PCRS Position Statement

Respiratory Data and Digital Care

March 2024

PCRS welcomes the opportunity that digital respiratory healthcare and the collection and analysis of respiratory data could bring. However, new technology for use in primary care must be interoperable with current patient consultation and management systems, should not be mandated for patients and should be an option as part of shared decision making. New respiratory digital health interventions must, as well as being clinically and cost effective also preferentially attend to the factors that currently maintain respiratory health inequality. As with prescribing medicines, any HCP advising patient use of digital technology should check its provenance and current status first and expect this information to be easily available from the commissioning authority they work within. New technology initiatives must come with formative and continuous training for HCPs, patients and carers. New technology should not be introduced until all primary care sites have access to standard digital healthcare resources e.g. spirometry and FeNO that is appropriate for infants, CYP and all adults.

Primary Care Respiratory Society 483 Green Lanes, London, N13 4BS
Registered Charity 1098117 Company No 4298947 VAT Registration Number 866 1543 09
Telephone +44 (0)1675 477600 Email info@pcrs-uk.org Website http://www.pcrs-uk.org

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Background

Anyone registered with or working in a GP practice in the UK will inevitably be a participant in some part of the established and growing NHS data and digital project. In 2023, NHS England and NHS Digital merged to create closer links between the collection and analysis of data to help drive improvement to patient outcomes[1]. Since 2018, however, patients can opt out from the data element of this project in line with the recommendations of the National Data Guardian[2].

PCRS welcomes the potential opportunities that digital respiratory healthcare and the collection and analysis of respiratory data could bring to improve respiratory outcomes and benefit the working life of NHS healthcare professionals (HCPs) and has been focusing recently on resources to help understanding of this[3].

There are clear benefits, for example, electronic prescribing can save prescribers and patients time and ensure that the dispensing pharmacist has at the minimum a legible prescription amongst other features that improve medicines safety, a universal scenario in primary care for decades though still not available across the system. Having a choice of consultation modalities such as video and telephone can be a more efficient option for some. However, we also know that there are problems to be overcome to ensure that for all there is at least an equivalent level of patient experience, safety, clinical efficacy and value for money as any established, evidenced and trusted analogue approach[4].

There are specific digital opportunities in respiratory to assist in diagnosis, therapy and supported self-management[5–9]. For long term respiratory illness there are smartphone applications that aim to monitor disease status, and claim to provide early warning of decline. Medication adherence systems, linking inhaler use with smartphone feedback could also in theory help to avoid worsening by giving advice on technique, alerting the busy or forgetful or by nudging the reticent to take their medication[10–12].

The respiratory research community has for some years already been utilising 'big data' by analysing aggregate population data captured as Read or SNOMED coded activity from primary care notes. This information has been recorded consistently and universally in NHS general practice for at least two decades as a result of the introduction of the Quality and Outcomes Framework in 2004[13]. The primary care element of the National Respiratory Audit programme (NRAP)[14] utilises data from general practice in Wales that has allowed respiratory system leaders to mobilise incentivisation for quality improvement in Welsh Primary Care.

However, attempts to launch NHS patient data projects have failed in the past as public confidence in how their personal data might be used has not matched the government's ambitions or approach[15]. It is notable that to date, there is no primary care audit respiratory programme for practices and populations in the other three nations of the UK and at least in part this reflects how difficult it is to get people and health providers on board with patient data collection and sharing due to a lack of trust about the appropriate use of their health data.

There is rapid growth in artificial intelligence (AI) and with it comes potential opportunities for better respiratory health outcomes8. Some look to AI with hope that it might be a means to reduce pressure on an overstretched workforce, a key issue of our times. However, AI might easily generate public trust issues in the same way that 'big data' did in the health system if attitudes and concerns about AI more generally are not recognised and attended to. Many involved in HCP education will already be aware how OpenAI resources such as ChatGPT are impacting on the ability of teachers to have confidence in student work being submitted. However it can be argued that fraud and plagiarism has always existed in academia and there is a need to be ahead of the technology and ensure its benefits are captured to aid learning and improve healthcare practice[16].

The infection control necessity of the COVID-19 pandemic meant that primary care, and people using those services who were already familiar with alternative consultation and communication modes accelerated in their use of remote and virtual connection. Whilst most see the utility and benefits there is concern about the potential loss of empathy and "human-ness"[5] and worsening of health inequality due to digital inequality.

