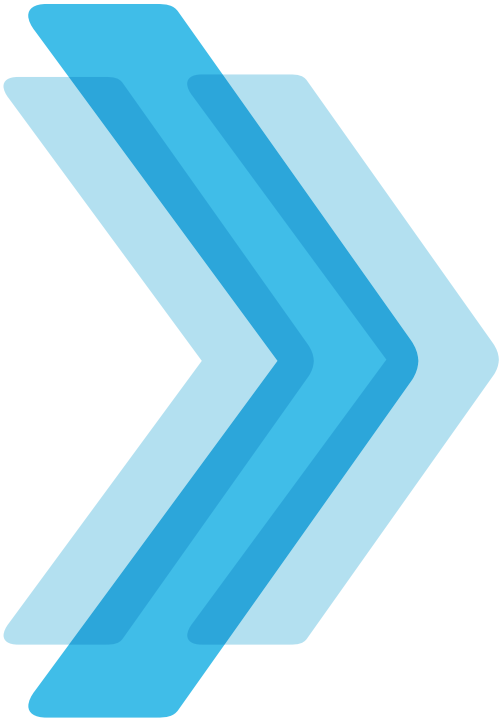
The King's Fund

Ideas that change health and care

Why do diagnostics matter?

Maximising the potential of diagnostics services



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About this project

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Introduction

The Covid-19 pandemic has increased awareness of the role that diagnostics play in disease detection, prevention and management. Policy-makers have also singled out diagnostics for greater focus in recent years, particularly given their pivotal role in supporting system recovery from the pandemic, including reducing waiting times for hospital treatment and earlier cancer diagnosis. This spotlight has revealed the scope for innovation through the introduction of new technologies, widening access and changes to patient pathways.

This briefing explores the role that diagnostics play in underpinning much of the activity that takes place in the health and care system, the policy focus to date and where attention is needed to ensure diagnostic capacity and capability are fit for the future.

Key messages

- Diagnostics play a fundamental role in clinical decision-making. Access to timely and effective diagnostic services is critical to providing high-quality care, reducing waiting times for treatment and improving health outcomes.
- Each year, the NHS undertakes more than 1 billion diagnostic tests, accounting for about 6 per cent of the NHS budget.
- Demand is rising across almost all aspects of diagnostics, with 4–7 per cent increases in activity seen for tests such as colonoscopies and magnetic resonance imaging (MRI) scans each year between 2014/15 and 2018/19.
- Growth in the diagnostic workforce has not kept pace with demand and activity, and there are now significant staff shortages across all specialties, but with imaging, radiology, pathology and endoscopy notably under strain.
- Historical underinvestment means that the supply of equipment such as computerised tomography (CT) scanners, MRI units and X-ray machines is inadequate and existing equipment is often outdated and in need of replacement.
- Patients are waiting longer for diagnostic tests. There are now more than 1.5 million people currently waiting, and the standard that patients should wait less than six weeks for a diagnostic test has not been met since February 2017.

- The roll-out of new community diagnostic centres across England is very welcome. However, government restrictions on the building of new facilities and the so-far limited range of tests on offer at these centres risk limiting their potential to increase diagnostic capacity and provide quicker and more convenient access to patients.
- Rapid innovations in diagnostic technology and the scope to improve patient pathways provide significant opportunities to expand the accessibility and delivery of diagnostics. But a concerted policy focus, an increase in the workforce and capital investments are required to support this if the much-needed increase in diagnostic capacity in the NHS is to be realised.

What are diagnostics?

Diagnostics are tests or procedures used to identify and monitor a person's disease or condition, allowing a diagnosis to be made (NHS England 2015). They cover the whole range of physical health conditions and are used across a range of health care settings, including urgent and emergency care, elective (planned) care and cancer care.

Different categories of diagnostics

There are four different categories of diagnostics.

Endoscopy is a procedure that examines an internal hollow organ using a thin tube with a light source. Examples include the inspection of the upper airways, trachea and lungs (bronchoscopy), the bladder (cystoscopy), the upper gastrointestinal tract (gastroscopy), the lower gastrointestinal tract (colonoscopy) and the lining of the large bowel (flexible sigmoidoscopy).

Imaging is a category of tests that take detailed pictures of areas inside the body. Imaging procedures use different forms of energy, such as X-rays (high-energy radiation), ultrasound (high-energy sound waves), radio waves and radioactive substances. They may be used to help diagnose disease, plan treatment or find out how well treatment is working. Examples of imaging procedures are computerised tomography (CT), ultrasonography, magnetic resonance imaging (MRI) and nuclear medicine tests.

