potential patients that are benefitting from DTx. The dearth of evidence, especially high-quality evidence, associated with determining effectiveness of these interventions will also be an issue (22). If HTA agencies consider evidence as a pillar for reimbursement, DTx will not be able to compete against traditional pharmaceutical drugs with its larger evidence base. Traditional analyses such as indirect treatment comparisons or cost-utility analysis may not always be possible due to the anticipated population heterogeneity expected from DTx users.

LOOKING FORWARD

With the recent FDA approval of the first game-based DTx used to treat ADHD, it demonstrates the expanding scope of DTx beyond patient monitoring (23, 24). Some areas of healthcare may never be fully replaced by technology, thereby, it will be likely that DTx will complement existing interventions to provide improved outcomes to patients. As DTx evolves, new HTA strategies and methods for assessing these interventions will be needed. ICER is in the process of conducting the first HTA review aimed to evaluate the health and economic outcomes of DTx in addition to medication assisted treatment in opioid use disorder (25). Based on the recent ICER protocol documents of opioid apps it appears there is a shift toward focusing on non-health related and societal based outcomes (e.g., accidental

pediatric exposure, employment-related outcomes, housing-related outcomes, and relationship-related outcomes) (26). Traditional HTA methods and guidelines will need to be updated and revised to take into consideration technological and socioeconomic factors that comes with using these new technologies.

AUTHOR CONTRIBUTIONS

KY performed conceptualization, drafted the article, and editing. ED and CB performed supervision, review, and editing. All authors have reviewed, added value, and signed off on the final version of this manuscript.

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Planning and Evaluating Remote Consultation Services: A New Conceptual Framework Incorporating Complexity and Practical Ethics

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Establishing and running remote consultation services is challenging politically (interest groups may gain or lose), organizationally (remote consulting requires implementation work and new roles and workflows), economically (costs and benefits are unevenly distributed across the system), technically (excellent care needs dependable links and high-quality audio and images), relationally (interpersonal interactions are altered), and clinically (patients are unique, some examinations require contact, and clinicians have deeply-held habits, dispositions and norms). Many of these challenges have an under-examined ethical dimension. In this paper, we present a novel framework, Planning and Evaluating Remote Consultation Services (PERCS), built from a literature review and ongoing research. PERCS has 7 domains—the reason for consulting, the patient, the clinical relationship, the home and family, technologies, staff, the healthcare organization, and the wider system—and considers how these domains interact and evolve over time as a complex system. It focuses attention on the organization's digital maturity and digital inclusion efforts. We have found that both during and beyond the pandemic, policymakers envisaged an efficient, safe and accessible remote consultation service delivered through state-of-the art digital technologies and implemented via rational allocation criteria and quality standards. In contrast, our empirical data reveal that strategic decisions about establishing remote consultation services, allocation decisions for appointment type (phone, video, e-, face-to-face), and clinical decisions when consulting remotely are fraught with contradictions and tensions—for example, between demand management and patient choice—leading to both large- and small-scale ethical dilemmas for managers, support staff, and clinicians. These dilemmas cannot be resolved by standard operating procedures or algorithms. Rather, they must be managed by attending to here-and-now practicalities and emergent narratives, drawing on guiding

principles applied with contextual judgement. We complement the PERCS framework with a set of principles for informing its application in practice, including education of professionals and patients.

Keywords: remote consultations, video consultations, evaluation, telephone consultations, E-consultations, PERCS framework, complexity

CONTEXT: THE SHIFT TO REMOTE CONSULTATIONS IN THE UK

On 30th July 2020, it was announced that all healthcare consultations in the UK should henceforth be "remote by default," not just during the pandemic but indefinitely (1). Remote services had been introduced in March 2020 to manage the spread of COVID-19 and reduce the burden on the National Health Service (NHS). Patients seeking an appointment with their general practitioner (GP) had to make contact by electronic form or telephone before getting a return call from a clinician (2). In secondary care, much routine outpatient activity was canceled or undertaken remotely (3).

In the UK as elsewhere, the expansion of phone, video, and e-consultations were part of a wider pandemic-driven shift to technology-mediated care (4). These changes included directing patients to approved websites for self-management, an expanded telephone and electronic advice service featuring a bespoke COVID-19 Clinical Advice Service (CCAS) to supplement NHS 999 (for emergency calls) and NHS111 (for urgent and out-of-hours care), expansion of electronic prescribing, and introduction of virtual wards for oximetry monitoring (3).

Primary care clinicians welcomed the infection control benefits, empty waiting rooms, and slackening of red tape that accompanied the initial shift to remote (5). But they also warned of an uncomfortable "brave new world" characterized by fewer consultations overall, loss of continuity of care, threats to the clinician-patient relationship, inequalities of access, and clinical risks (6–9). Lay media coverage of remote consultations mirrored this pattern, with an initial positive response followed by stories of inaccessibility, missed diagnoses and patients feeling "fobbed off" with phone calls (10, 11). Whereas, politicians and the press emphasized the transformative potential of new technologies, most remote consultations before and during the pandemic occurred by telephone (3, 12–15).

Policy talk about remote health services was typically technology-focused, depicting these as state-of-the-art, high-quality, efficient, and safe (16). Arguments against remote forms of care tended to be patient-focused, highlighting possible disbenefits such digital exclusion. The benefit-harm balance of remote care is fundamentally an ethical issue. Technology-focused arguments often imply a broadly utilitarian ethical standpoint—that an efficient, remote-by-default service will minimize (though not eliminate) suffering, maximize overall benefit to the population and free up clinician time to create further benefits. Patient-focused arguments are more deontological, focusing more on what good care for the individual patient means, especially the clinician's duty to provide care for every patient to the best of his or her professional ability. However, critiques of remote modes of consulting can also be defended using utilitarian arguments, since clinical care is complex, relationship-based, nuanced, and emergent. If the consultation is narrowly transactional and fails to capture these wider dimensions, it is suboptimal, leading to inefficiency and exacerbating unfairness.

To guide and theorize our research on remote consultation services, our team set out to develop a conceptual framework. We began with a generic framework which some of us had developed previously, called NASSS—non-adoption, abandonment, and challenges to scale-up, spread and sustainability of technology-supported services (17). The NASSS framework has been widely used across a range of settings for evaluating and explaining the fortunes of various kinds of health technology projects [see for example (18–20)] and draws on complexity theory (21). NASSS explores the dynamic interaction between multiple domains (the technology, the people and so on) in a complex system and how these domains and their interdependencies have evolved—and are likely to evolve further—over time. There are theoretical parallels with other complexity-informed implementation and evaluation frameworks including i-PARIHS (22), normalization process theory (23), and the consolidated framework for implementation research (24).

But whilst NASSS was our theoretical starting point, we quickly discovered that it did not fully explain all of our empirical data—especially findings around the clinical relationship and the ethics of allocating appointment type. By adapting NASSS to fit our emerging empirical findings and relevant literature, we sought to develop a framework which would guide both the prospective planning and real-time evaluation of remote consultation services. Importantly, both NASSS and the adaptation described here (PERCS) are *explanatory* frameworks to guide a holistic interpretation of a complex and evolving phenomenon. They do not offer predictive certainty and are not intended to be applied formulaically.

The remainder of this paper is structured as follows. In section Empirical Context: Mixed-Method Studies of Remote Care Before and During the Pandemic, we describe the methods, study designs, sampling frames and datasets from our studies on remote consultation services in the UK. We highlight the elements of those datasets—especially qualitative research with staff and patients and an online Delphi study—which directly informed the theoretical work presented in this paper. In section Findings, we present and explain the PERCS framework and a set of guiding principles to inform its application. In section Discussion we contextualize our findings in a wider literature review

and discuss implications for policy, practice, education and research.

EMPIRICAL CONTEXT: MIXED-METHOD STUDIES OF REMOTE CARE BEFORE AND DURING THE PANDEMIC

Overview and Data Sources

Prior to the pandemic, we studied the organizational challenges associated with roll-out of video consultations across multiple clinical directorates in the UK's largest acute hospital trust (25–27), including sub-studies on physical examination by video (28, 29). We also undertook contract research for the Scottish Government to evaluate the national roll-out of video consultations—an initiative that was driven partly by the policy goal of reducing carbon footprint and travel costs from remote settings (30). Others in our team have studied help-seeking behavior in urgent care settings, including NHS 999 and NHS111 (31, 32). Insights from these studies informed our theoretical work.

Since the pandemic began, we have been involved in three separately-funded but theoretically related case studies. Details of ethics approvals are given at the end of the paper, and full empirical reports of these studies are in preparation for publication elsewhere. All studies were of mixed-methods design but predominantly qualitative, using interviews, ethnography, and documentary analysis to generate and follow an emerging story of change, using quantitative data to illustrate and enrich the story.

First, we were funded by the Scottish Government (June–October 2020) to extend our evaluation of the video consultation service (branded "Near Me") to cover the early months of the pandemic to August 2021 (33). This study covered both primary and secondary care. It included 60 h of ethnographic observation; 223 interviews with healthcare staff, patients, and national-level stakeholders (policymakers, professional leaders, industry); quantitative analysis of automated activity reports on over 69,000 consultations (including over 18,000 patient assessments of consultation quality); and analysis of policy documents and implementation plans.

Second, we were funded by the UK Research and Innovation COVID-19 Emergency Fund from June 2020 to November 2021 for a study called Remote by Default, which addressed remote care in general practice. This study involves interviews (over 100 to date) with healthcare staff, patients and national-level stakeholders, as well as following four locality case studies in south London, Oxfordshire, Devon, and south Wales. Especially relevant to the development of PERCS were four online focus groups involving 19 participants (clinicians, support staff, and patients), four facilitated cross-sector workshops (held via Zoom) which brought together ∼160 national policymakers, clinicians, patients, and other stakeholders, and a four-round Delphi study (described in detail below) of ethical principles and decisions relating to remote consulting.

Third, we were funded by a medical charity from June 2020 to July 2021 to study the roll-out of video consultations across the UK. The Health Foundation Video Consulting (HFVC) study involved a quantitative survey of current practice (to over 800 NHS staff), qualitative follow-up interviews with a sample of 40 of these (repeated longitudinally with a sub-sample of 20 as the pandemic unfolded), interviews with 10 patients, and two group discussions involving 15 patient and public representatives. This study also included 7 locality case studies of video consulting services—four in secondary care (in London, Norfolk, Oxfordshire, and Cumbria) and three on group video clinics in primary care (in England, Scotland, and Wales).

In each of these studies, our research question addressed the individual-, organizational-, and system-level challenges to introducing remote consultation services at pace and scale and routinizing such services. We used an embedded virtual researcher-in-residence model: each case study had an assigned member of the research team who built relationships with key informants, developed an understanding of local issues and contingencies, and coordinated data collection and feedback. An external advisory group with a lay chair and patient representation met 4-monthly.

Developing the PERCS Framework

In all the above studies, we undertook an initial phase of data management and familiarization. Interviews, focus groups, ethnographic field notes, and workshop write-ups were transcribed, de-identified, entered onto NVivo software (or, in one sub-study, an Excel spreadsheet for pandemic-related practical reasons) and broadly coded (for example under headings such as "staff attitudes" or "technical infrastructure"). Quantitative data (e.g., waiting times, uptake rates and trends, survey responses) were analyzed using descriptive statistics. For each case study, narrative synthesis was used to pull together an initial familiarization document based on the first ∼3 months' data; this document was refined iteratively as data collection progressed.

Researchers discussed their ongoing findings in 2-weekly team meetings. Initially we used NASSS (described above) to organize and theorize emerging findings, but when this proved inadequate for explaining some of our key findings, we began to adapt it into the PERCS framework. Particularly germane to this revision of our previous theoretical work were the transcripts and field notes from focus groups and workshops involving clinicians, support staff, and patients who discussed the challenges of remote consulting in the real world.

Across our in-pandemic datasets, a number of themes were evident which had received little or no emphasis in pre-pandemic research on remote consultations (see Discussion for summary of that literature). For example:

- *Access to care*, especially patients' difficulty getting the kind of appointment they wished and conflict with support staff associated with this;
- *Remote clinical assessment* of patients, especially those with a complex clinical picture such as evolving symptoms, co-morbidities, learning difficulties, cognitive impairment or vision or hearing difficulties;

- *Clinical risk management and safety-netting*, especially in acutely unwell patients (e.g., deciding which patients with suspected COVID-19 to see in person or send to hospital);
- *Continuity of care*, especially how to create coherence over time when different consultation modalities and more than one clinician were involved;
- *The patient's home and family context*, notably concerns about privacy and safety (e.g., whether patients are safe from eavesdropping or coercion);
- *Digital exclusion*, including the impact of poor-quality technologies, low digital literacy and material aspects of the home environment (and, even more so, being homeless);
- *Organizational efficiency* such as the nature of, and reasons for, "double-handling" (e.g., when patients were transferred from e-consultation to phone or from phone to video or face-to-face);
- *Staff wellbeing*, especially stress and loss of motivation from lack of face-to-face contact and a perception that consultations have become more transactional;
- *Technical issues*, including technical infrastructure; interoperability (especially interfacing with the electronic patient record) and in patients' homes (e.g., linking with multiple devices), and the wasted time and stress caused by unreliable internet access and technologies;
- *Sociotechnical issues* such as use of workarounds—for example, patients strategically downplaying symptoms on e-consultations to avoid an algorithm-driven diversion to a call handling service;
- *New forms of clinician-patient interaction*, such as the growing importance of asynchronous messaging between patients and clinicians (in the form of SMS, e-consultations, and emailing); and the unfamiliarity and strangeness of communication via video, including some people's dislike of seeing their own face or body on video and a sense of inappropriate intimacy (e.g., a doctor's discomfort at seeing a patient part-naked in a bedroom rather than on an examination couch);
- *Knock-on effects on vulnerable groups*, for example the impact on people with drug dependency (e.g., reduced in-person pick-ups for controlled drugs has resulted in fewer opportunities for direct clinician-patient engagement);
- *New opportunities for inter-organizational collaboration* e.g., for clinicians to engage in multiagency work to prepare and plan patient care; and
- *The national regulation and procurement context*, which shaped not only what technology might be available and affordable in any organization, but also who could use it and for what.

These themes were interdependent, illustrating the "complex system" aspect of the phenomenon we were researching. They informed development of draft PERCS framework as we used it to manage and synthesize data both within locality case studies and in cross-case analysis. We discussed this emerging work in workshops with our professional and lay advisory group members. Further refinements were made iteratively as we progressed with our analysis.

Two prominent themes in our data were organizations' digital maturity in providing remote consultations and the need for proactive measures to improve digital inclusion. We drew out different qualitative dimensions of digital maturity from our data, and also constructed a semi-quantitative digital maturity scale, incorporating work by others (34–37). Given that previous attempts at introducing a comprehensive digital maturity scale for the UK NHS had been abandoned as unworkable (36, 38), we deliberately favored a short, pragmatic five-point scale over a detailed, exhaustive one. We also teased out qualitative dimensions of organizations' efforts at digital inclusion and included reference to these in the digital maturity scale. To be classed as fully digitally mature, an organization thus had to address digital inclusion as well as install and use advanced technology.

Developing the Guiding Principles

Evidence from policy announcements and our elite policymaker interviews revealed a relatively confident vision of an efficient, safe and accessible remote consultation service delivered mostly through state-of-the art digital technologies and implemented via rational allocation criteria and quality standards. But our front-line interviews, ethnographic observation, surveys, and service usage statistics revealed that, as in pre-pandemic times, the telephone was the dominant technology used and that decision-making at multiple levels—system-level strategic decisions about setting up remote consultation services, administrative decisions to allocate particular kinds of appointment (phone, video, e-, face-to-face), and clinical decisions when consulting remotely—was fraught with inherent contradictions and tensions. There were tensions, for example, between quality and efficiency, between demand management and patient choice, and between the needs and preferences of some patients and those of other patients in the context of limited staffing and material constraints (e.g., availability of safe waiting areas which limited face-to-face appointments during the pandemic). These tensions led to both large- and small-scale ethical dilemmas for managers, support staff, and clinicians. Few of these dilemmas could be resolved by resort to standard operating procedures or algorithms.

The contradictions and tensions in our data reflected clinical practice more generally. As Hunter (39) has argued, clinical decisions are governed not by hard and fast rules but by shared rules of thumb or guiding principles which she calls *maxims*, some of which are contradictory (e.g., "ignore the anecdotal" but "listen to the patient's story"). Maxims, which tend to be passed on orally from more to less experienced practitioners, encapsulate shared understanding and wisdom; they suggest a potential way forward but are high-level enough to be flexibly applied. Maxims and other high-level guiding principles require an understanding of the *circumstances in which the rule should be applied* rather than formulaic replication. Through experience, reflection on practice and discussion with more experienced colleagues, clinicians learn *which* guiding principle to use—and hence, what is the right thing to do—in a particular situation.

The situational application of such guiding principles has an important time dimension. With time, one constellation of

TABLE 1 | Sample for Delphi study of underpinning principles.

Round	Professionals	Patients or carers	Total attempting at least one item
Round 1	27 doctors, 4 nurses (2 of whom added that they were nurse practitioners), 1 physician associate, 2 physiotherapists, 1 health policy researcher, 1 from patient advocacy organization (total 36)	14	50
Round 2	22 doctors, 3 nurse practitioners, 1 physician associate, 1 physio-therapist, 1 medicolegal consultant, 1 policy researcher (total 29)	11	40
Rounds 3 and 4	21 doctors, 1 nurse practitioner, 1 physician associate, 1 physio-therapist, 1 medicolegal consultant, 1 policy researcher (total 26)	11	37

symptoms, signs, and contextual influences will evolve to a subtly different constellation, generating clues as to the nature of the illness and its likely regression or further progression. A raised temperature observed at a single time point may persist, settle or become a swinging pyrexia. Only when this longitudinal pattern emerges do the relevant maxims to guide next steps become salient. Whilst Hunter focused narrowly on clinical maxims, case-based ethical reasoning more broadly—whether, for example, to invoke child protection measures or ask a social prescriber to get involved in someone's life—operates along similar lines. We need to know the story, its context, and how it is unfolding over time.

At the time of our fieldwork, there were few established guiding principles for provision of remote services (exceptions include "see all young infants face-to-face promptly" and "don't provide end-of-life care remotely"). To develop some more, we focused on a subset of our data relating to ethical tensions. We were aware of the many different ways in which ethical dilemmas in healthcare may be theorized—including utilitarian, rights-based, fairness or justice, virtue ethics, and the common good (40), and took the view that each of these philosophical lenses might prove useful in different scenarios. We also sought to consider ethical issues at individual-, organizational-, and system-level.

To develop and refine some ethical principles to guide application of the PERCS framework, we used the Delphi method—a well-established semi-structured approach to working toward consensus among experts (41). Steps include defining a problem, selecting a panel of experts (including, in this case, both clinicians and service users), supplying a summary of evidence and outlining key uncertainties, collecting quantitative (numerical scores), and qualitative (free text) data on a set of statements, feeding scores and comments back to panel members and repeating until residual disagreement cannot be resolved. Advantages of this method include practicality (it can be done online, asynchronously, without specialist tools), anonymity (participants know the average group score but not individuals' scores), and iteration (through feedback, outliers are prompted to either defend their response to the group or change it) (42, 43).

To prepare background evidence for the Delphi panel, we began by examining the tensions in our empirical data through various ethical lenses (presented in Findings). In this way, TG and RR developed a "long list" of 60 draft principles. We organized these into 30 partially contradictory pairs (for example, "when consulting remotely, deal directly with the patient and ensure privacy" and "relatives or carers may provide technical, linguistic, or physical assistance in remote consultations") and grouped them under four categories (e.g., practice organization, matching appointment type with patient needs).

The four-round Delphi study was conducted virtually and asynchronously. Participants were recruited from our field sites, our advisory group and their networks, and a social media invitation (Twitter). We recruited and obtained emailed consent from an initial sample of 69, though 19 of these did not attempt any items (mostly because they found the exercise too difficult). The characteristics of those who participated are shown in **Table 1**; to avoid appearing intrusive we did not ask those identifying as patients or carers for details of occupation or illnesses.

For round 1, we provided participants with a summary of research on remote consultations, guidance from professional and regulatory bodies (e.g., Royal College of General Practitioners, General Medical Council) and instructions. We invited them to consider each pair of guiding principles on three dimensions—whether they belonged in the assigned category; whether to include this principle as worded or in an amended form (scored on a five-point scale from "definitely include" to "definitely exclude"); and suggestions for improving wording. Since the list was long, we split it into two parts, each sent to half the participants in round 1.

Participants were given 3 weeks to complete the survey and were sent two reminders. Responses were collected on the survey platform Survey Monkey (pandemic-related home-working precluded access to more specialized tools). The software generated a single document with the spread of quantitative scores and collated free-text comments. We analyzed qualitative data thematically and through discussion. An initial plan to analyse quantitative data statistically was abandoned when it became clear that presenting our draft principles in deliberately contradictory pairs had led to confusion and irritation (which we discuss briefly in the Findings section). We used people's free text suggestions to drop many principles (merging those that were near-duplicates), improve wording and introduce several new principles suggested by participants.

In round two, we abandoned the attempt to present the principles in contradictory pairs. We circulated a simple list of 25 principles and asked participants to repeat the scoring exercise on two dimensions—whether each item should be retained (quantitative, five-point scale) and whether its wording should be changed (qualitative, free text). We used descriptive

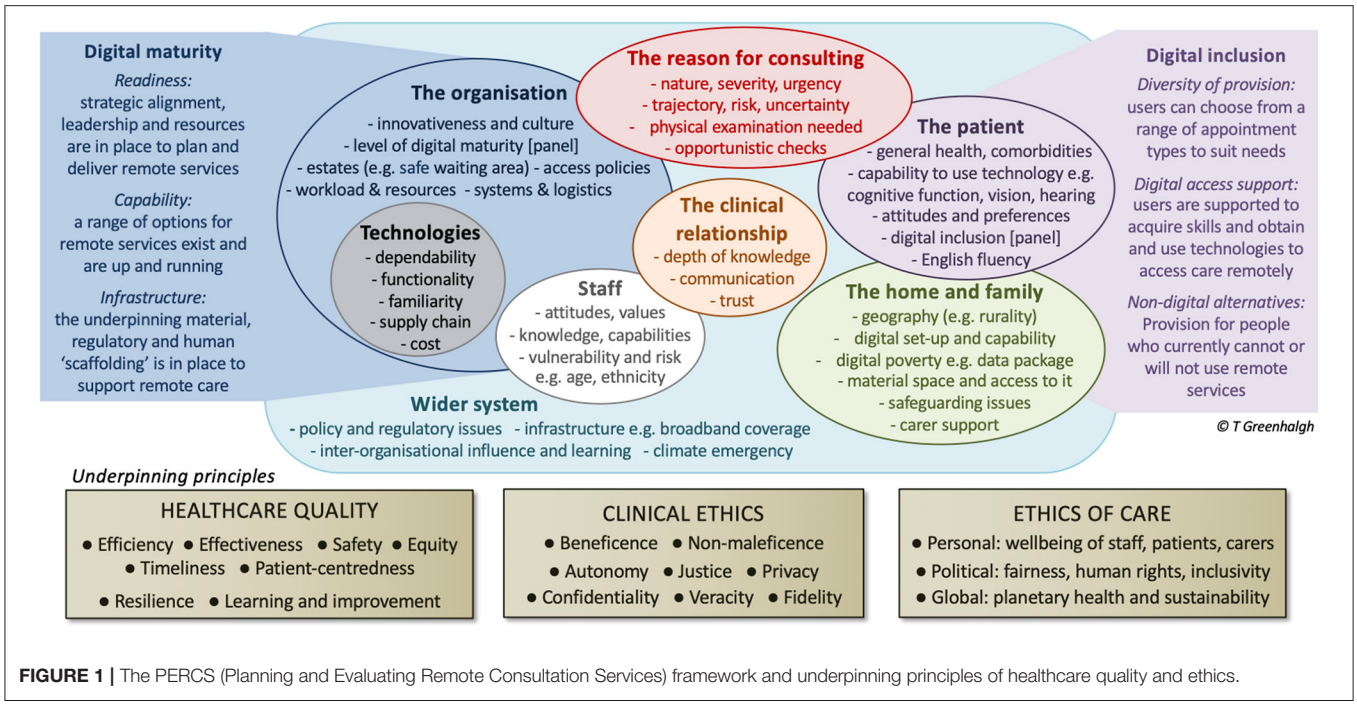

FIGURE 1 | The PERCS (Planning and Evaluating Remote Consultation Services) framework and underpinning principles of healthcare quality and ethics.

statistics to chart the level of agreement with each principle, and thematic analysis to organize free-text comments. This process was repeated in a third round. In a short fourth round, a single item (the only one on which 80% agreement had not yet been reached) was circulated to confirm a minor rewording suggested by several participants.

FINDINGS

The PERCS Framework for Planning and Evaluating Remote Consultation Services

The PERCS framework is shown in **Figure 1**. As noted above, it was adapted from the previously-published NASSS framework (17). We consider each PERCS domain in turn.

The reason for consulting considers not just the illness but why the patient wishes to be seen—or why the clinician wishes to see them—*now*. It draws attention to urgency and rate of progression, and to what the patient wants and expects (e.g., advice, treatment, referral). Relevant to this domain is the vast biomedical evidence base on the origin, progression and treatment of diseases and risk states, and sociological and psychological evidence on why people approach health services at particular points in their illness (44). Help-seeking for urgent care is a social process comprising illness work (to make sense of symptoms), moral work (to justify choice of service and help-seeking behavior) and navigation work (to access services) (31). Some reasons for consulting are clinician- or system-driven (e.g., invitations for screening or long-term condition monitoring). Clinical allocation criteria, perhaps built into algorithms, may suggest (though not determine) a type of appointment.

Several examples from our dataset illustrated the subtleties of the reason for consulting and why rigid algorithms or allocation criteria may prove too brittle to guide practice. Clinicians described over-riding such systems (for example when triaging e-consultations) because they had a gut feeling that a seemingly minor aspect of the history could indicate serious illness (45) or because they had safety-netting concerns that a particular patient should be checked more frequently than the recommended interval. They talked about the need to be alert to the possibility of the "doorknob phenomenon" —that people sometimes seek a consultation for one reason but bring in the real reason late in the encounter, hence withholding key information at the triage stage. The following quote illustrates the complex and subtle nature of gut-feeling reasoning (the doctor is highly reflexive and pulls together small fragments of the history and aspects of the patient's personality and past behavior, to justify their heightened concern):

> *"there was somebody recently who was, you know, feeling very low, young man had kind of quite a long history of off and on of things . . . not always . . . minimizing it . . . very, you know, quite . . . I work in deprived areas quite . . . you know, quite, quite a high powered job, and in his 30s, and anyway I ended up thinking there's something more here, and so I brought him down to the surgery [. . .] you know how you get a sense of stuff"* (GP, HFVC_BND)

The patient domain, which strongly influences the reason for consulting, includes the patient's (or parent's) attitudes toward illness in general and remote consulting in particular. It embraces the patient's identity, values, personality traits, and socio-cultural background—features a sociologist might call habitus (46)—, their health beliefs (44), health literacy and digital literacy, socio-demographic characteristics (47, 48) and their personal experience of illness or disability. All these factors may help

explain why the patient seeks a particular mode of consultation—and also why a clinician or support staff member may decide that it is in the patient's best interests (or not) to be seen face-to-face, as the following quote illustrates:

> *"I had a really interesting conversation with an 80-year-old with diverticular disease and he'd been phoning up every couple of weeks about his abdominal pain, which you routinely get with diverticular disease and there's no real cure and it's really just about managing his bowels. But nobody has sat down with him and drawn a section of the bowel and shown little pockets of diverticulae and how that's not gonna change and what he needs to do is to keep his bowels moving. So he doesn't understand what's going on for him and me trying to explain something over the phone like that is really hard to an 80-year-old who is losing every third or fourth word because his hearing is not brilliant anyway."* (GP, RBD_FM3)

The clinical relationship domain considers the clinician-patient interaction, including what might be called non-transactional aspects of the consultation—for example, the role of the clinician as professional witness to suffering (49), or what Balint, writing in a more medically-dominated era, called "the doctor as the drug" (50). It addresses the level of trust and positive regard that can be developed and maintained in different types of consultation. It also embraces the clinician's—and perhaps also the administrative team's—knowledge of the patient and their illnesses and consulting patterns. This knowledge may have been built over many years (or, alternatively, may be recent and fragmented). One of the most frequent and consistent themes in our dataset was a sense from both clinicians and patients that the clinical relationship is necessarily built—at least initially—face-to-face. For example:

> *"I think it's hard to build relationships over video and it's even harder over a phone call, OK? To really get to know somebody so that they trust you and you trust them and it's working. So, a lot of my phone calling is fine because it's people I've known for years because I've been in the same practice for eighteen and a half years and [distortion]... my patients."* (GP, HFVC_IT)

The home and family domain incorporates considerations of how the material features, physical layout and symbolic spaces of the home influence key issues such as privacy and comfort when consulting remotely (51). Our datasets include examples of patients who had no home or whose homes were small, crowded, lacking privacy (notably houses of multiple occupation, but also many family homes under conditions of lockdown) or not connected to the Internet. One GP expressed concern that a patient was consulting from the lavatory because this was the only quiet and private space available. Another described connecting to a teenager's bedroom where a parent may have been present but off camera. This domain includes socio-cultural aspects of family life such as family structure, English fluency and the expectations placed on different members, and the extent to which family and neighbors contribute to the "lay consultations" that either promote or prevent a subsequent attempt to access formal health care (31, 52). It also includes wider social determinants of health, notably the level of socio-economic deprivation and the education and digital literacy of family members who may or may not be able to support the patient. More prosaically, consulting behavior patterns previously learnt in the context of the clinic must now be transposed to the home space, which may produce dissonance, as the following quote illustrates:

> *"Well I had to like do... say to him, 'Look, sit down, please sit down,' and then he... I just felt so daft and like, 'Look, the doctor's going to tell you off if you don't sit down,' because of course [doctor] wasn't present. But that did kind of work. He kind of sat down and then he looked at her. But having him sat down and then like the others [siblings], you know, running around playing, is hard to prevent him from going off and playing."* (Mother talking about trying to do video consultation with young child, HFVC_BV)

Aspects of the home and family domain—especially material spaces and privacy—may also be relevant to staff working from home during or beyond the pandemic. The only available space for one (female) GP to consult from was the kitchen table, necessitating complex negotiations with other family members about access to the food supply.

The domain of *technologies* includes aspects of design—such as aesthetic appeal, functionality, technical performance and ease of use—as well as dependability. Telephone, for example, has less functionality video but is more dependable and familiar. Some software products (e.g., accuRx) potentially allow the clinician to instantly convert a phone consultation to video in real time, thus avoiding double-handling, but products which lack this functionality require a new appointment.

The technology domain also incorporates supply chain and costs—including up-front investment, maintenance and repair, and the risks to the service if a key supplier pulls out of the market or raises prices (thereby embracing the "value proposition" domain from the NASSS framework). Costs of technologies are typically unevenly distributed across the healthcare system. Telephone advice services, underpinned by advanced computer decision support systems, can be costly to set up and maintain and require new work skills to operate (32); their introduction may generate supply-induced demand (53). During the pandemic, some locality-based clinical commissioning groups became tied into commercial contracts with video software providers whose products were approved at speed at the height of the crisis and offered "free" or low-cost for the first year.

The *staff* domain includes a quantitative workforce component (are there enough of the right kind of staff?) as well as a qualitative component relating to staff capabilities, confidence, attitudes, and well-being. Staff attitudes are grounded in professional norms and values including deeply-held concerns about quality and safety of care. Many staff—rightly or wrongly—still considered face-to-face consulting to be the "gold standard" professional norm:

> *"They all miss face-to-face because that's what they were trained to do, they all work very, very closely with the children."* (Children's community services manager, HFVC_IC)
> *"And then also the barriers from, I think, healthcare professionals,*

> *so, 'How could I possibly have a difficult discussion over a video consult? How could I possibly discuss do not resuscitate [by video]? How could I break bad news when I can't touch my patients? How would I show empathy without touch? How can I be near and yet far? How could that be possible? You know, I need good eye contact, I need, you know, more non-verbals, I need to see the home, I need to see the person,' those sorts of thoughts maybe."* (Palliative care consultant, HFVC_TQ)

Our findings affirmed published claims that remote consulting is cognitively burdensome (54), excludes the physical touch on which the therapeutic relationship has traditionally depended (55), threatens continuity of care (7), brings greater clinical uncertainty, and makes the personal care afforded by the extended, face-to-face "long consultation" more difficult (8, 56, 57). For example:

> *"… it's maybe a slippery slope, you know, I'm trying my best in my consultations, I'm really focusing. I'm really tired from listening on the phone, because it is exhausting. I'm really tired from these Zoom meetings, because it's very different to have this sort of like overload of, you know, concentration and physically trying to do it, overload of information. And you feel like, you're failing, but actually, you're … but you can't do anything else to say, when you feel like you're not giving as good as services, as you know, somebody who was properly trained in all this, but you feel quite inadequate that, you know, but yet, you feel well, at least I'm doing something. But I need to be safe, and what are the unknown unknowns…?"* (Primary care nurse, RBD_IM)

Our interviews with less experienced clinicians confirmed published concerns from clinical trainees that the format of digital consultations has made it harder for them to observe and consult alongside more experienced practitioners, thereby accumulating the tacit knowledge that enables them to manage clinical risk confidently (58), as the following quote (reflecting on the collective learning that had happened pre-pandemic) illustrates:

> *"…we were having clinical meetings in the surgery. We [had] a new doctor who joined us, who is young, who [had] just started, who [was] very hot on a weekly meeting that is mandated. And then she always [had] a sweet way of saying, Well, I'm the youngest here. I want to start with my worrying cases. case number one, case number two, what would you do here? What would you do there? And then, of course, we [would] all contribute."* (GP, RBD_OS)

These complex effects of the remote modality on front-line staff added to the huge pandemic-related toll on their morale and well-being, which included the physical and emotional stress of clinical work, the personal risk of infection and its complications, and personal bereavements and other losses (59–61).

The *healthcare organization* domain incorporates the organization's general innovativeness and its readiness for a particular innovation (62). Innovative organizations tend to be large, competently led and with clear strategic vision, functionally differentiated, non-hierarchical and with adequate slack (people and resources that can be channeled into new projects to get them up and running). Readiness generally involves both top and middle-management support, absence of opponents, and a formal assessment of innovation-system fit (e.g., a business case), though such requirements were often relaxed during the pandemic. This domain also includes the complex question of how technologies become—or why they fail to become—taken up and maintained in organizations (23). Within the organization, the innovative technology or service model needs to be actively implemented and "normalized" or "routinized" (i.e., made business-as-usual), replacing one familiar and comfortable set of interactions with one that feels unfamiliar and awkward, as this quote illustrates:

> *"I think we all miss... you didn't realize it at the time, but actually there's something very comforting about just having a [face-to-face] morning surgery booked and... we all moan about it but, you know, it's actually... you don't realize until it's gone actually how cocooned and in your zone you felt. And I guess it's how practices organize themselves."* (GP, HFVC TU)

Normalization includes supporting staff to make sense of the new technology in the context of their work; engaging them to participate; coordinating their implementation efforts; and monitoring benefits and costs (23). Each of these phases can be time-consuming and exhausting, particularly when implementing technologies across multiple organizations (32). Small wonder that healthcare staff (both clinical and administrative) described themselves as "maxed out" and "knackered," with little capacity for learning the new work routines needed for remote care.

Another aspect of successful organizational-level innovation is the need for staff members to champion and support the innovation. An example from our dataset is the administrative staff member who won an award for supporting the spread and scale-up of video consultations in community services. This digitally-literate individual grasped the vision for the new service, became an early champion for it and a super-user (someone to whom others felt they could go for help). They influenced fellow staff members to give it a try (including calling in favors), developed bespoke training for colleagues and patients, and pushed for measures to help embed the change (e.g., better digital platforms) with support from management. Slow adoption of remote services in some other organizations or departments could often be attributed to absence of such individuals: nobody opposed the innovation, but nobody enthused about it either.

The *wider system* domain incorporates the powerful phenomenon of inter-organizational influence and learning, in which early-adopting organizations pass on insights and resources to those coming on stream later, as well as attention to how policy context may support—or interfere with—organizational innovation (62). An example of cross-system influence at national level was how Scotland, which had been an early and successful adopter of video consulting across the country, supported the other UK jurisdictions (Wales, England, and Northern Ireland) with advice and re-usable resources (e.g., protocols, patient information). Learning from models of good practice elsewhere tended to be a positive experience, whereas public release of performance data—in which each organization

or department is compared competitively with others (for example in the proportion of consultations undertaken remotely)—was viewed negatively by our participants.

An important aspect of the policy context for remote consultations during the pandemic was the use of emergency powers to slacken red tape in relation to approved suppliers and purchasing rules, allowing organizations to effectively obtain and use any system deemed locally appropriate and workable (63).

> *"…essentially, we were given the word from the Trust that had come down from the region saying, 'Look, all is forgiven so to speak. For the time being, till we get a proper governance structure in place, just anything goes.'"* (Service manager, HFVC_QA)

Our interviewees depicted these changes positively—indeed, they considered that the changes would have been impossible or much delayed without them—but they also expressed concern about what would happen when organizations returned to business as usual, since the longer-term trade-offs between convenience and regulatory control (e.g., data privacy) are unclear. Profit-oriented providers offering only a limited range of remote services and targeted primarily at low-risk patients such as young professionals were part of the landscape before the pandemic, competing with local GP practices. Their success during the pandemic at a time of regulatory laissez-faire raises questions about quality, safety, and equity of care going forward (64).

The wider system domain also includes policies that affect remote services indirectly. An example is cross-government measures to address the climate emergency through a range of green policies. NHS England, for example, recently announced a vision for a "net zero [carbon] NHS," including a major contribution of new modalities for delivering care (65). The evidence base for achieving greener health services by means of remote care is limited and contested, but one study suggests that a substantial reduction in carbon footprint could be made (66).

Another aspect of the wider system domain in PERCS is underpinning infrastructure. Even before the pandemic, there was a strong policy push in the UK to build and strengthen the enabling technical infrastructure for a digitally-supported NHS (67–70), resulting in some relatively state-of-the-art elements such as the Health and Social Care Network (referred to as "The Spine"), along with various local and regional legacy components (some of which posed challenges relating to coverage and interoperability). But as we found, not everywhere in UK has even basic broadband connection:

> *"we're in rural Northern Ireland, there is still areas of the peninsula that haven't got Wi-Fi; they have got no sort of connection to things. Broadband speeds in many parts of Northern Ireland are one megabyte per second. So, just video consultation just physically doesn't work."* (Service manager, HFVC_QA)

Infrastructure also includes human elements (e.g., organizational roles, routines, and relationships), shared understandings and historical path-dependencies (such as legacy technologies and commercial contracts), and the regulatory and professional standards noted above (27, 37). As Gkeredakis et al. (4) have pointed out, during the pandemic a sense of urgency, relaxing of regulations and policy investment in technological solutions produced many new technological components but there was not time to strengthen either technical or human infrastructure, yet successful embedding and use of these novel solutions will be *"contingent upon the openness, distributedness, recombinability, re-programmability, and accessibility of digital technologies"* (page 2).

The initial draft of the PERCS framework consisted of the seven domains listed above, along with a temporal domain in which the dynamic interaction between all the other domains is followed over time, using narrative as a summarizing and synthesizing tool. One England-based clinician, for example, reflected that whilst video services had been broadly successful during the pandemic, there was little enthusiasm from her colleagues to continue this mode, and she doubted the service would last beyond the pandemic. She planned to return to Scotland where there was a long-term strategy and vision to extend video-based clinical services.

We subsequently added two side panels to the PERCS framework to place special emphasis on *digital maturity* (of the organization) and *digital inclusion* (for the population it serves). Whilst these concepts are to some extent subsumed within the central domains, the terms are increasingly widely used in healthcare circles and are worth exploring in their own right.

The theme of digital inclusion recurred in our data. For example:

> *"We have pockets of significant deprivation in [City name] and people just don't have the IT capability or the connectivity. We've had a lot of difficulty around connectivity, and I am not IT, so I'm not sure if that is largely down to the device that a patient or service user has, or whether it's down to the actual Internet or, you know, whatever the infrastructure is for... do you know what, I actually don't know the terminology but you know what I mean?"* (Hospital clinician, HFVC_EY)
>
> *"…particularly with the with the outreach population, it's so easy to ignore them. You know, they are not jumping up and down and making a fuss and they can't jump up and down and make a fuss because they can't fill the forms in, because they've got to have internet access to fill the form in to complain. Yeah, it's really it's quite insidious. Really, how it, how it excludes people, and then it stops people complaining about it."* (GP, RBD_CK50023)

Digital inclusion should be considered in relation to inequalities more generally. Tudor Hart's (71) inverse care law states that people most in need of health care are least likely to seek it or receive it; the law reflects two mutually-reinforcing phenomena—worse health in deprived localities and barriers to accessing healthcare in those same localities (47, 48, 72, 73). Patients who already suffer the multiple jeopardy of poverty, low health literacy, poor housing, weak social networks, psychological stress (e.g., from fear of crime) and—for some—language and cultural discordance now face an additional problem of digital inequalities, defined as differential access to healthcare depending on digital access, digital literacy or both (74). These barriers are part of a wider digital shift whereby many aspects of life—insurance, banking, local government,

education, travel, and holidays, and many more—are increasingly presented to the citizen, client or customer as "digital first," thereby excluding (partially or wholly) those unable to access them in this way (75).

The digital divide needs to be studied at a granular level, not merely in terms of the presence or absence of Internet access (76) but also in terms of how much bandwidth, data, IT literacy and skills, and power (e.g., over who in the household has use of the computer or smartphone) people have (77, 78). Digital inclusion is high on the policy agenda in the UK and elsewhere (79, 80). Some groups (e.g., the neuro-atypical and some people with mental health conditions) are said to feel more comfortable with remote consultations than face-to-face, though anecdotal evidence outweighs rigorous research on this topic (81).

Drawing on previous research and policy work (76, 78, 80, 82–84) as well as our own empirical data, we conceptualized digital inclusion as requiring three kinds of measures. First, diversity of provision, to ensure that patients and carers are able to select from a wide range of options to suit their particular access needs and preferences; such options would ideally be co-designed with patients and carers. Second, digital access support—either directly from the organization or indirectly by signposting to third-party or community providers (libraries, community networks)—providing access to the equipment needed for remote services; help to acquire and use the skills to engage with digital health care and support to create coherence between multiple providers offering digital services in different ways. This might include upskilling individuals but also, where necessary, major infrastructural projects to improve broadband connection to remote localities. Third, provision of non-digital alternatives for people who are unable or currently unwilling to access care remotely.

Examples of digital inclusion efforts in our dataset included flexibility to accommodate patient preferences (some teenagers, for example, preferred to consult with the video switched off; some parents preferred to video their child doing a task and send the video to the therapist rather than the child perform live to camera), signposting to local digital literacy programmes, and making it clear to patients that face-to-face appointments were available on request. Co-design with digitally excluded groups is recommended by advocacy organizations (82). However, our dataset included numerous examples of capacity constraints which limited organizations' abilities to undertake co-design work, provide a high degree of flexibility or provide sufficient face-to-face slots to accommodate all requests.

Healthcare organizations participating in our studies were at different levels of digital maturity (for which a dictionary definition is "a measure of an organization's ability to create value [financial and non-financial] through digital"), as the following contrasting quote illustrates:

> "*When the COVID hit, obviously we had access to video consulting and we got on with it, but it very quickly petered out. So, we went to total telephone triage; we did some video consults. We got pictures sent to us via email and things like that. The functionality of our platforms … was generally quite poor; had a lot of problems connecting. So yeh, we did it for a bit, but I would say that we never exceeded probably ten percent of what we were doing actually using video. And now I don't use video at all. Only one of my partners is continuing to use it now and again.*" (GP, HFVC_YN)

Our digital maturity scale is shown in **Table 2**. It has three linked elements. First, *readiness*—the extent to which the organization has the strategic alignment, leadership and resources needed to plan and deliver an appropriate range of remote services, including measures to address digital inequalities. Second, *capability*—the extent to which such services, including digital inclusion measures, are already technically present and up and running. Third, organizational *infrastructure*—the extent to which the underpinning material, regulatory, and human resource frameworks are in place to support further development of remote services.

Findings on Practical Ethics of Remote Consultations

Evident in our interviews with clinicians were the four widely-cited principles of practical medical ethics—beneficence (act in the patient's best interests), non-maleficence (do no harm), autonomy (respect the patient's right to choice and self-determination), justice (treat people fairly, especially when allocating scarce resources). These principles were originally proposed by Beauchamp (who leant toward a consequentialist or utilitarian position, focusing on outcomes of decisions for the patient and others) and Childress (a deontologist focusing more on the clinician's duties) (85), and extended to consider scope of application by Gillon (86). Beauchamp and Childress (87) later added four further principles based on behavioral norms—veracity (tell the truth), privacy (ensure no intruders or eavesdroppers), confidentiality, and fidelity (avoid conflicts of interest such as the potential for personal profit). All these principles featured prominently—often as professional norms assumed to be self-evident—in our empirical data. They are reflected in guidance such as the General Medical Council's *Duties of a Doctor* (88), to which some clinical interviewees referred.