Respiratory health data and digital healthcare is a broad area to cover. It is being driven by government and the market place and is likely to be harder for the generalist to keep abreast of than, say, the medicines pipeline has ever been. This position statement aims to communicate the factors that respiratory HCPs, researchers, commissioners and service designers should consider when they are asked to engage in this sphere. It also gives some examples to show what may be on the horizon.

Key issues

Terminology

The ERS 2023 monograph on digital health has highlighted that arriving at a universally understandable terminology is a significant challenge when developments and changes come

Figure 1. ERS digital health terminology[5]

Terminology	Definitions
Big data	Extremely large datasets, which may be complex, multidimensional, unstructured and heterogeneous and which may be analysed computationally to reveal patterns, trends and associations [33]
Digital health	An umbrella term that refers to technologies that assist in providing healthcare services and information
Digital health framework	A structured strategy for digital transformation of healthcare services aiming to establish an efficient interaction among information coming from informal care, formal care and biomedical research, both for healthcare delivery and other purposes (*e.g.* quality assurance, research) [34]
Digital health literacy	The ability to seek, find, understand and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem [35]; sometimes referred to as e-health literacy
e-Health	Electronic health comprises the provision of healthcare products and services using information and communication technology [2]
Electronic health record	Electronic records of interactions with healthcare systems; often used interchangeably with electronic medical records and electronic patient records
Internet of Things	A network of physical devices and other items, embedded with electronics, software, sensors and network connectivity, which enables these objects to collect and exchange data [36]; the application of the Internet of Things to medicine is termed the "Medical Internet of Things"
m-Health	A sub-segment of e-health, m-health can be considered as the use of smart or mobile communication devices, such as smartphones and tablets, for the provision of health and well-being services and information [2]
Medical assistive robot	An autonomous or semi-autonomous machine equipped with advanced sensors, actuators and artificial intelligence modules, employed in healthcare contexts to perform assistive functionalities; social robots are designed with anthropomorphic features to improve their ability to interact with humans
Medical device	An instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability [37]
Personal health records	Online systems that include collections of patient healthcare and medical data, which utilise health informatics standards to enable patients to share, organise and manage these data according to their own views [38]; often linked with m-health
Telehealth	Often used interchangeably with telemedicine, but telehealth encompasses a broader scope of technologies and healthcare providers than telemedicine, which refers specifically to clinical health services [2]
Telemedicine	The provision of healthcare services and medical information using innovative technologies, especially information and communication technologies, in situations where the health professional and patient (or two health professionals) are not in the same location; it includes any remote interaction between patients and healthcare professionals, and between healthcare professionals themselves, whether synchronous or asynchronous [2]
Telemonitoring, teleconsultations, telerehabilitation	Specific modalities within telehealth

so fast. Helpfully, they have summarised the key definitions and their table is reproduced below.

Interoperability and reliability

PCRS would expect any new respiratory technology recommended for use in NHS practice to have been through an implementation process that demonstrates that as well as adding quality and value for money it also ideally provides HCPs with more time and certainly not less time. We are aware that new technology does not always work seamlessly with existing primary care patient consultation and management systems and secondary care systems and this creates problems with achieving integration goals, additional work and risks error due to operating multiple systems whilst under clinical time pressures.

Health inequality

In general, people experiencing health inequalities are over-represented in the group experiencing chronic and recurrent respiratory conditions, mainly due to poverty, exposure to poor air quality and tobacco smoking[17]. Some members of these inequality groups are already at a disadvantage due to health literacy limitations within an analogue scenario and could be further exacerbated within a digital system. We are concerned that existing respiratory expenditure should not be used for new respiratory digital health interventions unless the intervention, as well as being clinically and cost effective also preferentially attends to the factors that currently maintain respiratory health inequality. Whilst evidence-based digital technology is welcomed there has to be an added value to those

experiencing worse outcomes to avoid widening health inequalities.

Technology Regulation

Medicines regulation is well established in the UK through the Medicines and Healthcare Products Regulation Agency (MHRA). This UK government body also has a role in regulating devices deemed to have a medical use which now includes digital material such as software and applications as well as physical instruments and apparatus.

Medical devices include anything used for diagnosis, prevention, monitoring and treatment and will include items such as spirometers, blood-pressure machines and sticking plasters. This also now means that any smartphone capability aiming to diagnose or monitor e.g. asthma or encourage the person with asthma to take their medication would also need to be assessed within the MHRA regulatory framework.[6]

The role of the MHRA is to survey the UK market for medical devices in order to make safety decisions over its marketing and supply. It is the responsibility of the company to assess whether their product falls within the medical device regulations and if they do they must have a UK conformity assessed (UKCA) (post-Brexit) or European Conformité Européene (CE) (pre-Brexit) mark. The regulatory system for devices, however relies on some self- assessment and in the case of health software, the rapid emergence of new product with repeated updates to any product software means that it is a challenge to ensure it is comprehensive and up to date.