Pathology is the study and diagnosis of disease through the examination of organs, tissues, bodily fluids and whole bodies. Pathology tests are typically conducted in test tubes and similar equipment and are known as 'in vitro diagnostics'. The analysis is usually carried out in a pathology laboratory, but sometimes it can be done with the person present (called 'point-of-care testing'). Examples of pathology specialties include diagnostic haematology (the study of the blood) and cytology, which involve the close examination of cells under a microscope, and clinical genetic testing, which is the laboratory analysis of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) to aid in the diagnosis of disease.

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Different categories of diagnostics *continued*

Physiological measurement is a type of test that focuses on assessing the function of major organ systems and providing information on the extent of disease or disability and the response to treatment or interventions. For example, neurophysiology investigates the function of the central and peripheral nervous systems, echocardiography looks at the heart and nearby blood vessels and urodynamics investigate bladder problems.

Source: NHS England (2015)

What are the diagnostic pathways and why are they important?

Diagnostic activity forms part of more than 85 per cent of clinical pathways (McCaughey and Powis 2020). Diagnostics are used to help clinicians develop a more precise and complete understanding of a patient's condition and inform subsequent decisions around treatment and monitoring. (Although the same diagnostic technologies, equipment and workforce are often used to carry out tests as part of national screening programmes, these tests do not count as diagnostic activity as they are used to screen asymptomatic patients (NHS England 2015).)

Unplanned or 'acute' diagnostics refer to tests done with clinical urgency, often when a patient accesses urgent or emergency care, with both the test and the result needed very rapidly – for example, a CT scan of the head after a motorbike accident or an X-ray following a fall.

Planned or 'elective' diagnostics encompass tests that general practitioners (GPs) or specialists request – for example, a gastroscopy for someone with persistent

N-terminal-pro-BNP blood test – unplanned and planned use

Measuring the level of two proteins in the blood – B-type natriuretic peptide (BNP) and N-terminal-pro-BNP (NT-pro-BNP) – can help doctors determine whether a patient's shortness of breath is due to heart failure or to some other cause. The BNP/NT-pro-BNP blood test can be used as part of a planned diagnostic pathway, with a GP doing the test in the community to either rule out heart failure or decide whether further investigation with echocardiography is needed. It can also be used in urgent or emergency care as part of the 'rule-out' tests, which can determine whether heart failure is why the patient is acutely unwell (National Institute for Health and Care Excellence 2021).

Brighton and Sussex University Hospitals NHS Trust is carrying out a quality improvement project to ensure this blood test is being used appropriately to help streamline diagnostic pathways, reducing the number of unnecessary echocardiograms where heart failure has been ruled out (National Institute for Health and Care Excellence 2020b).

heartburn or indigestion. These tests often take place on an outpatient basis, predominantly within a hospital but also in community settings.

Most health conditions or diseases are more responsive to treatment at an earlier stage than at a later one, which means that speed of diagnosis is an important variable for patient outcomes. For example, early diagnosis of cancer improves survival rates, with the proportion of people with one of the four most common cancers who survive their cancer for ten years or more being significantly higher when diagnosed at the earliest stage 1 than at the latest stage 4 (**Cancer Research UK 2022**). Therefore, delayed diagnosis can significantly lengthen how long patients wait to start treatment and lead to avoidable morbidity and mortality.

Furthermore, treatment in the absence of a confirmed diagnosis can lead to poorer patient outcomes as the uncertainty can mean more time is spent pursuing inappropriate treatment options that do not have the desired effect (**Fleming *et al* 2021**; **Lingervelder *et al* 2019**).