Additional ethical tensions related to staff well-being and redistribution of the work of caring (often shifting to the patient or lay carer). These themes resonated with writing by feminist philosophers (89–92) on the ethics of care, including the hidden work and emotional labor of low-status workers such as receptionists and unpaid carers. Held's taxonomy (91) divides the ethics of care into personal (focusing on an individual's commitment and accountability to the person they are caring for), political (focusing on various kinds of inequality in caring—such as fairness, human rights, and inclusivity) and global (caring for the planet and its sustainability—and hence caring for future generations).

A related concept is what May et al. (93) have called burden of treatment—the additional burden placed on the patient when they are asked to "self-manage" —with the sickest and most vulnerable carrying the greatest burden. Burden of treatment also includes the effort needed from the patient to access services (31, 93), which technologies (especially e-consultations) could potentially alleviate. Pols (92) has developed what she calls an

TABLE 2 | Digital maturity scale for healthcare organizations in relation to remote services.

Organizational descriptor	How the organization currently uses traditional technology (e.g., phone, online access) and new technology (e.g., video, telehealth apps) to support remote consultations
Level 1: Traditional (reactive)	Limited leadership or vision for remote services (there may be a strategic decision and rationale to resist these). Phone is used for triage and call-backs e.g., for demand management and as a response to the pandemic. Patient online access is mostly disabled. Video and telehealth are rarely if ever used and may be actively discouraged. Key infrastructure may not be in place. Digital inequalities either not addressed or addressed by focusing on face-to-face services.
Level 2: Traditional with lone innovator (*ad hoc*, demonstration)	Within a traditional organization or department, one staff member is enthusiastic about remote care, s/he attempts to use novel technologies and engage others in doing so, but has not yet succeeded in getting others to share the vision, influencing practice strategy or changing practice routines or policies. Infrastructure may be inadequate. Digital inclusion not yet a priority issue.
Level 3: Digitally curious (experimenting)	The organization or department has a vision and plans for providing remote care. Traditional and new technologies are used creatively, and adjusted iteratively, to try to improve an aspect of care within the practice. These creative efforts may include measures to overcome digital inequalities. Focus is on technical details and feasibility (i.e., making something work). Infrastructure is adequate but may have limitations.
Level 4: Digitally embedded (learning and improving)	Both traditional and new technologies are used creatively and strategically, and benefits and disbenefits are evaluated, with the aim of improving remote care in all relevant areas across the organization, including efforts to meet the needs of digitally excluded groups. Digital capability is high (i.e., many services are successfully delivered remotely). Focus is on quality improvement and organizational learning. Work practices and routines are continuously adapted. Technical infrastructure is good as a result of strategic investment.
Level 5: System-oriented (extending and spreading)	Strategy and vision for remote services are strong and extend beyond the organization itself. Reducing digital inequalities is one aspect of a wider vision for an effective, efficient, equitable remote service. Digital capability is high. Staff are actively involved in developing and evaluating remote services beyond the practice—e.g., through inter-organizational benchmarking, quality improvement collaboratives, locality-wide planning, research, national guidelines.

empirical ethics of [technology-supported] care which considers technologies not as inanimate tools which make the clinical interaction more or less efficient (and as "cold" artifacts that contrast with "warm" human care) but as relational actors which, if creatively selected and "tinkered with" to fit specific situations, can *enhance and support* the personal ethical commitments and warm care relations between people.

Finally, our empirical data raised organizational- and system-level ethical issues, many of which could be mapped either to the US Institute of Medicine's (94) six dimensions of quality—safety, efficiency, patient-centeredness, timeliness, effectiveness, and equity—or to more recent work on organizational and system resilience—for which redundancy may be needed to help weather stress—and sustainability (95, 96). While these are quality principles rather than ethical principles, they draw implicitly on many of the ethical principles described above and have become widely used by those planning, developing, and evaluating services. These various ethical and quality frameworks were added as underpinning pillars to the PERCS diagram.

Of the 50 participants who completed round 1 of the Delphi survey, many put in free text comments that the paired principles were "contradictory" and "confusing." This had been our intention, but it was clear that whilst clinicians work comfortably with contradictory principles in their day to day work, they experienced strong cognitive dissonance when asked to confront them in a desktop exercise without a real, practical situation in mind.

All but one of the 25 revised principles in round 2 were supported in principle by 80% or more respondents, but many had suggestions for changes in wording (e.g., be less paternalistic, reduce jargon, split a maxim into two). All but one of the 26 revised principles in round 3 were supported by 80% or more participants with only minor suggestions for further revisions to wording; the final item was supported by 71%, with several respondents all suggesting omission of a particular phrase. After re-circulating this one item in a brief fourth round, there was high agreement on all 26 principles, which are listed in **Table 3**.

DISCUSSION

Summary of Main Findings

We have used selected elements of a large empirical dataset, drawn from multiple UK-based empirical studies, of the introduction and scale-up of remote consultation services both before and during the pandemic to develop the Planning and Evaluating Remote Consultation Services framework. PERCS, developed as an explanatory framework for analyzing research findings, has 7 domains—the reason for consulting, the patient, the clinical relationship, the home and family, technologies, staff, the healthcare organization, and the wider system—and considers how these domains evolve over time; it also focuses on the organization's digital maturity and digital inclusion efforts.

The PERCS framework enabled us to identify and explore how dynamic interactions between individual-, organizational-, and system-level factors influenced how remote consultation services were established and delivered (or not) in different local and regional settings. It also allowed us to surface a key paradox of the pandemic, namely the mismatch between policy vision and practical reality. Both during and beyond the pandemic, policymakers envisaged an efficient, safe, and accessible remote consultation service delivered through state-of-the art digital technologies and implemented via rational allocation criteria and quality standards. In contrast, our empirical data revealed that strategic decisions about setting up remote consultation services,

TABLE 3 | Guiding principles to inform application of the PERCS framework.

SECTION A: PRINCIPLES UNDERPINNING OUR REMOTE SERVICE

1. Infection Control (97% agreement)

We take all reasonable measures to ensure safety when there is an infection risk, including providing a range of ways for patients and staff to consult remotely.

2. A Fair Appointment System (97% agreement)

We have systems in place to allocate appointments fairly, prioritizing the most urgent. We take account of the fact that some patients are unable to use some or all types of remote consultation.

3. Informing Patients (97% agreement)

We provide information for patients on the different kinds of appointment available and the circumstances in which these may be appropriate. When offering appointments, we can explain why we think a particular type is suitable.

4. High Clinical Standards (91% agreement)

We are committed to providing the highest quality of clinical care for all patients, whatever the type of consultation.

5. Balancing Benefits and Risks (94% agreement)

We recognize that remote appointments have a different balance of benefits and risks—for example, greater convenience but less opportunity for physical examination, safe disclosure of sensitive information or raising potentially serious symptoms.

6. Technical Security And Usability (89% agreement)

The technologies we use for remote consulting meet high standards of data privacy and security while also being easy to use. We may support occasional use of less secure technologies that are more familiar to patients where benefits of doing so outweigh risks and patients accept these risks.

7. Patient Centredness (94% agreement)

Subject to capacity, we endeavor to offer all patients an appointment type which is timely, acceptable to them and addresses their needs.

8. Staff Wellbeing (88% agreement)

We manage appointments so as to take account of staff workload and wellbeing. As far as possible without compromising patient care, we allow clinical staff to choose their preferred mode of consulting (e.g., taking account of their own clinical risk and stage of training).

9. Environmental Responsibility (94% agreement)

Our policies on remote consultations reflect our commitment to reduce unnecessary travel and contribute to a greener, more sustainable future.

SECTION B: GUIDANCE FOR STAFF—BEFORE THE CONSULTATION

10. Deciding on Appointment Type (92% agreement)

Where possible and appropriate, we offer patients their preferred type of appointment. When allocating appointment type, we take account of the reason for the request and have processes in place to identify contextual factors, including but not limited to

- Whether the patient is known to the practice team
- Whether there is access to their full medical record
- Communication needs e.g., visual or hearing impairment, literacy issues, difficulty understanding, need for interpreter
- Privacy or safeguarding concerns
- Infection risk

11. Reducing Double-Handling (89% agreement)

We have measures in place, including effective triage, to ensure that patients are efficiently directed to an appropriate consultation type. Some phone or e-consultations will need to be followed up with a different type (e.g., face-to-face).

12. Making Complex Judgements (93% agreement)

Since each appointment request is unique we encourage staff to use their judgement and discuss decisions with patients and with a senior colleague where appropriate.

(Continued)

TABLE 3 | Continued

13. Mitigating Digital Exclusion (97% agreement)

When allocating appointment type, we try to take account of

- The patient's access to private space for a remote consultation
- The patient's digital set-up
- Their capability and willingness to use different kinds of technology

If patients are unable to manage a particular type of remote appointment, we offer a suitable alternative.

14. Supporting Continuity of Care (94% agreement)

Subject to resources, we aim to support

- Continuity of relationship (with own clinician)
- Continuity of information (of the patient record) and
- Continuity of multidisciplinary care (across a team)

15. Embracing Uncertainty When Allocating Appointments (87% agreement)

We recognize the uncertainty associated with allocating remote appointments. For example, we are alert to

- Patients who are concerned about seemingly minor or non-urgent complaints
- Patients who are keen to have a face-to-face appointment but do not wish to give a reason
- Patients whose condition has not improved following remote consultation(s)

16. Addressing Complex Needs (93% agreement)

We try to ascertain and address the particular access needs of patients who may be vulnerable (due—for example— to multiple medical conditions, advanced frailty, learning difficulties or cognitive impairment) in a compassionate and flexible way.

17. Safeguarding (100% agreement)

We are sensitive to the possibility that remote consultations may be compromised through interference or coercion. If there are such concerns, we offer a face-to-face appointment.

SECTION C: GUIDANCE FOR STAFF—DURING AND AFTER THE CONSULTATION

18. Supporting High-Quality Interaction (94% agreement)

When consulting remotely, we allow time for both parties to optimize the connection, deal with technical glitches and check understanding. We recognize that it may be harder to convey empathy and build therapeutic rapport in remote consultations.

19. Balancing Patient Autonomy with Support from Carers and Friends (100% agreement)

When consulting remotely, we deal directly with the patient if possible and respect their privacy. Subject to consent, and mindful of safeguarding issues, we welcome input from relatives or carers to help with the technology, communication or a remote physical examination.

20. Embracing Uncertainty During the Remote Consultation (94% agreement)

We recognize the uncertainty associated with assessing and managing patients in remote consultations. For example, we are alert to

- Poor audio or video quality
- Absent or limited visual cues
- Patient or practitioner stress
- Limited scope for examining the patient
- Possible presence of a third party off camera

21. Remote Physical Examinations (100% agreement)

When considering whether to examine the patient remotely (e.g., by video or by asking them to take measurements), we take account of

- The level of urgency
- The patient's comfort and confidence
- Their ability to assist (e.g., by placing a camera)
- Whether relatives are—with the patient's consent—able and willing to help

We invite patients to attend in person if an adequate physical examination cannot be done remotely.

22. Intimate Examinations and Images (94% agreement)

(Continued)

TABLE 3 | Continued

We do not undertake intimate examinations remotely. We follow legal and regulatory advice which limits exchange of certain kinds of intimate images.
23. Information Continuity and Action Points (100% agreement)
During or after a remote consultation, we ensure that notes, images and other data are entered on the patient's record and appropriately coded, and that agreed next steps (e.g., investigations, referral, follow-up) are actioned.
SECTION D: LEARNING AND IMPROVEMENT
24. Staff Training and Development (94% agreement)
We provide training, guidance and feedback to support staff on which type of appointment is appropriate in what circumstances, and for clinical trainees on remote consulting and triage.
25. Patient Training in Digital Skills (80% agreement)
We provide support or signposting (e.g., to community provision) for patients who wish to increase their digital skills and confidence with a view to consulting remotely.
26. Evaluation and Quality Improvement (87% agreement)
We measure our performance in remote consulting services, including capturing the patient experience, and set goals for improvement.

Showing % agreement with each item in the final round.

allocation decisions for appointment type (phone, video, e-, face-to-face), and clinical decisions when consulting remotely were fraught with contradictions and tensions, leading to both large- and small-scale ethical dilemmas that were either unique to the remote modality or greatly exacerbated by it. These dilemmas—which included how far to use technological triage to manage demand in an under-funded, under-staffed system; when to welcome support from the patient's relatives and friends in a remote consultation; when to accept a compromised physical examination rather than bring the patient in for a full in-per son assessment; how far informational continuity might compensate for relational continuity; and how much time and resource to put into mitigating digital inequalities—could not be resolved by standard operating procedures or algorithms. Rather, dilemmas had to be managed emergently by attending to here-and-now practicalities. To complement the PERCS framework, we used a Delphi process to construct a set of principles for informing the practical ethics of its application.

Our data affirm previous research (described below) which showed that the challenges of establishing and running remote consultation services operate at multiple levels: political (various interest groups may gain or lose from the introduction of new service models), economic (costs and benefits may be unevenly distributed across the system), organizational (remote consulting requires new roles and workflows), technical (dependable links and high-quality audio and images are needed), relationally (because of altered interpersonal interactions), and clinical (patients are unique; some examinations require contact; and clinicians have deeply-held habits, dispositions, and norms).

Strengths and Limitations

Our work to develop a multi-level theoretical framework for remote consultation services has three main strengths. First, we built on previous frameworks for organizational and technological innovation which had focused on the dynamic interaction between multiple influences in a complex system (17, 62); these have been widely-used and stood the test of time. Second, the combined empirical dataset which we used to refine and extend those frameworks was large and diverse; it included several pre-pandemic studies as well as a government-funded evaluation and two in-pandemic research studies, incorporating extensive primary data from surveys, ethnographic observations, interviews, focus groups, cross-sectoral workshops, and a Delphi panel. Third, PERCS was extensively revised as we worked through analysis of the different datasets until all elements of the data could be explained with reference to the framework.

There are, however, several limitations to this work. All our empirical studies were conducted in the UK, so the PERCS framework and linked guiding principles may not be transferable to contexts very different from the UK without further adaptation (we invite collaborations from researchers in contrasting settings). Pandemic restrictions made ethnography impossible for the later months of the study, and whilst we obtained research ethics approval to video and audiotape clinical consultations, this aspect of the work has so far proved impossible in practice. Hence our current insights are based more on what people said was happening than on direct observation. The Delphi exercise to develop guiding principles for applying the PERCS framework was undertaken on a relatively small sample and should be replicated and also tested prospectively.

PERCS is an explanatory framework, not a deterministic or predictive tool. In other words, the framework and guiding principles help prompt the development of rich narratives and contextualized explanations, including ideas about what could or might happen in the future. They are not intended to determine fixed relationships between variables or firm predictions about what *will* happen.

Comparison With Previous Research

Findings from our in-pandemic research on remote consultation services contrast sharply with research on such services undertaken before the pandemic which—in retrospect—was incomplete, skewed and lacking granularity. This earlier research, summarized briefly below, also failed to capture the complexity, messiness and associated ethical tensions of remote consultations across a range of settings once these modalities move from being evaluated in a tightly-controlled trial setting to contributing a major part of mainstream services.

A key driver for earlier research had been the hypothesis that remote models would increase efficiency of care. For this reason, many studies had emphasized measures of efficiency including repeat appointments, staff workload (including knock-on workload for other sectors), length of consultation, and the proportion of remote appointments that get converted to face-to-face (thereby double-handling a problem), as well as addressing technical feasibility, user satisfaction, clinical quality and safety, and operational considerations (97). Study designs had included randomized controlled trials, qualitative interviews, mathematical modeling, and detailed micro-analysis of verbal interactions and physical movements. Study participants had been carefully selected, usually excluding anyone considered high-risk.

Previous research on telephone consultations is surprisingly sparse and supports no firm conclusions, though several studies have suggested that double-handling may reduce efficiency (32, 98–102). There was very little research on e-consultations prior to the pandemic, and findings were limited (12, 103–107). One quantitative survey followed up 756 e-consultations in general practice and found that most generated either a telephone (32%) or face-to-face (38%) consultation (108). In contrast, there have been dozens of randomized controlled trials comparing video with face to face appointments in low-risk patients with stable long-term conditions (109–114). Overall, patients randomized to video did no worse clinically and were no less satisfied than those randomized to usual care, and that costs (where measured) were similar. However, almost all primary studies were underpowered and had highly-selected samples. Qualitative studies had indicated high patient and staff satisfaction but frequent technical problems (113–115).

Before the pandemic, there had been very few case studies of the introduction of remote consultation services in real-world settings. Most such studies lacked descriptive detail; both the clinical condition and the technology were often described in bland and brief ways, omitting the nuances that might have explained variations in findings across studies (116). The few detailed real-world studies in the literature suggest that efforts to implement remote consultation services even without an ongoing pandemic are logistically complex, resource-intensive and often stymied by technical and regulatory challenges (18, 26, 27, 115, 117, 118). Levels of remote consulting outside the research setting were very low pre-pandemic (12, 13, 119). Reasons for this included perceived increase in workload and stress, confidentiality concerns, technical problems, and demographics (e.g., the elderly were often cited as a group who found technology difficult).

Peer-reviewed research on the process and impact of the shift to remote consultation services during the pandemic is limited at the time of writing. Observational studies documented a sharp increase in remote consultations (telephone, e- and video, in that order) during the first wave in the UK (14, 15). Many findings from these studies aligned with our own: for example, that staff experienced the shift as organizationally and professionally challenging but considered it justified for safety reasons; they later reported feeling tired and under pressure as well as concerned about the loss of in-person care, threats to the therapeutic relationship, potential for missed diagnoses especially in deprived and vulnerable groups, and a rising backlog of unmet need. In surveys of staff and patients, most described their experience of technology-mediated care as "positive" but also questioned whether remote clinical care was as good as face-to-face (3). The most common concerns voiced by NHS staff were inadequate technological infrastructure and the fact that new technologies do not work for everyone. Other studies have described problems of increased antimicrobial prescribing (120), reduced ordering of diagnostic investigations (121) and delayed diagnosis of cancer (122, 123) attributed to the pandemic-related shift to remote consultations.

Implications for Policy, Practice, Education, and Further Research

We anticipate that the multi-level PERCS framework will have a number of uses and benefits. First, we hope it will help researchers, as well as planners and policymakers, conceptualize the introduction and delivery of remote consultation services as complex interventions in complex systems rather than as tools or technologies with predictable impact and fixed effect sizes. Many interacting factors need to be taken into account, and the fortunes of remote consultation programs will unfold differently in different circumstances. Those who lead healthcare organizations may wish to set goals to improve their digital maturity and their efforts at digital inclusion. Second, we hope that clinicians will find the framework useful when considering how best to deliver excellent care to the populations they serve—especially when managing risk. The best kind of consultation for a particular patient at a particular time, taking account of the needs of other patients and staff, cannot be decided formulaically, but we hope that the guiding principles will help inform ethical allocation decisions and high-quality remote consulting. Third, we propose that use of the framework by those designing systems of care may not only reduce digital inequalities, but also lead to reductions in wider inequalities in care and burden of treatment. Finally, we believe the framework could prove useful in both undergraduate and postgraduate education, especially for promoting rich learning through reflection on practice.

We recommend further research into the application of the framework and the principles, especially the in-depth analysis of hard cases which raise particular ethical challenges.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by NHS East Midlands Leicester Central Research Ethics Committee (REC ref 20/EM0128; IRAS ID: 283196 and subsequent amendments). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

All authors contributed to the empirical studies. TG conceptualized the framework, drafted the framework with RR and (to a lesser extent) other authors, and drafted the paper. TG led the Delphi study with support from RR and GW. RR is a case site lead for Remote by Default, led the focus groups and key cross-sector workshops, and wrote vignettes. SS leads a work package on Remote by Default, and provided theoretical expertise and led senior stakeholder interviews. RB is a case site lead for Remote by Default. CP leads a work package for Remote by Default. TG, RR, RB, LM, and SW contributed clinical, some social science and technology expertise, and other

authors contributed social science and technology expertise. TG is guarantor. All authors selected and supplied empirical data which illustrated and shaped the PERCS framework. All authors from RB to GW contributed approximately equally and are listed in alphabetical order. All authors have read and approved the final manuscript.

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The Sociotechnical Ethics of Digital Health: A Critique and Extension of Approaches From Bioethics

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The widespread adoption of digital technologies raises important ethical issues in health care and public health. In our view, understanding these ethical issues demands a perspective that looks beyond the technology itself to include the sociotechnical system in which it is situated. In this sense, a sociotechnical system refers to the broader collection of material devices, interpersonal relationships, organizational policies, corporate contracts, and government regulations that shape the ways in which digital health technologies are adopted and used. Bioethical approaches to the assessment of digital health technologies are typically confined to ethical issues raised by features of the technology itself. We suggest that an ethical perspective confined to functions of the technology is insufficient to assess the broader impact of the adoption of technologies on the care environment and the broader health-related ecosystem of which it is a part. In this paper we review existing approaches to the bioethics of digital health, and draw on concepts from design ethics and science & technology studies (STS) to critique a narrow view of the bioethics of digital health. We then describe the sociotechnical system produced by digital health technologies when adopted in health care environments, and outline the various considerations that demand attention for a comprehensive ethical analysis of digital health technologies in this broad perspective. We conclude by outlining the importance of social justice for ethical analysis from a sociotechnical perspective.

Keywords: digital health, bioethics, science and technology studies (STS), telemedicine, ethics

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INTRODUCTION

Hope in the promise of digital technologies to contribute to better health and health care continues to grow among many policymakers, health care providers, researchers and technology users around the world (1, 2). Documented perspectives among patients and the public about the use of digital technologies within health care systems are generally positive (3–5), and digital health is viewed at the policy level as a strategy to achieve more efficient and convenient health care delivery (6, 7). The World Health Organization (WHO) established its first global strategy on digital health for the years 2020–2025 (8), and several guidelines have been produced for the evaluation and implementation of digital health technologies in practice (9–11). Despite the persistent challenges in achieving meaningful implementation and use of digital technologies in health care (12), there is a general sense of optimism that digital health will play an important and positive role in promoting health and improving health care into the future (13).

The optimism around the potential of digital health and the commitment to advancing a digital health agenda represent only a partial perspective on the nature and implications of digitally-enabled health care. The COVID-19 pandemic raised awareness of the large body of work documenting the potential role of digital technologies in exacerbating health inequities (14, 15), along with issues such as the influence of large technology companies over public health policy (16). Furthermore, the distribution of digital technologies is linked with important changes to the ways in which people view and structure their lives, and these changes are deeply connected with the practices and institutions of health and health care (3).

These latter observations raise crucial questions about the many consequences of digital health and the ways in which societies might want digital health to develop into the future. These are normative issues connected to imaginaries of the roles that digital health technologies ought to play in promoting health and delivering health care (17, 18). However, research and writing on the normative foundations of digital health and its implications for health and health care has been limited. In this paper, we engage with existing perspectives on digital health from the field of bioethics, and propose an alternative approach to contemplating this important topic. Although there are alternative perspectives in the broad field of applied health ethics on which we could focus in our critique, such as public health ethics (19), we focus specifically on bioethics because it is the dominant approach to ethical analysis for issues in health care and medicine (20). Our critique is thus limited to the body of work analyzing digital health from a conventional bioethical perspective, but the critiques are relevant for related approaches to applied ethics outside of health and medicine as well. Indeed, the boundary around bioethics is porous at best, and many of the approaches addressed in our paper could be viewed as fitting within other fields of applied ethical research in addition to bioethics (e.g., computing ethics).

Digital health refers to a broad collection of technologies and practices that have shifted over time as new technologies have emerged. We align here with Marent and Henwood who bring four forms of technology-enabled care under the definition of digital health (2): telemedicine (synchronous or asynchronous care at a distance), eHealth (searching and exchange of health information), mHealth (use of mobile digital devices for health-related reasons) and algorithmic medicine (incorporating advances in data science and artificial intelligence in health care). In this way, our definition of digital health includes uses of digital technologies for self-tracking or self-care, health information search and exchange, and the direct delivery of health and social care.

THE BIOETHICS OF DIGITAL HEALTH: A CRITIQUE

Given the relatively recent emergence of the language of "digital health" as a way to demarcate the broader collection of applications of technologies we place into that category, it is understandable that bioethical analyses of digital health technologies have begun to develop only recently (21). However, several publications exist that have sought to advance scholarship and practice on the bioethics of digital health, as the recent growth of interest has generated a community of scholars proposing various approaches to understanding this domain of bioethical inquiry (22–25). As researchers working in the area of digital health and innovation ethics, we follow this literature closely. In this section, we group this literature into three categories of scholarly contribution, describe each category, and then provide an overarching critique of this literature.

The first type of contribution to the bioethics of digital health literature that we identify we refer to as "**applying ethical theory.**" In this body of literature, scholars adopt the perspective of an existing ethical theory and assess a subset of normatively relevant issues in digital health from that perspective (21, 26). The most common is some form of principlist approach, one that relies on a series of bioethical principles to guide assessment of the ethical implications of any given area of human activity (23, 24, 27, 28). The field of bioethics is dominated by a principlist approach to ethical thinking (20, 29), and it is therefore not surprising that the bioethics of digital health would also be dominated by such an approach. In this approach, contributors tend not to use elaborate justifications for a particular orientation to ethical theory, but rather focus primarily on applying the theory to substantive issues in digital health. For example, in a paper on the ethics of digital phenotyping for health-related uses, Mulvenna et al. simply state that "the four ethical pillars of medicine are autonomy (right to choice), beneficence (doing good), non-maleficence (do no harm), and justice (equal access), and these pillars should not be overlooked when democratizing digital phenotyping" (p. 8) (28). The authors then proceed to focus specifically on the principle of autonomy as the primary focus in their ethical analysis. Contributions in the "applying ethical theory" category have illuminated various dimensions of a set of well-defined normative issues in digital health from the perspectives of commonly known bioethical theories. These normative issues most prominently include privacy, security, data governance, and the distribution of benefits and burdens arising from the use of digital health technologies (16, 26, 30).

The second type of contribution that we identify we refer to as "**translating ethics for practice.**" This type of contribution is focused on enhancing the ability of stakeholders in the digital health ecosystem to understand and apply bioethical concepts in meaningful ways. Translating bioethics for practice is not about analyzing ethical issues from a particular ethical perspective, but rather is about linking ethically-informed statements or principles with actual practices of developing or implementing digital health technologies. For example, Milosevic gave a detailed account of deontologic ethical theory and outlined how specific deontic concepts can be linked directly to the software design process (22). Other contributions aim to further simplify the principlist approach to bioethics and specify its links to various aspects of digital health technology design (27). Approaches in this category aim to simplify and specify the implications of bioethical theory for the actual work of building and deploying digital health technologies (27).

The final type of contribution that we identify we refer to as "**identifying ethical harms.**" Contributions in this category aim to identify and describe the ethically relevant harms or normative issues presented by the domain of digital health. The harms identified in this category of contribution range in their proximity to the technology itself. Harms include issues closer to the technology, such as privacy or trust in digital health technologies (25, 31), and others farther from the technology itself such as the unequal resources available to procure and implement digital health technologies around the world (26). Although the focus of this type of contribution is primarily on the harms, issues or challenges of digital health (32), these are often also linked with the positively stated concepts that can address harms. For example, Vayena et al. specify that where trust is a challenge with digital health technologies, accountability is a strategy to promote trust in the field of digital health over the longer term. Contributions in this category have reinforced the high profile of normatively relevant issues associated with digital health, such as privacy and security, and also encouraged deeper thinking about previously unaddressed issues (26).

The three approaches summarized here have each made important contributions to the global discussion on the ethical challenges presented by digital health technologies and potential strategies to address them. Specifically, they have illuminated the significance of privacy, autonomy, security, consent, transparency, accountability, and fairness, and have explored various approaches to digital health governance. However, they are subject to important critiques that inform our own approach to understanding digital health ethics, based on the critique of bioethics as a field of research and practice (20, 33–35). Our critique relies on two central observations about bioethics as a field of applied ethics for health and medicine that apply directly to our review of literature on digital health ethics. First, that the field of bioethics is built on a foundational belief about the existence of moral universals that are essentially free from the influence of social, cultural, and political realities in different jurisdictions around the world (33, 36, 37). And second, that the common practice in bioethics is to accept the boundaries around a given advancement in health or medical technology that are established by the clinical or technological stakeholders supporting its implementation (34, 35). We address each of these critiques in relation to the digital health ethics literature just summarized.

The first two categories of the bioethics of digital health contributions, "applying ethical theory" and "translating ethics for practice," rely on a collection of existing ethical theories to address various issues in the field of digital health. These contributions rarely if ever include a detailed justification of the particular ethical approach taken in the analysis, and nor could they; an applied ethics paper is fundamentally not about the philosophical or theoretical justification of a particular ethical theory itself. However, relying on conventional approaches to bioethical theory is increasingly understood as problematic. Critiques of bioethics from the social sciences have clearly illustrated the problems with an assumed universal morality, which as Fox and Swazey have made clear, "is reinforced by the field's commitment to identifying and fostering universal ethical principles that constitute a "common morality" (sometimes referred to as "the common morality"), described by philosophers Tom Beauchamp and James Childress as "the set of norms that all morally serious persons… in all places… share." (p. 278) (38). Such an orientation toward ethics neglects the fundamental operations of power and culture in shaping moral beliefs (39, 40), and ignores the ways in which bioethics is infused with assumptions that reinforce efforts to maintain the status quo of existing systems of power (37, 41, 42). In our work, we aim to acknowledge these influences on bioethical discourse and promote a self-critical analysis of the assumptions made in ethics work and the particular normatively relevant positions we seek to advance.

The final category of the bioethics of digital health, "identifying ethical harms," is subject to a related but distinct critique: that bioethics practitioners tend to accept the boundaries placed around ethical discourse by proponents of a given a technology (34). This critique has been advanced clearly by Hedgecoe, who studied the work of bioethicists in the field of pharmacogenetics (34). He identified that bioethicists largely accept the claims made by scientists about the appropriate role of pharmacogenetic advances in medical care, stating, "It is quite clear that bioethicists can be skeptical of these scientific claims. It is just that they are not. Nor is it clear why bioethicists seem content to allow their discourse to remain within its current parameters, and are so unwilling to think in novel ways about the ethical issues raised by pharmacogenetics." (p. 15) (34).

Work in the bioethics of digital health appears to largely fall victim to the same critique. A series of common issues are frequently identified and discussed from an ethical perspective in relation to digital health technologies, such as those summarized earlier, without questioning the issues presented by such technologies outside of these commonly understood ethical harms. Challenges such as privacy and security can be cast as technical challenges, and it is in the interest of technology developers and other supporters of digital health to keep attention focused on technical challenges that can be contained and addressed using technical approaches (34). Although we acknowledge this is an over-simplification of privacy and security as normative issues, the contrast with issues such as digitally-driven inequities and corporate capture in public health care systems illustrate the immense complexity of potential normative harms that tend to be obscured or avoided in bioethical debate. In our work, we aim to situate the issues most commonly acknowledged in bioethical literature on digital health within the broader context of the social, cultural, and political realities that position them as such in the first place. In order to accomplish the latter goal, we turn to literature in Science and Technology Studies (STS).

TOWARD A SOCIOTECHNICAL ETHICS OF DIGITAL HEALTH

The sociotechnical approach to the ethics of digital health we propose in our paper arises directly from work in STS. STS is an interdisciplinary field of research that examines the

TABLE 1 | Domains of analysis in a sociotechnical approach to digital health ethics.

Domain of analysis	Brief description	Example ethical issue
Application Software	The lines of code that constitute a given digital health technology and the health-related practices they compel and discourage	Algorithms that perform with lesser degrees of accuracy for structurally marginalized communities.
Material devices and supply chains	The actual material used to build and distribute the devices through which humans interact with digital health technologies	The negative environmental effects of mining for materials to build digital devices.
Infrastructures	The infrastructure that is required for digital health to function, including material realities such as the buildings in which health care providers work when delivering virtual care, the cables and wires that enable digital signals to travel over distance, and the corporate structures of the organizations that make digital communication available	Lack of access to the Internet for people living in rural and remote areas.
Individual health-related practices	The activities and routines that are compelled by the use of digital health technologies	Adverse mental health implications of continual health-related surveillance.
Interpersonal relationships	Digital health technologies have the capacity to impact interpersonal relationships, through shaping the sources of information, expectations, and modes of interaction available to people	Negative impacts on interpersonal relationships as a result of health-related misinformation shared on social media.
Organizational policies	The structure, function and routines that characterize organizations, and the ways in which these are formalized in organizational rules and policies	The institution of corporate surveillance on staff.
Government policy and regulatory capture	The rules and approaches to governance put in place by state actors, and the influence of digital health stakeholders such as large technology corporations over health-related government policy	The growth in influence of large corporate technology companies over health-related policy.

interconnectedness and co-constitution of technology, science and society (43). In this way, STS highlights the people, practices, institutions, and other material realities that shape human understandings of science and technology and their implications for human life (43–45). The term "sociotechnical" refers to the observation that issues pertaining to technologies such as applications of digital health are never solely about the material technology itself, but about the mutual dependencies between technologies and the social arrangements in which they are built and used (46, 47). By the same token, "social arrangements" are always infused with various technologies, ranging from the chairs and whiteboards in design rooms to the smartphone applications and videoconferencing software that mediate human interactions. The term "sociotechnical" thus denotes a broadening of focus from the issues defined by a technology itself, to the broader universe of issues opened up by the recognition that technologies are built and embedded in the social world in ways that profoundly shape and are shaped by human life (48, 49).

We take the phrase sociotechnical system from the work of Selbst et al. on "fairness and abstraction in sociotechnical systems" (47). In their analysis, Selbst et al. outline how a series of biases arise in applications of data-intensive technologies not as a result of the technologies themselves, but as a result of the social and material systems in which they are built and embedded. In addition to their work, the theoretical precursors to our use of the notion of a sociotechnical system are many, but for the purposes of this analysis, we can specify two: infrastructure studies and the political economy of digital data.

Infrastructure studies refers to an approach in the field of STS that examines the often neglected material foundations that make everyday life possible (50, 51). One consequence of focusing on infrastructure is to uncover the inter-connectedness of the infrastructures on which many activities rely by tracing their extension and distance from a given site of analysis. In this way, by looking at digital technologies, we are encouraged to understanding the connected infrastructures on which their uses in health care depend.

In a related vein, work on the political economy of digital data has outlined the typically hidden incentives that characterize the collection, manipulation, and use of data for digital health technologies. In her introduction to a special issue on the topic, Prainsack outlined how studies of the political economy of digital data encourage attention to the institutions that govern and enable particular actors to generate value from data (52). Such an approach urges attention to the workings of power in a globalized capitalist economy that makes demands of local institutions to go along with the most recent capitalist trends. In this way, we also attend to these broader flows of power that shape the field of digital health, and encourage attention to them as important normative issues.

The broadening of perspective from the technology to the sociotechnical system raises attention to potential ethical issues that might have been overlooked from a technology-focused perspective. The sociotechnical approach has the effect of introducing a new series of potential ethical harms that require consideration in ethical analyses of technologies, and in so doing has a higher order impact on our ethical analysis: It

more explicitly orients our ethical attention to the question of what kind of world we hope to bring about through the design and deployment of a given technology. As opposed to simply assessing a range of issues that have been determined at the outset to be ethically relevant, this approach allows one to pursue a range of issues more distally connected to the technology that might also require ethical attention; indeed, ethical analysis is considered incomplete until this broader range of ethical issues is acknowledged, particularly in relation to their consequences for the effort to achieve the sort of world we hope to bring about. For example, in beginning with the design of a digital health technology, one might end up analyzing the policy framework in a given jurisdiction related to the presence of for-profit technology corporations influencing health policy (53). The health policy question in this scenario might have important implications for the structure of the health system as a public good, and therefore play an important role in the overarching ethical analysis related to the world we hope to achieve.

In the remainder of this section, we outline a general framework of the sociotechnical domains in which ethical harms of digital health might arise. In the following section, we outline an approach to ethical analysis that contemplates these harms to determine an ethical way forward. We present a typology of *domains* in which ethical harms can be considered in an ethical analysis of digital health technologies from a sociotechnical perspective. The purpose of this framework is simply to provide structure to a sociotechnical ethics approach to digital health, wherein the analyst can develop a sense of where one might look to identify the broader range of ethical issues we have referred to. These domains are not intended to be comprehensive of every feasible area of ethical relevance, but are intended to represent many of the most ethically salient considerations in the ethical analysis of sociotechnical systems in digital health. The domains are summarized in **Table 1**.

Application Software

The lines of code that constitute a given digital health technology and the health-related practices they compel and discourage are certainly of great ethical import. Much work has been done on the topic of the ethics of health-related artificial intelligence (AI) applications, related to the algorithms that determine the functioning of a particular digital health technology (30, 32). Although considerations such as transparency and fairness in the algorithms themselves are certainly important, it is also crucial to acknowledge that the ethical salience of these issues is closely linked with the broader systems of which they are a part (47). Ethical issues at the level of application software include effectiveness, usability, inclusiveness, transparency, and other issues related to the functioning and direct use of the digital health offering (30, 54).

Material Devices and Supply Chains

The actual material used to build and distribute the devices through which humans interact with digital health technologies are often ignored in ethical analyses, but are highly relevant for a comprehensive perspective on the ethics of digital health. The materials that are used to make smartphones and other digital devices are extracted from the earth and shipped internationally, having the effect of reinforcing low wage labor in low-income countries to benefit mostly large corporations in high-income countries (55). The systems created by such supply chains and the ever-advancing cycle of digital consumption in high-income countries deepens the entrenchment of geopolitical relations, structural racism, and the climate crisis (55), reinforcing their ethical relevance in a broad perspective on the ethics of digital health. Although acknowledging the relevance of the supply chain and the material that makes up the devices required for digital health creates immense challenges for an ethics of digital health, this does not mean they should be excluded from ethical analysis.

Infrastructures

Digital health relies on hardware and software, as addressed in the first two domains just outlined. However, digital health also relies on a series of different kinds of infrastructure. These infrastructures include the buildings in which health care providers work when delivering virtual care, the cables and wires that enable digital signals to travel over distance, and the corporate structures of the organizations that make digital communication available (56, 57). These and other infrastructures can have crucial ethical implications for digital health, where for example, a lack of high-speed internet availability precludes a particular community from accessing digital health care (54).

Individual Health-Related Practices

Digital technologies are used in a variety of health-related applications, many of which are intended to promote healthy activity and the management of disease among individual people (3). Digital health technologies are often infused with self-tracking mechanisms that have the impact of encouraging people to self-police their own actions and habits, meaning that they have heightened awareness about whether and how their action align with expected social norms (17, 18). Although the consequences of such self-policing can include enhanced health and prevented illness, there are broader questions to be posed regarding the power of self-tracking and "nudge" technologies to shape and constrain human behavior (58). The power of technology to influence mental well-being as a result of reduced self-esteem, and its power to influence individual actions, are ethically relevant, and should be acknowledged in related ethical analyses of digital health.

Interpersonal Relationships

Digital health technologies have the capacity to impact interpersonal relationships in variety of ways. One example is the very salient influence of social media applications on public understanding of health-related science and policy (59, 60). Health-related uses of social media have the potential to build interpersonal networks that reinforce particular epistemic viewpoints on health-related issues, with potential damaging effects on public health. A different example is the influence of technology-mediated communication on the relationship between health care provider and patient (61). Although the exact

implications of digital health and provider-patient relationships is as yet unclear, the comparison of in-person and digitally-mediated care remains ethically relevant to digital health.

Organizational Policies

Digital technologies have the potential to dramatically reshape everyday work practices, and therefore to also reshape the structure and function of organizations (62). The ways in which health-related organizations navigate the transition from analog to digital work environments is likely to have substantial implications for the nature of health care work and the nature of patient care (12, 53). The ways in which health care systems operate is very much in the public interest, broadening the range of ethical issues deemed relevant to the ethical analysis of digital health. One important point worth mentioning here is the impact of organizations such as insurance companies that use digital health technologies to collect information about individual behaviors and shape their product offerings accordingly (63). Such practices are made newly effective by advances in digital health technologies, and the role they ought to play in the insurance industry going forward is an organizational policy issue requiring close ethical attention.

Government Policy and Regulatory Capture

In the context of the growing corporate investment in collecting and analyzing large amounts of health-related data, government regulations become extremely important. More recent advances in data protection law that address health-related data such as the General Data Protection Regulation (GDPR) in the European Union represent important steps toward more comprehensive public protections. However, the rapid advancement of digital health technologies and the corporate practices of the organizations developing them pose important problems even for the GDPR. For example, Marelli et al. outline a series of practices in digital health that are not effectively addressed by the GDPR, including the growing influence of new corporate actors, creating stronger links between health care and lifestyle, increasing reliance on predictive analytics, and social sorting to place technology users into distinct groups (64). Beyond the capacity of existing policy to cover current corporate digital health practices is the growing influence of such corporate actors over the strategy and operations of health care systems. The increasing movement of for-profit technology corporations into the digital health field highlights the urgent need for ethical attention to the conflicting motivations of technology companies and health care systems (16, 65).

These domains in which ethically salient harms might be identified in a sociotechnical approach to digital health ethics represent a departure from the more limited perspective conventionally associated with the field of bioethics (34, 35). A sociotechnical approach encourages the ethical analyst to engage in the work necessary to develop a clearer understanding of the ethical issues presented by a given application of digital health in these various domains. Such an effort might require a review of social science literature on these topics, or new empirical research to uncover the implications of a particular technology and the ways in which it is produced and distributed. However, after the potential harms of such a technology are identified and understood, what would be the approach to adjudicating between those harms and the purported benefits to arriving at a meaningful ethical conclusion? We turn to this important point next.

TOWARD THE WORLD WE WANT

If the first important move of a sociotechnical approach to the ethics of digital health is to broaden the scope of issues under consideration, then the second important move is to focus on world-building. As opposed to a phenomenological notion of world-building, by world-building we mean the distributed contributions to producing a particular sort of world that are made by the practices and institutions that enable the sustained development of a given technology. This understanding of world-building is aligned with literature in STS more broadly that attends to the multiple sites of activity that constitute innovation, and the avenues of inquiry from critical political economy approaches that explore whether a particular innovation contributes to the sort of world we hope to bring about (52, 66). The broader focus encouraged by a sociotechnical approach raises awareness of the many ways in which the building and dissemination of a technology can impact the world in ethically relevant ways. In our view, the act of attending to such a broad range of issues invites a summary understanding of the kind of world that is being brought about by the consequences of a technology and the ways in which it is built. In this way, the summative assessment of a technology from the perspective of a sociotechnical ethics relies on an understanding of the sort of world it helps to create, who benefits in that world, and who is disadvantaged. Such an approach prioritizes social justice.

Broadening one's ethical perspective to the many elements of a sociotechnical system has the effect of broadening ones understanding of its normative implications. At this broad level of ethical analysis, we suggest that ethical attention is most naturally focused on world building and the value commitments that support a socially just world for all. When tracing the links in the sociotechnical system, the interconnections between communities that are otherwise considered unconnected come into view, and the interdependence between them becomes ethically salient. Aligned with recent approaches to public health ethics, such an approach calls for ethical attention to the global balance of benefits and burdens in the nested geographies of the local, the national, and the planetary (19). It is this attention to social justice, motivated by commitment to solidarity with the many inter-connected communities affected by a given digital health technology, that characterizes a sociotechnical ethics of digital health. Acting on such an approach requires methods that are familiar to ethically-informed governance in domains separate from but allied to bioethics, and we now turn to concepts from anticipatory governance to describe two of these methods.

Engagement and Foresight for Sociotechnical Ethics

A sociotechnical approach to the ethics of digital health resonates strongly with the notion of anticipatory governance

(67). Guston defines anticipatory governance as, "a broad-based capacity extended through society that can act on a variety of inputs to manage emerging knowledge-based technologies while such management is still possible" (p. 219) (67). This vision conceptualizes anticipatory governance as a distributed practice to be institutionalized in the innovation function of a given society. Although a sociotechnical approach to the ethics of digital health has a more modest aim of informing more immediate ethical analyses, it does draw two linked and important insights from anticipatory governance: the respective importance of "engagement" and "foresight."

The first insight drawn from anticipatory governance is the importance of engaging diverse lay publics to provide input into the meaning and desirability of a technology (67, 68). Such exchange of ideas and assumptions allows ethicists to better understand (a) the moral assumptions, and (b) knowledge and beliefs held by different publics as they relate to a given technology. Engagement in this way is intended to ensure that under-represented views in innovation, policy, and technology are brought to the discussion and have bearing on the ways in which ethical issues are framed. But engagement is not without its challenges. Defining which publics are to be engaged and securing the resources to do so in a meaningful way require committed action and a supportive, well-resourced context.

The second and related insight from anticipatory governance is the importance of foresight, which has been described in detail in relation to emerging technologies (69–71). In formal literature on anticipatory governance, foresight is incorporated in its full sense as a multi-method practice of identifying current trends and imagining the likelihood and significance of various potential futures (68). These potential futures, identified through consultation with relevant publics, then inform approaches to current governance decisions. In relation to a sociotechnical approach to the ethics of digital health, this is simply about anticipating the potential impacts of the broader range of ethical issues identified in the various sociotechnical domains outlined. The purpose is to anchor decision-making in a clearer understanding of the kind of world that is encouraged by the digital health technology of focus, and what its consequences will be for the inter-connected communities affected by its development and distribution.