To make a comparison, it is well understood how difficult it has been for generalist respiratory prescribers to keep track of the number of new inhaler devices and medicine combinations in recent years, but this challenge will pale into insignificance when compared to the pace and scale of health app development. Similarly, for people choosing a medical product over the counter (OTC), whilst they can be reassured by the current systems that control OTC medicinal product sales, the same will not be the case for much of the new technology at this current time.

Digital tools are now evaluated in the NHS by the digital technology assessment criteria (DTAC) and any developer or system supplier wanting access to the NHS markets or systems will need a DTAC evaluation. The evaluation includes measures of clinical safety, data protection, technical security, interoperability criteria, usability, and accessibility. NHS England understands that commissioning of digital healthcare will inevitably happen at all levels ranging from practice level and primary care networks, to integrated care systems and at a national level[6]. This will require any health organisation to have a system in place to ensure what is being procured is tested against the DTAC evaluation. There is an expectation therefore that in England, an ICB should have a medical devices safety officer (MDSO) to ensure compliance at procurement but also subsequently to ensure any digital healthcare is scrutinised to highlight any subsequent problems.

Since 2021, the national institute for health and care excellence (NICE) has embarked on its digital health promotion, support and assessment programme. They assess the value of digital health technologies that offer the greatest potential to improve health and wellbeing and offer a NICE approval where appropriate in order to give developers the best chance of product adoption by the health and care system[7].

Accessibility, interface, training and maintaining competence

Accessibility, suitability and optimisation of interface, training and maintaining competence in digital technology applications is relevant to both the HCP and the service user.

A vignette to consider is the digital capability of a newly qualified HCP who has had undergraduate training in digital health. Highly competent in their early career and finding the technology easily useable, over time, with the absence of new training, or a new onset of sensory and motor deficits associated with natural ageing or illness could result in their personal capability being compromised and introduce an additional burden to their work life and potentially affect patient outcomes.

There are also serious questions about how people living in areas underserved by network connectivity might be disadvantaged or those suffering inequalities that impairs their capability. In the UK the Equality Act[18] expects that any new or revised NHS service undergoes an equality, diversity and inclusion (EDI) assessment to consider these risks. It should be noted that there are particular challenges faced when considering how CYP will engage with digital health services.

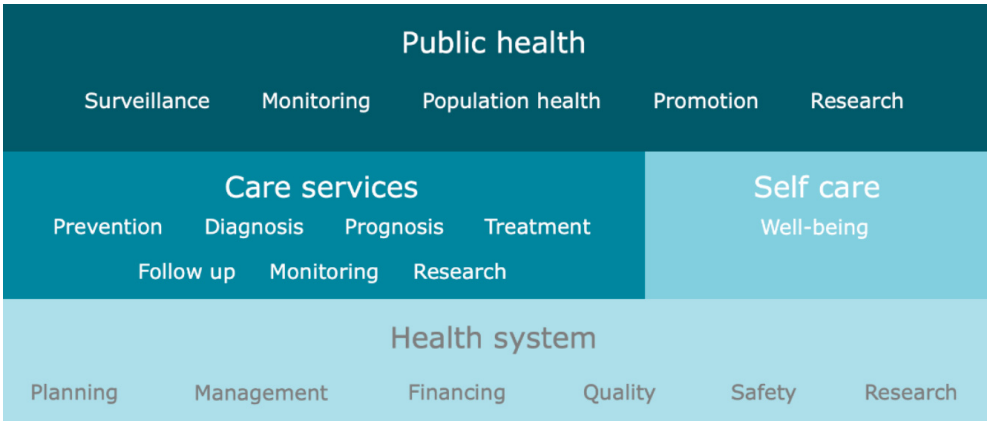
Environment

PCRS supports a comprehensive approach to reducing the impact of respiratory healthcare on the environment[19]. It is described that digital healthcare is a potential opportunity to reduce healthcare related emissions e.g. removing the need to use a vehicle to attend a health appointment, yet this must be balanced against the energy requirements to store digital data, something the digital department of NHS England have committed to[20].

Artificial Intelligence (AI)

AI in respiratory health is, to date, particularly strong in the in the field of imaging[8]. Though, it is envisioned that AI will be able to support healthcare broadly (Figure 2).