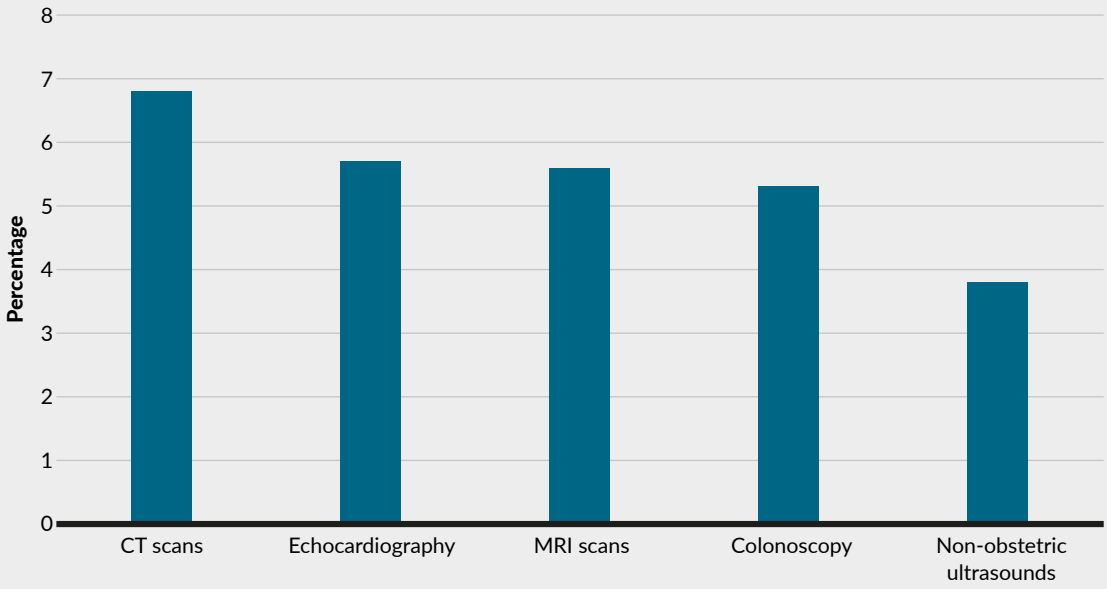
Diagnostics have an important role to play in making the shift to population health and a greater focus on prevention by improving early detection and diagnosis (**Becton Dickinson 2021**).

Diagnostic activity, demand and performance

Each year, the NHS undertakes more than 1 billion diagnostic tests, accounting for about 6 per cent of the NHS budget (The Academy of Medical Sciences 2021; NHS England and NHS Improvement 2019). In July 2022, 1,940,100 diagnostic tests were undertaken in the NHS. (Data on waiting times for 15 key diagnostic tests or procedures is collected at the end of each month. This data does not represent all diagnostic procedures as some are excluded from this data collection (NHS England undated c).)

Demand is rising across almost all aspects of diagnostics, with 4–7 per cent increases in activity seen for tests such as colonoscopies and MRI scans each year between 2014/15 and 2018/19 (*see* Figure 1) (Independent Review of Diagnostic Services for NHS England 2020), and that was before the Covid-19 pandemic.