The approach articulated here relies on both the engagement of diverse perspectives and the articulation of a future that is more desirable than the present. Neither of these activities can ever be perfect, and thus ethical analyses will always be only partial and incomplete. This is not a "lesser" version of ethical analysis, but from a sociotechnical perspective is simply the only form of ethics that is viewed as possible. It is one that intends to analyze the normative viewpoints of various contributors in relation to the implications of a particular technology, and then to assess their implications for the future. By focusing on social justice for the communities implicated in the development and distribution of a digital health technology throughout the sociotechnical system, the approach aims toward building a better world for all.

The practical implications of the approach we articulate here for health system and organizational leaders relate to the two practical insights just outlined. When health systems are intending to adopt new technologies, they can engage in a systematic process of community engagement to establish a process and governance approach that is meaningful and acceptable to diverse publics. This includes, but is not limited to, those who are structurally marginalized. Such an approach enables health systems to identify issues that might not be understood by those who are in paid positions to procure and implement digital health technologies.

Furthermore, health system leaders can implement an approach that explicitly anticipates the potential negative consequences of adopting technologies for health system stakeholders. Building on the insights of diverse community engagement, such potential negative consequences extend beyond the implications for clinicians who use the technology to the altered roles of administrative staff, leaders, patients, and other stakeholders who contribute to building, distributing, and managing the technology.

Finally, health system leaders can seek out input specifically from ethicists familiar with the unique ethical issues presented by digital health technologies. Although this is an emerging space, specific consultation on the ethics of digital health technologies will become increasingly important as digital health plays a more prominent role in health systems around the world. The broader view we articulate in this paper, and the practical implications we introduce here, help to promote the sustainable and ethical adoption of digital health technologies into the future.

CONCLUSION

The sociotechnical ethics of digital health we propose in this paper is based on a critique of the epistemic and normative foundations of much work done on digital health from within the field of bioethics. Informed by such a critique, we propose a view that draws attention to a much wider range of issues represented by the sociotechnical system implicated by a given digital health technology and the well-being of the many communities connected to it. When normative concern is directed to the well-being of these many communities, the value of solidarity and a commitment to social justice become more prominent in ethical analysis. The focus becomes on building a world that is better for all, as opposed to one that is only better for a few privileged stakeholders.

The view we outline in this paper carries forward a position that it is not only the technology itself that requires ethical attention, but also the world into which it is implemented and that it, in turn, creates. As Selbst et al. suggest, "fairness and justice are properties of social and legal systems like employment and criminal justice, not properties of the technical tools within." (Selbst p. 59). The digital health ethics community will need to engage with this basic insight in determining the most appropriate strategies for the ethical analysis of emerging technologies in health care and public health.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

JS led the drafting of the manuscript. JS and JD developed the ideas. JD provided critical comment and revision to drafts. Both authors approved the final manuscript.

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Developing Medical Technologies for Low-Resource Settings: Lessons From a Wireless Wearable Vital Signs Monitor–neoGuard

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The neoGuard™ technology is a wireless wearable vital signs monitor attached to a patient's forehead to continuously measure oxygen saturation, pulse rate, respiratory rate and temperature. Developed with feedback from more than 400 health workers, primarily in East Africa, the product has been designed to meet the unique constraints of low-resource settings. This perspective piece by the innovators of neoGuard™ and some of their key partners examines the complicated journey of taking a medical technology from concept through clinical validation and finally to market. By shedding light on some of the most critical steps and common challenges encountered along the pathway to commercialization, the authors hope that their experiences will provide some valuable insights to other aspiring innovators in this space.

Keywords: vital signs, wearable sensors, wireless health monitor, newborn health, digital health, medical technology

INTRODUCTION

In the aftermath of the COVID-19 pandemic, digital health products have gained increasingly wide appeal for the delivery of health services to patients in high-income and low-income settings alike. As researchers, clinicians and policy makers rallied to optimize patient care and alleviate the burden on health facilities and hospital staff at the height of the pandemic, global efforts to leverage digital health solutions became more invigorated than ever before (1–3).

Yet despite the recent uptick in digital health interest, innovators still struggle to navigate the existing ecosystem and face significant barriers to transitioning their ideas from concept to market (4), particularly in low-and-middle-income countries (LMICs) where the health technology space is maturing at a slower pace (5). At the same time, there is a tremendous opportunity for innovators worldwide to seize this unprecedented moment and capitalize on these recent digital health gains. In this perspective piece, the team behind the wireless vital signs monitor, neoGuard, reflects on its journey creating and commercializing a health technology product for patients in low-resource settings. By examining our own experience, we aim to offer some useful insights on potential pitfalls in medical device innovation and how to successfully navigate the current digital health ecosystem.

neoGUARD ORIGIN STORY

The idea for Neopenda's neoGuard device started with a mission of addressing an unmet need for vital signs monitoring solutions for newborns in low resource settings. Through a series of formal and informal needs assessments, we quickly established that conventional vital sign monitoring equipment were unable to meet the constraints of low-resource settings due to (i) the high cost of initial purchase and maintenance, (ii) infrastructure challenges such as space limitations and power outages, and (iii) their reliance on single-use accessories which are not always readily available.

Designing a product to adequately meet our user's needs while overcoming these salient challenges became the focus of our innovation efforts. Like many medical technologies and digital health solutions, Neopenda started in the academic world as a design project by a team of graduate biomedical engineering students. Driven by the mission and neoGuard's potential for positive impact on healthcare in underserved communities, we transitioned from academia to a startup venture. After consulting with more than 400 health workers, primarily in Uganda, we were able to design an affordable, reusable, wearable, multi-parameter vital sign measurement device over the course of 4 years.

The neoGuard device continuously measures temperature (temp), blood oxygen saturation (SpO_2), pulse rate (PR) and respiratory rate (RR), and wirelessly transmits readings to a central dashboard (NeoMonitor app) that is hosted on a tablet (**Figure 1**). The system provides real-time visual and audio alerts whenever a patient's vital sign measurements fall outside preset upper or lower limits. The NeoMonitor app can display data from up to 15 devices at a time, making it an ideal tool to simultaneously monitor multiple patients in health facilities with very low nurse-to-patient ratios.

EARLY TESTING

Between November 2018 and November 2019, we conducted two IRB-approved pilot studies that aimed to (i) evaluate the preliminary safety of neoGuard by describing and quantifying any adverse events, (ii) evaluate the ability of the device sensors to detect high fidelity PPG (photoplethysmogram) waveform signals from the newborns' capillaries, and (iii) assess the preliminary concordance of neoGuard measurements with reference measurements from a standard-of-care/conventional vital signs monitor. The pilot studies involved 22 stable newborns (aged <28 days) at Tufts Children's Hospital (formerly Floating Hospital for Children) at Tufts Medical Center in Boston, Massachusetts and 27 healthy newborns and infants (aged <16 weeks) at Jinja Regional Referral Hospital (Jinja RRH) in Jinja, Uganda. Regulatory approvals were obtained from the Tufts Health Sciences Campus Institutional Review Board for the Tufts study, and from the Makerere University School of Public Health (MakSPH) Higher Degrees Research and Ethics Committee and the Uganda National Council of Science of Technology for the Jinja study.

Results from both studies showed that the neoGuard device demonstrated comparable safety to standard-of-care equipment (with no adverse events recorded from either system) and sufficient signal quality to register changes in the PPG waveforms. However, accuracy of vital sign measurements was variable from patient to patient, showed high sensitivity to motion artifacts and device placement, and was further impacted by the large size of the prototype hardware device and inadequate design of the headband. Through an iterative design process, we recalibrated sensor settings and refined the vital signs algorithms to reduce noise (unruly signals) from these sources until we attained robust performance for the measurement of temperature, pulse rate, blood oxygen saturation, and respiratory rate. The hardware of the neoGuard device was also optimized, including reduction of the size by over 60%.

The design process involved three main hardware iterations, culminating in the first production release of the device, neoGuard wearable device (**Figure 2**). Feedback from clinicians involved in the Tufts and Jinja studies was also invaluable for the improvement of the neoGuard headband design. The band evolved from a disposable fabric band, to a two-piece silicone band, to an adjustable single-piece reusable silicone band (**Figure 3**). Later, an extender strap was created to enable the headband to fit adult patients as well. Being responsive to stakeholder feedback throughout the development process is crucial to creating a product that will be readily adopted by end users. Without this iterative, collaborative early phase, neoGuard would have performed less successfully in the human factors usability engineering studies and post-market clinical follow-up studies later on.

In addition to performance testing, early research on neoGuard also explored human factors and usability engineering (HFUE). HFUE, an essential component of the medical device design and development process, involves bringing users and stakeholders into the design process to make sure that the solution being created will meet their needs and be usable for them. Data on HFUE was collected through training workshops, simulation exercises and user surveys, and interviews. This HFUE data drives many design decisions and product requirements. In total, ∼70 health staff participated in the formative and summative assessments for HFUE. An additional 330 health staff constituted the voice-of-customer (VOC) research.

CLINICAL VALIDATION STUDIES

To comply with ISO/IEC standards for pulse oximetry (6) and temperature monitoring (7) across the appropriate measurement

Abbreviations: Bpm, Beats per minute; Brpm, Breaths per minute; COVID-19, Coronavirus disease 2019; DHF, Design History File; EMC, Electromagnetic Compatibility; EU MDR, European Union Medical Device Regulation; HFUE, Human Factors Usability Engineering; IEC, International Electrotechnical Commission; IRB, Institutional Review Board; ISO, International Organization for Standardization; LMICs, Low-and-middle income countries; MakSPH, Makerere University School of Public Health; NBCU, Newborn Care Unit; PMCF, Post-Market Clinical Follow-up; PR, Pulse Rate; RR, Respiratory Rate; RRH, Regional Referral Hospital; SpO_2, Blood oxygen saturation; UCSF, University of California San Francisco; VOC, Voice-of-Customer.

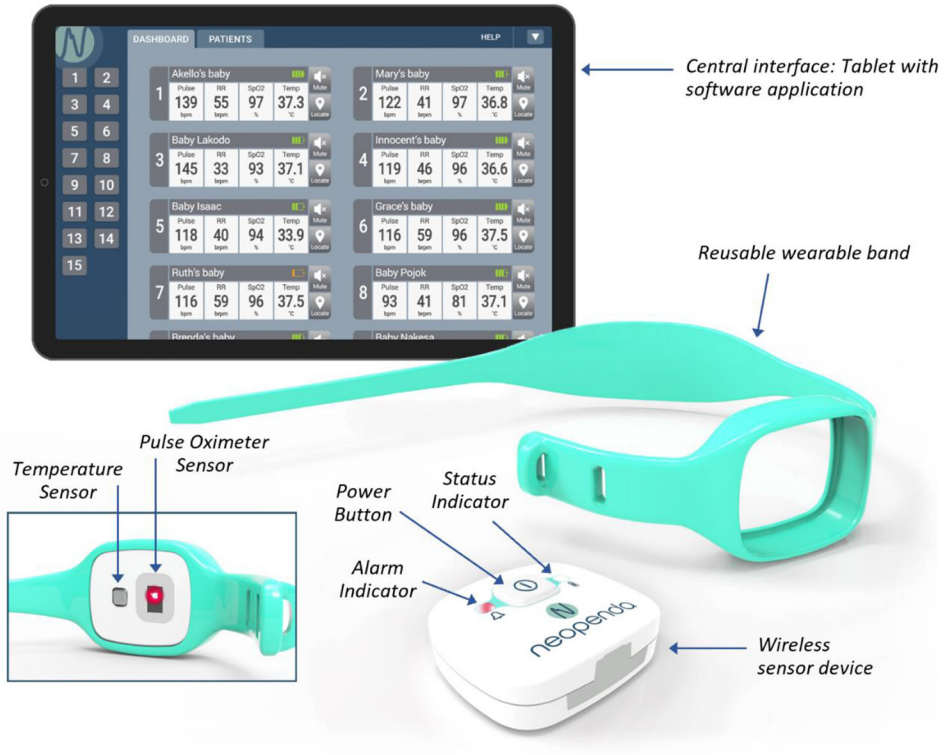

FIGURE 1 | The neoGuard V1.0 vital signs monitoring system.

ranges, final accuracy validation was conducted at Clinimark Laboratories in Louisville, CO, USA and the Hypoxia Lab at University of California San Francisco (UCSF). All testing was conducted with production-equivalent units, that is, the "final" product or equivalent. Testing on human subjects was conducted under IRB approvals from Clinimark Laboratories and UCSF.

We attained robustperformance for measurement of temperature (range 30–40°C, accuracy ±0.3°C, over a variety of ambient conditions), pulse rate [range 45–205 beats per min (bpm), accuracy ±3 bpm], blood oxygen saturation (range 70–100%, accuracy ±4%), and respiratory rate [range 5–30 breaths per min (brpm), ±5 brpm]; meeting the accuracy requirements of the applicable ISO/IEC standards (**Table 1**).

REGULATORY APPROVAL

As a medical device used in the clinical environment, neoGuard is subject to rigorous regulation in all markets to ensure it is safe and effective. To create a medical device meeting the standards for commercial, clinical use, a medical device company must implement a design control process, and quality management system in compliance with internationally recognized standards such as ISO 13485 (8). Early in the design and development process the applicable regulatory standards for the product should be identified and incorporated into the product requirements. If the design team does not have regulatory or quality expertise, external consultants are necessary.

FIGURE 2 | Prototypes of neoGuard hardware versions v1.0 (left), v2.2 (center), and v3.0 (right).

Neopenda began contracting regulatory and quality expertise in year 2.

In accordance with the CE mark classification guidelines, we categorized the neoGuard product as a class IIb medical device and pursued the CE marking regulatory pathway (route 1) to demonstrate compliance with the European Union Medical Device Regulation (EU MDR) (9). Under this process, we

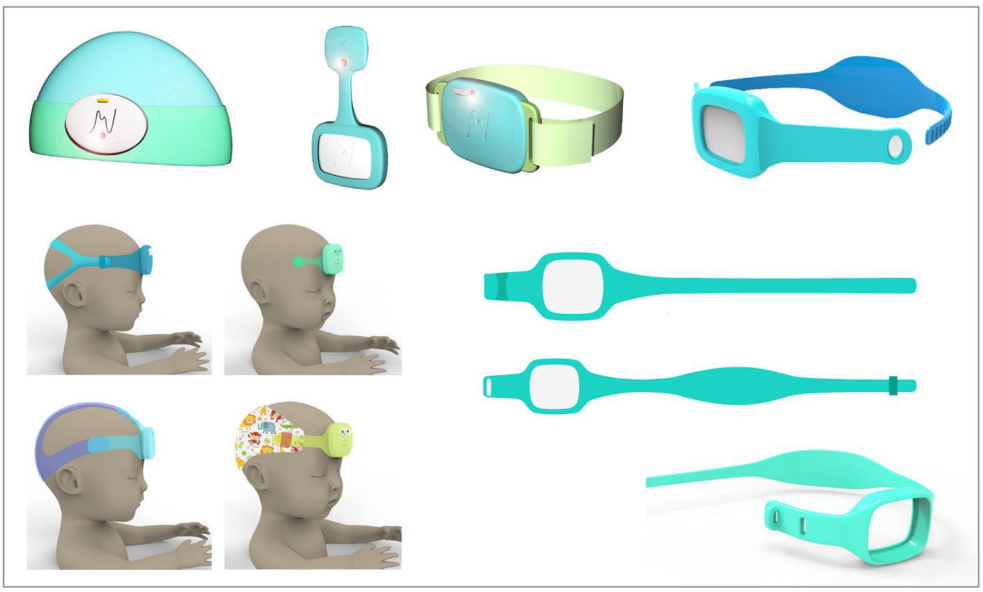

FIGURE 3 | Sampling of neoGuard headband design concepts.

TABLE 1 | Summary of clinical validation study results.

Vital sign	Accuracy	Resolution	Claimed range	Sample size (# subjects)	Sample size (data points)	Validation method	Study dates, sites
PR	±3 bpm	1 bpm	Baby mode: 75–205 bpm Adult mode: 45–145 bpm	N/A	50	Functional bench testing using an electronic pulse simulator	September 2020, Clinimark
RR	±5 brpm	1 brpm	5–30 brpm	20	655	Clinical respiratory rate study in comparison to end tidal carbon dioxide monitor	September 2020, Clinimark
SpO_2	±4%	1%	70–100%	13	275	Clinical hypoxia desaturation study in comparison to arterial co-oximetry	August 2020, UCSF Hypoxia Lab
Temp	±0.3°C Equilibration time ≤ 10 min	0.1°C	30.0–40.0°C	N/A	15	Functional bench testing using a NIST traceable fluid bath	October 2020, Clinimark

underwent a full quality assurance audit by a notified body and obtained ISO 13485:2016 certification for our quality management system. Next, we submitted a technical file for the neoGuard product to the same notified body. After review of the technical file and audits of both Neopenda and our critical sub-contractors, the EU certificate was granted. Then the CE mark and notified body number are affixed to the neoGuard product and a Declaration of Conformity is ratified.

CE mark certification is recognized by most medical device regulators in our target countries (10) and will allow us to bring the neoGuard product to market efficiently. In addition to CE mark, many countries also require appointment of a local agent/representative to complete product registration with the appropriate regulatory body and obtain final import and marketing clearance.

COMMERCIALIZATION EFFORTS

To reach most hospitals in emerging markets, medical equipment is often procured through a wholesale distributor. In Kenya and Uganda, where Neopenda has launched neoGuard, we have worked closely with a local authorized representative and distributor to register the neoGuard product and obtain import clearance from the Kenya Pharmacy and Poisons Board and the National Drug Authority, respectively.

Successful adoption of a new technology extends beyond the design of a product, and into appropriate implementation. This includes an emphasis on user training, installation, preventative and reactive maintenance, and adequate sales and marketing efforts. Our immediate strategy consists of leveraging the expertise of local distributors to implement neoGuard. This

model provides a scalable approach to penetrating new markets without having to build a large sales/marketing team in every country we enter into. Similarly, on the production side, we have outsourced manufacturing of the neoGuard devices to a contract manufacturer with the infrastructure, supplier network and quality management system necessary to mass produce, package, and deliver thousands of devices to our in-country distributors efficiently and cost-effectively.

POST-MARKET PERFORMANCE EVALUATION

Under the EU MDR requirements, it is recommended that medical device innovators complete at least one post-market clinical follow-up (PMCF) study after launching their product. In addition to the PMCF study, innovators are also encouraged to initiate broader scope evaluations encompassing a larger number of users/patients in order to supplement their pre-market approval findings on the safety and effectiveness of the approved device. Clinical data from post-market studies are not only valuable for post-market surveillance. These studies maybe referenced in updating claims on device efficacy, expanding the product's indications for use, as well as assessing market acceptance and uptake (11).

Neopenda has plans to implement at least six post-market research studies on the neoGuard product, including short-term implementation feasibility studies in Uganda, Kenya, Tanzania, Nigeria, and Mali, and a medium-to-long term clinical impact and cost-effectiveness study in Kenya. At least two of the planned studies will be led by independent non-profit partners in our target countries.

In parallel with our formal research, we will also conduct routine monitoring and evaluation where we aim to (i) capture monthly or quarterly performance metrics through the neoGuard backend data repository and (ii) gather additional user feedback through routine surveys with early adopters.

POTENTIAL PITFALLS AND LESSONS LEARNED

Pre-mature Product Testing

While there is an understandable temptation for innovators to begin testing their products as soon as they have a functional prototype, clinical research is an expensive endeavor, and even small scope pilot studies have considerable time and cost implications. It is important to plan out the phases of testing that will be needed, and to first generate sufficient evidence that your product will perform as intended before you put it to the test in a formal clinical setting. Where possible, this can be achieved through bench top testing in a lab setting; for instance, with the neoGuard product, we were able to employ a pulse rate simulator and water bath to test for pulse rate and temperature, respectively, before further testing on human subjects. It is also important to note that significant product modifications may arise from the early testing phase while you conduct thorough bench testing and gather user feedback. In some cases, it might require more than one pilot study before you are fully confident in initiating your design freeze. The "final" clinical validation study(s) must be conducted after design freeze, with the final or production-equivalent product. While the introduction of new devices requires testing within the target market, one bottleneck that innovators are likely to run into in LMICs is the limited access to gold-standard equipment or measurement techniques. For instance, our research team had intended to use end tidal carbon dioxide ($EtCO_2$) as a comparison method for the respiratory rate measurement by neoGuard; however, $EtCO_2$ monitors were not readily available in Uganda, so we opted to perform this component of testing with a US-based researched partner. As far as possible, innovators in low-resource settings should leverage partnerships with institutions that may have better access to the resources they need to perfect and test their early prototypes. This will significantly help reduce the risk of testing a product in-field before it is fully functional or ready to be tested by users. That said, the importance of early product testing in target markets should not be overlooked however complicated the process may be. Environmental considerations such as temperature, humidity, or the layout of health facilities can have a significant impact in the performance of your technology, and gathering this data early on will enable innovators to respond proactively.

Insufficient Preparation for Quality Management and Regulatory Affairs

A medical device should be designed within the existing regulatory framework and quality requirements. Innovators should know the product specifications that are deemed acceptable in clinical practice, as well as any electrical safety, electromagnetic compatibility (EMC), or radio frequency emissions standards pertaining to their product. Your target parameters and corresponding validation tests needed should be clearly defined in your technical file. Conduct extensive research on the regulatory pathway you are pursuing and engage experienced personnel and/or consultants to help you navigate any policy hurdles. It is important to be familiar with the IRB process and documentation that may be necessary. However, the IRB process for research involving medical devices is often not well-defined and is still evolving in many low-resource settings. Having IRB-approval from a US-based institute or other country where medical device studies occur more frequently may help strengthen your efforts for research clearance with a local IRB. In many cases, local IRBs may not have the necessary medical device expertise to adequately assess the risks and benefits or your research, so providing evidence of review by another IRB can help quail some of their concerns. In the same regard, selection of an IRB committee with relevant experience reviewing medical device research is critical. Some of the essential documents you should prepare to include in your research application are: a detailed protocol, operator's manual, investigator's brochure, informed consent forms, and preliminary safety and efficacy data. For devices that are above non-significant risk, which do not pose significant risk to human subjects, pre-approval and registration with the country's medical product regulatory agency may be necessary. It is important to be familiar with secure data

ownership and security requirements to protect subject privacy and health information. After initial IRB approval, studies will be subject to regular reviews and any significant protocol or device changes will require IRB approval. Having the right expertise on your team will help limit the amount of time it takes to reach your next milestone. In preparing your budget, anticipate that the quality and regulatory stage will almost definitely cost more and take longer than you project.

Applying Inappropriate or Impractical Research Methods

Think carefully about your choice of research methods and consider your justification for why your methodology is appropriate. The nature of a medical device, the context in which it is applied, and cost implications can often limit the study design to more simplistic single-arm trials. Regardless of the underlying reasons, it is important to reflect on the limitations of any study design. Seek out opportunities to collaborate with research partners from academia or non-profits who are working to address similar challenges. Collaborators may provide expert knowledge and external insights on the feasibility of your product.

Ensure that your data collection methods and data analysis approach are equally robust. Where possible, validate or pre-test your research tools for clarity, face validity, and content validity. Provide relevant training and guidance to study personnel involved in data collection. Research objectives should place equal emphasis on both the quantitative performance metrics and the qualitative user experience. A comprehensive analytical framework should also take into consideration the role of social forces (e.g., trust in medical authorities, myths around technologies) and how the requirements or expectations of a medical product may vary in different clinical situations and cultures. For instance, many users of the neoGuard technology shared concerns that the patients caretakers or family may feel anxious seeing a device affixed to a patients forehead, as this was an unusual attachment area for a vital sign monitor. However, when it came to actual implementation of the technology, we observed that this anxiety was not as prevalent as we had imagined. Patients' caretakers and family demonstrated a high level of trust in the medical staff attending to their patient, and the medical staff reported that they had no trouble explaining the role of the technology and responding to any questions or concerns that patients or caretakers harbored. Through user surveys and caretaker interviews, we concluded that the unusual placement of neoGuard on the forehead of the patient would be acceptable.

Finally, innovators must consider if the evidence they are generating will satisfy the requirements of their target audience. For instance, while local stakeholders might appreciate results from a familiar clinical setting within the target market, regulators will more often be inclined to accept performance findings from studies conducted in a more controlled lab setting or by an accredited third party with the ability to test your device against acceptable standards. As discussed previously, access to the acceptable standards maybe more limited in low-resource environments.

Lack of Emphasis on Human Factors and Usability Engineering

Focusing heavily on the performance aspects of the technology without considering how human factors can lead to user errors and how this might impact the safety and effectiveness of the product can yield unfavorable results. At Neopenda, we believe strongly in the theory of human-centered design, and we leverage VOC and HFUE data to drive design decisions. This is more important than ever for products intended for low-resource environments; sustainability of the design is essential, and the product must be long-lasting and easy to implement and use. When conducting VOC research, it is necessary to capture perspectives from all categories of users. For instance, for a phone-based application, the ability to correctly use the technology will be influence by factors such as age, smart-phone ownership, and/or experience and computer literacy. These factors will vary not only from person to person but from location to location. If a technology *s* intended to be implemented broadly in rural and urban facilities alike, then the VOC and HFUE data should be collected from all relevant settings.

Elements of VOC and HFUE are often conducted early on in the product development lifecycle. As a result, they are poorly documented and loosely structured. It is crucial to create some sort of guiding framework for your VOC and HFUE, however, flexible and imperfect it might be. For instance, if user testing in a real setting is not immediately practical, then consider how you might best simulate a testing environment or script hypothetical scenarios for users to respond to. To best understand what challenges or barriers users may encounter in using your technology, you want to recreate the same user experience as closely as possible to measure any recurrent errors. In a sense, your goal is to approach the user testing like a controlled experiment, leaving room for variability only at the user level. On the subject of documentation, innovators should record these early efforts in real-time and incorporate them in a Design History File (DHF). A DHF should systematically encapsulate every critical design change and all relevant feedback or data that helped inform that change. Tracing this pathway to the final product is important not only from a regulatory perspective, but also to remind the innovator of why certain design choices were made in case future product changes threaten to impact them. For Neopenda, our approach to VOC and HFUE was not clearly defined when we started; in fact, it took months of retrospective analysis and piecing together various sources of data gathered over the course of 3 years to map out how human factors had been accounted for in relevant design features.

Inadequate Stakeholder Engagement

Engagement with key stakeholders is required throughout the medical device life cycle. Failing to adequately consult the full breadth of potential stakeholders may have negative effects such as costing the innovator additional time and finances if any important early processes are skipped. Buy-in from various stakeholders—users, ministries of health, international non-governmental organizations, implementation partners, and hospital administrators, amongst many others—is essential to

success. Getting buy-in can be challenging particularly at the early stages of development, and building relationships takes time. Even once a stakeholder or partner is engaged, management of the partner and regular communication is key to sustaining their interest and support. Setting clear expectations of goals, responsibilities, timelines, and financial responsibilities is essential for continued engagement. While synergizing efforts between stakeholders can yield more efficient and effective results, managing stakeholders can become a time-consuming and challenging task if expectations are not set in advance and maintained throughout the relationship by both parties. Cultural differences will also influence how well stakeholders respond to your medical product and how your motivations are perceived. Foreign innovators coming into low-resource settings with only minimal experience in the subject they are addressing are likely to be met with far greater skepticism than innovators who have a solid foundation working in their target communities. This is why innovation hubs cropping from familiar entities like non-profits or academia appear to have a more positive experience implementing new products or strategies in LMICs than traditional startups operating on their own. To add to that, however well-meaning an innovator's intentions may be, it is difficult for stakeholders to ignore the commercial incentive behind an enterprise. In this regard, non-profit and academic actors tend to wield more power and influence in the innovation space in LMICs because they are generally perceived to be more altruistic than traditional startups. This is another reason why individual innovators should consider collaborating or having their products independently evaluated by reputable non-profit or academic partners. Working with stakeholders who have no commercial conflicts and are able to speak independently regarding the performance of a product will give stronger credibility to an innovator's claims.

Unreliable Pre-market and Post-market Revenue Streams

Taking a medical device from idea to commercialization is an arduous and iterative process that requires significant upfront capital. Innovators may elect to receive funding through non-dilutive capital (e.g., grants or competitions) and/or dilutive capital (e.g., through accelerators or investors), and the type of capital received is likely to evolve as the company matures. Planning and budgeting for the full life cycle of a medical device is a challenging but important task; many innovators fail to receive enough funding to get through the life cycle. Unlike many software or service provider startups, medical device development requires significant upfront capital. The capital is required to fund R&D efforts such as prototyping, field testing, clinical validation, scale-up to manufacturing (e.g., tooling costs to produce the device at scale), general operating expenses such as salary, rent, and legal fees, and regulatory and quality activities. Early-stage medical device innovators are often perceived as a high-risk investment due to the length of time it takes to get a medical device to market, and the upfront capital required before generating revenue. Defining a roadmap and associated budget can demonstrate an innovator's expertise in medical device development. Execution of the roadmap with acceptable pivots but within the planned budget will de-risk the company as innovators progress with their roadmap.

Beyond the initial financing for product development, innovators should have a clear understanding of the business environment(s) they are entering into and how long it may take before they are able to generate a steady stream of revenue. Evidence that there is a need for a product does not guarantee that the market will readily take up the product once it is available. In pursuing new leads, innovators should be conscious not to overestimate their market size as well as their customer's willingness and ability to pay. To establish some initial brand recognition and help kick-start market penetration for your technology, it is worthwhile to approach potential consumers or customer segments early on in the product development process to understand not only how they respond to your product, but how they evaluate and make purchasing decisions. In the buildup to the launch of the neoGuard product, Neopenda completed more than 80 hospital visits, and engaged with numerous implementing partners, health officials and health distributors across East Africa as part of our customer acquisition plan. It is important to remember that the end-users of a medical product and the buyers are usually two different entities. An effective marketing strategy should present a complete value proposition to appeal to both parties.

CONCLUSION

While many medical device innovators aspire to transition their concepts through regulatory approval and mass production to widespread adoption, very few are able to make it across that finish line. The journey is fraught with setbacks and challenges that unfortunately leave many promising ideas sidelined or abandoned.

Through our own experience developing the neoGuard product, we have learnt that the process takes an exceptional amount of effort, agility, resilience, patience, funding, and overall–teamwork. The myriad of problems that innovators face can be successfully managed or even avoided through interdisciplinary collaboration. To increase the likelihood that a solution will be actualized, innovators should surround themselves with engineering, clinical, manufacturing, regulatory, and marketing expertise at an early stage of their product lifecycle.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Makerere University School of Public Health Higher Degrees Research Ethics Committee and the Tufts Medical Center Institutional Review Board. Written informed consent to

participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

AN and SS discussed the lessons learned. TC, MT, and RK wrote content for the background on product development, early testing, and clinical validations studies. BA and NK contributed to the introduction and clinical components of the paper. All authors contributed to the final manuscript.

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The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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GLOSSARY

CE mark
An administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

Class IIb medical device
A category for medical devices with medium-to-high risk, such as incubators, long-term corrective contact lenses, surgical lasers, vital sign equipment, and defibrillators.

Design Controls
Interrelated practices and procedures that are incorporated into the product design and development process, i.e., a system of checks and balances. Design Controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use. For medical devices, the rigor of the Design Controls is prescribed by ISO 13485.

Design Freeze
The point in the design and development process at which the product is considered "done" and the baseline design is completed. Under ISO 13485-guided medical device development, changes to the design after the Design Freeze point are subject to engineering change control requirements such as traceability, impact analysis, risk assessment, verification, and validation.

Design History File (DHF)
A compilation of documentation that describes the design history of a finished medical device.

Declaration of Conformity
It is a formal declaration by a manufacturer, or the manufacturer's representative, that the product to which it applies meets all relevant requirements of all product safety directives applicable to that product.

Human Factors Usability Engineering (HFUE)
The application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability of the end product.

Technical File
A set of documents that describes a product and can prove that the product was designed according to the requirements of a quality management system.

Voice-of-Customer (VOC)
Customer's feedback about their experiences with and expectations of a product.

frontiers in Digital Health

METHODS
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Remote Patient Monitoring Program for COVID-19 Patients Following Hospital Discharge: A Cross-Sectional Study

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Background: The COVID-19 pandemic created an urgent need to act to reduce the spread of the virus and alleviate congestion from healthcare services, protect healthcare providers, and help them maintain satisfactory quality and safety of care. Remote COVID-19 monitoring platforms emerged as potential solutions.

Objective: The purpose of this study was to evaluate the capacity and contribution of two different platforms used to remotely monitor patients with COVID-19 to maintain quality, safety, and patient engagement in care, as well as their acceptability, usefulness, and user-friendliness from the user's perspective. The first platform is focused on telecare phone calls (Telecare-Covid), and the second is a telemonitoring app (CareSimple-Covid).

Methods: We performed a cross-sectional study. The data were collected through a phone survey from May to August 2020. Data were analyzed using descriptive statistics and *t*-test analysis. Participants' responses and comments on open-ended questions were analyzed using content analysis to identify certain issues and challenges and potential avenues for improving the platforms.

Results: Fifty one patients participated in the study. Eighteen participants used the CareSimple-Covid platform and 33 participants used the Telecare-Covid platform. Overall, the satisfaction rate for quality and safety of care for the two platforms was 80%. Over 88% of the users on each platform considered the platforms' services to be engaging, useful, user-friendly, and appropriate to their needs. The survey identified a few significant differences in users' perceptions of each platform: empathy toward users and the quality and safety of the care received were rated significantly higher on the CareSimple-Covid platform than on the Telecare-Covid platform. Users appreciated four aspects of these telehealth approaches: (1) the ease of access to services and

the availability of care team members; (2) the user-friendliness of the platforms; (3) the continuity of care provided, and (4) the wide range of services delivered. Users identified some technical limitations and raised certain issues, such as the importance of maintaining human contact, data security, and confidentiality. Improvement suggestions include promoting access to connected devices; enhancing communications between institutions, healthcare users, and the public on confidentiality and personal data protection standards; and integrating a participatory approach to telehealth platform development and deployment efforts.

Conclusion: This study provides preliminary evidence that the two remote monitoring platforms are well-received by users, with very few significant differences between them concerning users' experiences and views. This type of program could be considered for use in a post-pandemic era and for other post-hospitalization clienteles. To maximize efficiency, the areas for improvement and the issues identified should be addressed with a patient-centered approach.

Keywords: COVID-19, remote patient monitoring, telehealth, telemonitoring, user experience, evaluation

INTRODUCTION

Background

The coronavirus disease (COVID-19) pandemic has had many tragic effects and has been seriously testing the crisis response capacity of health systems around the world (1, 2)[1,2]. On March 11, 2020, the World Health Organization (WHO) declared the novel coronavirus outbreak a global pandemic (1). With the absence of effective vaccines and therapies to treat SARS-CoV-2 infections, lockdowns, physical distancing, and quarantine measures were adopted and generalized to minimize the impact and slow the spread of the disease as vaccines were being developed and approved and were proven effective by the end of 2020 (1, 2)[1,2].

However, these measures have had negative impacts on healthcare users (1–3)[1], including difficulties accessing care, isolation, anxiety, and depression, that have affected patients, their loved ones, and healthcare professionals, and had negative impacts on health outcomes and the quality of care provided (1–3). To counter these effects and maintain a high quality of care, health systems innovated and developed new models of care and intelligent remote patient monitoring (RPM) strategies that employ telehealth platforms (4–11)[1]. As early as the spring of 2020, various interventions using connected platforms were rapidly developed to deal with the virus. Several studies have presented telehealth platforms such as mobile health apps and several telemonitoring connected devices and telecare programs as promising solutions and reliable technological tools (4–11). It has been suggested that with their telemonitoring/telecare capacities and remote monitoring capabilities, telehealth platforms can provide patients with practical and timely access to care (4–11). Telehealth offers asynchronous communication, collecting and tracking data but also obtaining real-time clinical feedback that is well-suited to the remote patient monitoring process (4–12). Moreover, health technology experts and healthcare leaders have suggested that telehealth and RPM platforms can help facilitate continuity of care and provide considerable support for the organization and administration of care services during the current pandemic (4–12).

In this context, the Centre of Network Flow Optimization (CNFO) at the Hospital Center of the Université de Montrèal (CHUM), a major public University hospital in Canada, has developed and adapted two technological platforms to remotely monitor patients with COVID-19 following a hospital visit or discharge[3,4].

The first platform in this program is the TELECARE calls platform, which we will call Telecare-Covid in this paper. The second platform is a telemonitoring app called the CARESIMPLE Platform, which we will call CareSimple-Covid. Depending on their wishes and preferences, patients with COVID-19 have a choice when they are discharged: to be remotely monitored through the services of either the Telecare-Covid calls platform or the CareSimple-Covid app program. Patients can also choose to use both if they wish. The Telecare-Covid platform is a clinical follow-up incoming calls system with phone lines available 24/7 and dedicated to receiving calls from COVID-19 patients. Patients can discuss their clinical symptoms directly with a nurse, who will process and assess the clinical

Abbreviations: CHUM, Université de Montréal Hospital Center; CRCHUM, Université de Montréal Hospital Research Center; CNFO, Center of Network Flow Optimization; RPM, Remote Patient Monitoring; WHO, World Health Organisation.

[1] Available online at: https://www.inspq.qc.ca/covid-19/donnees (accessed October 25, 2021).

[2] Available online at: https://msss.gouv.qc.ca/professionnels/maladies-infectieuses/coronavirus-2019-ncov/ (accessed October 25, 2021).

[3] Available online at: https://www.chumontreal.qc.ca/crchum/nouvelles/le-programme-techno-covid-partenariat-un-programme-de-recherche-en-soutien-aux (accessed October 25, 2021).

[4] Available online at: https://CareSimplehealth.com/ (accessed October 25, 2021).

information. The CareSimple-Covid platform is a telemonitoring app downloadable on Android and iOS smartphone and tablet systems. Over the CareSimple-Covid platform, patients can enter and submit data on their symptoms and clinical information twice daily. The symptoms are then gathered, processed, and assessed automatically by the system. If the system detects a deterioration in the patient's health, a nurse will be notified directly, call the patient to check their symptoms, and further evaluate the situation with a physician and members of the care team. For both platforms, if the situation requires an urgent intervention, a transfer to the hospital will be offered by the call center staff. The staff is dedicated to the platform and consists of nurses, residents, and physicians accessible by phone and working 24/7[3,4]. Before referring patients to the remote monitoring platforms, selection criteria are considered, including the health status of patients and the progress of their COVID-19 disease, their ability and motivation to use the platforms, and their preferences. Based on these criteria, CNFO nurses managing the remote monitoring program will identify potential users among the COVID-19 patients discharged from the hospital. Then a CNFO nurse will present and explain to the patient how the two platforms work, and if a patient expresses an interest in using one of the platforms, the care team provides the necessary tools and information on how to use it. A technical support team available 5 days per week has been also included in the program to help resolve any technical or IT issues on either platform.

Although the two remote monitoring platforms operate in different ways, they were developed and adapted to achieve the same goals of providing (1) a safer return home for patients who are medically stabilized but at risk of decompensation by guaranteeing regular clinical follow-up and continuous remote monitoring for 14 days; (2) emotional support to reduce isolation and anxiety in patients by connecting them to clinical teams; (3) a medical safety net to reduce the risk of SARS-CoV-2 infections within care services; (4) improved workflows and reduced congestion in care services, which have been exacerbated by the pandemic, through better control of unnecessary visits to care services and facilities; and (5) eventually, continued good quality and safety of care.

Objectives

The objectives of this study are to (1) evaluate the user-friendliness of Telecare-Covid and CareSimple-Covid and through patient self-report how, they can provide quality, safe, and engaging care to patients; (2) identify factors that lead patients to choose one platform over another; (3) explore patients' perceptions of the added value provided by the platforms; and (4) identify any required improvements in how the platforms are used, from the patient's perspective.

METHODS

Study Design

A cross-sectional study was conducted using a survey of COVID-19 patients who were remotely monitored on the two platforms (13–18). This study received ethical approval from the Research Ethics Committee of the Université de Montréal Hospital Research Center (CRCHUM) (CER-CHUM: 20.040).

To achieve the study's objectives, we used three validated questionnaires that we adapted to the COVID-19 context to evaluated patients' perceptions on the following dimensions (19–21):

1) Quality and safety of care (access, safety, relevance, timeliness, etc.) (19);
2) Patient engagement and partnership (participation, collaboration, trust, empathy, recognition, relationship with the care team, etc.) (20);
3) The utilization capacity of the telehealth platforms (user-friendliness, usefulness, problems encountered, etc.) (21); and
4) The sociodemographic characteristics of the COVID-19 patients who used the two platforms (20).

A validated questionnaire of 20 questions grouped in 5 sections, including questions rated on a 5-point Likert scale (1—strongly disagree to 5—strongly agree), multiple-choice questions, and a general comments section, was administrated to the participants (**Table 1**). In the general comments section, participants were asked to share their thoughts on their experience with the platform. The general comments helped us identify what participants did and did not appreciate when using the platform. This also allowed us to identify some important issues and factors that lead patients to choose one platform over the other. Participants provided suggestions for improving the platforms and improving user experience in the general comments section.

Note, that the adaptation brought to the questionnaire is regarding two elements. The first one is linking the questions to the covid 19 contexts. The original questionnaire suggests when administrating the items to start the question by linking it to the disease or the clinical problem that motivates the patient to use the technological platform. e.g., In the context of the Covid-19 health crisis, "The platform care simple/telecare responded well to my needs or patient's needs?" also we added an open question in the last section of the questionnaire for general comments.

The second is on the demographic information. In fact, the demographic information collected through our question has been limited to age gender, and household composition, and geographical region. Although we wanted to collect the socioeconomic status, education, ethnic background as it was done in the original questionnaire, from our experience during the testing phase for the acceptability of the survey prior to the official questionnaire administration, we learned that 80% of respondents left the space blank when it came to those demographic questions and that is why we decided to not include them in the demographics section.

Recruitment

The selection criteria used to recruit the participants were: all patients infected with SARS-COV2 registered on the CNFO remote monitoring program who used at least one of the two platforms for 14 days following a hospital discharge from April to June 2020.

Data Collection

The data were collected remotely from May to August 2020. Data were collected by a team of three trained on good clinical research practices and on conducting interviews and administrating questionnaires. The data collection team included one Ph.D. Candidate and two students in the second year of a medical program (MD). After they have given their consent, participants were invited to complete the questionnaire through a scheduled phone call with the data collection members of the research team. Then the data collected were entered and recorded in CRCHUM's secure "REDCap©" computer system[5], which was designed specifically for surveys and quantitative data collection and processing.

TABLE 1 | Dimensions and elements examined with the questionnaire.

Section/dimension	Questionnaire items/attributes
Demographic characteristics of users (20)	Gender[a]
	Age[a]
	Geographic area[a]
	Living situation (living alone or with another person)[a]
Perceptions of the quality and safety of care (19)	Availability and access to a member of the care team at all times[b]
	Pertinence and frequency of the care received [b]
	Consideration of the psychological impacts of the care received from the care team[b]
	Support and consideration provided to the patient by the care team[b]
	Satisfaction with the quality and safety of the care received through the platform[b]
Perceptions of patient engagement in care and the relationship with the care team (20)	Information received on health status and care[b]
	Information given and communicated to healthcare teams on health status[b]
	Engagement in care and partnership with the care team[b]
	Patient participation in the decision making related to care[b]
	Decision making according to the patient's needs and preferences[b]
	Bond of trust with the health care team[b]
	Importance of the information received and shared between the care team and the patient[b]
	Empathy expressed between the patient and the healthcare team[b]
	Recognition of the patient's experience with the disease by the healthcare team[b]
Perceptions of utilization capacity (usefulness, user-friendliness, problems) (21)	Services offered by the platform are useful and meet the needs of users[b]
	User-friendliness and problems encountered while using the platform[a]
General comments (optional)	Additional comments and suggestions on the general utilization experience (improvements, issues, concerns, etc.)[c]

[a] *Multiple choice question.*
[b] *Likert scale question: (1-strongly disagree to 5-strongly agree).*
[c] *Open question (Additional Comment).*

Data Analysis

We used a quantitative design approach for the study, with only general comments being processed from a qualitative perspective (15). Data analysis was performed concurrently with data collection to allow for an iterative approach (15, 18).

We conducted a descriptive and *t*-test statistical analysis of the data collected using SPSS (Statistical Package for the Social Sciences) information processing software (13–18). We used descriptive statistics to describe, in a summative and complete way, the data on the four evaluated dimensions and to identify positive or negative trends in the results (13–18). Through this analysis, we arrived at a description of some central trends (mean, median, standard deviation) in participants' views. To identify significant differences in their views on the user experience with the two platforms, we performed a *t*-test analysis. The general comments collected in the last section of the questionnaire were transcribed verbatim and analyzed through content analysis using QDA Miner qualitative data analysis software (15, 17, 18).