Figure 2. AI potential in health[9]



Algorithm medicine is already a reality and is expected to be increasingly important in the years to come[9].

In the UK, where first response primary care is increasingly telephonic with the HCP increasingly likely to be someone other than a doctor, algorithms are already well established in order to standardise responses from HCPs with these different professional backgrounds. Whilst these approaches expect the HCP to follow the machines instructions, to date the process does not include the ability of the machine to learn and then perform tasks that would currently require the intelligence of the HCP to take the next steps. It is this advancement that is likely to be the most compelling application of AI to deliver reliable and repeatable precision medicine. However, it is also clear that the medicolegal aspects about where responsibility lies when an error is made are not yet resolved[21].

An example of AI in primary care diagnostics has recently emerged and has the potential to mitigate the national shortage of adequately trained and resourced primary care HCPs to diagnose COPD. The N-Tidal device combines a CO_2 sensor with an artificial intelligence platform which measures changes in lung function, from a single breath, that might point towards a diagnosis of COPD and provide an indication of a patient's risk of COPD within minutes. This ongoing study being carried out in GP practices in Oxford is seeking to discover whether this test could replace spirometry in some NHS diagnostic clinical pathways[22].

Respiratory technology for use in current UK primary care

Respiratory digital technology in primary care has been available for many years and new technologies are coming online at a rapid pace. We are aware of patchy availability of some technology that PCRS would recommend being available as standard for respiratory diagnostics and care. These include:

- Pulse oximetry (Adult, child and infant)
- Spirometry and microspirometry systems (Adult and CYP)
- Fractional exhaled nitric oxide (FeNO) testing (Adult and CYP)
- Physical activity monitoring
- Exhaled carbon monoxide monitors

There are other respiratory technologies that could become 'standard' for use or prescription in UK primary care. PCRS is aware of the following that remain under assessment for wider and routine use in the UK

- Smart inhalers and spacers
- Smart phone respiratory status monitoring
- Self-management applications
- AI analysis of breath tests and spirometry
- Messaging services between patient and named practitioner or service
- Behaviour change applications e.g. stopping tobacco smoking
- Point of care blood analysis

Nationally assessed digital technology relevant to primary respiratory care

A number of respiratory related digital technologies have been assessed by national bodies in recent years. To date most of the digital technology advancement has application in secondary and tertiary care. This includes the use of AI to support lung and thorax imaging and digital technologies that help with lung cancer detection and tumour sampling.

NICE has assessed a number of digital respiratory technologies applicable in primary care. Currently there are no recommendations for use of these technologies with guidelines applicable to primary care. It should be noted that NICE does not assess every new digital technology in the market place. Those assessed are likely to be only a proportion of technologies available and being potentially marketed to primary care.

Table 1. NICE assessed digital technology relevant to primary care

Asthma	**Smart Peak Flow for monitoring asthma**[10] • A digital peak flow meter and asthma tracking tool designed for monitoring asthma. • An alternative to a mechanical peak flow meter	**Assessed by NICE** • Requires validation against gold-standard mechanical version • Evidence needed to assess whether it affects outcomes, clinical decision making and adherence
	Smartinhaler for asthma[12] • It monitors the activation of a person's asthma inhaler. This information is uploaded to a mobile or cloud-based application. • An adjunct to personalised asthma plans and clinician review	**Assessed by NICE** • Requires evidence to show that the improved adherence improves outcomes • The resource impact may be greater than usual care unless there is a significant reduction in healthcare use.
COPD	**My COPD for managing chronic obstructive pulmonary disease**[23] • myCOPD is a digital tool for people with COPD and HCPs. It is intended to support people to manage COPD with functions that include: - education on how to use inhalers correctly - a self-management plan - a prescription assessment function to cross-check prescribed medicine, and identify any conflicts - a COPD assessment for people to track their symptoms and learn how to control them - access to an online 6-week pulmonary rehabilitation course including	**Assessed by NICE** • It is compliant with DTAC • It could be helpful to reduce unnecessary contacts • It is easy to use • Use declines over time • The recommendations were: - More research is required as there could be significant patient and health system benefits but evidence to date leaves too many uncertainties - The research should compare standard COPD to i) my COPD self-management and ii) myCOPD PR.
Not condition specific	**Smart One for measuring lung function**[11] • A portable spirometer used for measuring lung function • For use at home in additional to usual healthcare where repeated measurements are required	**Assessed by NICE** • Risk of overuse harm in cystic fibrosis. • Lacks safety and effectiveness data • Does not remove need for annual healthcare visits according to current guidelines for chronic respiratory diseases needing spirometry
Infection	**C- reactive protein testing in primary care** • Point of care (POC) tests that provide rapid results from blood, serum or plasma samples. • Can guide antibiotic decision making. • Some tests combine detection of virus.	**Assessed by NICE (3 products)**[24–26] • There is evidence that antibiotic prescriptions can be reduced by CRP testing and that lab and POC results are comparable. • The evidence provided is not always applicable to primary care • More evidence of cost benefit is required • More studies with extended follow up of patients is required