Figure 1 Change in demand for diagnostics each year, 2014/15–2018/19

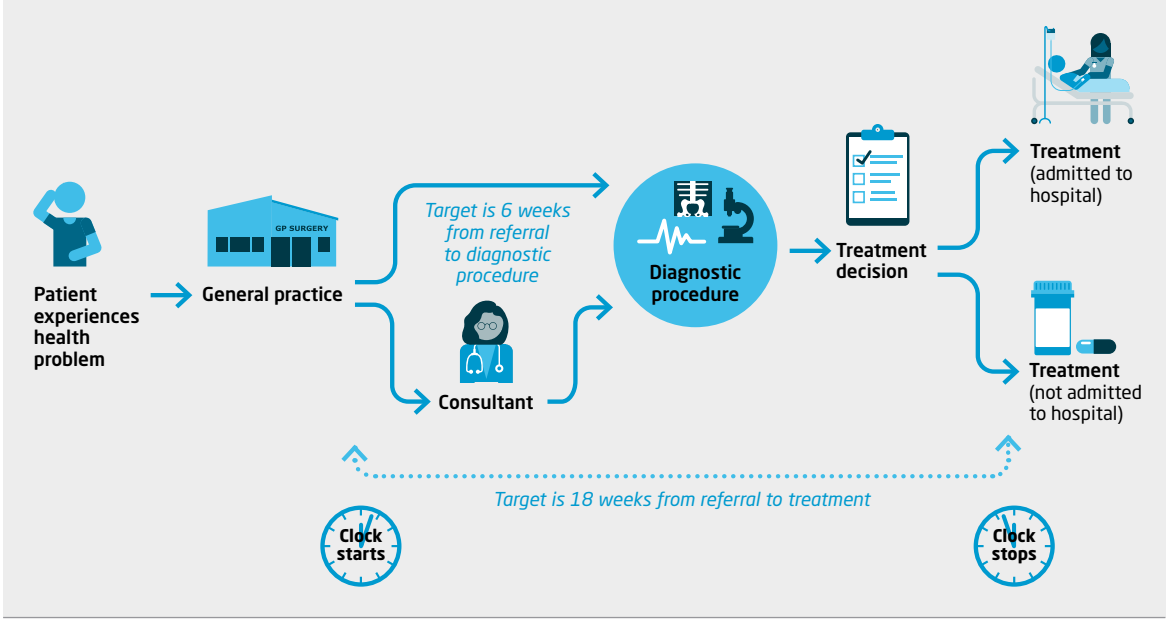


Source: Independent Review of Diagnostic Services for NHS England (2020)

Rising hospital attendances, increased numbers of requests from primary care, urgent referrals for cancer and broader categories, and therefore numbers of conditions or symptoms being assessed by existing technologies such as CT scanners, are driving these year-on-year increases (Independent Review of Diagnostic Services for NHS England 2020). While some diagnostic specialties have been better able to redesign ways of working to accommodate rising demand, such as pathology through the introduction of automation in laboratories, for many types of diagnostic services, demand is routinely outstripping capacity (Lewis *et al* 2021; Independent Review of Diagnostic Services for NHS England 2020; Karakusevic *et al* 2016).

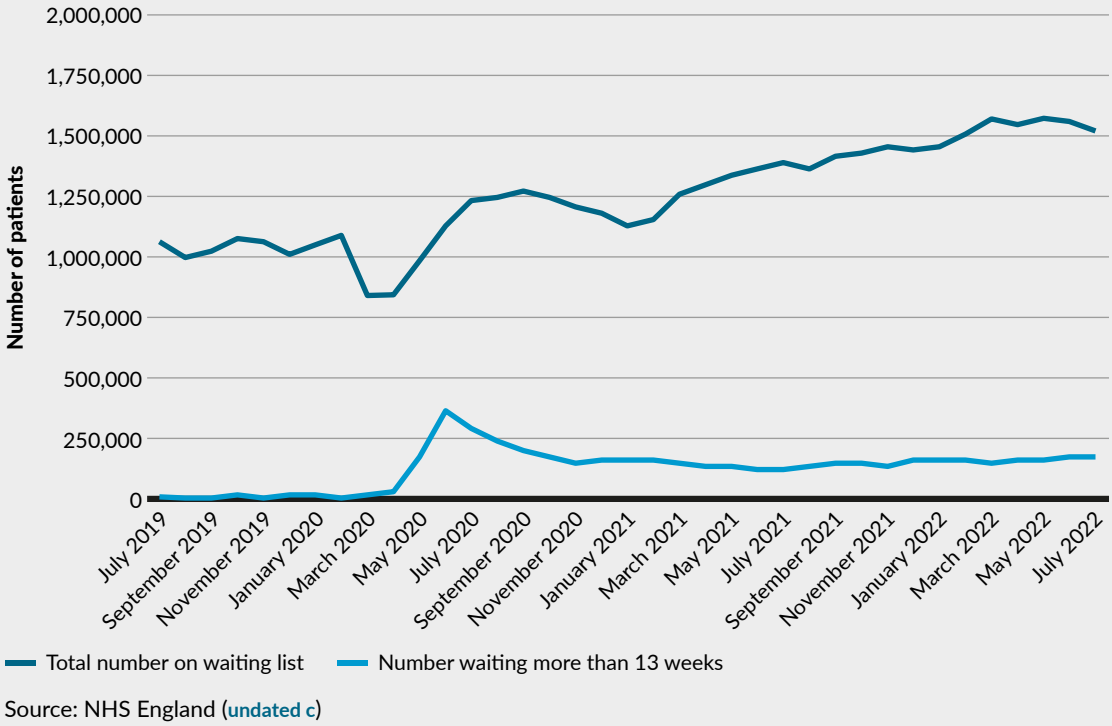
As a result, the number of patients waiting for diagnostics has been steadily increasing (NHS England undated c). A diagnostic waiting-times standard was introduced in March 2008 to support the achievement of an 18-week referral-to-treatment target and now forms a key part of the NHS Constitution. This pledges that patients should wait for a diagnostic test less than six weeks from when the request is received, with the target set at 99 per cent. This standard has not been met nationally since February 2017.