The data analysis was performed and reviewed by all members of the research team to ensure a high level of validity using an inter-researcher triangulation strategy (13–18). Interim reports and presentations were also communicated to the patients, participants, and actors involved in the platform's development, deployment, and use (patients, clinicians, managers, volunteers, etc.). These exchanges helped strengthen the validity of the analysis to help us compare our interpretations with those of the participants.

RESULTS

Table 2 presents the number of participants and participation rates in the study.

A total of 85 patients with COVID-19 diagnosed or hospitalized at CHUM from April to June 2020 agreed to register and use the remote monitoring program proposed by CNFO upon discharge from the hospital or after a hospital visit. Sixty-five patients (76%) used the Telecare-Covid platform and 20 patients (24%) used the CareSimple-Covid platform.

In total, 51 patients (participation rate of 60%) participated in the study: 18 participants used the telemonitoring app CareSimple-Covid (participation rate of 90%), and 33 participants used the Telecare-Covid platform (participation rate of 53%) (see **Table 2**).

Demographics

The average age of the participants was 52 years (standard deviation, SD = 13.5) and varied from 24 to 90 years old. Twenty-eight participants were female (55%) and 23 were male (45%). The majority of the users live in Montreal (76%) with at least one

[5] Available online at: https://redcap.chumontreal.qc.ca/redcap/ (accessed October 25, 2021).

TABLE 2 | Number of users, rate of use, and participation.

	Platform users			Survey participants		
	Total	**Telecare-Covid**	**CareSimple-Covid**	**Total**	**Telecare-Covid**	**CareSimple-Covid**
Number (*n*)	85	65	20	51	33	18
Rate (%)	100	76	24	60	53	90

TABLE 3 | Users' demographics.

Characteristics	**Total**	**CareSimple-Covid**	**Telecare-Covid**	***P*-value**
Patient gender *n* (%)	*N* = 51 (%)	*N* = 18 (%)	*N* = 33 (%)	
Female	28 (55)	9 (50)	19 (56)	a
Male	23 (45)	9 (50)	14 (44)	a
Age groups *n* (%)	*N* = 51 (%)	*N* = 18 (%)	*N* = 33 (%)	
20–39	10 (20)	4 (22)	6 (18)	a
40–59	28 (55)	8 (44)	20 (61)	a
60 or +	13 (25)	6 (33)	7 (21)	a
Mean	52	52	52	–
Median	52	56	50	–
Minimum	24	35	24	–
Maximum	90	65	90	–
SD	13.5	10.9	15.4	–
What region do you live in *n* (%)	*N* = 51 (%)	*N* = 18 (%)	*N* = 33 (%)	
Montreal	39 (76)	13 (72)	27 (89)	a
Lanaudière	6 (13)	4 (22)	2 (4)	a
Laval	3 (6)	1 (6)	2 (4)	a
Montérégie	2 (4)	0 (0)	2 (4)	–
Composition of your household *n* (%)	*N* = 51 (%)	*N* = 18 (%)	*N* = 33 (%)	
I live alone	14 (27)	4 (22)	10 (30)	a
I live with someone	37 (72)	14 (77)	23 (70)	a

a, Non-signifiant p-values.

other person (73%) (see **Table 3**). Comparing the demographic characteristics of the users of the two platforms, even though there is a numerical difference, no statically significant difference was found based on the *t*-test (p-value < 0.05) for independent samples. We found no significant differences in the distributions of users' demographic characteristics between the two platforms (confidence level of 95%). Thus, the sample of those who participated in the study (51 patients) is demographically representative of the larger group of patients who used the platforms (85 patients) (**Table 3**).

Perceptions of the Quality and Safety of Care

More than 80% of the participants completely agreed that they were very satisfied with the quality and safety of the care provided on the two platforms (**Figure 1**). Overall, participants were satisfied with the quality and safety of the care received through both platforms (mean, $M = 4.65/5$, standard deviation, SD = 0.78). The majority of participants agreed that: they received care promptly on both platforms ($M = 4$; 60/5, SD = 1.00); they had access to a member of the care team at all times ($M = 4.26/5$; SD = 1.17); and medical staff was available to help them deal with their health status ($M = 4.77/5$; SD = 0.72). They also reported, for both platforms, that the care team considered the impact of the provided treatments and services on their psychological state ($M = 4.32/5$, SD = 1.23) (see **Table 4**).

Besides the overall response rate, when comparing the participants' mean responses for each platform, the *t*-test for independent samples (p-value < 0.05) found statistically significant differences. For two items, "Overall I am satisfied with the quality and safety of the care I received" and "I feel like I received care at the right time," the mean responses were significantly higher for the CareSimple-Covid platform than for the Telecare-Covid platform (**Table 4**).

Perceptions of Engagement in Care and the Relationship With the Medical Team

Engagement in care and the relationship with the medical team were also very well-rated by the participants (**Figure 2**). "I gave important information about my condition or my care to the

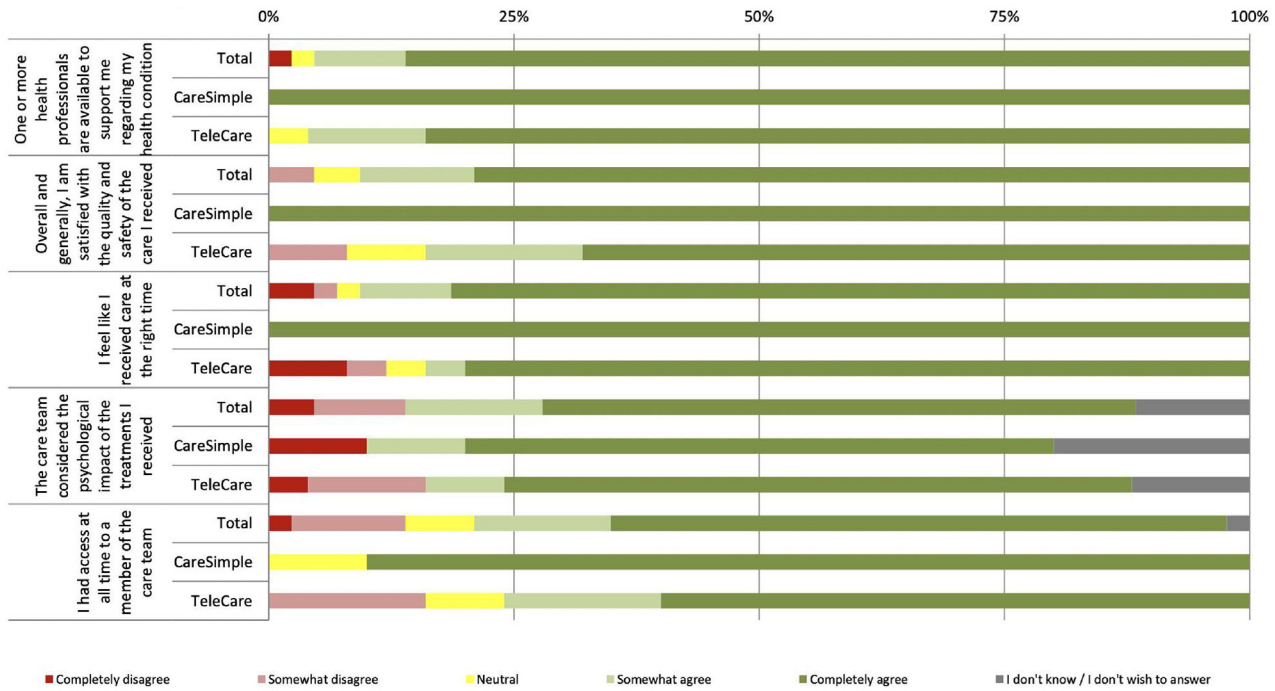

FIGURE 1 | Perception of the quality and safety of care.

TABLE 4 | Mean and SD relative to perceptions of quality and safety of care (overall and for each platform separately).

Attributes	Total		CareSimple-Covid		Telecare-Covid		*p*-value
	Mean	SD	Mean	SD	Mean	SD	
One or more health professionals are available to support me regarding my health status	4.8	0.7	5	0	4.8	0.5	a
Overall and generally, I am satisfied with the quality and safety of the care I received	4.7	0.8	5	0	4.4	1.0	0.0*
I feel like I received care at the right time	4.6	1.0	5	0	4.4	1.3	0.0*
The care team considered the psychological impact of the treatments I received	4.3	1.2	4.7	1.4	4.5	1.3	a
I had access at all times to a member of the care team	4.3	1.2	4.8	0.6	4.2	1.2	a

a, Non-significant p-values.
**Statistically significant difference ($p < 0.05$).*

care team" is the attribute that received the highest rating, at 84%, and with no participant disagreeing (**Figure 2**). Overall, participants reported feeling confident in the care team on both of the platforms ($M = 4.67/5$, SD $= 0.75$) and participated in the decision making related to their care ($M = 4.29/5$, SD $= 1.09$). They believe that through the two platforms, they were able to share important information on their health status ($M = 4.85/5$, ET $= 0.42$) and they also received important information on their health status and the treatments provided ($M = 4.24/5$, SD $= 1.14$). Concerning the rest of the attributes of this dimension, they all had a mean >4.24 and standard deviation of 0.90–1.02 (**Table 5**).

When comparing the participants' mean responses for each platform, only one attribute showed statistically significant differences based on the *t*-test for independent samples (*p*-value < 0.05). The mean response for the attribute "The care team showed empathy toward me" was significantly higher for the CareSimple-Covid platform than for the Telecare-Covid platform (**Table 5**).

Perception of the Usefulness and User-Friendliness of the Platform

Overall, the evaluation of this dimension shows that 91% of participants who used the Telecare-Covid platform and 89% of those who used the CareSimple-Covid platform felt that the services they offer are useful and responded to their needs (see **Figure 3**). Moreover, 87% of the users of the Telecare-Covid platform said that no problem was encountered while using

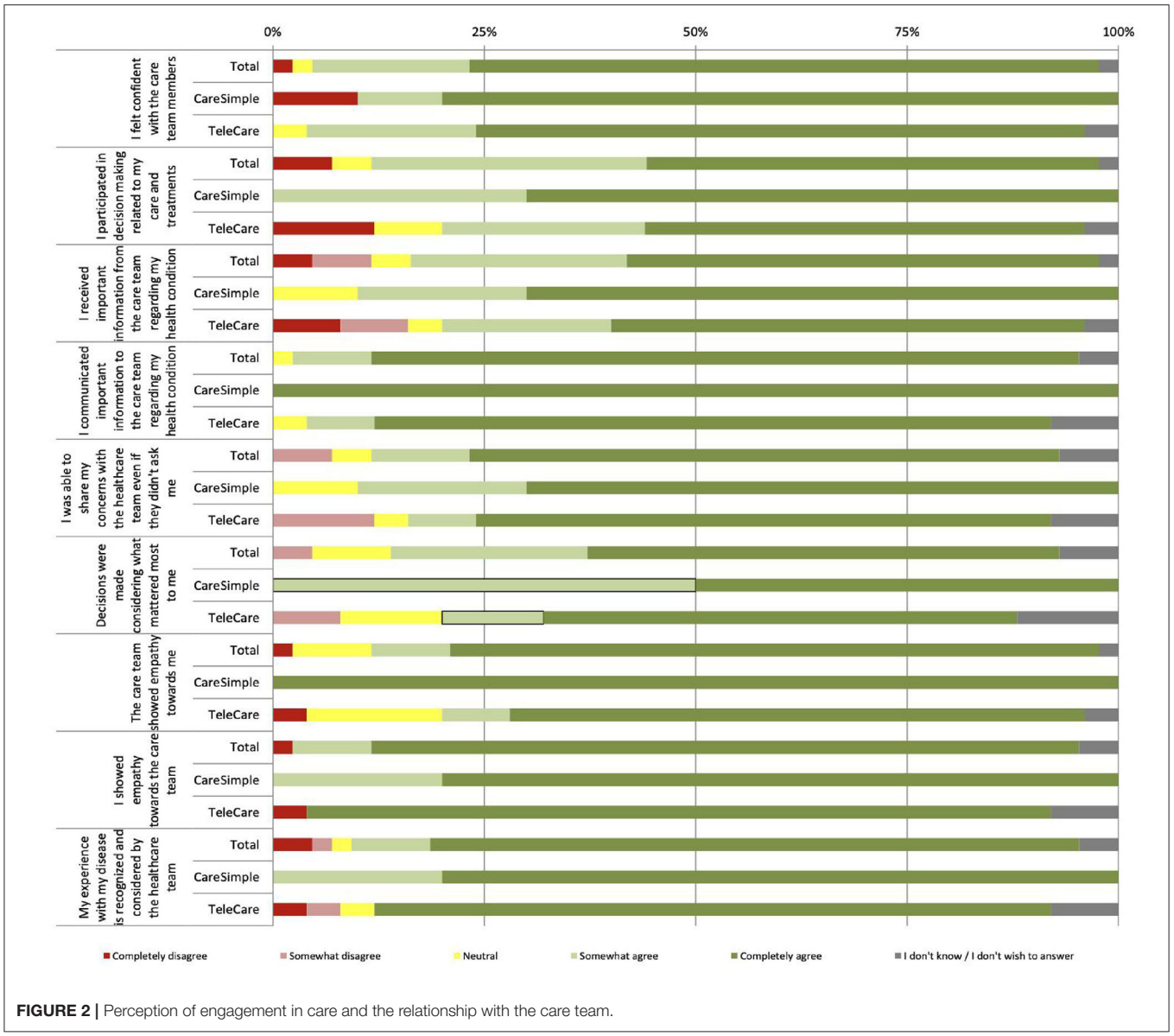

FIGURE 2 | Perception of engagement in care and the relationship with the care team.

it, while this was reported by only 61% of the participants who used the CareSimple-Covid platform. The main problems encountered include difficulties using the technology and a lack of training (17%), fears over confidentiality (11%), and difficulties accessing the connected devices (smartphones or tablets, etc.) (6%) (see **Figure 4**).

Besides the overall response rate, we did not identify any statistically significant differences through the *t*-test on independent samples (p-value < 0.05) when comparing the type of problems encountered on each platform (**Table 6**).

Results From the General Comments

Forty-three participants completed the general comments section (the optional section) of the survey. Of this group, 15 used the CareSimple-Covid platform and 27 used the Telecare-Covid platform. An analysis of the content of the comments allowed us to identify what the patients liked about using these platforms, what needs improvement, and what were their concerns or issues.

What Was Appreciated?

For both the CareSimple-Covid platform and the Telecare-Covid platform, we identified four main features that were highly appreciated by the majority of participants. First, they liked the ease of access to services in general but, more specifically, the accessibility and availability of the care team. Second, they appreciated the continuity of care and clinical monitoring from the hospital to the home. According to some participants, having the changes in their health status monitored as a continuous process, even if this was done remotely, helped them better manage their concerns about any deterioration in their health once they had returned home. Third, they appreciated the practicality and user-friendliness of the two platforms; in

TABLE 5 | Mean and SD of patient perceptions of engagement in care and the medical team (overall and specific to each platform).

Attributes	Total		CareSimple-Covid		Telecare-Covid		*p*-value
	Mean	SD	Mean	SD	Mean	SD	
I felt confident with the care team members	4.7	0.8	4.5	1.3	4.8	0.6	a
I participated in decision making related to my care and treatments	4.3	1.1	4.7	0.5	4.2	1.4	a
I received important information from the care team regarding my health status	4.2	1.1	4.6	0.7	4.2	1.4	a
I communicated important information to the care team regarding my health status	4.9	0.4	5	0	4.9	0.6	a
I was able to share my concerns with the healthcare team even if they didn't ask me	4.6	0.9	4.6	0.7	4.6	1.1	a
Decisions were made considering what mattered most to me	4.4	0.9	4.5	0.5	4.5	1.1	a
The care team showed empathy toward me	4.6	0.9	5	0	4.5	1.1	0.0*
I showed empathy toward the care team	4.8	0.7	4.8	0.8	4.9	0.9	a
My experience with my disease is recognized and considered by the healthcare team	4.6	1.0	4.8	0.4	4.7	1.1	a

*a, Non-significant p- values. *Statistically significant difference ($p < 0.05$).*

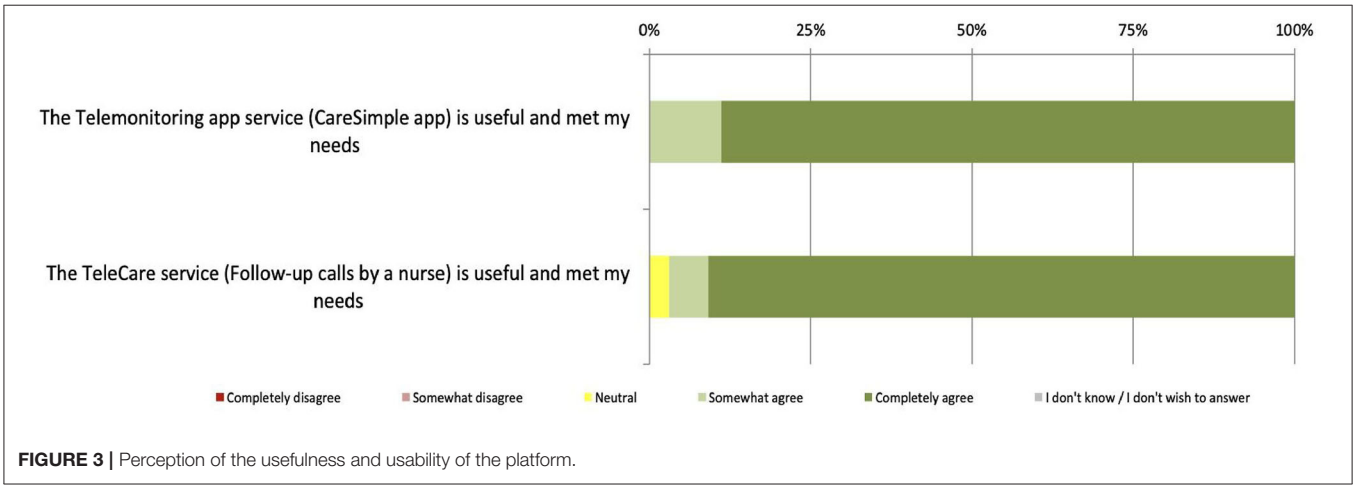

FIGURE 3 | Perception of the usefulness and usability of the platform.

particular, participants noted the dynamism of the CareSimple-Covid platform. Fourth, they liked the diverse range of services offered on the two platforms. Some participants, and especially those who live alone, reported that the psychological help received through the remote monitoring platforms reassured them and helped reduce feelings of isolation and anxiety due to the collateral effects of the quarantine. For example, the participants who used CareSimple-Covid felt that being monitored in this way has a favorable psychological impact because a CNFO nurse would assess and reassure the patient if the patient showed psychological distress through the platform.

What Needs Improvement?

Although the feedback and comments were generally positive, some participants nevertheless identified areas in which actions should be taken, knowing that these are roughly the same areas presented above in **Figure 4**. A small number of participants who used the CareSimple-Covid platform emphasized their difficulties accessing or owning connected devices (smartphones, tablets, etc.) and a lack of training in their use. Individuals with chronic health problems and/or a particular medical history spoke of wanting platform services that would be better suited to their realities and clinical profiles. Lastly, some participants requested faster and more responsive services in terms of their communications and correspondence and the remote interaction process with the care team over both platforms.

What Issues Were Raised?

The general comments and feedback also allowed us to identify certain issues with the two platforms. Participants mentioned

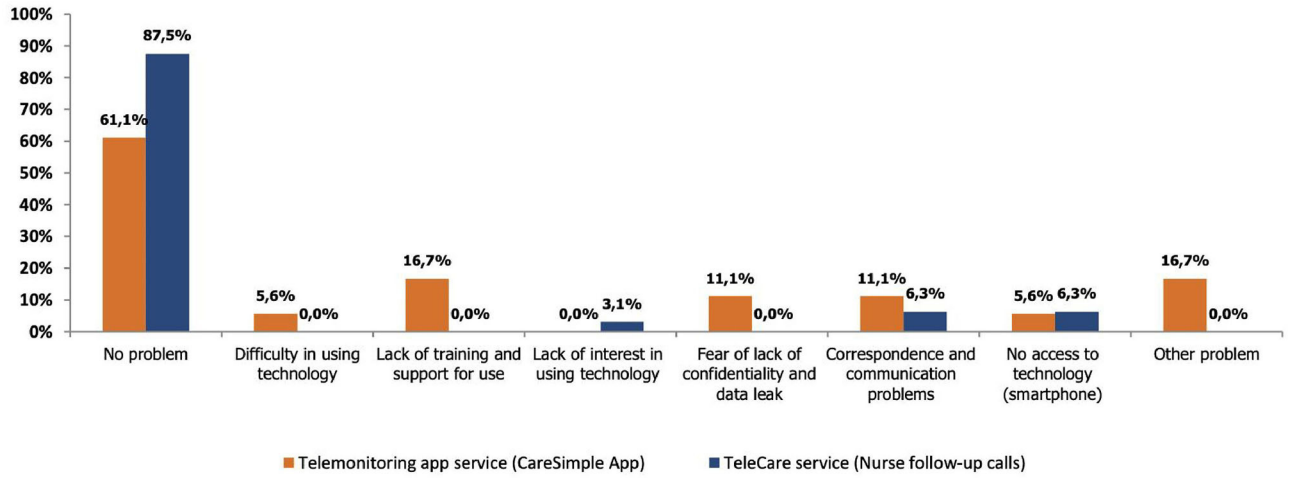

FIGURE 4 | Types of problems encountered using the platform.

TABLE 6 | *T*-test results and comparison of the types of problems encountered in using the two platforms (no significant statistical difference found).

Problem type	*p*-value
No problem	a
Difficulty in using technology	–
Lack of training and support for use	–
Lack of interest in using technology	–
Fear of lack of confidentiality and data leak	–
Correspondence and communication problems	a
No access to technology (smartphone)	a
Other problem	–

a, Non-significant p-values.
(-) means no comparison was possible (i.e., this category is not used in the comparisons because the proportion is equal to zero).

their concerns over maintaining human contact in care while stressing the importance of the warmth, connection, and interpersonal engagement between patients and care providers. In addition, data security and confidentiality seemed to be another concern for the participants. Some said that they feared a breach of confidentiality in the care relationship and required more clarity and guarantees regarding their data that is transmitted and shared on virtual platforms so that they could feel completely secure.

The following table presents some participants' quotes for each domain identified above (See **Table 7**).

DISCUSSION

Principal Results

In the era of COVID-19, hospitals have become testing grounds for innovation on how to reconnect COVID-19 patients with care teams, while improving patient flow and minimizing healthcare providers' exposure in a serious pandemic and difficult work conditions. We chose a survey approach to study the contribution that can be made by two different platforms designed and adapted for the remote monitoring of patients with COVID-19. From the point of view of the patients, we evaluated the user experience in various aspects on both platforms. Overall, the findings were encouraging, and the dimensions evaluated have demonstrated remarkable levels of appreciation for both platforms. The questionnaire results suggest that, in general, users' perceptions of the quality and safety of care offered on the two remote monitoring platforms were very positive. Therefore, we assume that both platforms have helped maintain a satisfactory level of quality and safety of care provided remotely. Similarly, users' perceptions of their relationship with the care team and their engagement in their care, despite its being offered remotely, were still favorable. Moreover, the majority of the participants on the two platforms affirmed that the remote monitoring services met their needs and indicated that they did not encounter any problems during use, which demonstrates the usefulness and user-friendliness of both platforms. However, one should also note that the survey identified a couple of significant differences in users' perceptions of certain aspects of each platform where empathy toward users and the quality and safety of the care received were significantly higher on the CareSimple-Covid platform than on the Telecare-Covid platform. We assume that this difference is because the CareSimple-Covid platform is a phone and tablet app that can be more interactive where the access and communication with the care team would be quicker and more dynamic than the Telecare-Covid platform that uses an incoming calls system.

The general comments we received corroborate these conclusions, and they have allowed us to identify and better understand the most valued and appreciated aspects of both platforms. The fact that the majority of participants appreciated the ease of access and the proximity of care teams, the continuity of care, the features' user-friendliness, and the many

TABLE 7 | Examples of comments related to specific areas of interest for patients.

		Comments
Areas that were appreciated	1	"I had quick access to the nurse through the telecare service". P17[a] "The follow-up services over the app were easily accessible and I felt very close to the medical team". P21[b]
	2	"It's wonderful, the continuity of services, even after hospitalization". P11 [a] "On the CareSimple-Covid app we have the impression of having a doctor or nurse by our side constantly and continuously, which reassured me a lot". P23 [b]
	3	"I found the nurse follow-up calls (on the telecare platform) very easy to use." P34 [a] "The concept of the CareSimple-Covid platform is great and the app is very easy to use." P43 [b]
	4	"The telecare services were fantastic. It was really beyond my expectations, and I had access to several services including psychological follow-up. I even had access to a psychiatrist through this platform." P10 [a] "On the CareSimple-Covid I had access to a whole team, a nurse, neurologist, and even psychiatric services". P38[b]
Areas for improvement	1	"The CareSimple-Covid app was on my daughter's phone. I had a lot of trouble using the service, especially since I don't have a smartphone and I wasn't trained on how to use the app. My daughter used to enter my data on her phone". P39 [b]
	2	"Sometimes, the response times were long". P03 [b] "The waiting time for my request to be processed after I entered my data was very long." P24 [b]
	3	"I received information about my health status and COVID-19 symptoms, but I didn't receive information related to my clinical history and my other health problems". P27 [a] "It would be a good idea to integrate more specific functionalities for monitoring COVID patients with specific clinical profiles, such as those who have undergone surgery, are pregnant, are taking immunosuppressants, etc.". P15 [b]
Other issues	1	"I really would have liked the doctor to be closer to the patient, not just on the phone". P06 [a] "The care team was competent, but honestly I believe it lacked human contact. Sometimes I would have liked to speak directly with the nurse or medical team member, rather than using the CareSimple-Covid app." P16 [b]
	2	"It is not very comfortable and reassuring to share certain information through a phone call". P36 [a] "I am worried about confidentiality, and I fear a lack of confidentiality and data leaks." P28 [b]

a, Participant who used Telecare-Covid platform.
b, Participant who used the CareSimple-Covid platform.

services offered through the platforms illustrates the concrete and undeniable positive contribution made by the two remote monitoring platforms.

Turning to our interpretation of the results for each platform, although they use two different approaches to remote monitoring, the results show significant differences in participants' perceptions of each platform based on the dimensions assessed. There are nevertheless a few differences in users' perceptions of certain aspects of each platform. More specifically, the results suggest that the users of the CareSimple-Covid platform had slightly better perceptions of the quality and safety of their care, as well as the engagement in care and their relationship with the care team. In contrast, the users of the Telecare-Covid platform had slightly better perceptions of its usefulness and user-friendliness. Furthermore, the participants who used the Telecare-Covid platform reported fewer problems compared to participants who used the CareSimple-Covid platform.

Although the feedback received on the experience of using the two platforms' services was generally positive and favorable, some areas for improvement were mentioned, such as training and access to connected devices as well as the need to customize the platforms further with clinical profiles. Above all, several social acceptability concerns need to be addressed. The first is that some participants mentioned the importance of maintaining human contact when providing care. Second, and despite the elaborate regulatory system approved by both of the institutions (CHUM and CRCHUM) regarding maintaining the confidentiality of data on patients, the issue of confidentiality and data leaks remains a concern to a small number of participants. CHUM and the two platform teams fully complied with the security and data confidentiality measures, and no incident of this kind was reported or observed. However, some individuals may still express concerns and different points of view on this issue, and this is socially understandable.

In summary, the results of this study highlight the contribution made by the two platforms during the first wave of the pandemic (April, May, and June 2020) in Canada. These results provide new information on how we can use technological platforms to support health systems in the continuity of their services, but also in maintaining the quality and safety of care, even during an extraordinary health event. Finally, it should be noted that the platforms were not initially designed to monitor COVID-19 patients; they were multidisciplinary virtual platforms that existed long before the pandemic. But in order to quickly respond to the need to intervene and support care services and maintain safe care of high quality, it was decided to develop and adapt the existing platforms, within a very short timeframe, for remote monitoring of COVID-19 patients. Therefore, in addition to the encouraging results that we recorded, we would like to highlight the success of the decision-making and technical transformation process that allowed us to better exploit the two platforms and quickly respond to urgent needs. This paper provides a sense of the effective collaboration achieved between the CareSimple and Telecare teams and the leaders of CHUM and CRCHUM and the considerable effort invested in this program, which could be considered a good model.

Suggestions for Improvement

Regarding potential improvements to technical and practical aspects of the platforms, we suggest (1) promoting access to smartphones, tablets, and other connected devices by offering, for example, smartphone and tablet loan services and formally training patients in how to use the platforms by introducing simplified tutorials or practical videos; (2) developing and

enhancing the correspondence mechanism to speed up the communication and exchange process between patients and care teams and make it more responsive; and (3) developing and adapting the platforms' content to the needs of COVID-19 patients with chronic diseases and adding more clinical profiles to the platforms to provide a more specific more customized, and less generic follow-up process.

We believe that the most important area for improvement is not technical or practical in nature but rather related to social acceptability concerns. In fact, the issue of maintaining human contact in care, and the issue of confidentiality and data security appear to be real concerns. Hence, on this particular issue, healthcare institutions could better develop their communications with patients and the public. Patients and healthcare users should be systematically informed that the security and confidentiality of their personal data are fully protected by their health institutions. In addition, institutions could better explain and communicate their regulatory standards and ethical principles to the public in order to reassure them and reduce their concerns and skepticism around the use of technological platforms.

Regarding the issue of maintaining human contact when receiving care, we recommend entering into discussions and consultations with patients, the public, and experts in public health, ethics, technology, and politics to address this issue in a transparent and democratic deliberative process. Furthermore, the integration of the participatory 4P (Precise, Predictive, Personalized, Preventive) approach during the development and deployment of telehealth platforms would be a tremendous asset. The 4P approach would better help care providers and other interested parties make the most informed decisions while offering patients greater understanding and control of their choices on how to be monitored and receive care, whether remotely, virtually, or in-person (22, 23).

Finally, research in this area should be promoted, and studies that focus on these particular issues should be facilitated and supported.

Comparison With Prior Work

This study contributes modestly to enrich and deepen the knowledge already available in the literature in the field of telehealth and telemonitoring in general, but in particular on the impacts and challenges of using such approaches in an extraordinary context. This study also stresses the importance of the decision-making and leadership process that supported and facilitated the successful development of the technological platforms within only 4 weeks, despite the difficult circumstances caused by the COVID-19 pandemic.

In the literature, we find several studies that suggest the positive impact of the use of telehealth platforms, in particular on the quality and safety of care (4–12). The positive impact on the acceptability, usefulness, and user-friendliness of technological tools and devices used in telehealth platforms has also been demonstrated in several clinical fields, notably in long-term care, mental health, and oncology. Since the beginning of the COVID-19 pandemic, the impacts of telehealth platforms have increasingly been studied, tested, and demonstrated in the clinical context of COVID-19 (24–29). Therefore, our study corroborates the findings of numerous other studies, and especially those related to the two areas highlighted above. However, what is special about our study, and what distinguishes it from other studies in the literature on this particular topic, is the innovative application of patient engagement and the partnership with the care team that we have assessed – no other study has evaluated this dimension of patient engagement and partnership with the care team through remote monitoring platforms in the context or clinical setting of COVID-19.

Finally, the concerns raised in our study over social acceptability have often been highlighted in studies on ethics and telehealth, whether or not they were in the context of COVID-19 (30–35).

Strengths and Limitations

This study has certain advantages. Several stakeholders, researchers, and experts in the field either supervised or were involved in the study. Our intervention has been rigorously and promptly developed to cope with the urgent needs of the first wave of the COVID-19 pandemic in Canada. Nevertheless, our study has some limitations. First, it was a single-center study, and our design did not include a control group, i.e., patients with COVID-19 who were not monitored remotely. Studying the views of patients who did not use the remote monitoring platforms would have been highly worthwhile, and this could have lent support to our main findings. In addition, our inclusion criteria provided a wide range of cases with an unknown variety of comorbidity and clinical profiles among the participants. Furthermore, we did not study all the 85 users registered on the two remote monitoring platforms. Consequently, we consider that our full sample size of 51 for the two platforms was relatively average, and as a result, the two sub-samples for the platforms we studied were not equal. The participation rate in the study varied between users of the two platforms (53% for the Telecare platform and 93% for the CareSimple platform). This may have provided an additional source of bias and may limit the generalizability of our findings.

Finally, we could not go deeper to explore and explain in-depth the issues and concerns yielded in the open-ended questions because of the quantitative design of our study. This will be considered in-depth in our upcoming study regarding the qualitative evaluation of the two platforms. Also, we think that the integration of socio-economical and ethnic information in the demographical section could have been very interesting and beneficial for growing insights and focus on equity of access to digital health but, unfortunately, participants were not responsive to these demographic elements and that's why they have not been considered in this study and we will reconsider integrating those demographics information in the upcoming study.

Perspectives and Implications for Decision-Makers, Healthcare Professionals and Researchers

In light of the feedback provided by patients in this study on the individual preferences and challenges experienced we can appreciate the importance of measuring the patients' views and exploring their perspectives. This can help improves the services provided and better respond to users' aspirations and respecting

their choices in an innovative socio-technological process even in abnormal circumstances such as COVID19. This paper's findings contribute to the growing literature and regarding the pros and cons of remote monitoring and recommendations for improvements. We encourage healthcare professionals and researchers, to conjugate their efforts, collaborate together, and to not only focus their research and evaluation on technical or clinical aspects but also on organizational, social, and of course ethical aspects because as we have seen in our study, the ethical and social aspects the acceptability aspects can occupy an important interest among the care users and patients and these aspects should never be neglected.

Finally, our evaluation experience of the two RPM platforms recognizes the importance of the resources and time required to implement and evaluate new technologies. The RPM platforms, are very promising tools and can bring great added value for both health professionals and health users. However, we learned that RPM platforms need multiple resources to be maintained, supported, managed, and even evaluated and studied such as IT, human and financial resources as well as organizational resources. In addition, these programs require the goodwill, support, and involvement of all actors and stakeholders.

CONCLUSIONS

This study provided evidence suggesting that the two remote monitoring platforms we evaluated were useful, user-friendly, and well-received by users with no significant difference in the users' experience between the two platforms. Further research is required to support our findings and endorse if the two follow-up approaches can be used for other post-hospitalization clientele and can be considered for use even in a post-pandemic era. Finally, to maximize efficiency, improve usability, and achieve results that are even better than those recorded here, the areas for improvement and the issues identified need to be considered in a patient-centered manner.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

M-PP, KM, AT, M-ÈD, and FL developed the idea for the study and oversaw intervention development and implementation. MT and ER collected the data. KB processed, analyzed, and interpreted the data and structured and drafted the manuscript. M-PP, BL, and DL contributed to the analysis and interpretation of the data, and supervised the writing of the manuscript, and revised it. All authors contributed to the article and approved the submitted version.

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Beauty Is in the AI of the Beholder: Are We Ready for the Clinical Integration of Artificial Intelligence in Radiography? An Exploratory Analysis of Perceived AI Knowledge, Skills, Confidence, and Education Perspectives of UK Radiographers

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Introduction: The use of artificial intelligence (AI) in medical imaging and radiotherapy has been met with both scepticism and excitement. However, clinical integration of AI is already well-underway. Many authors have recently reported on the AI knowledge and perceptions of radiologists/medical staff and students however there is a paucity of information regarding radiographers. Published literature agrees that AI is likely to have significant impact on radiology practice. As radiographers are at the forefront of radiology service delivery, an awareness of the current level of their perceived knowledge, skills, and confidence in AI is essential to identify any educational needs necessary for successful adoption into practice.

Aim: The aim of this survey was to determine the perceived knowledge, skills, and confidence in AI amongst UK radiographers and highlight priorities for educational provisions to support a digital healthcare ecosystem.

Methods: A survey was created on Qualtrics® and promoted via social media (Twitter®/LinkedIn®). This survey was open to all UK radiographers, including students and retired radiographers. Participants were recruited by convenience, snowball sampling. Demographic information was gathered as well as data on the perceived, self-reported, knowledge, skills, and confidence in AI of respondents. Insight into what the participants understand by the term "AI" was gained by means of a free text response.

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Quantitative analysis was performed using SPSS® and qualitative thematic analysis was performed on NVivo®.

Results: Four hundred and eleven responses were collected (80% from diagnostic radiography and 20% from a radiotherapy background), broadly representative of the workforce distribution in the UK. Although many respondents stated that they understood the concept of AI in general (78.7% for diagnostic and 52.1% for therapeutic radiography respondents, respectively) there was a notable lack of sufficient knowledge of AI principles, understanding of AI terminology, skills, and confidence in the use of AI technology. Many participants, 57% of diagnostic and 49% radiotherapy respondents, do not feel adequately trained to implement AI in the clinical setting. Furthermore 52% and 64%, respectively, said they have not developed any skill in AI whilst 62% and 55%, respectively, stated that there is not enough AI training for radiographers. The majority of the respondents indicate that there is an urgent need for further education (77.4% of diagnostic and 73.9% of therapeutic radiographers feeling they have not had adequate training in AI), with many respondents stating that they had to educate themselves to gain some basic AI skills. Notable correlations between confidence in working with AI and gender, age, and highest qualification were reported.

Conclusion: Knowledge of AI terminology, principles, and applications by healthcare practitioners is necessary for adoption and integration of AI applications. The results of this survey highlight the perceived lack of knowledge, skills, and confidence for radiographers in applying AI solutions but also underline the need for formalised education on AI to prepare the current and prospective workforce for the upcoming clinical integration of AI in healthcare, to safely and efficiently navigate a digital future. Focus should be given on different needs of learners depending on age, gender, and highest qualification to ensure optimal integration.

Keywords: artificial intelligence, AI, radiography, education, workforce training, digital health, radiotherapy, adoption

INTRODUCTION AND BACKGROUND

The AI Accelerating Trajectory

In the last decade, Artificial Intelligence (AI) implementation has accelerated but has also become an increasingly divisive topic in medicine, particularly so within medical imaging. The development of more sophisticated computers with greater storage capabilities and faster graphics processing units (GPUs) have allowed systems architectures to develop in a way which was not possible before (1). This has allowed convolutional neural networks (CNNs) in image recognition tasks to develop. These systems learn iteratively until acceptable performance is achieved relative to the previous interpretive standard (2). Wider availability of large medical imaging datasets and advancements in neuroscience further perpetuated AI technology advancement (3).

While AI is considered to be a promising, fast changing area of healthcare innovation (4), able to revolutionise care delivery, it is often seen with suspicion and mistrust by many healthcare professionals working in radiology, leaving them concerned about their future careers (5–7). In response to the impending digital healthcare revolution, the NHS has prioritised the development, testing, and validation of AI tools and digital health systems as part of their long-term improvement plan (8).

AI Implementation Creates Controversy Among Medics, Including Radiologists

Despite these technological advances, implementation of AI into the clinical setting has been perceived differently across the multidisciplinary team. Difference research projects surveyed radiologists and radiology trainees, the medical practitioners within medical imaging. In 2019, Waymel et al. (9) surveyed 270 senior radiologists and radiology registrars in France and reported an optimistic view as clinicians felt that implementation of AI will have a positive impact on clinical practise. Respondents thought that AI will speed up reporting turnaround times, i.e., the time taken to produce a clinical diagnostic report, with a possible reduction in the number of imaging-related medical errors and subsequent increased contact time to enable more direct patient care. Further work by Oh et al. in Korea (10), surveyed the confidence of 669 doctors and medical students when using AI, where 62% of respondents reiterated the perception that AI

would speed the collection of clinical data. In Germany, 83% of 263 surveyed medical students felt that AI will never replace the radiologist (11) however this is contradicted by reports ranging from 26 to 78% of respondents (doctors, nurses, and technicians) fearing that AI could replace them in their clinical role (10–13). A lack of trust and acceptance of AI systems is also apparent in the literature (14, 15) with results in Korea reporting that 79% of respondents would always favour the doctor's opinion over the AI when a conflict arose. Whilst in Germany (10), 56% of 263 surveyed medical students, stated that AI would not be able to establish a definitive diagnosis (11). The perceived advantages of AI in the current evidence-base are clear; however contradictory views exist internationally on how exactly AI will work in the clinical arena and whether it will lead to role depletion among physicians/healthcare workers and students.

The AI Training Gap May Challenge AI Implementation Among Clinicians and Perpetuate Long-Standing Workforce Shortages

The majority of published literature has further highlighted a lack of training to empower healthcare practitioners to optimally use the capabilities of AI, as well as the lack of regulatory frameworks of AI-enabled healthcare products (16, 17) and lack of thorough scrutiny of reported studies, ensuring a robust knowledge base (18). The majority of physicians feel they have received insufficient previous information on AI and would consider attending continuous medical education or technically advanced training on AI, if available (9–12). Similarly medical students have reported either no AI training at all or insufficient training in AI with many believing it should be taught at undergraduate level and be part of the compulsory curriculum (11, 19).

Lack of adequate training on AI to prepare clinicians and explain basic AI concepts and applications may impact on the number of physicians choosing to specialise in radiology after graduation, as was highlighted by recent research in the UK (20). A total of 19 medical schools participated in a survey assessing attitudes of medical students toward AI, 49% of respondents reported that they would be less likely to consider specialising in radiology due to the impact of AI. A similar picture is emerging in the United States, where 44% of 156 survey respondents reported they would also be less likely to choose radiology as a specialty due to the influence of AI (13).

The lack of knowledge of AI benefits and risks and the skills gap on using AI tools by clinicians needs to be urgently addressed to cater for the workforce shortages in medical imaging and radiotherapy; the current Royal College of Radiologist statistics which state that "the NHS radiologist workforce is now short-staffed by 33% and needs at least another 1,939 consultants to meet safe staffing levels and pre-coronavirus levels of demand for scans" (20). This staffing shortage in medical imaging is further compounded by the College of Radiographers census of the diagnostic radiography workforce in the UK. Results reported that the average current UK vacancy rate across respondents was 10.5% at the census date of 1 November 2020 (21). It is imperative to use dedicated educational provisions to dispel the misperception that "AI will replace radiology staff, or that AI may deter staff from specialising in the role in the first place." Further training is required not only on how to use AI itself but also on the advantages, challenges, and issues surrounding AI implementation into clinical departments to ensure the confidence of clinicians interested into these careers increases.

The Impact of AI on Radiographers

Radiographers are registered healthcare professionals who work predominantly and directly with patients, families, carers, and service users but very closely with Radiologists. In the UK, diagnostic and therapeutic radiographers form the largest proportion of the workforce in clinical imaging (radiology) and radiotherapy departments, respectively. There are more than 30,000 members of the radiographers' professional body, the Society of Radiographers (SoR) (2020) (22), and 36,941 currently registered with the regulator for health and care professions, the Health and Care Professions Council in the UK (23). Collectively their roles encompass the provision of health screening services, clinical imaging for diagnosis, and imaging and therapeutic services to facilitate curative, palliative, surveillance, end of life, and forensic examinations. Radiographers interact with and care for thousands of people each day. This requires a wide and encompassing range of skills and knowledge and the ability to empower people in shared decision making. Radiographers work on the interface between technology and service users in clinical imaging and radiotherapy. They operate the equipment, produce, and report on diagnostic images.

Radiology and radiography, two interconnected but distinct professions, are traditionally considered to be early adopters of AI technology (24, 25), with computerised diagnosis used as early as the 1960s (8). Since then, there have been several periods of high activity in AI research and development with intervening periods of lower activity, so-called AI "winters" (26, 27). Pattern recognition computer aided diagnosis (CAD) tools have been part of mammography image interpretation since the 1980s (28, 29), some of which are extant today and perpetuate significant human input due to high false positive rates (14, 30).

While research related to radiologists' roles, clinical practise, and education in relation to AI has flourished, as discussed in the abovementioned paragraphs, very little research has considered the impact of AI on radiographers and their perception of using it in clinical practise. The limited literature available would suggest that radiographers are keen to engage with AI but controversy still exists whereby some radiographers feel that AI may deplete or threaten their jobs in the future whilst others think it may lead to more advanced role developments (31–34). Abuzaid et al. (35) surveyed the opinions of 34 radiologists and 119 radiographers in the UAE on their willingness to accept AI into practise. Staff were excited and ready to embrace AI, however 17% of respondents stated they had no knowledge of AI, 40% were self-taught, and 73% reported difficulty accessing training courses to fill the knowledge gap for staff. Further work by Botwe et al. (36) surveyed 151 radiographers in Ghana. Most respondents (83%) were positive and would embrace the implementation of AI into practise, however 83% expressed concerns about AI related

errors and job displacement. A further 69% felt that AI could lead to reductions in radiation dose whilst maintaining image quality. Overall, they concluded that there was a need for further education for radiographers to alleviate these fears. Similar fears and apprehensions regarding trust and knowledge gaps have been expressed by radiographers in Canada, America, and Ireland (32–34). In particular the survey of 318 diagnostic and 77 therapeutic radiographers from Ireland has identified resistance of AI use in particular for patient facing roles. Respondents felt that radiographers would always have a primary role when caring for the patient and that AI would not be able to replace that human touch. Similar to other studies, >50% respondents worried about changing roles and fewer jobs for radiographers, as AI will take over clinical delivery. However this notion of role depletion was not universally supported in this survey as 47% of diagnostic and 38% of therapeutic radiographers felt AI will create new specialised/advanced roles in the future. This may mean the radiographers can work together with AI tools to fulfil roles that address the ongoing staff shortages.