Big respiratory data

National big data health projects have been controversial in the past[15] and obtaining public trust in this area remains a challenge as general awareness of data misuse and digital fraud has grown in the intervening period.

The key respiratory data project in the UK is NRAP[14] which for primary care only collects and analyses data from Wales. The Clinical Practice Research Datalink (CPRD) collects anonymised patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data encompass 60 million patients, including 18 million currently registered patients and many important insights have been made in respiratory primary care[27].

It should be noted that whilst primary care activity embarked on a programme of digitised notes in the 1990s that was essentially universal by the initiation of QOF in 2004 our PCRS members still report that secondary and tertiary care systems use paper notes that often means they cannot report on aggregate respiratory patient activity for audit, quality improvement and operational planning without trawling through sets of notes which may or may not represent the entire denominator of the population being observed.

The government's intent for NHS collected data to be utilised for quality and service improvement and research has recently emerged with the i) the 2023 *Major Conditions strategy*[28] (MCS) that signals the availability of significant future resource for digital health innovation and the ii) *NHS Federated data platform*[29] that is described as a place that supports staff to

access the information they need in one safe and secure environment to improve patient care.

- The major conditions strategy
  The MCS interim report published in August 2023 by the Department of Health and Social Care (DHSC) represents a further significant opportunity for respiratory health improvement in England, building on the ambitions of the 2019 Long Term Plan (LTP). Both the LTP and MCS feature respiratory as a key area for national health improvement those at risk of future respiratory disease. The report highlights an intent from government to drive improvements for people with major conditions through the development and implementation of digital healthcare.
- NHS Federated data platform (FDP)
  This platform is expected to bring separate operational systems together to help providers better manage the number of beds in a hospital, the waiting lists for elective care services, or the availability of medical supplies. By linking the different tiers of service within an integrated care system (ICS) it is hoped that the transfer of a patient from a hospital to the community will be a more seamless experience. It is intended to reduce the workload of HCPs and other NHS staff by avoiding duplication of activity or not needing to make calls to different departments to get results sent through or make appointments. Until March 2025 NHSE will be asking members of the public to help shape how the NHS uses their health data to improve patient care. This will include the FDP but will also be exploring the more challenging ground of how patient data might be collected and used.

PCRS position

- PCRS welcomes the potential opportunities that digital respiratory healthcare and the collection and analysis of respiratory data could bring to improved respiratory outcomes and benefits to HCPs, patients and carers.
- We know the technology already exists to provide the data analysis to run national quality improvement programmes for respiratory primary care, yet Wales is the only nation investing in this. We call for all four nations to resource such a programme.
- A universally understandable set of terms for digital healthcare is necessary to engage HCPs, patients and carers. PCRS recommends the definitions as described in the ERS monograph on digital respiratory healthcare.
- New respiratory technology for use in primary care must be interoperable with current patient consultation and management systems, ideally saving HCP time and certainly not adding extra burden. Any new technology should not be mandated for patients and should be an option as part of shared decision making.
- We are concerned that existing respiratory expenditure should not be used for new respiratory digital health interventions unless the intervention, as well as being clinically and cost effective also preferentially attends to the factors that currently maintain respiratory health inequality. Whilst evidence-based digital technology is welcomed there has to be an added value to those experiencing worse outcomes to avoid widening health inequalities.
- As with prescribing medicines, any HCP advising patient use of digital technology should check its provenance and current status first and expect this information to be easily available from the commissioning authority they work within.
- New technology initiatives must come with formative and continuous training for HCPs, patients and carers.
- We recognise that more digital healthcare and efficiencies delivered with better data and analysis could reduce the healthcare impact on the environment but system leaders must also consider the counter impact on the environment from data storage.
- New technology is welcomed when it is clinically and cost effective but should not be introduced until all primary care sites have access to standard digital healthcare resources e.g. spirometry and FeNO that is appropriate for infants, CYP and all adults.

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