Figure 2 Diagnostics and the elective care referral-to-treatment pathway



The significant decline in the number of tests undertaken during the Covid-19 pandemic has compounded this situation. There were more than 1.5 million people waiting for the 15 diagnostic tests and procedures included in NHS England's data collection in July 2022, with 424,605 waiting longer than six weeks, compared with 37,206 in July 2019 (NHS England undated c). The number of patients waiting longer than 13 weeks has also risen, with 164,043 people waiting this long in July 2022 compared with 4,724 people in July 2019 (*see* Figure 3).

Figure 3 Total number of patients waiting for diagnostic tests and number of patients waiting more than 13 weeks, July 2019–July 2022



Source: NHS England (undated c)

Why do waits for diagnostics matter?

Given the key role that diagnostics play as a foundational part of clinical pathways and often as a precursor to the start of treatment, any delay in access can result in prolonged waits for needed care. Waits for care were increasing before the pandemic, with the 62-day waiting-time standard for cancer treatment not being met since 2013/14 and the 18-week standard for planned hospital treatment not being met since February 2016 (**The King's Fund 2022a**). Following the pause or reduction of many routine NHS services during the pandemic in 2020 and 2021, waits for care are continuing to grow, with the number of people waiting more than a year for elective care rising to 377,689 by July 2022 compared with 1,032 people in July 2019 (**NHS England undated b**).

Growing waits for diagnostics also inevitably lead to the prioritisation of urgent access routes, leading people to wait longer for planned diagnostics. At best, longer waits for both diagnostics and care mean inconvenience and discomfort for patients, but for some it will mean deteriorating health and more severe illness, waiting in pain and cancers being diagnosed later. This in turn puts greater pressure on primary care and outpatients while patients wait to be diagnosed.

Diagnostics are central to cancer outcomes (**House of Commons Health and Social Care Committee 2022**). The faster-diagnosis standard, which sets out that patients who GPs have urgently referred for suspected cancer must be diagnosed or have cancer ruled out within 28 days, is also being missed. In June 2022, 66,350 people had been waiting longer than 28 days for cancer to be diagnosed or ruled out and 16,845 had been waiting longer than 62 days (**NHS England undated d**). The increasing number of patients missing the 28-day faster-diagnosis standard is due to diagnostic delays.

The interdependent nature of the care pathway means that a major acceleration in diagnostic activity needs to be co-ordinated with capacity elsewhere in the system so that patients can progress on a care pathway once they have their diagnosis. Otherwise, patients will end up waiting less time for their diagnostic tests but could then face further delays as they enter another waiting list for treatment.

Inequalities in access

Inequalities in access to timely diagnostics are highly likely to be both a symptom and a cause of health inequalities. Health inequalities lead to varied access to services (Holmes and Jefferies 2021), disparate outcomes and poor experiences of care. Inequitable access means people receiving less care relative to their needs, or more inappropriate or sub-optimal care, than others, which often leads to poorer experiences, outcomes and health status (Williams *et al* 2022). This is evident in cancer referral and detection rates, as the least deprived areas have a higher referral rate of 4,000 per 100,000 people compared with 3,200 per 100,000 people for the most deprived areas, despite the incidence of cancer being higher in more deprived areas. More deprived areas also tend to have fewer GPs per person (Nussbaum *et al* 2021) and lower rates of admission to elective hospital care (Public Health England 2021) than less deprived areas (Williams *et al* 2022). This suggests both better access to referral routes in less deprived areas and potentially higher presentation rates for care compared with more deprived areas.

Furthermore, in analysis on inequalities in access to care, The Strategy Unit has shown that, between 2009 and 2018, the growth in the use of new diagnostic technologies, colonography (which looks at the colon) and single photon emission computed tomography (SPECT) scans (which provide images of the flow of blood around the body) was greater for those living in the least deprived areas (Wyatt and Parsons 2021). It appears that those in the most deprived areas could be experiencing the long-observed 'inverse care law' (Tudor Hart 1971), which means that the availability of medical care, or diagnostics in this case, tends to vary inversely with the need for it in the population served.

In its *Delivery plan for tackling the Covid-19 backlog of elective care*, NHS England recognises the risk that health inequalities will be exacerbated in the current operational performance context, and so has specifically asked NHS trusts to manage the waiting lists and diagnostics through a health inequalities lens, therefore prioritising certain groups (NHS England 2022b). Importantly, the diagnostic health inequalities metrics that NHS England is developing will support the exploration of the impact of health inequalities on diagnostics (Sloman *et al* 2022).