The Future of AI Within Medical Imaging and Radiotherapy: Challenges and Opportunities for Integration and the Importance of Education

Sarwar et al. (37) have predicted the full integration of AI in healthcare in the next 5–10 years. Implementation of AI into the clinical setting is not without barriers; these include a lack of trust and acceptance of the systems offered (9, 29), lack of training to empower healthcare practitioners to optimally use the capabilities of AI, as discussed above, the lack of standardised regulatory frameworks of AI enabled healthcare products (10, 12) and lack of thorough scrutiny of reported studies, ensuring a robust knowledge base (15) to name just a few. It is essential for the design, validation, and adoption of AI that radiographers are knowledgeable, competent, confident, and well-trained to be able to fully materialise the benefits of new technology while minimising risks but also to be in position to explain these benefits and risks to the patients; thus radiographers could be contributing to and sustaining of a safe, efficient medical imaging and radiotherapy service, one that is based on trust and research evidence on the use of appropriate AI technology.

A number of suggestions to allow AI systems to make their way into clinical application have been offered, such as various measures to make AI more interpretable or explainable (38, 39). The users of AI technologies, for instance the radiographers, radiologists, and oncologists and those responsible for the procurement of AI for healthcare, need to have adequate knowledge, and understanding of the functionality and applications of the proposed systems to enable unbiased selection, i.e., the best application choice for the intended function with an awareness of potential limitations and risks.

The Topol review (40) reiterates the need for education in AI to be integrated into preregistration programmes, and for the necessity of upskilling the existing workforce in AI applications and technology. Recent draught HCPC guidelines (41) state that radiographers should "be aware of the principles of AI and deep learning technology, and the methods of assessing the performance of AI algorithms" (p. 45). Recent recommendations and standards jointly delivered by the International Society of Radiographers and Radiological Technologists (ISRRT) and European Federation of Radiographer Societies (EFRS) (42), state that radiographers need to have functional and performance assessment knowledge of AI systems. This can be described as a form of "AI literacy" that should be included in both pre and post registration programmes, along with education for the whole workforce. The Society and College of Radiographers' AI Working Party has also recently offered recommendations for education and training of radiographers on AI theory and applications (43).

Rationale, Aims, and Objectives

The paucity of information available on radiographers perceptions of AI and its implementation into daily clinical practise provides a strong rationale for the design of a dedicated study. As identified by Lai et al. (44) AI in healthcare will only be accepted and satisfactory for everyone, if we invest on collaborative effort and include everyone within the multidisciplinary team in the decision-making process. Hence, this exploratory study aims to highlight the perceived, self-reported, knowledge, skills, and confidence of UK diagnostic and therapeutic radiographers in relation to AI. Further objectives were to investigate the adequacy of training provisions currently available and to propose content and format of further education on AI.

METHODS

Questionnaire Design

A questionnaire was designed using the Qualtrics® survey platform. This is an online survey builder which allows for open dissemination via an internet link, hence optimising participant reach (45). This voluntary, fully online survey was designed and reported to adhere to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (46) and approved by City, University of London, School of Health Sciences Research Ethics Committee (ETH1920-1989). No incentives were offered to complete this survey.

This was a fully open survey, available from the 12th of February 2021 to the 6th of April 2021, for everyone who had the link. The survey was set to collect fully anonymous responses, therefore neither IP addresses nor any other identifying information was collected from participants. An opening slide gave participants information on the study rationale and aim, provided information on current literature on the subject, informed participants of the approximate time commitment to complete the survey and gained consent to proceed. A final survey slide notified respondents of submission of responses, although a full review of responses was not given. Participants were permitted to freely navigate back to previous questions and allowed to save responses and finish the survey at a later time in order to maximise response completeness. All responses were

included in data analysis, even if the survey was not complete. Time for completion of the survey was, therefore, not analysed.

The questions included in the survey were loosely based on a previous, unpublished, survey undertaken by one of the co-authors. These initial survey was further modified and expanded with new questions based on input from all listed authors, many of whom are members of the "Society and College of Radiographers Artificial Intelligence Working Party," who have a range of senior clinical and academic experience. The survey content is drawing upon current research evidence as outlined in introduction, as well as from the themes presented on the Society of Radiographers (SCoR) AI guidance document for radiography professionals (43).

The Survey Instrument

The questionnaire consisted of 91 questions in total, divided into five main sections or "blocks"—(i) participant demographics, (ii) AI knowledge, (iii) skills and confidence in AI (including questions on education provision), (iv) perceptions of the impact of AI on clinical practise (v) expectations for the future of radiography with AI and finally, (vi) the effect AI may have on image perception and reporting. Most questions were either multiple choice format, with some free text options to allow for more detailed responses or Likert scale questions. Only one question required a fully open response.

The demographic section included seven questions to gather data on the age, number of years' experience, highest academic qualification, region of the UK, clinical setting, and nature of current role. This information was requested to allow investigation of any relationship between these independent variables and dependent variables of knowledge, skills and confidence in AI. An eligibility filtering question placed at the beginning of the survey enquired if the respondent was a practising or student radiographer; this was to ensure that anyone other than a radiographer did not complete the survey. If the participant responded that they are not a radiographer, they were redirected to the end of the survey and no further data was collected.

Only the results of the first three sections of the survey (i–iii) are discussed in this paper; the remaining will be presented in different publications given space limit and richness of findings.

Validity and Reliability of the Survey Instrument

For each new survey face and content validity are vital measures of quality (47).

Face and Content Validity

Face validity, a subjective measure which concerns whether or not the instrument appears to potential test takers to be assessing what it intended to measure (48) has been assessed and ensured for our study (in terms of feasibility, readability, consistency of formatting, the clarity of the language used), through the piloting phase of the survey (49). Content validity, "the degree to which items in an instrument reflect the content universe to which the instrument will be generalised" (50) was ensured by the design and review of this work by the SCoR AI working party and other AI radiography experts, the piloting with another team of AI experts with varying demographics and professional backgrounds and by being grounded on relevant research evidence, including the SCoR AI guidance document for radiographers, which outlined priorities for AI adoption within the radiography workforce in all areas of practise, including education (43). The validation of the questionnaire was conducted by a panel of experts in the medical imaging and AI field, which included 12 qualified, practising radiographers, academics, students, and clinical staff, with a range of clinical experience from <1 year to >20 years. This tested both the technical aspects of the survey format (face validity) as well as the suitability of the questions (content validity). Minor formatting issues involving difficulty in navigating to the next question were reported and fixed before final dissemination of the survey.

Internal Consistency

Cronbach's alpha was calculated *post-hoc* for the Likert scale questions of this instrument to be able to confirm internal consistency (47). Acceptable internal reliability was found for the scale questions for both professions ($\alpha = 0.736$ and $\alpha = 0.777$ for diagnostic and therapeutic radiography, respectively).

Participants

This survey was intended to give a national (UK) perspective on perception of knowledge, skills, confidence, and educational needs of both the diagnostic radiography and therapeutic radiography workforce in the field of AI. All radiographers (student and trainees, practising and retired, academic, and researchers) across all sub-specialisation areas, including sonographers, were invited to participate. The survey was disseminated via LinkedIn® and Twitter® employing non-probability snowball, sampling (51), and widely shared by the authors through their radiography-specific professional networks, many of whom are members of the SCoR AI Working Party or hold different AI leadership positions within decision making agencies. Academic colleagues were also approached to distribute within radiography academic communities and students.

The link to the survey was also sent to the leads of many clinical centres throughout the UK for dissemination to all colleagues, therefore ensuring maximum reach to relevant parties.

Data Analysis

The IBM SPSS (version 23) was used for analysis of the data (52). Descriptive statistics, in the form of frequencies have been reported for most of the responses. One question required an open-ended response, which has been analysed by thematic content analysis, using NVivo (version 12) (53). Descriptive and inferential statistics were calculated using SPSS and graphs produced within MS Excel® (Microsoft, 2018). Data was presented in percentages for single response questions and counts/frequency for questions where more than one response was permitted. There were no weightings applied to any questions for analysis.

Combinations of some of the variables have been analysed to determine if any patterns emerged in order for hypotheses to be proposed for future studies (54). The correlations of independent variables such as: years practising, highest academic qualification, and age with dependent variables such as: understanding of AI, confidence in AI, understanding of the underlying terminology of AI, feelings of being well-trained in AI, and agreement that they have developed some skill in AI, were all explored and measured on either four-point or seven-point Likert scales, with the exception of "understanding of AI," which was measured on a scale of zero to ten. Spearman's rank (rs) and Kendall's tau-b (v) correlations between ordinal data were run using IBM SPSS® (55). Responses which did not fit with the ordinal classification of the data were recategorised as "missing" before calculation, such as level of highest qualification option "other" and years' experience options "I do not work in the clinical setting" and "I am in retirement." Missing data were excluded pairwise, meaning that data could be included even if the respondent did not enter a response to some other question. Bootstrapping was activated for 1,000 samples at 95% confidence levels. Subgroup analysis was then carried out to better understand the reason for any statistically significant correlations between ordinal data.

Chi-square test for independence was run for comparisons between nominal and ordinal data. In many cases, assumptions necessary to allow accurate interpretation of the Pearson's chi-square were found to be violated, so the "likelihood ratio Chi-square" statistic was used as an alternative. The likelihood ratio compares the likelihood of obtaining the observed data compared to the likelihood of obtaining the data if there is no significant difference in the variables, i.e., the data which would have been observed if there is no statistically significant relationship between variables ($p \leq 0.05$) (56). Cramer's V (V) was then performed to quantify the magnitude of any relationship.

The resultant cross tabulations were interrogated to identify any major differences between observed and expected counts within subgroups for significant findings. Subgroup analysis was then carried out to better understand the reason for any statistically significant correlations.

Thematic analysis using NVivo® was performed to analyse qualitative responses (52). Responses to the open-ended question "Can you describe the term Artificial Intelligence in your own words?" were read and coded. Codes were reread and collated into four key themes.

RESULTS

Demographic Information

Cleaning of the data removed any blank responses from the initial participants. A total of 415 radiographers responded to the survey. Four participants selected the option of "no consent," leaving 411 survey responses for analysis.

Of the total respondents, 66.4% stated that they were practising diagnostic radiography ($n = 273$), 14.4% were diagnostic radiography students ($n = 59$), 16.1% stated they were practising therapeutic radiography ($n = 66$), and 2.7% were therapeutic radiography students ($n = 11$). This calculated to an approximate 1:4 ratio of therapeutic: diagnostic radiographers, which broadly represents the UK workforce ratio of 3,794 therapeutic to 20,231 diagnostic radiographers (57). The most recent data from the HCPC, stated above, is not broken down into diagnostic and therapeutic radiography (23). Two respondents indicated they were practising both diagnostic and therapeutic radiography.

There were responses from throughout the regions of the UK with the exception of therapeutic radiographers in the Channel Islands (**Table 1**).

A range of years of experience was indicated in both diagnostic radiography and radiotherapy. Visual inspection would indicate there is a similar distribution amongst respondents in each profession (**Table 1**).

There was representation across all age groups except for the over 65 years old group in radiotherapy (**Table 1**).

Of the diagnostic radiography respondents (including students), 26% indicated they were male, 72.2% female, 0.6% non-binary/third gender, and 1.2% preferred not to say. This is similar to the radiotherapy respondents of whom 22.4% responded that they were male and 77.6% female, which is broadly representative of the UK radiographer workforce, which has an approximate 1:3 ratio of male to female (47).

Highest Academic Qualification

For both diagnostic radiography and therapeutic radiography, most respondents indicated their highest level of academic qualification as a BSc, with 24.2 and 35.5%, respectively. There were fewer diagnostic radiographers who have attained a MSc (19.6 and 36.8%) or doctoral level qualification (e.g., Ph.D., Ed.D.) (1.9 and 3.9%) than therapeutic radiographers, respectively. Those with A-level or equivalent are assumed to be student radiographers. This data is represented in full in **Table 1**. Those who selected "other" were asked for further explanation, with the majority of the respondents across both professions stating they hold a Diploma of the College of Radiographers (DCR) ($n = 7$). Other responses included conversion degrees such as MRad ($n = 2$), or other types of master's degrees such as MEd ($n = 1$) and MA ($n = 2$).

Clinical Setting

The greatest proportion of participants from both professions indicated that they work in university teaching hospitals, closely followed by the district general hospital setting. Full details of other responses are given in **Table 1**.

For those who responded "other" in therapeutic radiography, two stated they worked in a foundation trust, three in a specialist cancer centre, two were students, and one stated they were a university lecturer. Most free text responses from the diagnostic radiography participants indicated that they worked in the university setting as either an academic or researcher ($n = 15$), followed by responses from students ($n = 10$).

Role Description

Most of those in clinical practise from both professions indicated that they were practising as a clinical radiographer (39.1 and 38.2%, diagnostic radiography and radiotherapy, respectively), followed by those choosing the "advanced

TABLE 1 | Respondents' demographic details presented as percentages (%) and frequencies (n).

		Diagnostic radiography	Therapeutic radiography
Region of UK where respondents currently work	England	56.7 ($n = 183$)	88.2 ($n = 67$)
	Scotland	30 ($n = 97$)	9.2 ($n = 7$)
	Wales	1.9 ($n = 6$)	1.3 ($n = 1$)
	Northern Ireland	11.1 ($n = 36$)	1.3 ($n = 1$)
	Channel Islands	0.3 ($n = 1$)	0 ($n = 0$)
Years practising radiography	0–2 years	22.7 ($n = 75$)	23.4 ($n = 18$)
	3–5 years	10.6 ($n = 35$)	16.9 ($n = 13$)
	6–10 years	13.9 ($n = 46$)	11.7 ($n = 9$)
	11–20 years	23.0 ($n = 76$)	23.4 ($n = 18$)
	>20 years	27.5 ($n = 91$)	22.1 ($n = 17$)
	Not practising	1.2 ($n = 4$)	1.3 ($n = 1$)
	Retired	1.3 ($n = 4$)	1.3 ($n = 1$)
Age range	18–25 years old	19.3 ($n = 63$)	23.7 ($n = 18$)
	26–35 years old	28.4 ($n = 93$)	26.3 ($n = 20$)
	36–45 years old	27.2 ($n = 89$)	25.0 ($n = 19$)
	46–55 years old	12.5 ($n = 41$)	18.4 ($n = 14$)
	56–65 years old	11.3 ($n = 37$)	6.6 ($n = 5$)
	>65 years old	1.2 ($n = 4$)	0 ($n = 0$)
Highest academic qualification	A-level	14.9 ($n = 48$)	11.8 ($n = 9$)
	BSc	24.2 ($n = 78$)	35.5 ($n = 27$)
	PgCert	19.9 ($n = 64$)	1.3 ($n = 1$)
	PgDip	13.0 ($n = 42$)	6.6 ($n = 5$)
	MSc	19.6 ($n = 63$)	36.8 ($n = 28$)
	PhD/EdD/DProf or equivalent	1.9 ($n = 6$)	3.9 ($n = 3$)
	Other	6.5 ($n = 21$)	3.9 ($n = 3$)
Clinical setting/counts (respondents were permitted more than one selection)	University teaching hospital	$n = 195$	$n = 50$
	District general hospital	$n = 103$	$n = 19$
	Private sector	$n = 12$	$n = 2$
	Poly-trauma unit	$n = 30$	$n = 0$
	Mobile unit	$n = 4$	$n = 0$
	Other	$n = 14$	$n = 5$
	I do not work in the clinical setting	$n = 25$	$n = 4$
Current role	Assistant practitioner radiographer	1.2 ($n = 4$)	0 ($n = 0$)
	Undergraduate radiography student	19.6 ($n = 63$)	13.2 ($n = 10$)
	Clinical radiographer	39.1 ($n = 126$)	38.2 ($n = 29$)
	Research radiographer	0.9 ($n = 3$)	2.6 ($n = 2$)
	Advanced practitioner	15.8 ($n = 51$)	17.1 ($n = 13$)
	Ph.D. researcher radiographer	0.6 ($n = 2$)	0 ($n = 0$)
	Other	3.1 ($n = 10$)	6.6 ($n = 5$)
	Academic in radiography: teaching only	0.9 ($n = 3$)	1.3 ($n = 1$)
	Industry partner	0.3 ($n = 1$)	1 ($n = 0$)
	Consultant radiographer	4.3 ($n = 14$)	13.2 ($n = 10$)
	Clinical academic/Lecturer: practitioner	3.1 ($n = 10$)	1.3 ($n = 1$)
	Radiology/ Radiographer/ Radiotherapy manager	6.2 ($n = 20$)	6.6 ($n = 5$)
	Retired radiographer	0.9 ($n = 3$)	0 ($n = 0$)
	Academic in radiography: teaching and research	3.7 ($n = 12$)	0 ($n = 0$)
***Diagnostic radiography* sub-specialism/counts (respondents were permitted more than one selection)**	General radiography including emergency, theatre, and fluoroscopy	$n = 207$	
	Mammography	$n = 32$	
	MRI	$n = 56$	
	CT	$n = 100$	
	Ultrasound	$n = 25$	
	Interventional	$n = 44$	
	PET/CT	$n = 3$	
	PET/MRI	$n = 1$	
	DEXA/DXA	$n = 5$	
	Reporting	$n = 63$	
	Radiology manager	$n = 20$	
	PACS administrator	$n = 9$	
	Education	$n = 54$	
	Policy maker/professional advocate	$n = 11$	
	Other (diagnostic)	$n = 22$	
***Therapeutic radiography* sub-specialism/counts (respondents were permitted more than one selection)**	Pre-treatment, simulation, contouring, immobilisation		$n = 35$
	Treatment planning		$n = 15$
	Treatment delivery		$n = 54$
	Patient information/support/review		$n = 23$
	Educator		$n = 7$
	Research		$n = 7$
	Management		$n = 10$
	Quality assurance/Quality improvement		$n = 7$
	DEXA/DXA clinical applications		$n = 0$
	Other (therapeutic)		$n = 7$

practitioner" option (15.8% and 17.1%, diagnostic radiography and therapeutic radiography, respectively). There are fewer consultant radiographers responding to this survey in diagnostic than therapeutic radiography (4.3 and 13.2%, respectively), although it should be noted that there were more options available for the diagnostic radiography respondents. This was to best reflect the specific career landscape in both professions (**Table 1**).

Area of Expertise/Sub-Specialism

Respondents were given the option of selecting up to three options from the list, along with a free-text option for further explanation. Most diagnostic radiographers indicated that they were involved in general radiography (32%) followed by CT (15%), followed closely by those working in reporting, MRI and education. The responses from respondents in the radiotherapy cohort indicated that the majority were involved in treatment delivery (33%), followed by pre-treatment, simulation, contouring, and immobilisation (21%) (**Table 1**).

From those who selected "other" in diagnostic radiography, most responses were cardiac catheterisation ($n = 4$) and nuclear medicine ($n = 3$). Radiotherapy respondents indicated areas of sub-specialism in breast cancer ($n = 1$), research ($n = 1$), stereotactic radiosurgery ($n = 1$), and Information management and technology ($n = 1$).

Perceived Knowledge, Skills, and Confidence in AI

An understanding of perceived knowledge, skills and confidence in AI was sought through an open question, asking respondents to describe the term "artificial intelligence" in their own words and a number of Likert-scale questions.

Understanding of the Term "Artificial Intelligence"

Responses were initially coded using thematic analysis for each of the professions, resulting in 21 codes (**Supplementary Table 1**; **Supplementary Figure 1**). Most codes were common across both professions (**Supplementary Figure 2**). Four general themes emerged from thematic analysis: (i) clinical applications of AI, (ii) advantages of AI, (iii) disadvantages of AI, (iv) technical information of AI technology (**Supplementary Table 1**).

The top three most frequent codes in the responses from the diagnostic radiographers' cohort included:

(i) understanding of AI as used in the identification of pathology or abnormality (clinical applications), for example the following quotes are presented as relevant;
"reporting, without a practitioner looking at the film. Used to detect cancers…"
"…report diagnostic images"

(ii) statements regarding the AI tasks which would normally require human input for example, the following quotes are presented as relevant;
"…automated use of computers to perform human tasks."
"…computer algorithms performing tasks that usually rely on human interaction."

(iii) comments with evidence of deeper understanding of "modern" AI systems, such as descriptions of systems which learn from example and "computer vision" for example the following quotes are presented as relevant;
"...machine learning."
"…can be programmed to develop themselves on their own writing their own code, developer might even cease to understand the code."

The top three codes from the therapeutic radiographers' responses were similar, with the majority of comments relating to:

(i) changing radiography workflows (AI replacing or augmenting tasks which require human input) for example the following quotes are presented as relevant;
"…the use of technology, reporting, and verify systems, treatment planning systems to support patient pathway."

(ii) technical description of "modern" AI systems, for example the following quotes are presented as relevant:
"…use of computer algorithms to do mundane tasks e.g., outlining organs at risk (OAR)."
"The use of complex interconnecting self-designing algorithms to achieve a specific outcome…"

(iii) clinical applications of AI in radiotherapy, such as segmentation, planning, and/or contouring. The following quotes are presented as relevant:
"Automated RT planning to standardise planning"
"Using software algorithms to calculate/determine outcomes previously determined manually, such as auto-contouring…"

Finally there were very few comments regarding the disadvantages of AI systems in both professions, with only two comments from diagnostic radiography and one from the therapeutic radiography cohort. A representative quote from the diagnostic radiography is noted below:

> "Its current role is very 'task dependent' and limited as it struggles to understand poor quality images, artefacts, or normal variants, or post-surgery image appearances, often it is classed the 'next best thing' but most likely it is the new 'emperors clothing'"
> Another representative comment was offered by the radiotherapy respondents:
> "Human reliance on technology… create(s) more work to me at work for simple decision-making process."

Perceived Knowledge and Understanding of AI Terminology

Examples of terms associated with modern AI technology and development were provided in the question represented in **Figure 1**—algorithms, deep learning, neural networks, computer-aided detection diagnosis, data mining, and over-fitting. The results demonstrate that 42.3% of diagnostic radiography and 50% of radiotherapy respondents were not confident at all in the terminology used in AI.

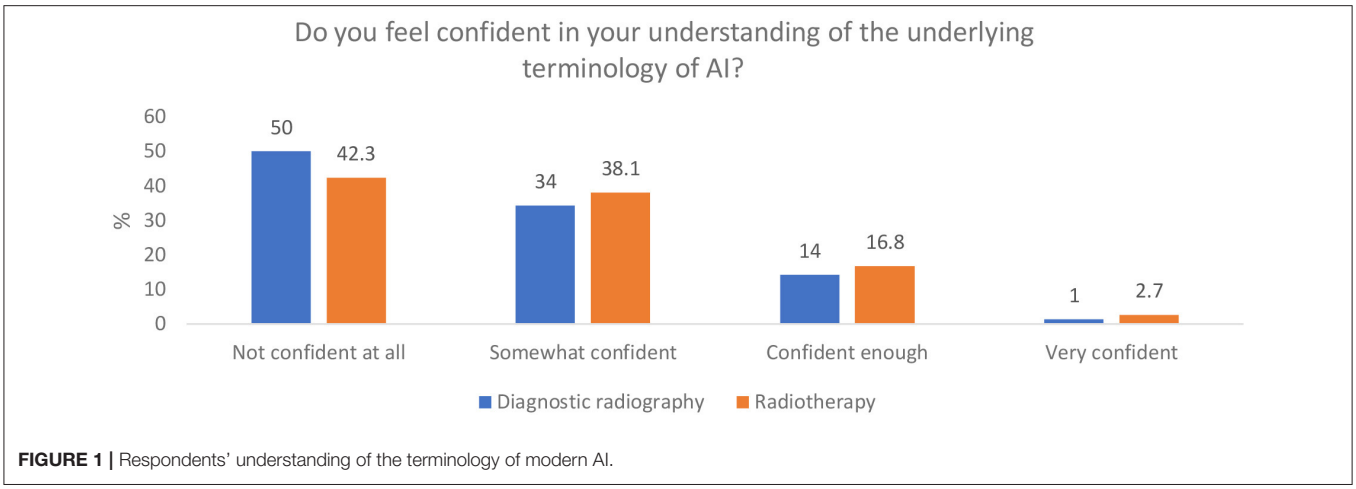

FIGURE 1 | Respondents' understanding of the terminology of modern AI.

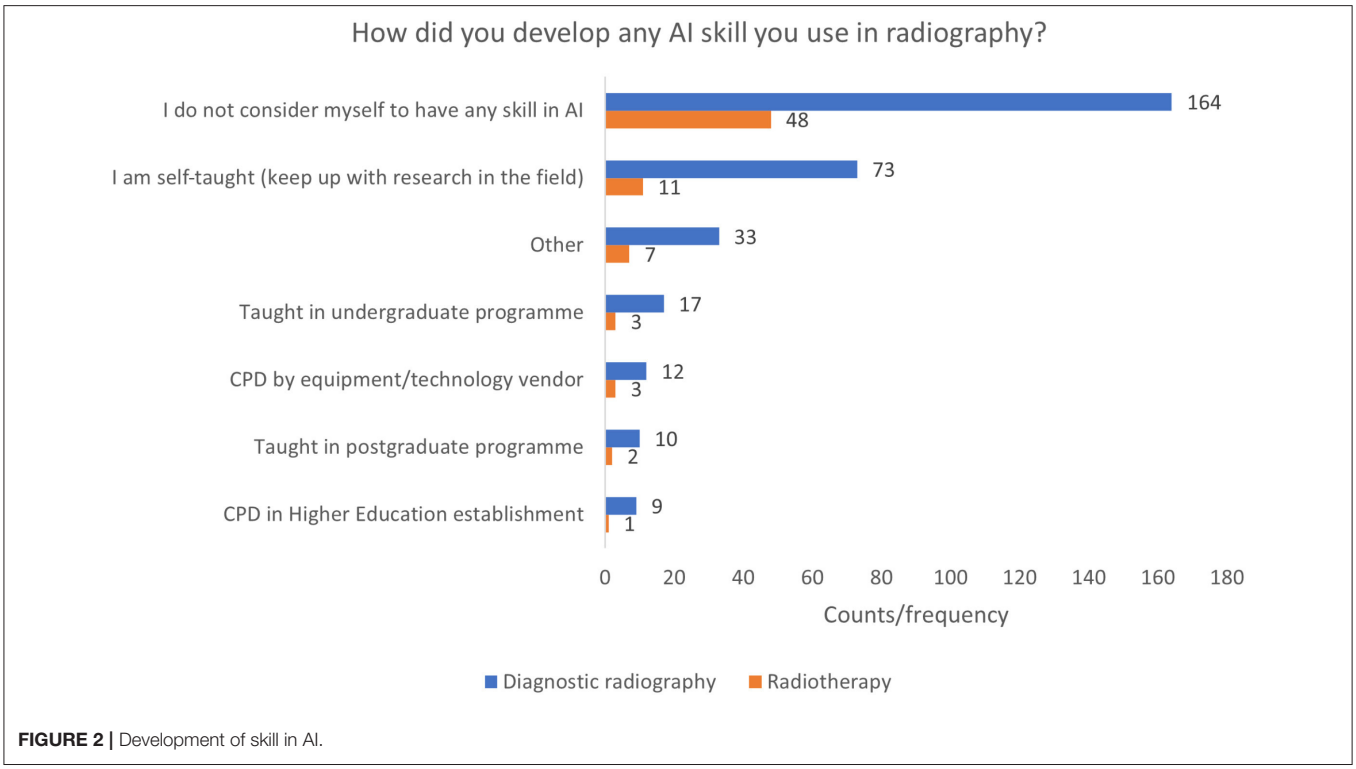

FIGURE 2 | Development of skill in AI.

Development of Skill in AI

Most of both diagnostic radiography and radiotherapy respondents indicated that they do not feel they have developed any skill in AI used in radiography (51.6 and 64.0% of total responses, respectively) (**Figure 2**). Out of the other options presented, the majority in both professions indicated that any skill has been developed from their own, self-directed learning (21.0%). In both professions, the fewest responses came from the "CPD in a higher education establishment" option. The "other" option was selected by 40 respondents over the two professions. The diagnostic radiography respondents indicated that they have undertaken assignments or dissertations in AI ($n = 8$), have read around the subject or taken online courses ($n = 4$), have had equipment training or in house training ($n = 4$), contributed to a research project conducted by someone else ($n = 3$), listened to presentations at conferences ($n = 3$), or had some form of AI training integrated into a postgraduate qualification ($n = 3$). The radiotherapy comments included, workplace/applications training or through current use ($n = 4$), knowledge from a previous career ($n = 1$), and one respondent stated that they work for an AI company.

Confidence in Using AI in Radiography

More of the diagnostic radiography respondents indicated that they understood the term AI than the radiotherapy respondents (yes, no, unsure) (78.7 and 52.1%, respectively)

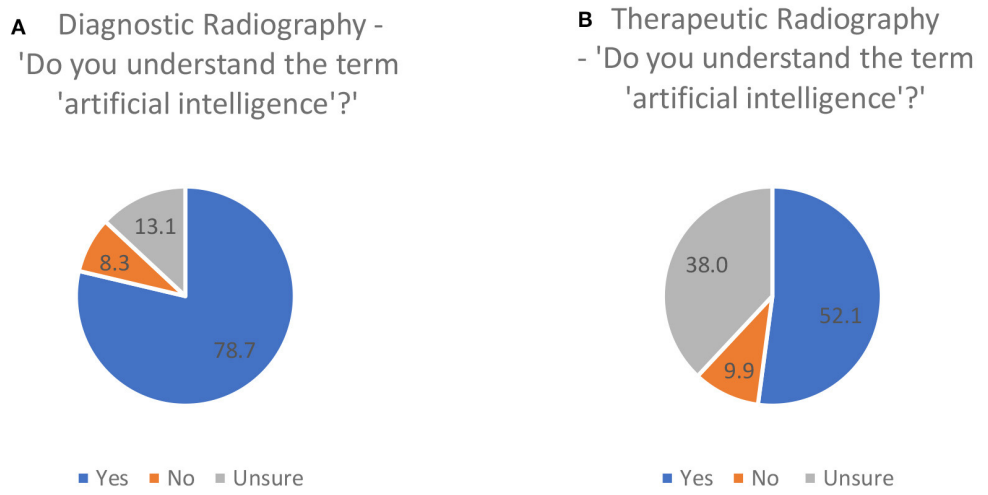

FIGURE 3 | Respondents' perception of understanding of the term "artificial intelligence" [**(A)**, diagnostic radiography, **(B)** therapeutic radiography].

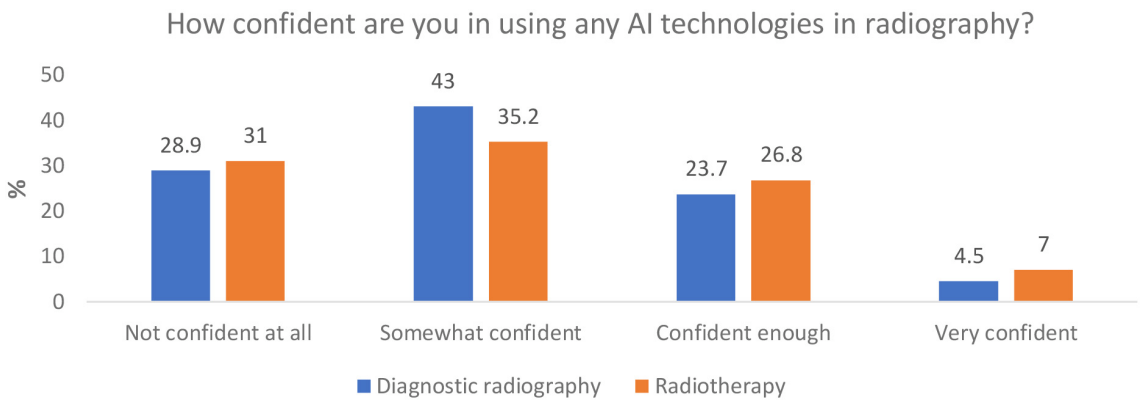

FIGURE 4 | Respondents' perceived confidence in using AI technologies.

(**Figures 3A,B**), although a slightly smaller percentage of diagnostic radiographers stated that they felt confident in using AI technologies in radiography, compared to the radiotherapy responses (28.2 and 33.8% confident or very confident, respectively) (**Figure 4**). Respondents from both professions indicated a moderate understanding of AI and asked to rate it using a 0 to 10 scale, with 0 representing no knowledge at all and 10 representing "expert." A mean response of 5.5 and 4.5 (0–10 scale) was reported for diagnostic radiography and radiotherapy, respectively.

Perceived Acquired Skills in AI and Training to Support These Skills

Questions were posed to respondents regarding their perceived level of skill in AI, how they have developed this skill, the nature of any training they have received and how prepared they feel their skills or training has made them for the implementation of AI in the clinical setting.

Perception of Availability of AI Training for Radiographers (Generic)

The majority of respondents from both professions either disagree or strongly disagree with this statement, with a "disagreement" aggregate (somewhat disagree, disagree, and strongly disagree) of 77.4 and 73.9% and an agreement aggregate (somewhat agree, agree, and strongly agree) of only 6.7 and 6.1% for diagnostic and therapeutic radiography, respectively (**Figure 5**).

Perception of Adequacy of Training Provisions for AI Implementation

Both professions indicated they did not feel well-trained to implement new technologies and AI, with over half (56.5%) of diagnostic radiography respondents indicating they either disagreed or strongly disagreed with this statement. This proportion was only slightly lower for radiotherapy (49.2%) (**Figure 6**).

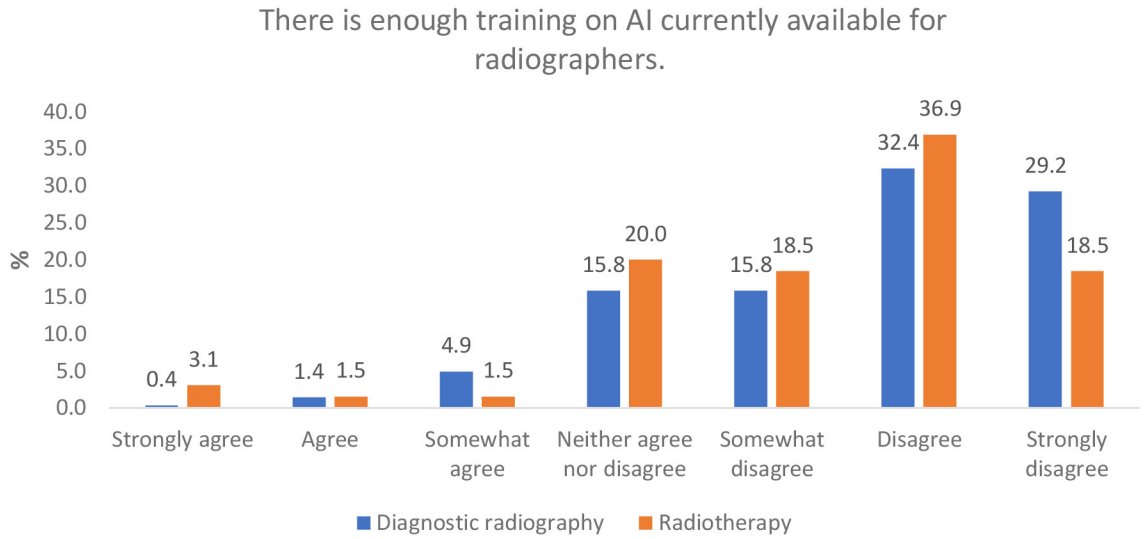

FIGURE 5 | Perception of AI training availability for radiographers.

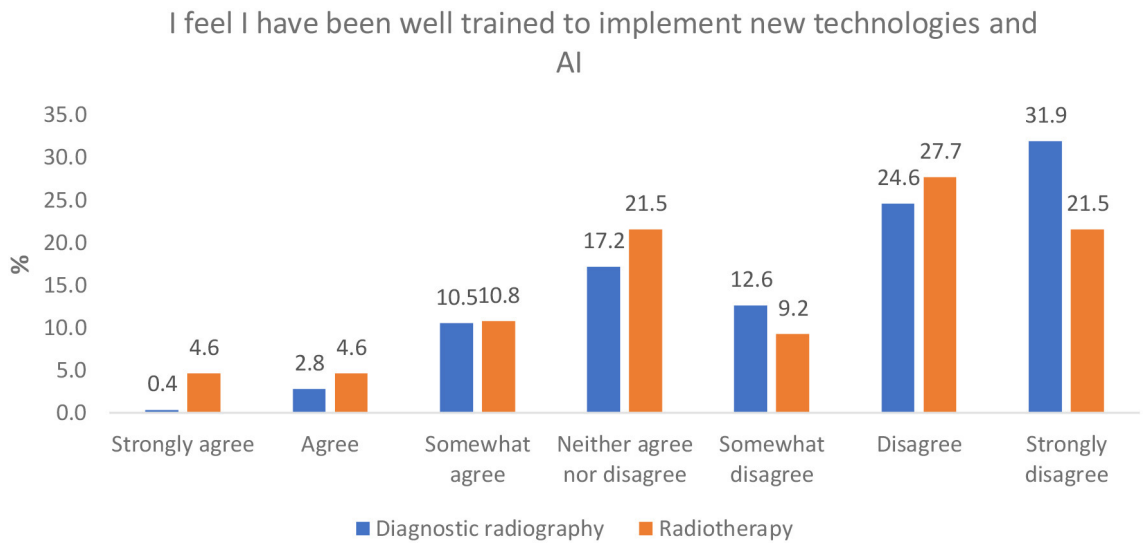

FIGURE 6 | Perception of 'adequacy of radiographers' AI training for clinical implementation.

Perception of Skill Acquisition in AI Clinical Applications

An aggregate of responses in the disagree categories (somewhat disagree, disagree, and strongly disagree) and agree categories (somewhat agree, agree, and strongly agree) from respondents in both professions indicate that they did not feel they had developed skill in AI, with "disagree" in diagnostic radiography being higher than "agree" (54.2 vs. 30.3%). This is similar to the radiotherapy responses (50.8 vs. 27.7%) (**Figure 7**).

Future Training Content and Format on AI-Enabled Technologies

To determine the type of training and education requirements needed in radiography, two questions were asked. One question sought to gather information on the content of any training—what topic areas radiographers felt should be included in any training delivered, and another question on how or in what format this training might be best delivered in.

Topic Areas Needed for Training

Most respondents from both professions indicated that they were interested in learning about potential applications of AI and AI technology, techniques, and terminology. Programming and computer science and AI development and entrepreneurship were not popular choices (**Figure 8**). The "other" option was chosen by 16 respondents from the diagnostic radiography cohort and mostly included comments suggesting uncertainty

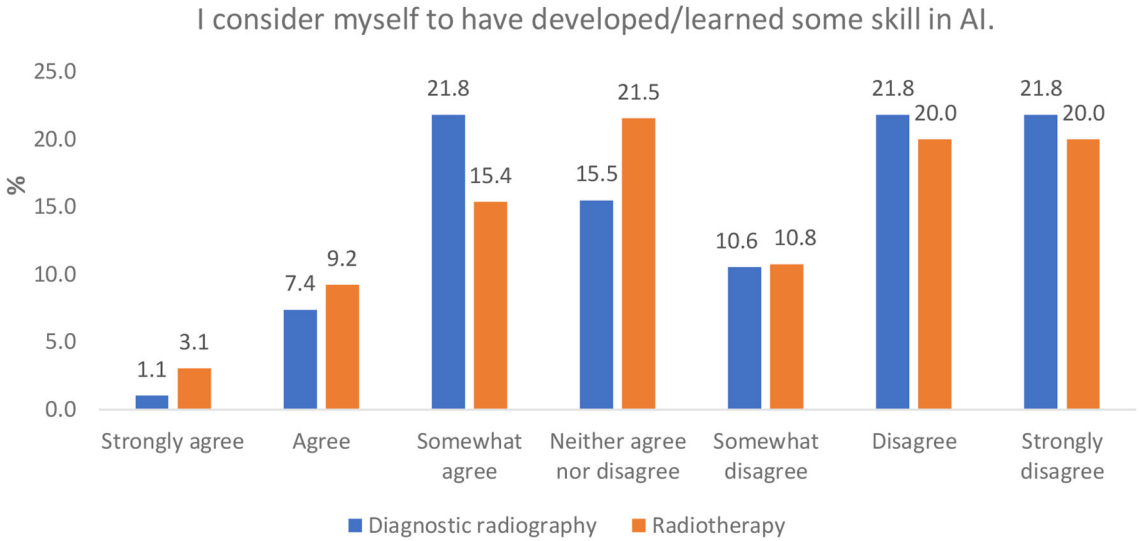

FIGURE 7 | Perceptions of having developed/learned some skill in AI.

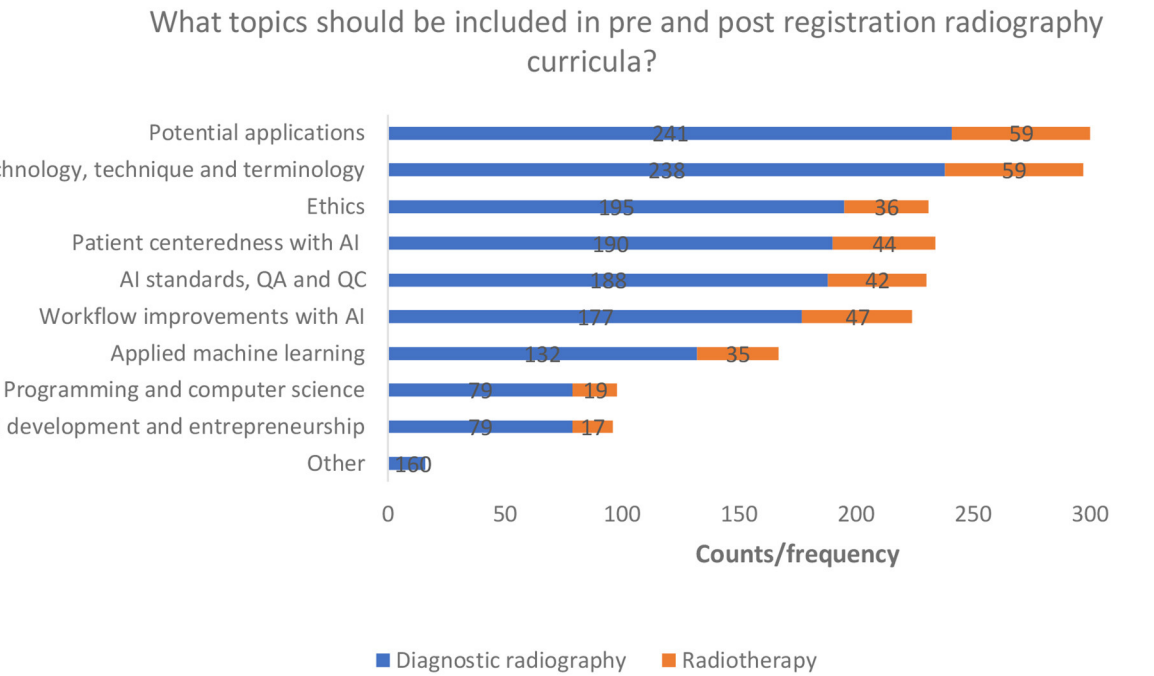

FIGURE 8 | AI education topic preferences.

around what should be included. Two comments suggested that it is too early to consider any education in AI.

Training Format Preferences

Most respondents indicated that training would be best delivered as part of a preregistration degree programme. E-learning/webinars and study days also received a high proportion of the total responses. All options were selected by some respondents (minimum respondent frequency $n = 92$ counts) (**Figure 9**). Eight diagnostic radiography respondents selected the "other" option. Suggestions included; annual CPD days for qualified staff and summer schools for pre and post registration radiographers to allow time for this training to take place in an already busy academic year.

COMPARISONS

Ordinal vs. Ordinal Comparisons

A selection of ranked variables (ordinal data) were compared using Spearman's rho (*rs*) and Kendall's tau (*v*) to identify

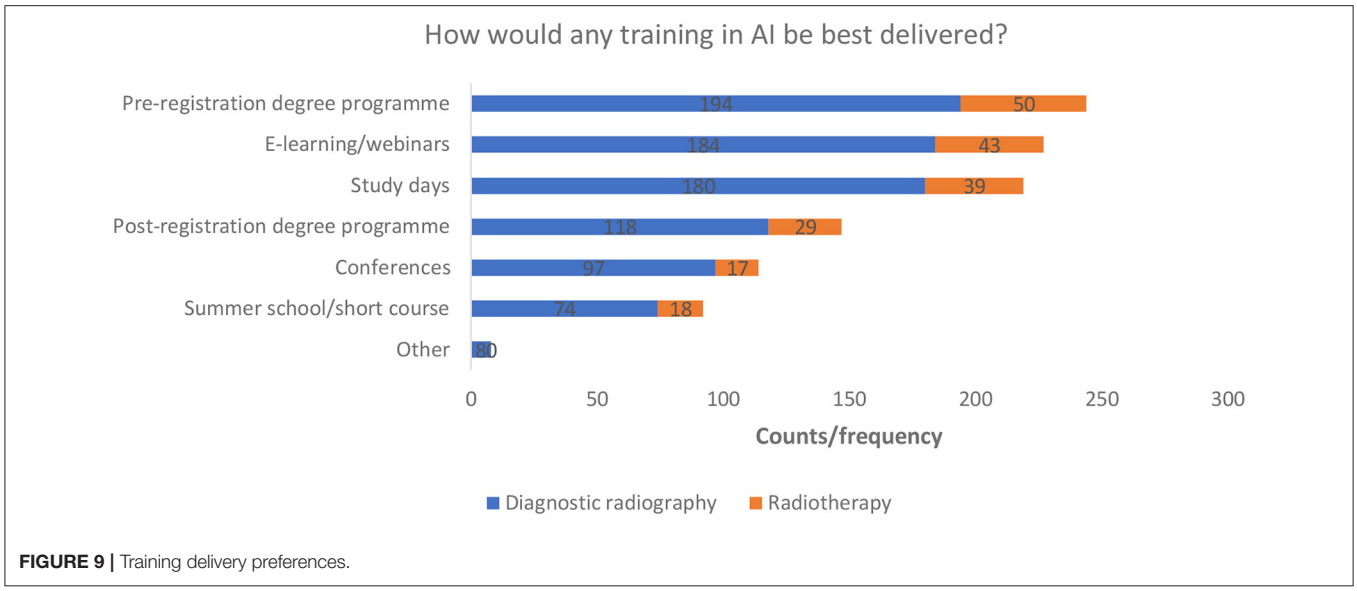

FIGURE 9 | Training delivery preferences.

any correlations. The results are presented in full in **Supplementary Table 2**. There was only one combination of variables which produced statistically significant results in both professions i.e., the relationship between highest level of academic qualification and understanding of AI on a scale of 0–10, where a medium strength positive correlation was found in both professions (54). Sub-group analysis revealed that for both the diagnostic and therapeutic responses, there was a general downward trend in the lower rating of confidence (i.e., scoring 0–3) as level of academic qualification increased, with the reverse apparent for the higher ratings of confidence (i.e., score of 7–10), i.e., as level of highest academic achievement increased, the number of respondents reporting higher levels of confidence increased. This data is presented in full in **Supplementary Tables 3–6**.

In the diagnostic radiography responses, there was also a significant positive relationship between highest level of academic qualification and confidence in AI terminology ($rs = 0.151$, $v = 0.218$, $n = 271$, $p = 0.05$), but this was not the case in the radiotherapy cohort. Further analysis of the groups reveals that very few respondents across all categories are very confident, or confident enough and a general downward trend in the "not confident at all" selection, i.e., as level of highest academic qualification increased, from undergraduate to Ph.D./Ed.D./D.Prof. or equivalent, the proportion of respondents indicating that they were "not confident at all," decreased (**Supplementary Table 7**).

Additionally, a significant, medium strength positive association ($r_s = 0.417$, $v = 0.313$, $n = 71$, $p = 0.01$) was found in the radiotherapy responses between age and understanding of AI (scale 0–10) and respondents' years' experience and understanding of AI (scale 0–10) ($r_s = 0.437$, $v = 0.332$, $n = 70$, $p = 0.01$). This was not mirrored in the data obtained from the diagnostic radiography responses (**Supplementary Table 2**).

Visual analysis of the subgroup data indicates that, there was a general downward trend in the lower rating of confidence (i.e., scoring 0–3) as both age category and years practising increased, with the exception of the 55–65 years age group, as demonstrated fully in **Supplementary Tables 8–11**.

There was no significant correlation in any of the other comparisons.

Nominal vs. Ordinal Comparisons

There were no associations found between variables in the majority of tests, presented in full in **Supplementary Table 12**. There were four tests in diagnostic radiography and three tests in radiotherapy which showed a significant relationship between variables.

In both professions there was a statistically relationship between gender and the confidence in AI terminology, with a medium and large magnitudes in diagnostic radiography and therapeutic radiography, respectively.

Additionally, in diagnostic radiography, the "likelihood Chi-squared test" showed a significant relationship between:

(i) gender and confidence in using AI technologies a medium association strength, where male respondent report greater perceived confidence than females (**Supplementary Table 12**),
(ii) gender and confidence in the terminology of AI with a medium association strength, where male respondent report greater perceived confidence than females (**Supplementary Table 12**),
(iii) radiographers' role and their perceptions of the adequacy of training available, with a medium association strength, where perceptions of adequacy of training was lowest in the student radiographer responses (**Supplementary Table 12**), and

(iv) UK region and confidence in AI terminology with a small association strength, with no apparent pattern (**Supplementary Table 12**).

In radiotherapy, significant relationships were found to exist between:

(i) gender and understanding of AI with large association strength, where male respondent report greater perceptions of understanding than females (**Supplementary Table 12**),
(ii) gender and confidence in the terminology of AI, where male respondent report greater perceived confidence than females (likelihood ratio with a large association strength; **Supplementary Table 12**),
(iii) radiographers' role and understanding of AI with large association strength, where perceptions of understanding was lowest in the student radiographer responses (**Supplementary Table 12**).

DISCUSSION

The focus of this survey was to establish a "snapshot" of UK radiographers' perceived knowledge, skills and confidence in AI and to establish the specific detail of the educational need and preferences of this workforce, in line with AI radiography guidance and priorities (43). Furthermore, as an exploratory study it would help provide direction for future targeted AI research projects in the under-researched field of radiography.

Perceived Knowledge, Understanding, and Confidence

Although a large proportion of both professions indicated that they understood AI in general, further specific responses from both professions made it clear that respondents were not very confident when using AI technologies. There was also a lack of understanding of the specific terminologies used in modern AI, such as "algorithms," "deep learning," "data mining," "over-fitting," and "neural networks" (**Figure 1**). This may indicate that, perhaps, initial reported "confidence" was surrounding AI in general rather than AI in radiography and modern AI. Abuzaid et al. (35) surveyed radiographers and radiologists in the United Arab Emirates (UAE) and found that 40% of respondents were not familiar with AI and a further 30% had merely a basic understanding. Other studies also report that there is a general lack of understanding of AI amongst radiologists (58, 59). The knowledge and understanding of AI at this level of detail is essential when engaging with literature around modern AI (60). Many applications of AI in medicine are currently in the development stage and therefore it is imperative for all clinicians to understand the literature in order to have a critical appreciation of the "potentials, pitfalls, and risks" of proposed technology as we move into the inevitable implementation phase (6).

Level of Skill and Importance of Education and Training

A barrier to clinicians' confidence and understanding may be the dearth of education on the subject, with many radiographers in both diagnostic and therapeutic radiography stating that they do not consider themselves to have any skill in AI. Botwe et al. (36) conducted a survey of African radiographers on their perception of AI in diagnostic imaging and reported that 82.2% of 151 respondents felt that a lack of knowledge will be a significant barrier to the implementation of AI in the clinical setting. This is supported by the responses from our survey indicating that very few respondents felt that they were well-trained to implement AI and new technologies in the clinical setting and why both professions overwhelmingly agree that there is not enough education and training available in AI for radiographers (**Figure 5**). Abuzaid et al. (35) further support this in their survey of radiographers and radiologists in the UAEs, reporting that 74.5% of radiographers and radiologists responding to their survey had not studied AI as part of their degree, that 73.9% indicating that the availability of education and training will be a barrier to the implementation of AI and that 68.6% of clinical staff lack even a basic understanding of the technology.

As radiography is an evidence-based, applied science profession our day-to-day learning is supported formally, and informally, through our clinical placement and later on clinical roles (61). This is evidenced by the number of respondents, who reported that, despite not always having been formally trained, they did have some skill in AI, indicating that they had to seek out their own learning (**Figure 2**) and that AI has started to permeate radiography practise. Abuzaid et al. (35) concur, with 39.9% of respondents to their survey being self-taught in AI. Radiographers tend to learn to work with the tools which are introduced into the clinical setting, perhaps without the time or resources to fully understand the technology (62). This may have implications when newer, more complex forms of AI are introduced, which need to be approached more critically due to complex systems architectures and whose method of decision making are not so humanly interpretable (2, 15, 38). Being in position to know the theory behind the practise will enable healthcare professionals and radiographers to query, flag, escalate, and troubleshoot concerns in the functionality of AI ecosystems and intervene, as and when needed, with human intelligence, for the safety of the patients.

Suggestions for the Type and Format of AI Learning

The radiographers responding to the survey indicate they wish to have education on potential AI applications, technology (technique and terminology), patient centeredness with AI, AI ethics, AI standards (quality assurance and control), and workflow improvements. These are areas which, perhaps, the workforce foresees or even witnesses as being the most impacted by AI (63). These may also be the areas that radiographers feel they can more easily relate to, and grasp given their training at level 6 (Bachelor's level) to allow for a smoother transition into a new field. Other proposed topics included

applied machine learning, programming and computer science, and AI development/entrepreneurship, although these subject choices were less popular. The above list of topics is similar to those identified in the literature as important for inclusion in AI curricula, although it is also suggested that a more flexible curriculum should be offered to best suit the students' interest and current developments in the field (64, 65). A minority (2.5%) of respondents across both professions indicated that they had received training as part of a CPD programme in a higher education setting. This could lead to some national or global disparity and variability in the type and standard of education being delivered in AI knowledge in the future (35) and could impact speed and quality of AI adoption and implementation as well as job satisfaction. The development of a standardised or recommended AI curriculum, as suggested for radiology trainees, may provide a solution for this (16, 58, 59).

The respondents indicate that the best place for any AI training was in the pre-registration setting. This aligns with the proposed changes to the HCPC Standards of Proficiency (radiographers) which highlight the necessity for all radiographers to have an awareness of both the principles of AI, and of the methods of assessment of performance of any AI algorithm (41). If accepted, these changes would make it essential that all HCPC registrants and aspiring registrants have this knowledge, and therefore this learning must be front-loaded in the radiography education, in both the pre-registration as well as post-registration stages. The Topol review (40) supports this by recommending that training in digital technologies and computer science should be integrated into undergraduate education for health care professionals. A systematic review by Schuur et al. (16) examines training opportunities in AI for radiologists and found that there was an overwhelming prevalence of short courses offered, rather than those integrated fully into curricula, with education providers only involved in a limited capacity. Interestingly this is not fully supported in the results from our study which found that, although the respondents indicated they did not receive specific training in AI, there was a statistically significant relationship between the level of highest academic qualification and understanding of AI. This suggests that the higher the level of academic qualification, the greater the perception of understanding in AI. In the absence of specific AI training, this may be simply due to the way which postgraduate students are required to develop transferable skills as fully independent learners and the encouragement of those studying for higher academic qualifications to become agents of change and therefore actively investigate current and future developments (such as AI) for clinical practise themselves (66).

Gender, Age, Qualification, and Role Correlations in Artificial Intelligence for Radiographers

The results from the analysis of the nominal data indicated that there is a relationship between gender and confidence in using AI terminology across both professions. Further exploration into the reason for this relationship were investigated from the cross tabulations of the likelihood ratios. This found that, on the whole, the observed values (responses) from the male respondents were higher than the expected values for "confident" and "very confident" and the female respondents were generally the reverse.

The reason for this is unclear, although it should be noted that there were fewer male respondents than female in both professions (approximately 1:3 male:female respondents from both professions, which is representative of the workforce gender distribution). Studies indicate that AI and computer science are male dominated fields (67), with only 18% of authors at AI conferences are considered female and that in general, females are less confident in using technology than males (68). This may be an issue for the radiography workforce, where there is a much greater proportion of females than males (57). This is in contrast to the radiology workforce demographics, where 60% of the workforce are male (69). According to the Dunner-Kruger effect (64), self-reported confidence is no measure of competence. A possible explanation for the lower confidence scores for women in our study may be due to the gender confidence gap and the tendency for women to think less favourably about their scientific reasoning ability and underestimate their performance (65).

Studies suggest that while there remains a gap in female perceived self-confidence in AI technology related terminology and tasks, there is no difference in performance or accuracy between genders (70). Kim Nilsson writes in "Forbes," that, to mitigate service inequalities, it is essential that those professionals working in AI are representative of the population for which the AI will be used (71). There therefore, may need to be more targeted investigation into the causes for this disparity to allow timely intervention in education, training, mentorship, and representation before further integration of AI into this female-dominated clinical setting.

The Digital Natives Report (72), a multi-generational survey of over 1,000 UK business decision makers reported that AI is used in the daily lives of those born after mid-1995, so-called "Generation Z," the youngest participants in the survey. The report also found that those in this age category have a hunger for new technology and are comfortable using it. The findings from our survey support this by the relationship found between the diagnostic radiography respondents' role and the perception of adequacy of training available in AI. The greatest discrepancy between actual and expected responses, as determined by the likelihood ratio, noted was in the student radiography cohort, with three times as many responses than predicted disagreeing with the statement "There is enough training on AI currently available for radiographers." Additionally, there was a relationship found between role and understanding of AI (yes, no and unsure responses available). Interrogation of the responses would indicate that student therapeutic radiographers were more likely than expected, based on the likelihood ratio, to respond that they did not understand AI, and less likely to respond "yes" (**Supplementary Table 12**). The young professionals, and radiography students, of today are ready to embrace technology and education providers and employers should be in a position to maximise this potential.

A positive correlation between respondents' age and perceived confidence in AI and years practising and perceived confidence in AI was found in the radiotherapy responses, indicating that those in the younger age categories and those with fewer years' experience felt less confident in AI, which to some extent

contradicts the literature referenced above. This may be due to progressively greater exposure to new technologies in the clinical setting over time (61). Also a positive correlation was found between confidence on AI tems and applications and highest academic degree, which suggests the need for a customised approach to AI learning provisions for different healthcare practitioners depending on the level of their prior knowledge, as expected.

Finally, a correlation was also found between diagnostic radiographers' UK region and confidence in the terminology of AI, although interrogation of the crosstabulation revealed no apparent pattern (**Supplementary Table 12**).

LIMITATIONS AND FUTURE RESEARCH

This exploratory study gathered responses from a diverse sample of diagnostic and therapeutic radiographers, focussing on the UK radiography workforce. The male to female ratio (1:3) and diagnostic-to-therapeutic radiographers ratio (4:1) within the survey are representative of the actual UK radiography workforce. However, given that the survey employs convenience sampling (53), the results cannot be generalisable to the wider UK radiography population. This might relate to selection bias in relation to IT literacy and interest and knowledge of AI, as the participants were invited from the professional networks of the co-authors, many of which are established academics and researchers in the AI field. In reality the results of this work may possibly underestimate the lack of knowledge, skills, and confidence about AI as the respondents may come from settings of more established AI cultures and environments. However, convenience sampling remains an inexpensive sampling method for hard-to-reach populations (53). The sample size and sampling method is also comparable with similar studies in the field of radiography in other countries (34, 35).

Limited free response information was obtained as many of the questions required Likert-scale or closed type responses. The team is planning focus groups with purposive sampling to understand in greater depth the educational need and challenges faced with the upcoming integration of clinical AI.

The study is exploratory in nature to set the basis for future studies; hence a hypothesis was not used but an explicit aim with objectives was stated alluding to workforce readiness for AI adoption.

Finally, the survey instrument used did not employ a validated knowledge, skills, confidence scale as the team wished to contextualise and customise the survey to the priorities and needs of the workforce and validated questionnaires do not offer that flexibility; instead survey questions were developed by professional experts to get the information required to inform practise change in educational provisions in the near future.

It is hoped that this study will provide some useful material for future studies to build on.

CONCLUSION

The results from this survey demonstrate that the UK radiography workforce is not yet knowledgeable, appropriately skilled, confident, or sufficiently educated for full integration of modern AI into the clinical setting. Some of the workforce are resorting to educating themselves on AI using short courses online but there is a need to prioritise formalised education and mentoring at all levels of the profession. This should not discriminate against those who do not have or do not wish to have postgraduate qualifications but also should allow flexibility by availability of postgraduate and CPD provisions for those who wish to keep abreast of technological developments after graduation. Radiographers, as integral to patient care and as direct consumers of AI technologies, need to be educated to critically embrace the emerging technologies, to ensure optimal patient care and outcomes and to be able to lead the way toward an AI-enabled future in health care.

Radiographers are usually the first and, many times, the only point of patient contact in medical imaging or radiotherapy service. Consequently, an imperative exists for all radiographers to be part of the conversation as equal members in the decision making and co-designers of any new AI technological developments in the clinical setting. In order to appropriately engage in these conversations, we need to have a workforce where all feel confident and adequately educated to be able to have a critical appreciation of the technology, its capabilities, challenges, and risks. This should come naturally for the radiography workforce, which has been traditionally trained on the interface between technological innovation and patient care. This does not mean that radiographers need to become computer science experts; but it does mean that they should be in position to safely and expertly apply AI solutions in clinical practise, be able to meaningfully appraise, interpret, and apply the evidence from literature for the benefit of their patients and collaborate in the design of new AI solutions addressing clinical challenges. With this realised, the radiographic profession would in a position to procure, use, and validate the most clinically useful AI tools for the context and patient population within which they operate, and additionally, influence the system interfaces to allow for optimal integration into current workflows.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by City, University of London SHS REC. The patients/participants provided their written informed consent to participate in this study. Electronic consenting format was used in this online survey.

AUTHOR CONTRIBUTIONS

CM and SM have equally contributed to the conceptualisation and design of this study and are therefore sharing joint last

authorship. CR, CM, SM, and TO'R have contributed to different aspects of data analysis and write up. All authors contributed to the design of the online survey, recruitment of study participants, reviewed different drafts of this document, and approved the final draft.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2021.739327/full#supplementary-material

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Achieving Spread, Scale Up and Sustainability of Video Consulting Services During the COVID-19 Pandemic? Findings From a Comparative Case Study of Policy Implementation in England, Wales, Scotland and Northern Ireland

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Requirements for physical distancing as a result of COVID-19 and the need to reduce the risk of infection prompted policy supporting rapid roll out of video consulting across the four nations of the UK—England, Northern Ireland, Scotland and Wales. Drawing on three studies of the accelerated implementation and uptake of video consulting across the four nations, we present a comparative and interpretive policy analysis of the spread and scale-up of video consulting during the pandemic. Data include interviews with 59 national level stakeholders, 55 health and social care staff and 30 patients, 20 national documents, responses to a UK-wide survey of NHS staff and analysis of routine activity data. Sampling ensured variations in geography, clinical context and adoption progress across the combined dataset. Comparative analysis was guided by theory on policy implementation and crisis management. The pandemic provided a "burning platform" prompting UK-wide policy supporting the use of video consulting in health care as a critical means of managing the risk of infection and a standard mode of provision. This policy push facilitated interest in video consulting across the UK. There was, however, marked variation in how this was put into practice across the four nations. Pre-existing infrastructure, policies and incentives for video consulting in Scotland, combined with a collaborative system-level approach, a program dedicated to developing video-based services and resourcing and supporting staff to deliver them enabled widespread buy-in and rapid spread. In England, Wales and Northern Ireland, pre-existing support for digital health (e.g., hardware, incentives) and virtual care, combined with reduced regulation and "light touch" procurement managed to override some (but by no means all) cultural barriers and professional resistance to implementing digital change. In Northern Ireland and Wales, limited infrastructure muted spread. In

all three countries, significant effort at system level to develop, review and run video consulting programs enabled a substantial number of providers to change their practice, albeit variably across settings. Across all four nations ongoing uncertainty, potential restructuring and tightening of regulations, along with difficulties inherent in addressing inequalities in digital access, raise questions about the longer-term sustainability of changes to-date.

Keywords: video consultations, spread, national policy, infrastructure, comparative national analysis, UK, crisis management, implementation

INTRODUCTION

With a view to containing novel coronavirus (COVID-19), healthcare organizations across the world rapidly introduced new service models in 2020 intended to help avoid in-person clinician-patient contact and reduce the risk of transmission. Video consulting was a key part of this major service innovation, involving rapid and widespread logistical, cultural and technical change (1–3) and redefining what an accessible and technology-enabled health service looks like (4–10). Set up of video consulting services has been widespread during the pandemic, with adoption and use varied across countries and clinical settings (11).

Pre-pandemic, adoption of video consulting was slow, time-consuming and resource intensive, with activity limited to specific clinical services and settings (typically with a local clinical enthusiast leading). Evidence on the use of video consultations in health services was mixed (1, 12–14). There was a small but rapidly growing literature on feasibility and acceptability of video consultations across clinical areas [e.g., diabetes (15, 16), ophthalmology (17), cancer (18, 19) and therapies (20–22)]. Patients generally welcomed video consulting services (23–25). While evidence supported the potential of video consulting in small scale implementations, little was known about how to successfully spread, scale-up and sustain it. What little research there was tended to adopt a technology-centric approach (in which the technology is the primary focus, rather than the service or organization in which the technology is being used) and use trial methodology to study whether video consultation technology does or does not work (1). Studies were often small scale and focused on initial adoption in the context of a research study (26, 27). Video consulting services frequently encountered difficulties when attempting spread in "real world" complex health systems (28–30). There was limited formal evaluation of policy initiatives supporting spread and scale-up of video consulting, with political and policy realities and institutional structures typically sidelined or ignored (30, 31).

This has begun to change in the context of the COVID-19 pandemic, what scholars on crisis management would describe as a highly unusual and volatile situation with potentially far-reaching negative implications (32–34). Such crisis situations—"*critical junctures in the lives of systems*" [(32), p. 6]—are characterized by *threat* (in which the core values or life-sustaining systems of a community are put at risk), *uncertainty* (about the nature of the threat and/or possible consequences), and *urgency* (in terms of being here and now, and needing to be urgently managed). Response requires policymakers to rapidly mobilize multiple organizations and sectors, and align different professional logics and ways of working; grapple with a complex and multifaceted picture of proximal and distal concerns; contemplate actions that would otherwise not be on the policy radar (e.g., introducing "lockdowns"); and, guided by national leadership, act rapidly and at scale through "*field operations and in networks that lack clearly defined authority relations*" [(32), p. 17]. As we set out below, in the context of the pandemic, this led to rapid rollout of telehealth initiatives and digital services, an urgent need for health systems frameworks that could support spread, and an explosion of research on the rise of telehealth (35). The later has typically focused on demand trends, rapid set up and adoption, implementation at scale and pace, and future sustainability of services (11, 36–43). While national policy and regulation are frequently acknowledged as integral to spread and scale up (e.g., 36, 40), the everyday practices allied to policy implementation have rarely featured. Requirements are frequently set out (e.g., funding for telehealth services, training for health professionals, redesign of clinical care) but, as Smith et al. (36) so neatly put it, the assumption is that "*the consideration of whether telehealth could be used in emergencies [is] redundant as it should just happen*" (p. 4). Similarly, literature on policy and health innovation tends to focus on policy formulation or how specific discourses shape ideas about innovation [see e.g., (44, 45)]. In sum, existing evidence tells us little about how to implement policy on the rapid spread and scale up of video consulting during a time of crisis.

In this paper we unpack what could or should happen to achieve spread and scale up of video consulting services during a time of crisis. Much earlier research and analysis takes policy as a technocratic process involving a set of given steps or stages—and the transition from *policy* to *practice* as somehow given. Drawing on an interpretive approach to policy analysis (46, 47) we challenge this, seeking to unpack the black box of policy implementation during the pandemic.

Our focus is on the UK National Health Service (NHS). In the context of COVID-19, policy across the UK four nations has been to facilitate roll out, spread and scale-up of remote consulting as a means of managing the risk of infection while continuing to deliver safe and accessible health care (48). This was overseen by the then Secretary of State for Health, Matt Hancock, who took up position in 2018 with the ambition of making the NHS more digitally enabled (earning him the nickname "Matt The

App")—since the start of the pandemic in 2020 he repeatedly called for NHS services to become "remote by default" (49, 50).

Despite significant take up of video consulting across the UK since the start of the pandemic (often, but not always, building on adoption pre-pandemic), there has been variation in the speed and scale of set up and spread. This raises questions about why some countries were more able to rapidly implement video consulting when policy across the four nations supported use of video consulting as an important means of managing the risk of infection during the pandemic. We therefore ask:

1. What is the social and policy context shaping video consulting across the UK?
2. What has been the approach to enacting policy during the COVID-19 crisis, and how has this shaped, enabled and constrained the spread and scale-up of video consulting across the UK?
3. What lessons can we learn from comparative analysis of policy implementation guiding the spread and scale-up of video consulting across four UK nations, and how might this inform sustainability of services beyond the pandemic?

In the Methods section below we set out the methods used, drawing on three on-going studies focused on remote and video consulting across the UK, and detail our theoretical and methodological approach grounded in interpretive policy analysis. In the Results section, we present case studies of the spread of video consulting in each of the four nations as well as cross-national comparison. In the Discussion section, we discuss the implications of our findings for future spread, scale-up and sustainability of video consulting services and for policy implementation on video consulting.

METHODS

Study Design and Use of Existing Datasets

Building on 10 years of research on video consultations [e.g., (1, 51–53)], our focus was on the extent to which the evolving crisis and policy response has shaped spread and scale-up of video consulting in England, Scotland, Wales and Northern Ireland, each being a member of the UK with varied devolved legislative powers and political processes (**Table 1**).

In 1999, the UK devolution settlement created autonomous, elected governments for Northern Ireland, Scotland and Wales and transferred powers for health from the Westminster UK Parliament to the Scottish Parliament, Welsh Assembly, and Northern Ireland Assembly (54). Many challenges have since remained in common (e.g., developing and implementing effective information technology) (55). However, devolution inevitably led to further divergence in health policy (56). The ways in which each of the four nations negotiated the pandemic therefore provided a naturally-occurring opportunity for comparative analysis. To do this we drew together datasets from three separate studies, each examining video consulting in one or more parts of the UK.

First, we undertook a national evaluation of video consultation services in Scotland in early 2020, funded by the Scottish government. This work involved quantitative and qualitative data collection and the production of narrative case studies to illustrate the successes, failures and partial successes of efforts to use this technology in different settings and services. The Scottish example is interesting because much work was put into building a national infrastructure and branding for the video consultation model (48). We were then commissioned by the Scottish Government to extend this work and document how things changed during the COVID-19 response.

Second, we conducted a longitudinal analysis of the scaling up of video consultations across the UK during the pandemic. Funded by the Health Foundation, we extended the work already conducted in Scotland to include England, Wales and Northern Ireland by conducting a UK-wide survey on video consulting, along with follow up interviews with NHS staff, and interviews with patients and national-level stakeholders. This allowed us to understand the extent to which the evolving crisis shaped scale-up and gain transferable insights into the development of sustainable service models. It also provided comparisons across the four nations.

Finally, we received funding from the UK Research and Innovation emergency response fund to look at "remote by default" primary care in the context of the pandemic. Because COVID-19 is so contagious, patients could no longer walk into a GP surgery and ask to be seen but had to apply online or phone the surgery for an appointment. Our focus in this paper is on the macro (national infrastructure) aspects of a remote-by-default service model in primary care that supported these rapid and widespread changes and sought to rapidly strengthen the supporting infrastructure for digital innovation in the NHS. Other elements of the research focused on the micro-(technical tools, clinical techniques), and meso-(organizational change) aspects of remote by default consulting and supporting the change process through action research and are reported elsewhere [e.g., (57, 58)].

As detailed in another paper in this special issue (57), these three studies all addressed—in one or another version—the following question: "what are the challenges—at individual, organizational and system level—of introducing remote consultation services at pace and scale and routinizing such services to become business as usual?" Data included here were collected over a 20-month period (January 2020 to August 2021), capturing the start of the COVID-19 pandemic and on-going progress. All three studies included an explicit policy (macro-level) component.

Theoretical and Methodological Approach

We turned to interpretive policy analysis (46, 47, 59) to guide our understanding of the policy process, particularly policy implementation (i.e., the actions and interactions that bring policy into being). Through this lens "policy" is a set of processes and actions (or inactions) that have some broad purpose rather than, say, a discrete decision or program administered at a particular moment in time, and emerges rather than being predetermined (59, 60). The health system can be thought of as a complex and dynamic network of actors, practices and interactions (61, 62), with control typically dispersed and the direction of the system shaped by multiple decisions and

TABLE 1 | Overview of the structure of health systems and selected health and healthcare indicators in each of the UK four nations*.

	England	Scotland	Wales	Northern Ireland
Health system structure				
Government department	Department of Health and Social Care	Health and Social Care Directorate	Department of Health and Social Services	Department of Health
Purchaser-provider split	Yes	No	No	Yes (in theory, but not always in practice)
Main bodies involved in commissioning and planning services	NHS England; clinical commissioning groups; local authorities; Public Health England	Seven special NHS boards*; Public Health Scotland; joint boards comprised of 14 regional health boards and local authorities (i.e., social care)	Three NHS Trusts; Welsh Health Specialized Services Committee; seven regional partnership boards (seven local health boards and local authorities)	Health and Social Care Board; Public Health Agency; five local commissioning groups
Main organizations with scrutinizing or regulatory roles	Care Quality Commission (i.e., all health and care services: public and private); NHS England/Improvement	Healthcare Improvement Scotland (i.e., healthcare services: public and private)	Healthcare Inspectorate Wales (i.e., all health-care services: public and private)	Regulation and Quality Improvement Agency (i.e., all health and care services: public and private)
Financing model, expenditure on health and entitlements				
Predominant model of financing	General taxation	General taxation	General taxation	General taxation
Spending on health per capita (financial year 2017–2018), £	2,168	2,353	2,310	2,306
Annual spend on private health insurance per household	104	36	62	47
Workforce				
General practitioners per 1,000 people, 2018	0.58	0.76	0.63	0.67
Hospital consultants per 1,000 people, 2018	0.88	1.04	0.86	0.96
Nurses per 1000 people, 2018	6.60	9.07	8.36	9.16
Population and demographic characteristics, 2019				
Population size, millions	55.98	5.44	3.14	1.88
Population density, people per km	432	70	153	137
Proportion of pop'n 65 or over, %	18.4	19.1	21.0	16.6
Proportion of pop'n 85 or over, %	2.5	2.3	2.7	2.0

**Adapted from the LSE–Lancet Commission on the future of the NHS.*

interactions of varied actors. This theorization is critical for our study of policy implementation. The policy process is recognized to be more complex than previously understood, with earlier literature on the "policy-implementation gap" now supplemented by complex systems thinking informed by notions of unpredictability, non-linearity and adaptability (63). Here the factors that shape and influence implementation are seen to be complex, multifaceted and multileveled (60, 64).

This focus on complexity and social action stands in stark contrast to the prevailing view of policy as a formal, rational process that can be planned in advance. This is deliberate. Scholars of health policy have often [but not always, see e.g., (65)] aligned themselves with an instrumental approach that situates individuals and institutions within a "rational choice" framework [see (66–68) for a detailed review]. What follows is a tendency to see policy as somehow separate from politics, and policymaking as a linear process involving problem identification, collection of data on alternative solutions, and selection of the alternative that best resolves the problem (46, 69). Such an approach focuses on the instrumental goals that people seek to achieve (e.g., influencing specific policies); assumes that policy actors generate "objective", policy-relevant knowledge in a void; and tends to adopt quasi-experimental designs and quantitative methods to evaluate the goals of policy programs. In contrast, our focus is on social actions that contribute to the meaning of policy (70), the role of varied actors [from national-level political actors to "street level bureaucrats" (71)], and the interactions, values and processes involved in enacting it.

Sampling and Data Collection

An interpretive approach recognizes policy as negotiated and renegotiated in the social practices and encounters of administrators, regulators and other street level bureaucrats (46, 59, 72) (e.g., those liaising with suppliers, rolling out software or tracking and reviewing activity). We therefore focused data collection on national-level policy and planning and

TABLE 2 | Overview of data sources and analysis.

Data source	Data collected	Contribution
UK-wide evaluation of spread and scale-up of video consulting	Accounts of 59 senior-level, national stakeholders involved in digital health and video consulting (17 in England, 12 in Wales, 7 in Scotland, 5 in N. Ireland, and 18 with UK focus), including:	Social and political context, including rapid onset and evolution of COVID-19 pandemic
	• 21 civil servants/policymakers	Policy and regulatory drivers, system-level and infrastructure blocks and changes over time
	• 15 professional groups	Logics by which spread and scale up of video consulting have been planned and put into practice
	• 12 business and industry	Reflections on longer term planning and the role of video consulting across settings
	• 8 senior executives	Extent of set up, uptake and spread, timeframes, geographical distribution and patient demographics; and any changes over time
	• 3 patient representatives	
	20 documents, outlining policy and guidance on digital health and video consulting across the four nations	
	Quantitative data and reports on activity	
Staff and patient experiences of video consulting	Responses from UK-wide survey of NHS staff (n=809) about adoption and use of video consulting, with 52% of responses from NHS staff in England, 35% from Scotland, 8% from Wales and 5% from NI.	Sense-making about the design, delivery, experience and spread of video consulting services in the context of COVID-19, including national and inter-organizational networks, policy directives and regulation
	Accounts from 40 (clinical and non-clinical) staff across the four UK nations, including:	Acceptability/popularity of video consulting services
	• 11 in Northern Ireland	Required/available human, social and financial resources
	• 9 in Wales	Changes needed to underlying infrastructures (technical, organizational, workflows)
	• 10 in England	Professional, ethical and moral questions about video consulting and rapid service change
	• 10 in Scotland	Learning shared across sites and networks
	Plus follow up interviews with 20 of these (5 in each country)	
	15 interviews with primary care staff from 8 GP practices in England involved in group video consulting	
	Accounts of 15 patients receiving individual or group consultations (or having declined the option)	
	Two focus groups with a total of 15 patients/public about engagement with, and experiences of, video consulting	

organizational-level enactment. Data sources are summarized in **Table 2** and described in more detail below.

We identified national level stakeholders through a mix of purposive, snowball and maximum variation sampling. We began by connecting with teams conducting policy relevant work on technology implementation and digitally-enabled care (e.g., NHS England, NHS Scotland), inviting individuals to participate in interviews and asking for nominations of further people that they recommend we speak with. To spread the net wider, we reviewed policy documents and staff interviews (see below) for mention of individuals, teams or organizations leading work on the spread of video consulting and invited them as further interviewees. This gave a broad sample across civil service, professional and patient groups, regulators and industry. Some interviewees were able to give a UK-wide perspective (e.g., from industry), others a national perspective. For the latter, we reviewed our sample across the four nations and then actively sought interviewees who were able to fill any gaps (e.g., interviews in Northern Ireland tended to focus on secondary care, leading us to proactively identify primary care professionals leading technology-enabled change). This provided a final sample of 59 interviewees (**Table 1**).

We tracked evolving policy in the four nations and asked interviewees to suggest relevant documents, resulting in a sample of 20.

The survey focused on spread and scale-up of video consulting during the pandemic, aimed to capture NHS staff experience across the UK and was designed using SurveyMonkey with input from Barts Health NHS Trust (JM), NHS England, NHS Scotland, NHS Wales and NHS Northern Ireland [see (73) for link to final version]. We used a combination of opportunity and snowball sampling to distribute the survey to NHS staff across the UK, using NHS and research networks (full list available from authors). The survey was also distributed *via* social media, with targeted tweets aimed at increasing diversity of respondents (e.g., geographical areas, specific groups; e.g., LGBTQ NHS networks). The survey was live for 3 weeks in September 2020.

We asked survey respondents to indicate if they would be prepared to be contacted for interview, then selected 40 ensuring maximum variation of country, organizational and clinical setting, role (clinician, support staff or manager) and rural/urban location. Patients were recruited *via* Patient and Public Involvement (PPI) networks in London and Oxford, the NHS England public participation team and voluntary sector organizations. We sought maximum variety in terms of age, ethnicity and location and ensured representation from health advocates to capture views from people who were not able to use remote methods of interviewing.

We adopted a narrative approach to interviewing, aiming to capture the story of how video consulting developed before and during the pandemic, experiences of this and perspectives on if/how health system policies and incentives enabled spread and scale-up of video consulting within and across the four nations of the UK. We interviewed five national level stakeholders and 20 NHS staff twice to capture accounts over time. We held two online focus groups to share emerging findings and discuss views and experiences of video consulting.

Analysis

SS led the analysis, working with a core analytical team and following an interpretive approach (46, 47, 70). This involved initial thematic analysis of qualitative data. Quantitative data were aggregated and analyzed using basic statistical methods. Guided by the "wider system" elements of the PERCS (Planning and Evaluating Remote Consultation Services) framework, all data were then brought together into an emerging narrative of each of the four UK nations focusing on the policy context (e.g., technology-enabled care, planetary health), infrastructural elements (e.g., broadband availability) and opportunities for cross-national influence and learning. The PERCS framework is an adaptation of a more generic framework for considering the complexities involved when introducing new technology (74) consisting of 8 interdependent domains (e.g., reason for consulting, clinical relationship)—development and rationale are explained in a separate paper (57).

We then undertook cross-case comparison, informed by dialogue with relevant theory and leading us to identify five key themes that helped to explain similarities and differences in the implementation of policy shaping the spread of video consulting during the pandemic. At the start of this process, we were struck by the ways in which some interviewees discussed the collective sense-making involved in the initial stages of the pandemic and in shaping the ways in which they negotiated and sought to implement emerging policy on video consulting. As we engaged further with our data it became clear that this differed within and across nations. We therefore drew on work on "making policy happen" (62, 64, 75) to examine the approach to putting policy into practice (before and during the pandemic), as well as the ways in which decision makers went about the work of supporting implementation.

This process raised questions about how the "crisis context" of the pandemic shaped policy implementation. To examine this we drew on a small (but growing) literature on crisis management (32, 33). This describes the features of crises—threat, uncertainty, urgency and collective stress—and the combination of critical tasks that need to be effectively managed including that critical decisions are made by the right people, the efforts of those responding are orchestrated and that government communicates with the public effectively (32, 76). As we explored the intersection between policy implementation and crisis management in our data, we identified two different approaches to crisis response that shaped how critical implementation tasks were—and weren't—accomplished. Firstly a traditional approach grounded in rationalism and focused on *principle-guided crisis management*, in which complexity is often negated and attempts are made to tame uncertainty by relying on longstanding principles and—often technocratic—ways of working (33). Secondly, a pragmatic approach in which the focus is on sense-making (e.g., enabling ongoing, collective reflection), decision-making across multiple networks, meaning making (involving credible and convincing interpretation and public explanation of a crisis), learning-while-doing and developing adaptive capability (e.g., with decision makers and health care staff trained to tinker with technologies and processes, and make judgements) (33, 61, 76). This later approach resonated strongly with the interpretive approach outlined above, the concept of intelligent policymaking (64) and the recognition that policy implementation takes place in complex systems (63, 74).

RESULTS

Overview of Policy Approach to Video Consulting in Each of the Four Nations

Health systems across the UK have evolved differently (**Table 1**), shaped by historical and national contingencies (54, 77). Below we provide an overview of the varied development of video consulting in each of the four nations (**Table 3**), before presenting five cross-cutting themes.

England

England has a population of over 55 million and a large health system (**Table 1**), with over 200 NHS Trusts and Foundation Trusts and over 6,500 general practices. Geography is varied, including dense urban areas and remote and rural communities. There is a mixed economy of care with, for instance, multiple providers supporting services to a diverse population (>9 million) across Greater London, through to single providers supporting expansive rural areas. Video consulting technology has been available in healthcare for many years, though use has varied across specialties and settings.

While there has been overarching national guidance on remote and online consulting, there has been no defined national policy on video consulting *per se*. Since 2010 a series of announcements has emphasized digital innovation and remote care (78–83), reflecting concerns to generate efficiencies *via* use of technology, increase access and reduce the NHS's carbon footprint. In 2016 the General Practice Forward View set out plans to offer every practice support to

TABLE 3 | Overview of policy approaches to video consulting across the four nations, before and during the COVID-19 pandemic.

	England	Scotland	Wales	Northern Ireland
Pre-pandemic policy and infrastructure	Longstanding concern with new technology as a means of generating efficiencies, with impetus for innovation-driven change in health care, including *video and e-consulting*; early adoption of platforms in some settings; evolving but limited infrastructure	Longstanding policy vision and support for *technology-enabled care* and allied infrastructure, including Near Me, national video consulting service; significant impetus from cross-government agenda to reduce carbon emissions	Policy push for technology-enabled care, including *video consulting*; with support for local pilots, regional spread then national roll out, but limited/varied infrastructure	Policy supporting *virtual* consulting largely oriented to phone consulting; ambition for digital health, with video consulting evolving via small quality improvement programs; digital infrastructure limited with widespread absence of broadband
How the immediate crisis response was framed in relation to digital technology	*An opportunity to innovate*—to accelerate set up and spread of novel forms of remote consulting across the NHS, thereby achieving the policy goal of "remote by default"	*An opportunity to scale-up*—building on established infrastructure, to extend and learn from existing models of technology-enabled care, bringing all parts of the country to the level of exemplar sites	*An opportunity to become known as a national digital innovator*—to build national video consulting service and gain political and health system currency	*A window on challenges*—revealing gaps in infrastructure and digital readiness, as well as dilemmas about how to organize and deliver care at time of crisis
Policy and regulatory shifts during the pandemic	Centralized procurement, slackening regulation, relaxed information governance; fast-track research into remote consulting	Centralized procurement, slackening regulation, relaxed information governance; rapid evaluation and learning	Centralized procurement, slackening regulation, relaxed information governance	Slackening regulation, relaxed information governance, rapid quality improvement set up
Approach to technology supply during the pandemic	Mixed approach, with central contract to single supplier (Attend Anywhere) for secondary care, combined with encouraging other suppliers in to the wider NHS who met minimal standards and could deliver a usable product at speed	Extension of existing contract to single supplier of video consulting platform (Attend Anywhere) in strongly-branded national program (Near Me)	Mixed approach, seeking to learn from, and emulate, Scotland's success with a single national supplier while also recognizing multiple suppliers	Continued arrangements with existing multiple suppliers, with interest in learning from Scotland's success with a single national supplier
Approach to spread and scale up of video consulting during the pandemic	Rapid roll-out and implementation of innovative technologies, central support and guidance, varied procurement (e.g., locally driven in primary care, centrally steered in secondary care)	Extension of successful models of good practice using principles of quality improvement—with facilitated adoption, central support, training and guidance, and system learning	Rapid roll-out and implementation, central support and guidance, central procurement	Continued emphasis on virtual consulting with extended use of existing video platforms supported via evolving quality improvement program
Key sources of learning for national roll-out	Cross-national peers (esp. Near Me in Scotland), on-going research and evaluation, NHS data and provider feedback, industry/tech suppliers	Dedicated quality improvement cycle, involving collaboration among service leaders, capturing data in a "learning health system" model and external evaluation; sharing learning with cross-national peers	Cross-national peers (esp. Near Me service in Scotland), in-house evaluation, provider feedback	Predominantly in-house quality improvement and provider feedback, plus external input from peers in other nations (esp Near Me service in Scotland)
Adoption and use of video consulting	Wide variation by setting and specialty. Very little sustained uptake in primary care	Substantial national adoption overall, though used significantly less in primary care	Wide variation by setting and specialty. Very little sustained uptake in primary care	Wide variation by setting and specialty. Limited uptake in primary care
Longer term policy focus	Promote innovation-driven new service models, support supplier diversity, address digital exclusion, generate patient-led demand and extend video consulting services	Routinize Near Me service, ensure solid infrastructure, support patients and professionals, address health/digital inequality, evaluate and share learning; achieve carbon reduction goals	Extend national video consulting service, address digital exclusion, develop and support infrastructure	Refine and implement policy on digital health, develop digital infrastructure including strengthening broadband coverage, grow quality improvement collaborative on video consulting

adopt online consultation systems, committing an estimated £45 million investment (78). In 2019 the NHS Long Term Plan (79) set out the aim for up to a third of face-to-face appointments in outpatient care to be avoided by embracing technology and arranging services around patients' lives. The vision was for "digital first" primary care to become a reality by 2024.