Diagnostics policy

While earlier and faster diagnosis has been an objective of health and care policy for many years, the specific focus on diagnostics has been more recent.

In the 2019 NHS Long Term Plan, NHS England acknowledged that introducing 'faster, modern diagnostics' into the NHS would be key to achieving the ambitious commitments on clinical priorities, which include cancer, cardiovascular disease, stroke, diabetes and respiratory care (**NHS England 2019**, p 28). It committed to this in the form of rolling out new rapid diagnostic centres (**NHS England 2019**) and investment in new equipment, including CT and MRI scanners. However, it also noted the need for a longer-term strategy and asked Sir Mike Richards, former National Cancer Director and Chief Inspector of Hospitals, to lead a review that would look at how to 'modernise and expand diagnostic capacity' (**NHS England 2019**, p 58).

The review report, *Diagnostics: recovery and renewal*, published in October 2020 (**Independent Review of Diagnostic Services for NHS England 2020**), recommended significant reform and investment in diagnostic services and highlighted the need for:

- new service delivery models
- equipment and facilities
- consideration of the workforce
- digitisation and connectivity.

A key recommendation was the separation of emergency diagnostics from elective diagnostics to improve efficiency and reduce delays for patients. Central to achieving this separation was the recommendation to establish a series of community diagnostic centres across England. The government accepted the latter recommendation and in October 2021 it announced that 40 new community diagnostic centres would be launching across England to address the 'blockage in access to diagnostics and deliver tests closer to home' (**Department of Health and Social Care *et al* 2021**).

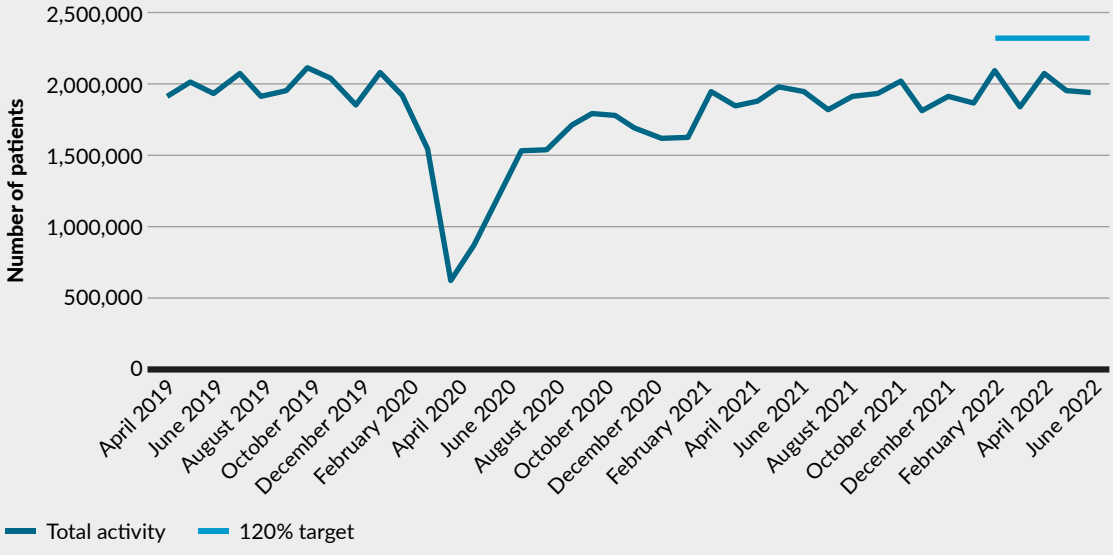
Community diagnostic centres

The aim of community diagnostic centres is to deliver additional diagnostic capacity in England to provide quicker and more convenient access for patients, reduce pressure on hospitals and reduce regional inequalities (Department of Health and Social Care *et al* 2021). These centres were to be operational by March 2022 and were given a £350 million investment to provide around 2.8 million scans in the first full year of operation.

In April 2022, the government announced that '73 centres [were] already open and carrying out 30,000 extra tests a week' and the aim to have 160 centres across England by 2025 (Department of Health and Social Care 2022a). As a minimum, community diagnostic centres are required to carry out a range of imaging, cardiorespiratory, pathology and endoscopy tests.