Pre-pandemic video consulting remained a largely *ad hoc*, bottom up activity, led by enthusiasts. While there was early adoption in some settings [e.g., "Skype clinics" for young

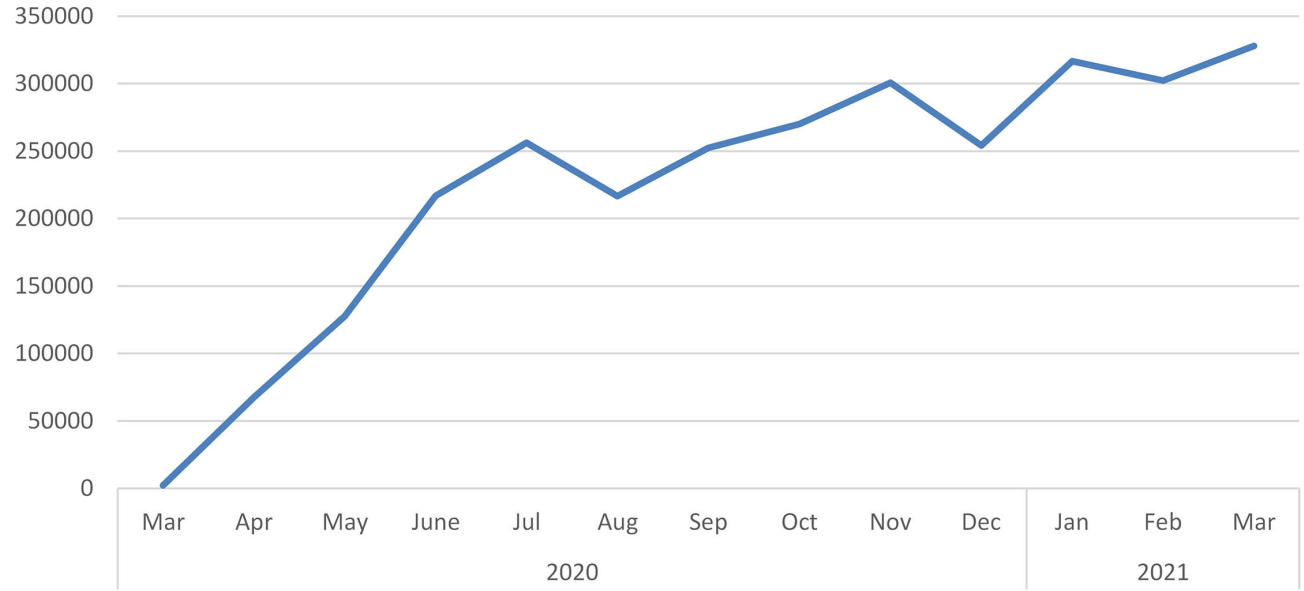

FIGURE 1 | Growth of video consultations during the pandemic. Graph shows total number of video consultations for NHS hospitals in England using the Attend Anywhere platform, March 2020 to March 2021.

adult diabetic patients (51, 84)], limited infrastructure and the challenges of embedding video consulting in existing "in person" clinical pathways, meant slow spread to other services. The use of video consulting therefore remained relatively low until March 2020.

As the pandemic hit, NHS England and Improvement (NHSE/I, **Table 1**) focused on accelerating access and uptake of remote consulting, including video consulting, across the English NHS. In primary care, the NHSE/I Digital First Primary Care team worked closely with NHS Digital to set up a new, rapid procurement route for online consultation and video consultation platforms (part of the Digital Care Services Catalog), allowing commissioners to sidestep the diverse and complex supplier market and instead procure one of 11 nationally assured products. All practices were asked to rapidly shift to "total triage" (85), requiring patients to contact the practice (typically online), provide information and be triaged before making an appointment. Central guidance, combined with multi-agency regional support, aimed to facilitate implementation and service improvement, along with support from NHSX (the body supporting digital transformation in the English NHS). A separate strand of work involved commissioned training for video group clinics in general practice—a relatively new service innovation involving two or more patients and one or more clinicians.

In secondary care the NHSE/I Technology Implementation Team had closely followed developments in Scotland (where a national video consulting service had already been established—see below), and set up several pilot video consulting services following a similar approach with the same platform. Off the back of the pilot, and under pressure to rapidly accelerate rollout to all NHS hospitals in England in 4 weeks, NHSE/I procured and funded a national license for Attend Anywhere, giving hospitals the option to use the platform for 12 months. Training and materials to support swift deployment were quickly made available, along with £20,000 funding per provider to support implementation (regardless of whether they used the Attend Anywhere platform or not), a national helpdesk, provision of over 5,000 iPads to frontline staff and negotiation of zero-rated 4G on major networks to support patient access to video services (86). The use of video consulting increased significantly, with close to 3 million video consultations *via* Attend Anywhere in 2020/21 (**Figure 1**). The greatest increase in activity occurred in the first month (which saw a 32-fold increase, 3130%). Growth slowed as physical distancing requirements slackened but continued steadily (**Figure 1**). Close to half (48%) of video consultations took place in psychology/mental health, physiotherapy and pediatric or child/young adult services. A further 1.5 million video consultations took place in the same period *via* other platforms (87).

National procurement of Attend Anywhere ended on 31 March 2021, with NHS hospitals then procuring their preferred platform (frequently Attend Anywhere), supported by central guidance and funding to 31 March 2022 (when they will need to be locally procured and funded).

In sum, remote consulting activity pre-pandemic provided foundations for rapid set up of video consulting in the English NHS. Evolving national infrastructure and a diverse supplier market proved challenging. Adoption and use varied by sector, with use growing significantly in secondary care and primary care largely declining due to use of telephone and asynchronous e-consultations.

Scotland

Scotland (population 5.5 million, with low density—see **Table 1**) has a rugged geography and outlying islands, resulting in access challenges for many people. The Scottish NHS is underpinned by a strong public-sector ethos that emphasizes professionally-led quality improvement and reducing inequalities (88). Health and care services are mainly delivered by 14 territorial health boards with remote care framed as a means to progress access to services, improve outcomes and reduce inequalities. Video consulting has long been advocated, initially *via* the eHealth Strategy in 2008 and, more recently, *via* the 2018 Digital Health and Care Strategy (89).

In 2014, the Scottish Government established the Technology Enabled Care (TEC) program, focused on driving widespread adoption of technology to support self-management of illness (e.g., self-monitoring of long-term conditions) and improve access to care. The initiative was, at least in part, a response to rising demand for health and social care and the need for service transformation. Funded by the central government, the TEC program included a series of work streams aimed at supporting local deployment, strengthening national infrastructure, and placing Scotland at the forefront of delivering technology enabled care.

The video consulting work stream was seen as enabling pooling of expertise and provision across the country to ensure high-quality patient experience. In the early years of the program, this involved various pilot studies that used varied technologies (e.g., Cisco Jabber), before the national decision was made by the TEC team in 2015 to introduce a bespoke product. Based on the success of an initial co-design and quality improvement program in one health board in 2017, a national video consulting service using the Attend Anywhere platform was then established, branded as "Near Me". In 2018 the TEC program launched a £1.6 million ($2.3 million) "scale-up challenge" to support rollout across all health boards. By 2019, a national program to extend the service was well under way, driven by an ethos of collaborative quality improvement, reducing inequalities and achieving cross-government low-carbon goals.

Before the pandemic (i.e., by February 2020) all 14 health boards and the Golden Jubilee National Hospital (one of the main tertiary referral centers) were enrolled in the program. The Near Me video service had been adopted by about 180 services, spanning 35 different clinical and social care specialties. Levels of implementation varied: use of video within most services remained relatively low, with use largely "*ad hoc*" rather than business-as-usual. Two of Scotland's 14 territorial health boards (where enthusiasts were based) accounted for most activity, with on-going spread elsewhere supported by a national team who steadily worked through regulatory, infrastructural and operational challenges.

The Scottish Government's Programme for Government 2019–2020 referred to a planned expansion of Near Me and committed to using it as a means of opening up services to those who may struggle to travel (90). When the COVID-19 outbreak reached Scotland in March 2020, this planned expansion was accelerated *via* a 12-week scale-up plan, led by a rapidly-assembled national implementation team within the TEC program. Staff were drafted in from across Healthcare Improvement Scotland (a Special NHS Board, with a remit to help implement healthcare priorities), Scottish Access Collaborative (a government program to sustainably improve waiting times for non-emergency procedures) and the Care Inspectorate (a regulatory body focused on social care services). They prepared guidance and resources for deployment of video consultations across health and care settings and built links with the government's Primary Care Division (that then mobilized resources for implementing the service in general practices), and other government departments. This led to a rapid and dramatic expansion of the service (**Figure 2**). Between March and June 2020, the number of video appointments increased 50-fold, from about 330 to 17,000 appointments per week nationally, with over 50 clinical specialties, across the 14 health boards, introducing video consultations for the first time. As in England, the majority of activity fell within psychology/mental health, physiotherapy and pediatric or child/young adult services.

In sum, national-level groundwork and strategic planning to create technical infrastructure, service readiness and positive attitudes to a national video service, combined with targeted implementation support, all helped services transform, at scale and at a massively accelerated pace, as the pandemic took hold.

Wales

Wales is a small country with a relatively dispersed population of just over 3 million, with many living in rural areas and a slightly higher proportion of older people than other nations (**Table 1**). There is a strong public sector ethos. Like Scotland, successive Welsh governments have elected not to follow the market-based approach of English health system reforms, focusing on co-operation rather than competition in health care. Health inequalities, and more recently digital inequalities (91), have been a longstanding concern.

Use of IT has long been on the agenda for NHS Wales (92), with technology-enabled care and video consulting part of strategy since 2015 (93). The broad aim was to use technology to "modernize" the NHS, with a focus on "implementing the technology". A cross-party Parliamentary Review of Health and Social Care in 2018 (94), was quickly followed by publication of Healthier Wales in the same year (95), setting out government plans for transformation of health and social care. The later placed "digital and data" as central to that agenda, while recognizing significant limitations posed by existing digital and infrastructural arrangements. This provided foundations to support development of an NHS Wales Video Consulting Service, with significant work required to "*better leverage… technology and infrastructure assets*" [(95), p. 27]. In this

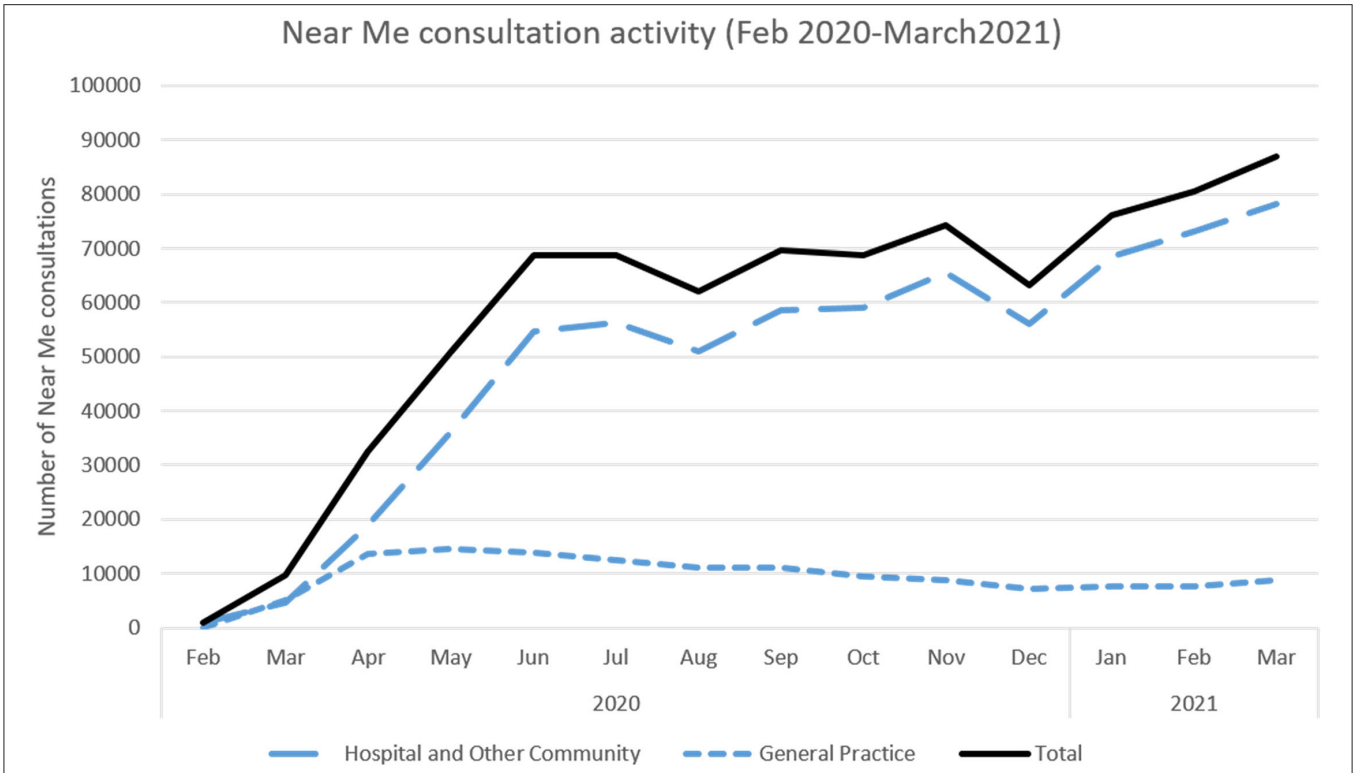

FIGURE 2 | Growth of video consultations before and during the pandemic. Graph shows total number of video consultations for GP, hospital and other community services, February 2020 to March 2021.

pre-pandemic phase, bureaucracy frequently stifled innovation (e.g., with long timelines for business case development, and digital procurement), a program of work to install Microsoft Office 365 was planned but not yet actioned, and support for implementation and scale-up of digital innovations *via* the National Welsh Information Service (NWIS, the national organization responsible for building and designing digital services, now Digital Health and Care Wales) was patchy.

A new national program for Technology Enabled Care quickly followed, with TEC Cymru (a hospital-based team focused on developing and supporting technology enabled care) given a national mandate to roll-out video consulting in 2019, and central government funds available to support NHS organizations to purchase equipment. TEC Cymru's development of video consulting services was modeled on a well-trodden digital innovation blueprint in Wales involving local pilot initiatives, regional spread and national roll-out. Looking to Scotland's Near Me Service as a beacon site (48), Attend Anywhere was adopted as the platform of choice. Pilot services were set up in secondary care and community services (e.g., speech and language therapy) with a focus on supporting early adopters and generating learning. Results were promising. However, when the pandemic hit in March 2020, video consulting remained the preserve of a small group of (largely secondary care) enthusiasts.

As part of the emergency response to the pandemic the Welsh Government invited TEC Cymru to lead an accelerated national roll-out of video consulting services, across health (and social) care; initially focusing on primary and then secondary care. NHS Wales, with support from NWIS, quickly switched the Welsh NHS to Microsoft Teams (via rapid acceleration of the planned program). A government announcement of £50 million recurring funding *via* a new Digital Priorities Investment Fund a year earlier (96), in 2019, meant updates had been done to legacy hardware and software, providing a significant boost to underlying infrastructure and easing rollout. A newly formed "Digital Cell", bringing together the central health and social care team, with digital leads from 11 organizations, met frequently each week to enable rapid decision-making.

TEC Cymru provided implementation support to providers taking up the offer to rapidly develop video consultation services, especially in secondary care. Limitations in server capacity during the early emergency period (Attend Anywhere was overwhelmed with demand), combined with kickback from the GP community who felt that Attend Anywhere was not a good "fit" with general practice (preferring other platforms that, e.g., allowed greater use of text-based and asynchronous communication), meant that the roll-out was not limited to one platform, with others (e.g., AccuRx) also in use. Interest in group video consulting grew, with training sessions commissioned to support development and rollout.

There is limited detailed evidence on how policy played out on the ground, since national level activity data is hard to come by. Data from the TEC Cymru team (who conducted an

in-house evaluation of the evolving national video consulting service), reported over 38,000 video consultations using the Attend Anywhere platform across primary, secondary and community providers from the start of the pandemic to the end of August 2020 (97). To date two evaluation reports provide extensive data and useful insights into the use of Attend Anywhere during the pandemic (97, 98). However they do not report data on the use of other platforms. These documents describe many successful aspects of the program but pay scant attention to the kinds of challenges and conflicts that characterize adoption and spread of digital technology generally and that were documented across the other three nations.

In sum, the Welsh approach to developing video consulting services seems to have been characterized by tensions between those committed to delivering a national service by driving through Attend Anywhere as the main platform (as Scotland did) and others who favored a more pluralist and flexible approach to technology providers. Digital infrastructure was historically weak but had been quickly updated, allowing rapid roll-out and spread of video consulting, with coordinated national scale-up remaining a longer-term strategic objective.

Northern Ireland

Northern Ireland is a small country, with a population of close to 2 million around a third of whom live in rural areas. It has a rich, if complex, history. Established in 1921 when Ireland was partitioned, Northern Ireland has a turbulent, and at times violent, political history characterized by competing perspectives (mostly drawn along religious lines) on the future of Northern Ireland. The "Good Friday" agreement enabled a coalition government to be established in 1999, though this has since been suspended several times. Relationships between Northern Ireland, the rest of Ireland, and the rest of the UK are complex. Recent Brexit negotiations, which frequently placed border arrangements with the UK and Europe center stage, have not helped. Against this challenging backdrop the health system in Northern Ireland is perhaps the least developed of the four nations.

Policy on digital technology and innovation is relatively new to Northern Ireland. Pre-pandemic there was a focus on addressing demographic changes, rising demand and significant health inequalities (99, 100). Proposals for service transformation recognized the value of innovation and the need to maximize use of technology (100, 101). However, while there was an ambition—and growing political support—for digital health; limited capacity, restricted resources and a lack of nationally-coordinated digital infrastructure meant a disconnect between high level policy and frontline practice. At this time the focus was on virtual consulting, which largely (though not completely) equated to telephone consulting (e.g., "*when we talk about virtual consulting in Northern Ireland, we're talking about telephone or video*"). Video consulting services were rarely, if ever, identified as a defined area for health policy and remained a fringe activity that was led by a small group of enthusiasts. Beacon sites existed however these developed *ad hoc* and seemingly with limited central support. With multiple platforms across primary and secondary care and reliance on bottom up, discretionary adoption, spread was limited.

As the pandemic hit, those leading digital innovation focused on engaging with Trusts and primary care providers to work with the small number of clinicians and their teams who had already successfully set up video consulting, run quality improvement programs to support interorganizational networks and peer-to-peer learning, and provide resources for providers and patients to support the use (and hence spread) of virtual consulting. With diverse video technologies and platforms already procured across the system—largely by individual providers, and with limited central input or guidance—development was *ad hoc*, locally driven and informed by existing infrastructure and capacity. In this sense, the response to the pandemic revealed significant gaps in national infrastructure and digital readiness, and dilemmas about how best to coordinate, organize and deliver health care at a time of crisis.

As the pandemic evolved, there was a continued emphasis on virtual consulting with support provided *via* an evolving quality improvement program. Consulting in Northern Ireland involved a mix of telephone and video, with in-person consulting as needed and in line with evolving guidance on physical distancing. A structured and systematic approach to virtual and video consulting remained the ambition however, while progress was clearly made, that ambition has yet to be achieved.

National level activity data is hard to come by, hence there is limited detailed evidence on how policy played out on the ground. Stakeholder interviews suggested wide variation in video consulting, with limited uptake in primary care. A press release from the British Medical Association Northern Ireland in September 2020 indicated that GPs across the country had "*carried out 14,000 video consultations*" (102) in the previous 6 months (i.e., since the pandemic started). It's not clear where this figure came from, or which platforms were used.

In sum, Northern Ireland was behind other nations in terms of digital health strategy and infrastructure. During the pandemic significant effort went into spreading virtual consulting, with video consulting one part of a blended approach. However, while quality improvement initiatives and shared learning about video consulting services helped, much of this effort was bottom up, led by frontline enthusiasts and often in spite of, rather than because of, national efforts.

Cross National Comparison

National narratives on video consulting show that, even in the context of an unprecedented global emergency, establishing and sustaining video consultation services as business as usual is challenging. Despite calls from senior policymakers for "remote by default" services (103), analysis of interview, survey and activity data indicates variability in approach across the four nations, and in levels of spread and scale-up of video consulting (see **Figure 3**).

The following sections tease out similarities and differences in policy approach and areas of learning relating to spread, scale-up and sustainability of video consulting.

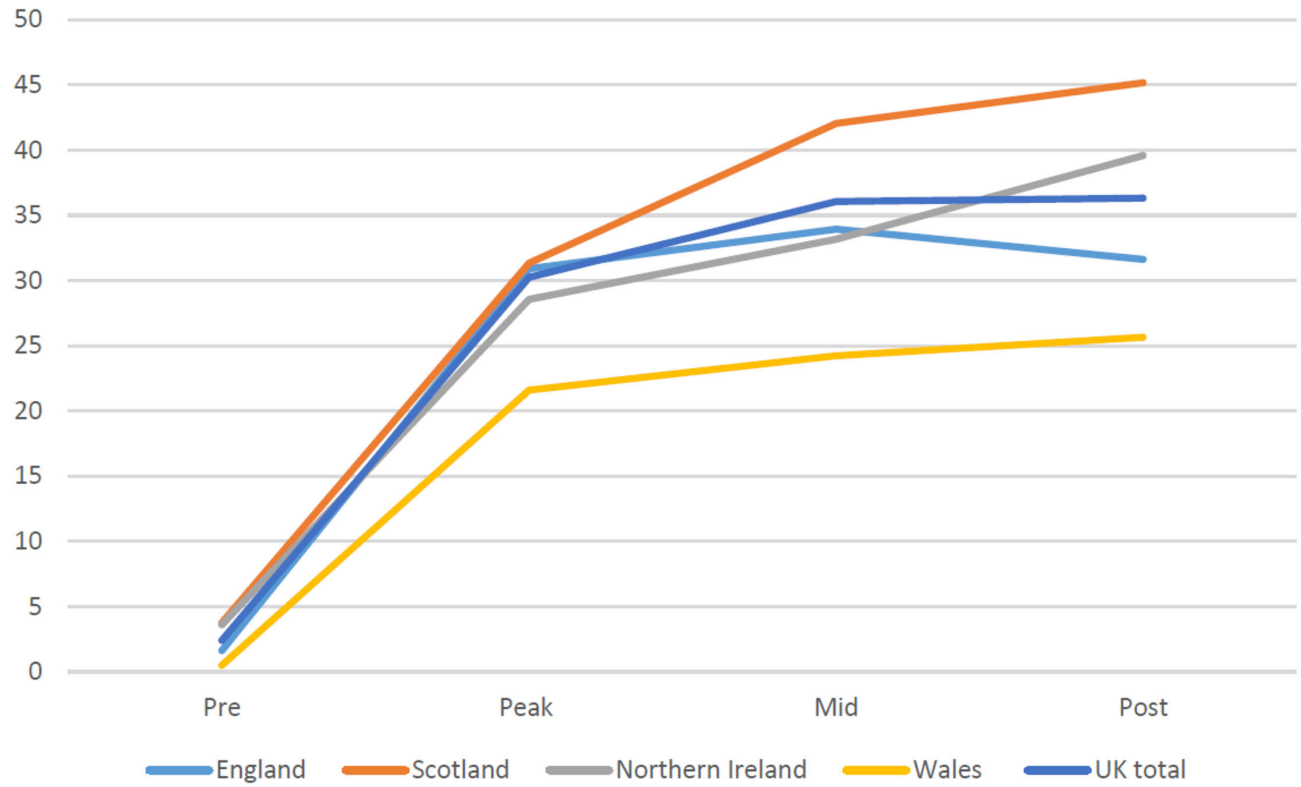

FIGURE 3 | Reported proportion (%) of consultations carried out by video in each nation during the first 6 months of the pandemic. Data is taken from our national survey of NHS staff, conducted in September 2020, with pre-COVID before March, peak during March/April, mid during May/June and post in July/August.

Infrastructure as the Foundation for Spread and Scale-Up

Across all four nations, the pandemic was situated as an opportunity (104) for rapid growth of video consulting services. Such spread and scale up was reliant (at least in part) on the extent of infrastructure, what Star referred to as "*what other things run on*" (105), including technical, material, operational and logistical arrangements. Infrastructure largely runs in the background and is visible only on breakdown (52, 105)—it requires foregrounding and active (usually long-term) planning as part of the policy process.

In Scotland, the Government's longstanding commitment to using technologies to achieve high-quality, accessible and equitable care and contribute to a low-carbon future meant that investment in digital infrastructure was well under way when the pandemic hit, providing strong foundations to rapidly scale-up its national video consulting programme. Scotland had foregrounded the on-going investment and work (105, 106) required to maintain and evolve digital infrastructure. For instance, while remote areas had limited or no broadband access (e.g., some outlying islands only had broadband outside the largest town for a few years), this was improving due to an on-going policy push for connectivity.

When the pandemic hit the pre-existing infrastructure in Scotland meant that the Near Me service could be immediately mandated across the country. This clearly paid off, with significant spread and scale up (**Figures 2**, **3**). Elsewhere, while pockets of innovation existed (e.g., in specific regions) the national infrastructure required to rapidly spread video consulting in England, Wales and Northern Ireland was only partially in place. Challenges included rural broadband access (e.g., in parts of Northern Ireland), lack of bandwidth, outdated equipment, limited investment and staff training, and partial guidance and support. While England, Wales and Northern Ireland were considering or piloting Attend Anywhere, none had procured it (or any other platform). This was neatly summed up by one senior clinical decision maker in Wales, who told us, "*the fact that Attend Anywhere wasn't ready was the biggest challenge*".

Recent and rapid investment helped. As a senior policymaker in Wales reflected: "*we had a lot of new… infrastructure, software as well as hardware, and so that helped because it could soak up the very sudden dial up in demand capacity that we needed*". But on-going work and investment (pre- and in-pandemic) was needed. What this meant was that, while individual providers were clearly able to (in some cases, rapidly) develop video consulting services, the partial infrastructure and the on-going effort required to continually rework it as new resources and products came online, presented a major challenge to scale-up.

One aspect of infrastructure that all four nations focused on at the start of the pandemic was the removal of regulatory and administrative blocks. As one hospital doctor in Scotland put it, "*when COVID happened—the red tape seemed to vanish*". This

included removal of regulatory blocks to rapid procurement, the use of bespoke software for supporting video consultations (e.g., *via* procurement of Attend Anywhere in England and Wales), and relaxation of regulatory rules around information governance. As one senior policymaker in England told us in relation to data sharing:

> "*nationally there's been information governance guidance that's gone out…that's been managed through the COVID notice which allows data sharing between [providers]…to make that information for direct care purposes available… traditionally, you know, going through data sharing agreements takes time.… Whereas actually this has been taken on centrally, some of that bureaucracy I suppose has been lightened in this crisis*".

This focus on information governance was critical at the outset of the pandemic, shaping how and when video consulting was adopted and which platforms were used (e.g., some providers issued guidance to prevent use of Zoom early on in the pandemic due to concerns over privacy and security), and enabling spread.

Governance, Politics and Digital Technologies

Health system governance and politics shaped policy implementation. In England, guided by the market-oriented approach characteristic of the English NHS (**Table 1**), the crisis response to digital technology (104) was framed as an *opportunity* to innovate (**Table 3**), accelerate change and shift toward a "remote by default" model of health care (103). Freed from the fetters of heavy-handed state control in earlier "Big IT" projects [notably the UK's National Programme for Information Technology (NPfIT), a nationally-led program, characterized by centralized authority, that aimed to bring NHS "use of information technology into the 21st century", but failed to deliver on a massive scale with costs to the UK taxpayer of over £13bn (107, 108)], the approach was to enable middle out and bottom-up change.

Previously the commissioner-provider split (in England since 1991, but resisted in Scotland, Wales and Northern Ireland—**Table 1**) has created practical hurdles for the introduction of new technologies (109). At the start of the pandemic two significant changes were quickly put in place to better manage the market: central procurement of a single platform (Attend Anywhere), and release of central guidance on procuring other platforms. This eased rapid set up and spread, particularly in secondary care:

> "*we knew as a team the only way we were gonna get this off the ground quickly is to use Attend Anywhere, obviously it was a client procurement process, but…the end result was it has to be Attend Anywhere to make this happen because of all the learning through the pilot*" [Senior policymaker, England]

In Northern Ireland legacy agreements between suppliers and largely autonomous hospitals placed limits on the potential for national or regional coordination. As one policymaker told us: "*Because they [the five Trusts] cover a wide area and they have obviously a lot more autonomy, so they basically kind of wanted to do their own thing*". Pockets of innovation enabled video consulting services to develop (notably in antenatal care). However, the challenges allied to developing digital infrastructure and of rapidly reorganizing services at a time of crisis, left few options for policymakers beyond continuing arrangements with multiple suppliers and using existing platforms.

In Scotland and Wales the aspiration was to develop national video consulting services. Rather than engaging multiple suppliers (as in England and Northern Ireland), the focus was on establishing and managing central provision. Prior policy and investment in Scotland, along with advanced digital infrastructure and the Near Me service, meant that the immediate pandemic response provided an opportunity to accelerate scale-up, extend successful models of good practice using principles of quality improvement (with central support, training and guidance, and system learning), and rapidly bring many providers to the same level as pre-pandemic exemplar sites.

In Wales, with one eye on the success of the Scottish service, the overarching crisis response was framed as an *opportunity* to become known as a national digital innovator—to build a national video consulting service and gain political and health system currency. The aspiration for a national service was well-received in government and TEC Cymru (see above). However, the reality on the ground was problematic: historic lack of infrastructure, limited resources, collective modes of decision-making and the work required to bring providers across sectors on board with the logistical, technical, material and cultural aspects of video consulting proved challenging. As one policymaker reflected, the pandemic brought opportunities to rethink this approach:

> "*How do we move away from having two years to write a business case and that, you know, particularly IT—digital procurement—takes years for us to do and we'll buy some and it'll take seven years to implement. That's not always about procurement, that's about everybody agreeing what they want and how we're actually taking that forward. So, I think there are opportunities in this for us to rethink some of that*".

Cross-national politics also played a role in shaping, at least peripherally, the approach to scaling up video consulting. Several interviewees described longstanding competition across Wales, Scotland and England (which typically fell out along party political lines) and spurred the vision for respective health systems to "lead the way" in technology-enabled care across the UK.

Making Policy Happen: Operational Crisis Management and the Spread of Video Consulting

It was the operational crisis management (32, 33) of senior civil servants and health service executives—focused on the implementation of evolving policy by frontline NHS staff—that shaped understanding of evolving policy, approach to implementation and what played out on the ground.

In Scotland and England this often (but not always) involved a pragmatic approach to both policy implementation and crisis management (33), with senior civil servants taking proposals to develop "remote by default" consulting and turning them into workable "real world" policies. Rather than relying on the kind

of technocratic problem-solving that tends to be characterized as "policy" (e.g., with a series of linear steps involving problem definition, policy formulation, implementation and evaluation), these individuals and their teams focused on "making policy happen" at a time of crisis (33, 75). This process involved often senior and experienced staff in a process of sense-making (requiring judgements about set up and use of video consulting in the context of heightened ambiguity and uncertainty), decision-making and coordination (across multiple providers, suppliers, networks and political contexts; and involving legitimate explanation of decisions to NHS staff) and "learning-while-doing" (emphasizing adaption and bricolage in shaping video consulting services in the unfolding crisis response). Take the following example from a policymaker in England, supporting roll out of video consulting in secondary care:

> "*It's very much carrot, not stick, mentality. And we've done some learning on quality improvement and things like that and…I'd say working with [head of directorate] it's been a completely different experience to any other role I've had in the NHS. It's just given the freedom and the space for us to kind of work in a different way and more of a, I guess you'd say more of a creative way*".

Rather than being an explicit set of policy instruments or tools, this approach to "making policy happen" was grounded in practical rationality (33), coalition- and consensus-building (75) and use of process-oriented knowledge (75), while also acknowledging the unpredictability, uncertainty and complexity of the evolving system response to COVID-19 (64). Negotiating this terrain, while engaging and gaining support from NHS organizations and staff (e.g., regional leads, service managers) who were involved in, or could influence, the spread of video consulting, was critical to success. This was evident in the Scottish Government's enabling (rather than command and control) approach, with the TEC program creating the ethos and infrastructure within which professionals could be creative and locally adaptive; and with engagement of professional bodies (such as Royal Colleges) situated as critical in endorsing the TEC program's vision and guidance documents. Proactive communication between government, civil servants and professional bodies ensured that front-line clinicians believed that changes were professionally endorsed and led rather than imposed.

Evaluation and system learning was a key part of strategy in Scotland and England (and, to some extent, in Wales). We were particularly struck by the focus on region-by-region quality improvement in Scotland—and in secondary care in England—grounded in a system-wide approach that involved senior civil servants negotiating both political vision and frontline realities in ways that led to tangible and implementable actions (e.g., changes in procurement, technical guidance) that, in turn, supported the spread of video consulting.

In contrast, in Wales the operationalization of policy on video consulting was characterized by what policymakers and professionals described as centralized authority, a rigid approach to rollout and "*strongly embedded tribal interests from professional groups*". While there were glimmers of system learning ("*everybody kind of came together*"), there was also tension across local and national interests that made it "*difficult to come to an all Wales consensus*". In Northern Ireland, the focus remained largely on *virtual* (primarily phone) consulting, without an explicit policy on video consulting.

No matter the approach to making policy happen, cross-national exchange was critical in bolstering spread, enabling trusted relationships and sharing of expertise. As one program manager in Wales told us: "*We've certainly learned from NHS England; we've learnt those lessons [on confidentiality and governance challenges with video group clinics]*". England, Wales and Northern Ireland all turned to the Scottish TEC team—before and during the pandemic—as a site of shared learning and, in England and Wales, a means of gaining additional capacity (e.g., *via* spare "waiting rooms" in the Scottish Near Me service). These links were not new, but were reinforced in the pandemic and proved critical in progressing rapid spread and scale-up.

Policy Diffusion vs. Bottom Up, Service-Led Adoption of Remote Services

Implementation of policy supporting spread of video consultations was a critical part of service change supporting the pandemic response (103, 110–112). However, the policy vision did not always match on-the-ground realities of health service provision. This was evident in primary care, where most consultations took place by telephone (37, 113–116).

GPs in our dataset repeatedly commented on how they reverted to use of the telephone first telling us, for instance, how "*I sometimes invite a patient to engage in a video consultation during a phone consultation, where I feel this would be helpful. I don't do it very often, as I am very used to the telephone consulting and find this adequate for around 90% of encounters*" (survey respondent), or how "*I mostly use telephone, sometimes use photos…*". This was reflected in activity data, which showed only a small proportion of general practice consultations taking place *via* video (see e.g., **Figure 2**). Some GPs were uncomfortable with the video medium:

> "*Having been quite pleased and quite excited by doing something new they then [after the first wave] became increasingly concerned that you hear lots of people saying, you know, 'I didn't go into this business to be a call center doctor,' 'I like patient contact,' 'I feel unsafe'*" [Senior professional]

This "telephone first" approach was reflected across much of our dataset. In Scotland a high volume of GP practices introduced the Near Me service model, but use remained infrequent (23% of video appointment activity compared to 77% for hospital and other community services). A similar picture was evident in England where, despite rapid set up of 99% of practices at the start of the pandemic (set up being what one senior policymaker described as "*different from utilization, it's available in the practice*"), video consulting made up only a small proportion of general practice consultations. The focus was on digital triage, phone consulting and asynchronous e-consultations. As the same interviewee continued:

> "*Our data shows they're increasing, I mean I think we're seeing about two and a half million a month being submitted.… When I'm talking about e-consultations I'm talking about this sort of route to access, asynchronous access to the practice: you get the information up front, and then you can kind of sort people to the right place*".

This approach to remote consulting had received a significant policy push several years before the pandemic, with a drive for digital innovation in general practice and central funding to support it (78, 80, 117). Multiple suppliers came on board, with the technology typically service oriented, aligned with existing workflows and cheap to install. Comments ($n = 575$) from survey respondents across the four nations about choice of platform frequently referred to AccuRx, known to many before the pandemic (who were using it for texting patients), and considered readily available, easy to use and integrated with clinical systems. This resonates with the experience in Wales where the national video consulting service, using Attend Anywhere, was perceived by some to be aligned with secondary care workflows. GPs often reverted to AccuRx, "*which offered some really GP specific functionality, and there was…a misunderstanding about what was it GPs wanted or needed from video consulting software; so GPs wanted something to integrate with their practice systems*" [senior policymaker]. This made sense given that AccuRx was sold direct to practices (and was freely available during the first few weeks of the pandemic) as a general work support tool: as one industry representative told us, the focus is on "*trying to show primary care that it is possible to have software that works and is intuitive and its reliable*".

Through this lens, policy implementation during the pandemic was unsuccessful. Rather, primary care provides a good example of bottom up, service-led adoption of a technology that was perceived as a good "fit" with existing workflows and clinical systems.

Longer Term Sustainability of Video Consulting

Moving beyond the initial crisis response, the ways in which the four nations made sense of the evolving pandemic and use of digital technology shifted to one of increasing exposure, highlighting *"the significance, actions and issues of people, social groups, systems, organizations and infrastructure that have previously gone unnoticed*" [(104), p. 5]. The focus across the four nations (albeit to varying degrees) was on three practical and moral questions about the organization and delivery of health services issues.

First, was increasing concern about digital exclusion of some patients and families, including potential longer term consequences:

> "*We need to do more for people who don't have access to broadband or can't afford a laptop. … I don't believe that [remote] should be the default. We've come a long way in healthcare, we don't want to ruin it now*" [Service Manager, Scotland]

This raised moral questions for policymakers about how to balance the desire for digital transformation of health services with the need to ensure patients weren't excluded from services, or disadvantaged when they did so remotely [see (57) for examples].

Second was the level of uncertainty about the future organization and delivery of services. Three system issues were pertinent. Firstly confusion, especially in England and Wales, about whether the NHS is a "remote by default" service, with interviewees often uncomfortable with the push for everyone to access care remotely. Secondly the impact on the health care workforce, with some clinicians describing the use of video consulting (and the speed and scale of the switch) as demotivating, devaluing and challenging their sense of professional purpose and identity. Thirdly, how services would be redesigned as the pandemic evolved and what this meant for patients. As one program manager in Wales reflected in relation to group video consulting:

> "*… we don't see it as a response to COVID; we see it as a response to COVID recovery planning, but also as a sustainable business-as-usual approach as part of that outpatient service delivery toolkit*"

Our dataset was peppered with similar examples situating video consulting as an integral and on-going part of the NHS offer (rather than a temporary response to the pandemic). This aligned with the renewed interest of politicians who were now: "*really excited about the speed with which digital transformation has changed…and at that policy level it's really helped to help people to grasp how digital can help drive change*" [Senior policymaker]. This interest was often couched in deterministic terms, seeing technology as a "quick fix" to problems of service delivery and redesign and failing to acknowledge the social-technical work involved in spreading and scaling up digital innovation. Work was underway to manage expectations:

> *"I spend quite a lot of my time trying to talk people down a little bit… For some things we maybe could aim for five months, but there are also some things that are just inherently complex where we've got a lot of dismantling…and rebuilding to do"* [Senior policymaker, Wales].

Finally, there was significant concern about a return to pre-pandemic levels of governance and regulation. As one senior decision maker put it, "*there's this tension between how much do we maintain the lightweight rapid governance that we had versus how much do we bring back a degree of stability"*. Interviewees across all four nations repeatedly told us that this light touch regulatory approach was critical for spread and scale-up.

DISCUSSION

Summary of Key Findings

In this paper we have focused deliberately on policy informing the spread and scale-up of video consulting services across the four UK nations, with the COVID-19 pandemic a burning platform for change. Drawing on data from three studies we have shown the following. First, an interpretive approach to policy analysis combined with theory on crisis management has allowed us to surface the varied national approaches to developing and

enacting policy during the pandemic, the challenges faced by national decision makers in negotiating complex systems at a time of crisis, and the varied national policy-level influences aiding progress toward rapidly scaling up video consultation services. Second, following from this, we have shown how different approaches to understanding, negotiating and enacting policy during a time of crisis, variably shape spread and scale-up. Through the combined lens of policy implementation and crisis management, it is clear that those who are able to work flexibly and adaptively in the midst of an evolving crisis appear to be more effective in enabling the spread of video consulting services. Such work involves facilitating the capacity and articulation work needed to enable an iterative approach to implementation; involving multiple actors across the system to work together to solve emergent problems; engaging with processes and actions over time [rather than discrete decisions administered at a particular moment in time (72)]; and continually reviewing, monitoring and evaluating progress as part of a wider approach to quality improvement and system-level learning.

Third, we have shown how digital infrastructure (and on-going investment in, and adaptation of, that infrastructure) is foundational—without it, national-level scale-up is nigh on impossible even during a crisis. Investment in digital infrastructure in Scotland in particular is evidence of this—not only was Scotland uniquely well placed to expand its video consultation services at pace and scale when the pandemic hit (leading to a dramatic increase in the number of services adopting video and in consultations conducted), but the level of *infrastructuring* involved—i.e., the "*continuous collaborative and inherently political process*" [(118), p. 205] supporting iterative design and development of digital infrastructure—enabled continuous, steady and sustainable growth in ways that was appropriate to different sectors, organizations and needs.

Fourth, in some settings (often where a more technocratic policy approach was in play) we found a contrast between "work as imagined" by policymakers and "work as done" by frontline practitioners. This was evident in primary care where, in spite of significant policy enthusiasm for video consulting in England, Wales and Scotland, many clinicians reverted to using existing ways of remote consulting (e.g., telephone consultations), that aligned closely with clinical workflows and practices.

Finally, while there has been significant (if varied) spread of video consulting across the UK during the pandemic, findings indicate that sustainability of these services and potential for further spread will only be feasible if questions about the future shape of service delivery and resolution of digital inequalities are addressed.

Strengths and Limitations

Our data is drawn from three studies that, together, provided a rare opportunity for cross-national analysis, enabled significant insights on evolving policy relating to video consulting, and shone a light on issues of policy implementation that have largely been ignored in literature on telehealth and video consulting to date.

Our dataset brought together national survey and interview data, with analysis of documents and activity data. While every effort was made to identify a diverse group of stakeholders in each of the four nations, the level of engagement from senior politicians at a time of crisis was limited. Those we did interview were able to provide a policy narrative on the spread and scale-up of video consulting. In this sense, we were able to access the national-level perspectives needed in each of the four nations and compare across these. UK-wide activity data was harder to come by. There is no readily available central dataset on consulting activity across the UK; and in England, Wales and Northern Ireland there is no readily available national dataset of consulting activity. In England we were able to access Attend Anywhere data for secondary care *via* NHSE/I (in line with confidentiality and data sharing agreements), but no data on use of other platforms, or in primary care. In Scotland, we were able to access national level data on the use of the Near Me service (using Attend Anywhere) but, again, no data on the use of other platforms. This means that, while the activity data we have provides a helpful snapshot, it falls short of providing a full picture of activity and, as different countries use different approaches and criteria for monitoring activity, cannot be used to draw direct comparisons. We only have reported data for Wales and Northern Ireland. Finally, our studies were primarily qualitative, focusing on the experiences and perspectives of those involved in setting up and running video consultation services at multiple levels. We are therefore unable to make a causal link between specific policy initiatives on the one hand and the spread of video consulting on the other.

What Our Findings Add to Existing Literature

Our findings add to the literature on video consulting, which has tended to focus on specific clinical setting or condition, pay limited attention to policy initiatives and/or processes, and look at implementation *within* services, rather than knowledge sharing and other learning needed to achieve spread and scale-up of video consulting *across* settings (26). Comparison across countries is helpful here. Findings indicate that there was significant and rapid effort at system level in Scotland, England and Wales (less so Northern Ireland) to give space and impetus to scaling-up video consulting services in the midst of the pandemic, both by *national level* decision makers (e.g., civil servants) and *street level* bureaucrats (e.g., health service executives). The legacy of Scottish policy supporting video consulting, combined with the explicit focus on developing a national program, clearly enabled a rapid and coherent response in the midst of crisis. That the other three nations turned to Scotland for advice and support is telling in terms of the on-going need for system-level learning and exchange.

Disruptive technological innovation has been shown to be complex, uncertain, challenging and risky (74, 119, 120), with success not just about new technologies but also how we make them work and whether health service infrastructure can accommodate them at speed and scale (52, 121). This kind of infrastructure takes time and effort to develop and is achieved incrementally (105) with, for instance, new devices and platforms requiring reorientation and reworking of existing

infrastructure over time (52, 118). For video consulting this includes hardware and software, as well as the language of clinical applications, a human-computer interface, people who interact with it (including developers, support staff, staff and patients), internal organizational features (e.g., environment, policies, procedures), the scaffold for a learning health system, external rules and regulations, and the measures and metrics used to monitor it (106, 122). This resonates with our findings: on-going work and investment in infrastructure in Scotland enabled the vision and foundations to support adoption to be in place ahead of the pandemic and on which rapid scale-up of the national video consulting program was possible. Elsewhere, limited investment in infrastructure and lack of infrastructuring pre-pandemic placed limits on spread and scale up in-pandemic.

The crisis context gave a critical boost to the implementation of policy on spread and scale up of video consulting. To our knowledge, this focus on crisis and the intersection with implementation of video consulting is new. A small number of pre-pandemic studies explored the technological, contextual and practical challenges to be overcome pre-pandemic for video consulting to be more widely used. One multi-level, qualitative study in the English NHS, undertaken by our team, examined the development, implementation and use of video consultation services (1, 51), focusing on national-level policy, organizational-level implementation, and micro-level use of video consultations within patient-clinician consultations. A key finding was the distinct mismatch between the policy narrative of transformation and efficiency (to be achieved through technological innovation) and the reality of services *not* being transformed by the available technology (which may be experienced as unfit for purpose). Findings from our research suggest that this policy narrative, and the mismatch with frontline experiences, has continued during the pandemic: what decision makers viewed as an *opportunity* to scale up video consulting appeared to be at odds with what many in primary care viewed as *disruption* in terms of the work involved in "*rapidly shifting existing organizational practices to new digital spaces*" [(104), p. 4]. This builds on earlier work on technological innovation in health care and the challenges of routinizing new technologies in everyday practice [e.g., (48, 74, 123)].

The approach to policy implementation and crisis management in each of the four nations was key in rapidly spreading and scaling up video consulting. To date, research has tended to focus on the political and institutional context of policy making at a time of crisis or on strategic crisis management [see e.g., (124, 125)]. Our research adds to this growing body of work, foregrounding *approaches to crisis management* that are informed by complex systems thinking and notions of unpredictability, radical uncertainty, non-linearity, and adaptability (60, 61, 63, 126); and effective *implementation of policy* as involving pragmatic and iterative cycles of sense-making, meaning making and learning-while-doing (33, 34, 75). In short, an approach to implementing policy on video consulting that is grounded in pragmatism and practical rationality appears more likely to facilitate spread—particularly at a time of crisis—than one grounded in technocracy and technological determinism (33).

Conclusions and Recommendations

Pre-pandemic video consulting was a marginal activity (1, 58). This changed with COVID-19. The combination of a highly infectious disease and requirements for physical distancing, with increased funding, relaxed regulation, engaged suppliers and an approach to "making policy happen" (33, 64), enabled spread of video consulting at a pace and scale that was previously unimaginable. This shift was logistical, as well as technical and cultural, and required significant policy input. Further spread may well have been possible, however, digital infrastructure was only partially in place hampering speed and scale of progress. As the acute phase of the pandemic passes, senior decision makers would do well to: (a) advance the infrastructural building blocks that are now in place to support video consulting services, (b) recognize and accommodate the level of infrastructuring (118) required to sustain and extend scale-up going forward, and (c) take an active interest in the ways in which the policy process—particularly implementation—can be further strengthened and supported. This is critical if the UK NHS is to be ready in the face of further unexpected and rapidly evolving crises that require foundations for action to be in place, and rapid application of plans and skills. As Boin so neatly puts it, "*the leadership challenge is to have good plans and professional responders in place*" [(32), p. 8/9].

Consideration of the longer term sustainability of video consulting services will be crucial given the policy vision for video consultations as replacing or supplementing a significant proportion of in person care (79, 127, 128). The jury is still out with regard to if and how nationally coordinated (as in Scotland and Wales) and locally devolved (as in much of England and Northern Ireland) video consulting services are best placed to enable continued scale-up and the extent of sustainability offered by different approaches in the longer term. There is much to learn across the four nations: research is needed that focuses, not only on design, development, procurement and regulation of different kinds of video consulting services (e.g., national/local, one/many suppliers), but also on the cross-national learning that can support effective policy implementation, crisis management and spread and scale-up.

Scale up of video consulting during the pandemic has exposed the lack of attention previously given to those with limited access to services and digital resources [in terms of "*magnified high levels of inequality*", [(104), p. 6]. Some work is already underway to redress this, but policymakers and researchers need to do more to improve uptake and ongoing use of video consultation services for marginalized and/or underserved groups (129). Without this, further scale-up and longer term sustainability of video consulting services is unrealistic and the potential to respond quickly and appropriately in the face of similar crises limited.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by NHS East Midlands Leicester Central Research Ethics Committee granted research ethics approval for the study (REC ref 20/EM0128; IRAS ID: 283196 and subsequent amendments). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SS leads a work package on the Remote by Default study and is Chief Investigator on the Health Foundation Video Consultation study. She provided theoretical expertise, led senior stakeholder interviews (with support from AR, RR, and TG) and documentary analysis, and drafted the paper. TG is Chief Investigator of the Remote by Default study and joint Chief Investigator (with JW) of the Scottish telehealth evaluation study. RR leads a work package on Remote by Default. CP is lead for group video consulting on the Health Foundation study. GH, LM, and JW led on interviews across the four nations. GW led on survey design and reporting, AR on analysis of the Welsh case study, and JM on patient experiences of video consulting. TG, RR, and LM contributed clinical and some social science and technology expertise. SS, GH, JW, CP, AR, JM, GW, and SF contributed social science and technology expertise. All authors contributed to the empirical studies and selected and supplied empirical data that illustrated and shaped the analysis. All authors have read and approved the final manuscript.

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Health Technology Adoption in Liver Disease: Innovative Use of Data Science Solutions for Early Disease Detection

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Chronic liver disease (CLD) is an ignored epidemic. Premature mortality is considerable and in the United Kingdom (UK) liver disease is in the top three for inequitable healthcare alongside heart and respiratory disease. Fifty percentage of patients with CLD are first diagnosed with cirrhosis after an emergency presentation translating to poorer patient outcomes. Traditional models of care have been based in secondary care when the need is at community level. Investigating patients for disease based on their risk factors at a population level in the community will identify its presence early when there is potential reversibility. Innovation is needed in three broad areas to improve clinical care in this area: better access to diagnostics within the community, integrating diagnostics across primary and secondary care and utilizing digital healthcare to enhance patient care. In this article, we describe how the Integrated Diagnostics for Early Detection of Liver Disease (ID-LIVER) project, funded by UK Research and Innovation, is developing solutions in Greater Manchester to approach the issue of diagnosis of liver disease at a population level. The ambition is to build on innovative pathways previously established in Nottingham by bringing together NHS organizations, academic partners and commercial organizations. The motivation is to co-create and implement a commercial solution that integrates multimodal diagnostics via cutting edge data science to drive growth and disrupt the currently inadequate model. The ambitious vision is for this to be widely adopted for early diagnosis and stratification of liver disease at a population level within the NHS.

Keywords: liver disease, diagnosis, pathway, implementation, community, artificial intelligence

INTRODUCTION

Liver disease is a significant health burden worldwide and is recognized as a leading cause of mortality and morbidity in the UK. In 2011 it was first highlighted that despite improving mortality rates in neighboring Europe, deaths from liver disease continued to rise in England (1). In the UK it is the fifth highest cause of death and standardized mortality rates for liver disease have

risen by 400% since 1970, contrasting with improvements in mortality for other major diseases (2). Furthermore, in the UK liver disease is the leading cause of death in the 30–49 age group (3).

The prevalence of lifestyle related liver disease has spiraled over the last decade with prevalence of diseases such as non-alcoholic fatty liver disease (NAFLD), a spectrum of disease in which there is increased fat in the liver cells, being estimated at ∼20–30% worldwide (4). Timely diagnosis makes potential reversal of early liver fibrosis with behavioral intervention feasible; 90% of liver disease is lifestyle related (5). Nearly 50% of patients are only diagnosed with liver disease following an emergency admission to hospital (6). Liver disease is in the top 3 for inequitable healthcare (7); the median age of death for people with chronic liver disease (CLD) differs by 9 years in those residing in the most deprived quintile compared to the least deprived (8). Furthermore, the COVID-19 pandemic highlights a disproportionate impact on CLD; the risk of dying (hazard ratio of 1.5) was the highest of all the chronic diseases in a study of 15,000 hospitalized patients (9).

Although good at detecting advanced disease, no single diagnostic test is currently available or adequate for reliably detecting and stratifying early liver disease. Traditionally a set of blood tests termed "liver function tests" (LFTs) are carried out to determine if liver disease is present. These include enzymes and molecules present when there is liver damage. These tests are frequently requested but often do not identify liver disease; up to 20% of LFTs have an abnormal result however only 1.26% of these patients are later diagnosed as having chronic liver disease (10). Conversely, liver blood tests can be normal in up to 90% of people with severe liver disease (11). Other methods of assessing a patient's probability of having liver disease within the community include non-invasive scoring systems, such the FIB4 score which is based on a patient's blood test results and age, which are widely used in clinical practice (12). The Enhanced Liver Fibrosis (ELF) test can be used to predict presence of liver fibrosis but there is varying availability of this test across the UK (13). A FibroScan® is a specialist ultrasound, which generates a numeric assessment of the degree of scarring, or fibrosis, of the liver.

EARLY DETECTION OF LIVER DISEASE IN THE UK

The Integratrated Diagnostics for the Early Detection of Liver Disease (ID-LIVER) consortium, made up of NHS clinicians, academics and industry leaders in both diagnostics and Artificial Intelligence (AI), are working together to develop solutions for identification of early liver disease. We identified three gaps which we believed would improve the identification of early liver disease. The first critical gap is how we improve the detection of liver disease at a stage that early intervention makes a difference. The second critical gap is moving diagnostics and initial management from hospital-based care to community-based care. The third critical gap is to focus on diagnosis and intervention at the sites of need based on objective data and not historical needs. Our hypothesis is that an innovative approach paired with the experience needed to implement a clinical pathway within the NHS may help address all three of these needs. The novelty of our approach includes both inter-sectoral collaboration and broad disciplinary involvement; highlighted by the diversity of partners encompassing the NHS, two major universities and industry. The aim is to have an iterative and integrated solution that traverses the traditional boundaries of primary and secondary care.

The need for a comprehensive strategy to tackle the burden of liver disease was first highlighted at a national level in 2011 and first priorities on the agenda are strengthening detection of early liver disease (1, 2). Currently formal pathways for diagnosis and management of liver disease do not exist in many UK healthcare settings. Screening of the general population for liver disease is not recommended by the American Association for the Study of Liver Diseases nor European Association for the Study of Liver disease (14, 15). Local initiatives aiming to diagnose liver disease earlier in the general population have been implemented with heterogeneous approaches taken across the UK. Three established approaches are discussed below.

In Nottingham, the Scarred Liver Project (SLP) established a commissioned pathway in which the General Practitioner (GP) identifies patients for screening for CLD based on risk factors. Initial pilot studies in 2013 focused on risk factors for CLD and the pathway is applicable to both metabolic and alcohol related disease etiologies (11, 16). GPs having direct access to FibroScan® is an integral feature. Based on the FibroScan® result, patients at high risk of CLD undergo further investigations in secondary care whilst low risk patients are discharged with lifestyle advice. It has been shown to have both diagnostic efficacy and cost effectiveness in comparison to normal standard of care (17, 18).

Another approach developed is using a "reflex" testing method in which further testing is triggered if the initial screening result is abnormal. Dillon et al. described the "Intelligent LFTs" (iLFTs) pathway which started in Dundee, Scotland, where an abnormal LFT results led to a reflexive cascade of further blood investigations being carried out. Diagnostic and management advice based on these results is then issued to the GP (19). The iLFTs pathway has been shown to allow 75% of abnormal liver blood tests to be managed in primary care (20). Reflex testing has also been used in the Gwent area of Wales, with automatic calculation of the ratio of LFT results of aspartate aminotransferase (AST) to alanine aminotransferase (ALT) following an abnormal ALT, which has resulted in increased detection of patients with cirrhosis in a community setting (21).

Two stage stratification pathways have been set up in areas of the UK and adopted as routine clinical care. An example of a two stage pathway is in North London where Srivastava et al. put in place a "NAFLD pathway" using FIB4 scoring and ELF test for stratification of patients with a clinical diagnosis of NAFLD or an abnormal ALT (22). Patients with a new or established diagnosis of NAFLD are eligible for participation in the program and based on the initial FIB4 result the patients are stratified to be at either low risk, indeterminate risk or high risk of advanced liver fibrosis. Subsequently cirrhosis detection rates

were reported to have increased three-fold compared to those on a standard care pathway.

The three separate pathways have individual strengths and weaknesses. For example, starting with abnormal liver enzymes may miss disease and focusing on risk factors provides a challenge on resources in the short term even if long-term savings are realized. The ability to iterate and evolve these pathways will be important in the rapidly dynamic NHS landscape.

LESSONS LEARNED FROM THE SCARRED LIVER PROJECT

As a forerunner, the SLP is an important resource for future pathway implementation, including the ID-LIVER project.

Co-operation between primary and secondary care was critical to the success of the SLP. As described in the King's Fund report "Adoption and spread of innovation in the NHS" in 2019 the presence of senior clinical champions in primary and secondary care not only allowed co-production of the pathway but were imperative in the education of stakeholders and dealing with inevitable problems that arose during implementation (23). The sense of shared ownership by primary and secondary care stakeholders facilitated agile solutions for implementation problems and prevented conflict between the involved parties.

Deliberately having a pilot phase when rolling out the project in different geographical locations was important in managing capacity and identifying issues early on. This multi-stage process has needed long term commitment, proactive engagement and negotiations from the clinical champions to gain traction in primary care and ongoing funding at every stage of the process. A major barrier for the project was based on the financial budgets being contained within operational silos. The long-term health economic arguments were understood by commissioners, but they were constrained by the focus on short term annual budgets. Similar challenges have been highlighted in many innovation reports, including the King's Fund report, with funding for transition to clinical care often being cited as the main obstacle for successful delivery of innovation (23).

The initial studies of the SLP were conducted in different geographical and socio-ethnic areas and showed that feasibility, engagement and disease detection was similar. However, during evaluation of the commissioned pathway it became evident that 30% of referrals originated from only 5% of practices (Guha et al., Internal Audit- unpublished). These practices were not based in the highest areas of disease prevalence and this highlighted that traditionally "hard to reach" groups (including disease characteristics and socio-ethnic factors) may need bespoke solutions. This learning has been carried forward to ID-LIVER when considering need for targeting regions of highest liver related morbidity and mortality.

A key barrier has been the ability to match the resources with evolving demand with rising prevalence of lifestyle associated risk factors. Finding effective triage tests, especially in the context of normal liver enzyme tests, has been challenging. Thus, there is a clear need to fine tune the diagnostic pathway; exploring novel tests or hypothesis free approaches (such as machine learning techniques) in future iterations is an attractive approach.

PROACTIVE IMPLEMENTATION OF HEALTH TECHNOLOGIES

The ID-LIVER Project

The Integrated Diagnostics for Early Detection of Liver Disease, or ID-LIVER, is a novel consortium targeting identification of early liver disease. We aim to use machine-learning algorithms to integrate patient and diagnostic data from multiple sources to develop a model to detect patients at the highest risk of progression to clinically significant disease. These individuals can then be targeted for intervention to reduce this risk with the potential to improve health outcomes and costs. The project is funded by the UK Government's Innovate UK Industrial Strategy Challenge Fund who will provide £2.5 million, with £2 million matched in-kind funding from industry partners. It represents a partnership between clinical and academic colleagues from The University Manchester, Manchester University NHS Foundation Trust, The University of Nottingham and Nottingham University Hospitals NHS Trust, as well as major industry partners GE Healthcare and Roche Diagnostics.

The North West of England is amongst the highest for liver disease prevalence in the UK with up to 30% of the adult population having risk factors for liver disease (8). In Greater Manchester this equates to one million people at risk of liver disease highlighting the need for population level diagnostic solutions. Greater Manchester recently underwent devolution of its health and social care and in 2015 37 NHS authorities and ten boroughs combined to form the Greater Manchester Health and Social Care Partnership (GMHSCP) as the first region in the UK to be delegated control of their health and social care budget. In a region covering 2.8 million residents, with diverse socioeconomic backgrounds, the aim is to target both health and social care in unison to improve health outcomes.

Pathway Inception

The clinical care pathway established in Greater Manchester has been designed in collaboration with the Integrated Care System (ICS) and Primary Care Networks (PCNs) to enable a pathway which facilitates both primary and secondary care needs. The new liver assessment clinics will blur the traditional paradigm of primary and secondary care. The early engagement of commissioners and having clinical champions in both primary and secondary care were important factors in the SLP (Section Lessons Learned From the Scarred Liver Project). The ID-LIVER team actively considered factors at each step of the patient's journey, from identification to investigation, which not only improve efficacy but also address equity of access (Section Improving Equity of Healthcare Delivery).

Working within the devolved healthcare system allows the team to approach liver disease on the scale of a population health concern, in comparison to the operational silos often encountered in a traditional healthcare system of Clinical Commissioning Groups (CCGs). The ambition is this will

provide a potential solution to the short term and silo budgeting issues that faced the SLP.

The advantages of an initial pilot phase, as seen in the SLP, provides a mechanism to roll out clinics in an agile, stepwise fashion. This iterative approach makes it easier to quickly resolve unique challenges of individual sites and populations.

Improving Equity of Healthcare Delivery

The geographical location for the clinical interactions for the liver assessment clinics is an ongoing deliberation for ID-LIVER. Working with a health analytics platform, Sollis Clarity, the intention is to understand the context of population health. Adding in collaboration with primary care organizations, such as the ICS and PCNs, we can start to understand where the risk profiles for liver disease are located geographically through disease "heat maps" and then establish new community liver assessment clinics in these areas. The clinics can be located according to higher disease burden, disproportionate liver mortality or liver-related outcomes. This will work toward addressing referral bias and improve equitability of the delivered service.

With Vocal, a Patient and Public involvement organization, open discussion with different patient groups with risk factors for liver disease within Manchester has been initiated. Involving the "hard to reach" patient groups in the patient design aims to enhance service accessibility and is a critical part of improving equity of healthcare delivery.

Identifying "at Risk" Patients Using Digital Search Tools

With limited resources within the current NHS, patient identification for further clinical investigations is a pertinent issue. To facilitate identification of patients with risk factors for CLD, screening of GP practices is being carried out using North-West EHEALTH's FARSITE (Feasibility and Recruitment System for Improving Trial Efficiency) technology. This is a centrally run profiling tool which identifies if a patient has risk factors from de-identified records. All patients with risk factors for liver disease documented in their records can be approached directly *via* written communication from the GP which is a critical enabler when implementing a pathway design fulfilling GDPR regulations. Critically, once optimized, this technology requires very little input from busy clinical and clerical staff and rate of invitations can be controlled to map to an individual assessment clinic's capacity.

Following an initial search of central Manchester practices (serving ∼900,000 people), FARSITE has identified 2005 patients with three or more risk factors for liver disease who have never been investigated for liver disease. A further 55,286 have one or more risk factor for liver disease. This shows how significant the potential target population for investigation is, even in a small geographical area. The project will thus provide a proof of concept if digital search tools such as this can be integrated into clinical pathways of care. Importantly this will provide a mechanism of identifying patients where there is a disparity in individuals and practices, which have a burden of risk factors but are not being stratified for CLD.

Providing Diagnostic Services to Those Most at Risk of Liver Disease

Optimizing delivery of resources to individuals with the greatest risk of liver related outcomes is imperative in a financially constrained model. It is critical to identify those with advanced liver disease or those with early disease and high risk of disease progression. We are employing an AI approach to address this so that stratification can be carried out on a larger scale than previously established pathways. In collaboration with Jiva.ai, a company specializing in predictive analytics powered by AI, we are developing an algorithmic tool to predict risk of clinically significant liver disease. Using the carefully phenotyped cohort from the SLP, initial models are being developed and then validated using the prospective Greater Manchester cohort. Novel biomarkers are also being explored in the ID-LIVER cohort including serum markers of fibrogenesis, genetic markers of fibrosis, imaging and platform "omics" technologies. Putative biomarkers will be prospectively validated and incorporated into AI modeling.

Improving Clinician Access and Acceptance

Nationwide there are numerous electronic patient records systems, which often do not interact with the other systems in place in healthcare settings. Collating and managing the multiple data streams required in a patient's care is often challenging. As a tool to aid this challenge, a novel clinical interface which is a cloud-based platform is being co-developed with Roche diagnostics (**Figure 1**). Ideally, this will be accessible to all healthcare professionals involved in a patient's diagnostic pathway from Practice Nurse to Consultant Hepatologist, reducing duplication and providing consistency. Clinical decision influencing data will be automatically sourced from GP records, hospital records and imaging assessments (including novel imaging assessment like Perspectum Liver*Multi*Scan®).

THE VISION FOR AN INTEGRATED DIGITAL SOLUTION FOR COMMUNITY CLD

The Richards Report, part of the NHS Long Term plan focusing on "Diagnostics: Recovery and Renewal", stated that "Effective pro-active management of patients at risk and at earlier stages of the [liver]disease course can improve outcomes for patients and lower costs for the NHS" (24). Establishing infrastructure, such as community diagnostic hubs, provide an opportunity for liver disease. Using the clinical caveats in **Figure 2**, we illustrate how CLD is managed now and could be managed with implementation of our pathway.

A key goal of the technologies and pathways being developed, as part of the ID-LIVER project, is scalability. The ambition is to develop tools that can be exploited for patient benefit, nationally and internationally. Translatable technologies from ID-LIVER will be the use of "heat maps" to locate areas best served by specialist services and the ability to remotely screen for patients more likely to have disease through both targeting patients with risk factors and use of an AI algorithm to stratify patients for

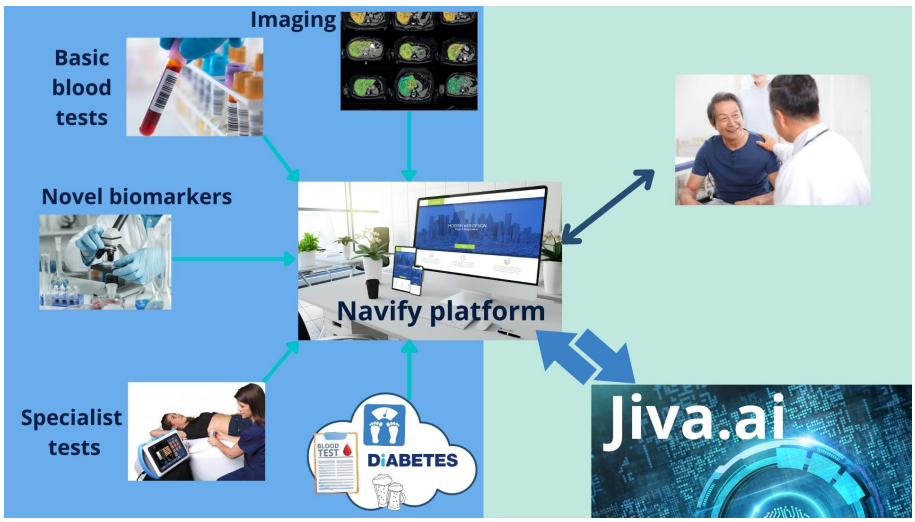

FIGURE 1 | Unifying data—the NAVIFY® platform.

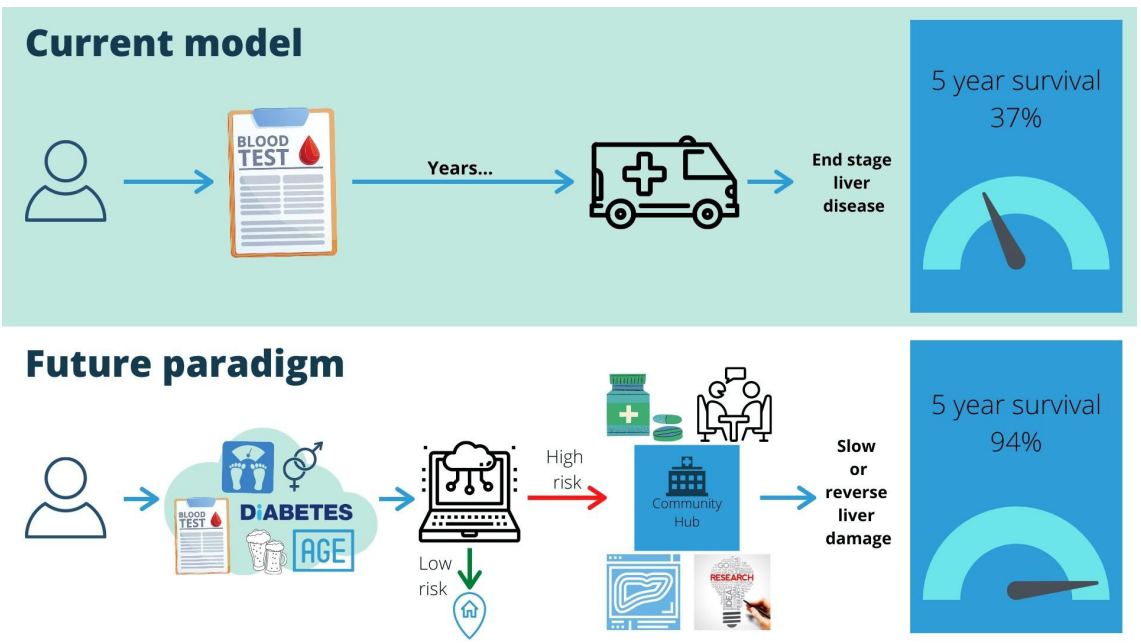

FIGURE 2 | Comparison of services with novel pathway.

investigation. This is in line with the government's aim for both improving inequalities in healthcare and providing "proactive, predictive, and personalized prevention" in regards to long term morbidity and mortality (25).

DISCUSSION

Improving equity of healthcare provision and proactive case finding to prevent long term morbidity and mortality is a key priority in the current UK healthcare system. Up to 30% of the population may have liver dysfunction and a more comprehensive method than is currently available for patient identification and stratification is needed due to scarce resources, high numbers of people affected and "hard to reach" groups.

Using innovative technology, ID-LIVER aims to overcome hurdles preventing earlier diagnosis of liver fibrosis within the community and pave the way for population level management of CLD. Collaboration with primary and secondary care clinical champions when designing and implementing this technology, with assessment and remodeling at every step, will allow flexibility in adoption and diffusion of this novel approach.

There are a number of uncertainties and challenges to our approach. Whilst the devolved care system in Manchester provides a vanguard model for the integration of health and social care it does not mean success here translates to success elsewhere. An understanding of contextual factors will be imperative and the pace of integration in other areas of the UK may lag behind. The involvement of industry provides an opportunity to instill innovative solutions but challenges remain. Ensuring the highest standards of information governance has been a priority for this project and this will need to be maintained in any future implementation program. If a model of mutual trust can be established the potential for synergy is obvious. Traditionally, there have been challenges in how industry and NHS operating systems interact with each other. The ability to describe if and how we overcome these barriers during the adoption of new pathways in Manchester will be a critical piece.

The use of digital technology, particularly artificial intelligence and machine learning methods, will be crucial to identify, stratify and manage patients with chronic liver disease in the community. Ultimately, the aim is to provide a bridge between personalized medicine and population health to improving clinical outcomes and reduce preventable premature death.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because no data is currently published for this work. Requests to access the datasets should be directed to neil.guha@nottingham.ac.uk.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by North of Scotland Research Ethics Committee 1. The patients/participants provided their written informed consent to participate in this study (IRAS ID: 273633).

ID-LIVER CONSORTIUM

NAH is Chief Investigator of ID-LIVER. Member organizations of the consortium, in alphabetical order, are: the British Liver Trust, GE Healthcare, Health Innovation Manchester, Jiva.ai, Manchester University NHS Foundation Trust, NorthWest EHealth, Nottingham University Hospitals NHS Trust, Octopus Ventures, Perspectum Diagnostics, Roche Diagnostics, Sectra, Sollis, the University of Manchester, the University of Nottingham, TRUSTECH and Vocal.

AUTHOR CONTRIBUTIONS

OS, NAH, KPH, JM, VA, and ING have contributed to the writing of this manuscript. All authors are acting on behalf of the ID-LIVER consortium. All authors contributed to the article and approved the submitted version.

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Making Digital Health "Solutions" Sustainable in Healthcare Systems: A Practitioner Perspective

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Digital health solutions have the potential to bring about great improvements in the delivery and quality of services in healthcare systems. In this paper, we draw on the extensive experience of NHS (National Health Service) England to develop a practitioner perspective on the challenges of effectively implementing and sustaining such solutions. We argue that a properly sustainable approach requires a shift in both thinking and practice when it comes to the spread and adoption of such technologies. Our thinking needs to shift from a focus on the technology itself to how we bring about the changes needed to deliver more efficient and effective care for patients. In practical terms, this means focussing on the changes involved to integrate digital health solutions into the delivery of services. In particular, it requires greater attention to the motivations, constraints and specific contexts that influence users and patients. The technical expertise of innovators therefore needs to be complemented by other forms of insight into change processes, including clinical and behavioral insight, process engineering and knowledge management. In this paper, we show how these different pillars of the NHS Sustainable Healthcare approach help to ensure the effective implementation and use of digital solutions. We draw out the implications of this approach for policy-makers in healthcare systems, highlighting the need to give greater attention and resources to the downstream challenges of implementing digital health solutions.

Keywords: innovation, adoption, digital health, sustainability, implementation

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INTRODUCTION

The emergence of a new wave of healthcare innovations based on digital technology has raised great hopes and expectations around the transformation of healthcare systems to offer more effective, efficient and personalized services in the future. A number of reports have highlighted the potential benefits to be gained from different forms of digital health technology (1, 2). In this article, we build on experience gained from the NHS in England to argue that expectations based on the potential of these digital technologies need to be balanced by greater recognition of, and investment in, the forces that enable them to be successfully and sustainably applied in practice (3, 4). We should not expect these new technologies to bring about sustainable improvements in healthcare in their own right. In fact, the assumption that digital technology is *the solution* to healthcare problems is a major barrier to bringing about the sustainable change that we need (5).

The evidence for the limitations of a technology-driven approach in healthcare is extensive (6). Many of the past failings of EHR (Electronic Health Record) systems, for example, were attributed to the lack of user-centered design (6). Such systems met the needs of the hospital administrators, but were not seen as meeting the needs of clinicians (7). This example highlights two important limitations of the technology-driven approach. First, the focus is on technology and not on the transformation of practices or processes. Wachter, for example, argue that we need to distinguish between such "technical change" and the "adaptive" approach to change required in healthcare (8). As a Nuffield Trust report on the spread of digital technology in the UK healthcare system observed: "Where technological interventions have failed, technology has simply been layered on top of existing structures and work patterns, creating additional workload for health care professionals" (1). Second, the design of systems fails to take account of the user. As this same report notes; "staff are too often seen as "passive recipients" of new technology and not involved in the development of systems architecture or user interfaces". In short, as another recent report puts it; "The barriers to uptake are often the patient or user and badly-designed and implemented technology" (7).

We argue instead that a properly sustainable approach requires both a shift in our thinking and in our practice when it comes to the spread and adoption of digital health technologies. Our thinking needs to shift from a focus on the technology itself to how we bring about the changes needed to deliver more efficient and effective care for patients. In practice, this involves being much more focussed on how digital technologies will be integrated and applied in services, and the motivations, constraints and specific contexts that influence those applying them and benefitting from them (9). Digital technology is viewed as one strand in a process of change, and the change itself is seen as nested within a wider policy environment and specific contexts which may also need to be changed or adapted.

NHS SUSTAINABLE HEALTHCARE APPROACH

At NHS England, this shift in thinking and practice is exemplified by the work of the Sustainable Healthcare team. This team has developed a programmatic approach through which new digital applications are integrated into a wider process of change which begins in the early stages of development and extends through to the long run sustainable implementation of an innovation or intervention. Making the adoption of digital health technologies sustainable involves understanding and addressing this complexity in the change process (3). As outlined in **Figure 1**, this approach rejects the traditional linear model of the innovation process in favor of an interactive model where implementation is not an afterthought but a primary focus of co-design efforts. The process of change applied by the NHS Sustainable Healthcare team does this by injecting four pillars of insight.

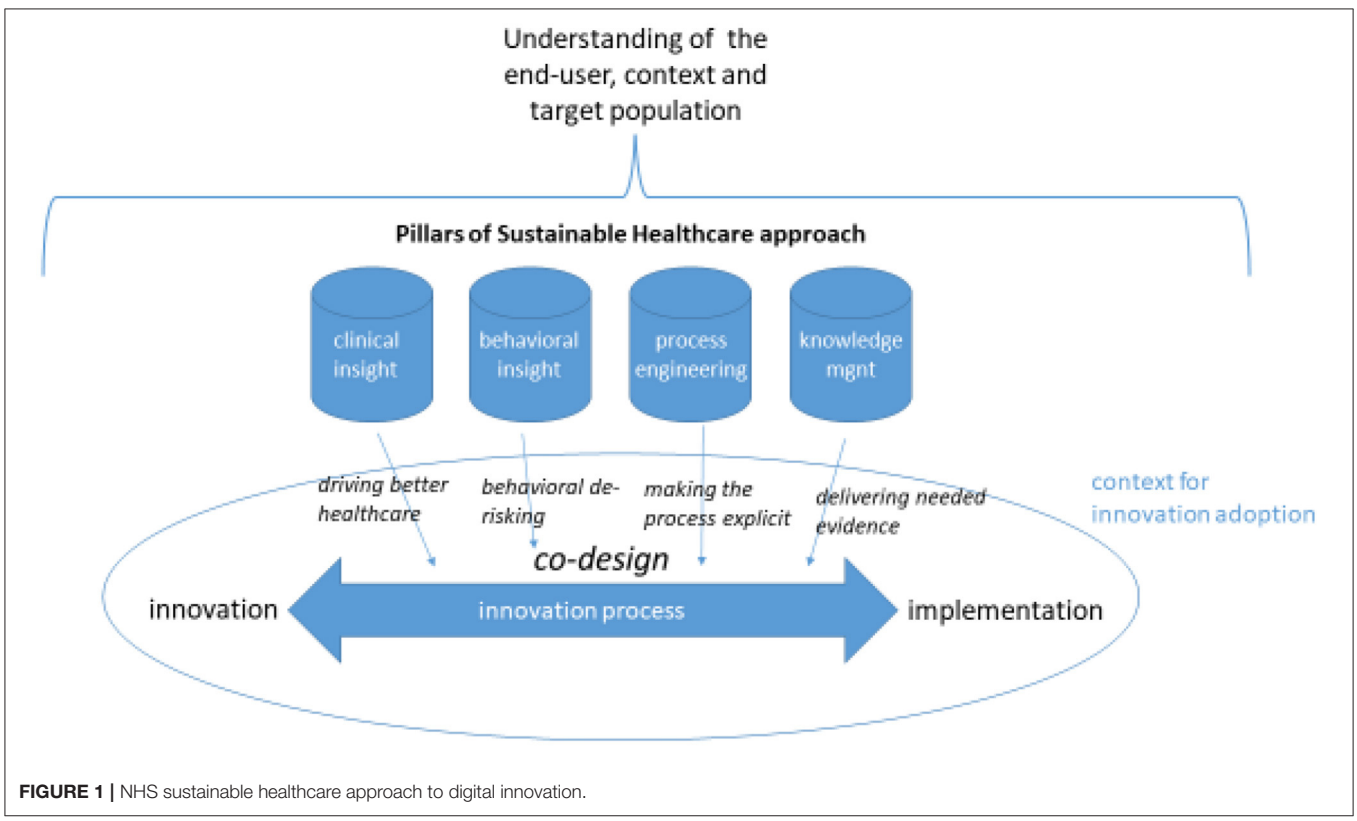

FIGURE 1 | NHS sustainable healthcare approach to digital innovation.

Pillars of Insight

The first of these pillars is *clinical insight*. In other words, not losing sight of the ultimate purpose of the innovation. Whatever form of change is being introduced in the NHS, even if it is a logistics or catering project, the ultimate purpose is to support delivery of better healthcare to the population. Any change process within the NHS needs to take account of this purpose. Changes which do not serve this purpose, or which create barriers to it, will not be sustained over the longer term.

The second pillar is *behavioral insight*. This draws on a range of disciplines including psychology, sociology and data sciences to understand how people might respond to new services or technologies. The aim is to "nudge" people so that evidence-based change is positively received by framing it appropriately in communications around the project. Taking the responses of end users into account from the early stages of design in this way allows for "behavioral derisking" to pre-empt implementation problems.

The third pillar is *process engineering*. The aim here is to make the process of applying the new technology or service as explicit, simple and comprehensible as possible. In the dialogue between the team, adopters and users, flowcharts are developed that clearly map out the steps involved, and their sequencing. People can be confident that if they follow the process steps, they will get the right outcomes more often. Making the process explicit helps, whether it is self-managed care or the running of an outpatient department. It also helps to guide changes in the context to make sure that a new technology or service can be delivered effectively.

Finally, *knowledge management* provides valuable insight on the evidence underpinning the need for change, and how best to deliver it. It is important that efforts are directed toward the right kind of change so that the ultimate purpose is achieved. This is something that needs to be addressed throughout the change process, so that whatever direction it takes and whatever outcomes are achieved, they are demonstrably based on the best available evidence.

Understanding of End Users

As highlighted by **Figure 1**, these pillars build from the outset on an understanding of the likely responses and motivations of the "end users" of the technology, including public and frontline staff users, and the context in which they will be using it. Effective change processes need to incorporate perspectives from all such user groups (10). Frontline staff groups, for example, are doing a lot more than use the technology—they are making it an active part of their service delivery and the treatment of patients. This requires intensive communication to ensure that staff understand, own, and are motivated to bring about the changes that are in needed in their practices and ways of working.

The adopters and users of technology are too often an afterthought for developers who are more concerned with the functionality of their kit. But this risks resistance or poor take up of new digital tools, not by intention but by failing to consider the users' needs and responses to what is being proposed (3, 11). The Sustainable Healthcare team's approach is always to identify the target audience or population early, and engage with them or their representatives to understand the "end user", in particular the behavioral barriers and drivers to them adapting to and adopting the innovation or new behavior. This also allows for co-design and ensures that the system's efforts to support mobilization are informed by what the end user needs to be enabled. Acceptance and sustained use of an intervention or innovation is much greater if people feel that it has been designed *with them*, not dropped *on them*. This is as much the case for a new digital health application as for any other change (10).

The need for this approach is reinforced where the user population is more diverse and less homogeneous. Neurological diversity may be an important challenge, for example; people with autism, dyspraxia, and dyslexia might be unintentionally prevented from interacting with a digital app if it is not designed to account for their needs. Similar challenges apply to different levels of digital literacy, access to the internet, and so on (12).

The Importance of Context

The responses of adopters and users are also shaped by the context in which they operate, which tends to buttress the status quo against change (9). Failure to anticipate these contextual influences can quickly undermine even the most beneficial of innovations. One example here is the powerful influence of financial and incentive systems. To cite a recent instance of this, the COVID-19 pandemic prompted the widespread introduction of virtual consultations in place of outpatient attendance at hospitals in the NHS. This innovation has arguably produced some positive benefits for patients in terms of easier access to services, but its spread and sustainability may ultimately be dependent on its financial consequences. If the effect of virtual consultations were to reduce the number of more financially lucrative in-person consultations with hospital-based consultants, this may create a perverse incentive for hospitals to back away from the use of this innovation.

To further underline the importance of context, the greater use of virtual consultation implies concomitant changes on the primary care side, including the need for greater resources to support primary and community care, and the need to create a new group of advanced care practitioners to take some of the increased burden away from GPs. All of these ripple effects from the introduction of new virtual consultation technologies mean that the changes involved will not be sustainable if the context is not also changed to accommodate them.

This change approach is based on a set of principles and is applied flexibly rather than dogmatically. It works best when the NHS Sustainable Healthcare team are involved from the earliest stage, but they are sometimes co-opted later in the process to help overcome barriers to adoption and use. This often involves bringing a sharper focus to the responses of end users, seeing how change cascades through different levels; asking, for example, what are the barriers to senior leaders or clinical champions deciding to do this, and then what about the front line staff, who may be being asked to adopt new changes every day? Beyond that, we need to ask how do the frontline engage with the wider population, and how do comms and media help persuade that

population? At each level, and for each group, it is important to ask; what are the barriers, what are the drivers?

This approach has produced excellent outcomes in a number of cases. But it has to be applied in a reflective and adaptable way. One technique used by the team to ensure this is called "pre mortem planning". The aim of this technique is to encourage team members to tease out prospectively the kind of problems or unintended effects in a change process which would normally only be picked up retrospectively, by virtue of the effort to leverage change being unsuccessful, or less successful than aimed for. It permits a project team to imagine, pre-emptively, that their planned approach does not work and ask the question; how did this project fail? This technique frees team members up to take a more critical stance toward their change plans, their design prototypes etc., and thus avoids any kind of groupthink creeping into their deliberations.

DISCUSSION

The approach to change described here represents a response to the specific challenges of implementing and sustaining digital health innovations in NHS England. At the same time, many of its features echo a body of practitioner and policy-maker experience with digital innovation which is emerging globally. For example, UNICEF has long emphasized "human-centred design" in its work[1], and many international development organizations have benefitted from applying the ideas and resources created by the Principles of Digital Development organization[2], including the formulation of principles such as "design for scale" and "build for sustainability". Within the digital health field specifically, recognition of the contribution which digital innovations can make to healthcare globally, including in LMIC countries, is increasingly matched by an understanding of the challenges which need to be overcome in scaling and sustaining such innovations. Studies have highlighted, for example, the importance of policy-level barriers which may reinforce other challenges such as the mobilization of evidence for innovation (13). Factors seen as critical to overcoming these challenges include gaining input from end-users from the outset and an understanding of the ecosystem within which the innovation is being deployed (14). As evidence mounts on the impact of different digital innovation programmes globally, these key findings are contributing to a more holistic appreciation of the scope of the wider changes involved in making them successful and sustainable, including "systems integration" to ensure implementation support, and ultimately the creation of a supportive digital health ecosystem (15).

While the Sustainable Healthcare team's approach is focussed within the NHS at the organization and individual rather than ecosystem level, this work from the global health field does raise some important questions about the sustainability of innovative digital health solutions once adopted. In this respect, the Sustainable Healthcare attention to context reinforces the finding from these other studies that a supportive context is vital to the scalability and sustainability of digital innovations (16). One question which arises, however, is whether this focus on context requires the Sustainable Healthcare team to apply a different approach to digital vs. non-digital innovations. Since their approach is attuned to behavioral and contextual features more than to the characteristic features of the innovation, it is clearly more concerned with how an innovation *lands* in a specific context. To that extent, it may be viewed as being agnostic toward the particular form of technology being deployed within a process of change. However, it is important recognize that there are also distinctive features of digital technology which in themselves may serve to raise or lower the barriers to adoption or use. This particularly applies where digital technology is being introduced into an analog world; that is, an environment where policies, infrastructures and practices have not been adapted to the potential of digital health (6). One emerging concern in the adoption of new AI technologies in healthcare, for example, is that they may fall foul of elaborate information governance requirements that make it difficult to access patient data effectively (17).

A further issue arising from the Sustainable Healthcare team's experience with this approach to change has to do with the value of their public health and end-user perspective on the adoption of innovations. Much research and policy interest in this area has focussed on what has been termed the "front end" of innovation; that is the development of new technologies and processes aimed at "early adopter" groups of individuals and organizations. Greenhalgh, for example, comments in a recent report that: "Planners and policymakers have often been overly focused on technologies and distracted by simplistic models and metaphors of technology adoption by individuals" (7).

Viewing innovation adoption from the perspective of end users and the wider public, however, involves a greater focus on how new tools and solutions are used, and how they can be spread to the widest possible extent. This may involve placing a much greater emphasis on the usability and accessibility of digital health solutions—having the right infrastructures and skills in place, for example—and much less on the cutting-edge properties of the solution itself (8). And where the digital solution is highly innovative, this perspective suggests a more intense focus on how it can be spread and used effectively, especially since it is often challenging to bridge the gap between early and later adopters of an innovation (18); something which is observable in the many pilot implementations which never achieve widespread take up (19).

This shift in perspective away from the front end of innovation seems to be an important requirement for the sustainable adoption of digital health solutions in healthcare. But, its implications are not only practical. It also raises important questions about healthcare policy and whether it is sufficiently attuned to the challenges of spreading digital health solutions in a sustainable way. We need to remember that many innovative technologies and treatments have been introduced into healthcare without ever being spread widely or used effectively, despite ample evidence of their benefits

[1]https://www.unicef.org/innovation/hcd.
[2]https://digitalprinciples.org

to patients (20). Worryingly, policy-makers attracted to the progressive imagery of new digital technologies may be more likely to allocate resources to their front end development than to the more complex downstream challenges of putting them into practice. As a recent UK report puts it; "Government innovation policies seem often to imply a relatively simple hand-over from innovators to technology-savvy commissioners and purchasers, who in turn pass the wizardry onto willing patients, users, and consumers" (6). This may result in a slow and uneven spread of digital health solutions which not only deprives patients of their clinical benefits, but also increases health inequalities amongst the wider population (21).

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

MC provided the practitioner perspective and practical examples for the paper. HS provided input from academic research and literature. HS and MC wrote the paper. Both authors contributed to the article and approved the submitted version.

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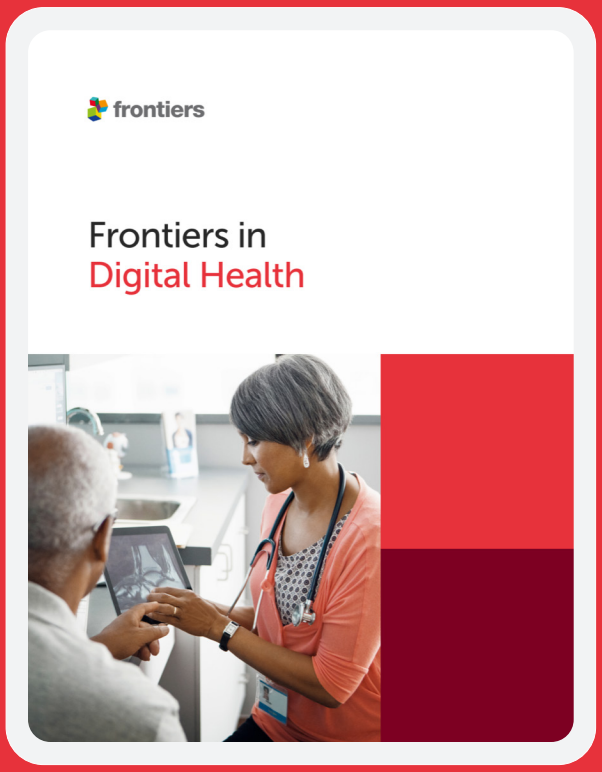

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