NHS England's 2022 elective recovery plan underlined the importance of increasing diagnostic activity to support elective recovery and early cancer diagnosis (NHS England 2022b). New targets for integrated care systems were introduced to support this, including increasing diagnostic activity to a minimum of 120 per cent of pre-pandemic levels across 2022/23 and that 95 per cent of patients would receive a diagnostic test within six weeks of referral by March 2025 (NHS England 2022c). However, in July 2022 the number of diagnostic tests remained below July 2019 numbers (*see* Figure 4) – at 94 per cent of the pre-pandemic level of activity – and

Figure 4 Diagnostic activity over time and the 120 per cent target



Source: NHS England (undated c)

so integrated care systems will need to consider how to boost activity to meet the 120 per cent target. Alongside this was additional funding for diagnostics in the form of £248 million to 'modernise' through investment in digitisation alongside £2.3 billion of capital funding announced at the Spending Review to increase the number of community diagnostic centres to 100 and for equipment including CT, MRI and ultrasound scanners (**Department of Health and Social Care 2021**).

Community diagnostic centres – initial reflections

Community diagnostic centres are intended to move diagnostics closer to the people who need to use them and to increase capacity. However, looking at the roll-out so far, some questions are emerging about where they are and how much they are contributing to activity levels.

Government guidance makes clear that large new-build projects to establish community diagnostic centres will be considered only on 'an exceptional basis' and that they must be accommodated within the existing NHS estate (NHS England 2022a). This poses an issue as the estate across primary and community care is unlikely to have many suitable facilities to accommodate the range of diagnostics that community diagnostic centres require. This means that these centres may still need to be located outside of the community on hospital sites. Indeed, Maria Caulfield, then Minister of State for Health at the Department of Health and Social Care, confirmed in August 2022 that 47 of the 92 community diagnostic centres are on existing hospital sites. It is also possible that community-based community diagnostic centres may not be able to achieve the expected volume of tests and activity that the Department of Health and Social Care anticipates, given space constraints.

The latter point is potentially being borne out already as, while there are reports of 30,000 tests being performed weekly across the community diagnostic centres, this equates to just 411 tests a week for each centre, which suggests that not all centres are able to offer the full range or volume of tests that the Department of Health and Social Care expects the sites to meet (Baines 2022; Department of Health and Social Care 2022a). At a meeting of the NHS England Board, National Director of Transformation, Dr Tim Ferris, stated that the current operational community diagnostic centres are only adding 2 per cent of diagnostic capacity, and after two years this will increase to just 5 per cent (Ferris 2022). However, how much the centres have increased capacity could be questioned given there has been a concerted effort to increase diagnostic activity as part of the elective recovery plan and much of this could have taken place in existing diagnostic facilities.

Community diagnostic centres may increase the physical capacity to deliver services through more facilities and equipment, and potentially be nearer patients, but concerns have been raised that there are not enough staff to run both new community diagnostic centres and pre-existing facilities. Fears have been expressed over the sustainability of running community diagnostic centres without further recruitment (Baines 2022). Those working in this area have highlighted that there is a need for a diagnostic workforce strategy that includes the community diagnostic centres at a system level, to ensure that the centres can perform the range of tests needed to meet their local population health needs (Baines 2022). Without it, staff shortages and skills gaps will undermine the community capacity that community diagnostic centres aim to create.

Addressing demand – opportunities of transformation and innovation

The recent policy focus on diagnostics has made clear that the aim is not just to expand diagnostic capacity and pathways in the NHS, but also to transform them. The rapid and significant innovations in diagnostics, technology and supporting infrastructure in recent years provide opportunities to improve the accessibility and delivery of diagnostics.

In many ways, innovation in diagnostics is looking to widen and personalise access to diagnostics through better distribution of them across the health and care system (Becton Dickinson 2021).

Technological advances

New diagnostic technologies, and supporting infrastructure, have the potential to improve care for patients by changing how diagnostic tests are conducted and analysed. For example, the increased miniaturisation and improved portability of technology have moved tools such as X-ray and ultrasound machines into the community. Similarly, minimally invasive diagnostic tools, such as ingestible sensors, are diversifying the offer to patients.

Advances in understanding of genomics and the use of artificial intelligence have opened new avenues for innovation, enabling increasingly precise diagnostics and analysis of scans or complex diagnostic data. There is particular scope for artificial intelligence to benefit diagnostic pathways by supporting reporting and reducing the workforce time needed, but this will require significant upfront investment and evaluation to ensure accuracy (Warren and Clarke 2020).

From endoscopy to Cytosponge™

Endoscopy can be used to investigate symptoms in the digestive system to diagnose a range of conditions, including oesophageal cancer. It is an invasive procedure that can be painful for the patient as it involves inserting a tube – an endoscope – down their throat to see whether there are any growths or other abnormal-looking areas and taking a biopsy if needed. The procedure is expensive for the health and care system.

To address these issues, an innovative new diagnostic tool has been devised – a Cytosponge™ (National Institute for Health and Care Excellence 2020a) – which is an ingestible small capsule attached to a fine string (Matson 2020). After the patient swallows it, the capsule's coating dissolves in the stomach to release a small brush, which when removed allows cell collection from the lining of the oesophagus (gullet or food pipe). The sponge is then sent to a laboratory, where the cells are analysed for abnormalities. Unlike endoscopy, this test can be done at the point of care in the community. A pilot is being implemented in secondary care across 30 NHS hospital trusts, for patients with reflux symptoms on routine referral for endoscopy (Sloman *et al* 2022; Fitzgerald *et al* 2020).

NHS England introduced the MedTech Funding Mandate in April 2021 to fast-track and increase the adoption of emerging technologies across the NHS, fulfilling a commitment in the NHS Long Term Plan to support commissioners and health care providers to bring life-changing innovations to patients more quickly (NHS England 2019). This follows on from the Accelerated Access Collaborative (AAC) innovation programmes, such as the Innovation and Technology Tariff/Innovation and Technology Payment (ITT/ITP) programme, recognising that there are financial and procurement barriers to introducing new diagnostic technologies. This can therefore contribute to health inequalities due to variation in the take-up of the innovation across England and unequal access.

The National Institute for Health and Care Excellence (NICE) can review new diagnostic tests and also issue diagnostic guidance to help the NHS make efficient, cost-effective and consistent decisions about adopting new diagnostic technologies. This can help improve understanding of the potential of new technology across the system. However, NICE does not mandate the uptake of diagnostics that it has reviewed in the NHS, unlike NICE-approved medicines, which must be made available across the NHS within 90 days of approval. The system needs the capacity and capability to engage with the NICE recommendations on diagnostics.

Point-of-care testing

Point-of-care testing is the ability of a health care worker to test and diagnose a clinical problem in real time and in the care setting in which the patient presents. This allows for treatment and next-step decisions to be made rapidly and as part of the same clinical encounter (Fleming *et al* 2021). Simple point-of-care diagnostics have been around for many years but changes in technology have expanded the number of diagnostic tests that can be carried out at the point of care. Now there is potential for more accurate and timely diagnosis of diabetes, cardiovascular disease, various cancers and other high-prevalence conditions, such as urinary tract infections. An example of this is the D-dimer blood test, which is used to assess possible deep vein thrombosis and pulmonary embolism (Schols *et al* 2018).

Phlebotomy – drive through and 'phlebotobus'

Phlebotomy is the process of taking blood. The demand for diagnostic blood tests was increasing before the Covid-19 pandemic and the number of tests available has been increased. Referrals for blood tests can come from both primary and secondary care but access to blood-taking services is currently patchy across primary care and the community (Independent Review of Diagnostic Services for NHS England 2020). This means that people often have to visit acute hospitals to have their blood taken, which can entail greater travel and disruption, particularly for patients who need regular testing to monitor their condition.

The pandemic has been a catalyst for innovative thinking on access to phlebotomy. The need to keep patients out of hospital settings to improve Covid-19 infection control has driven this. Examples of new approaches include drive-through access, whereby patients have their blood samples taken through their car window. The Buckinghamshire, Oxfordshire and Berkshire West Integrated Care System has taken the opportunity of community diagnostic centres to set up a blood-testing facility in a bus, known as a 'phlebotobus', as part of the drive to increase convenient access to testing (Association of British HealthTech Industries 2022).

Point-of-care testing widens access by locating diagnostics as close as possible to the patient and where they are likely to first present. It offers benefits to the health and care system through better and more informed decisions about treatment and care. It supports a reduction in the number of referrals to secondary care. And patient experience is likely to be more positive, with less time involved and reduced travels costs in getting to appointments, which could increase access for those who experience health inequalities (Fleming *et al* 2021).

Changing pathways

The Independent Review of Diagnostic Services for NHS England (2020, p 21) highlighted how diagnostic pathways had 'remained almost unchanged for decades', despite being wasteful of NHS resources and patients' time, and ignored the opportunities that modern technology offered. The use of point-of-care testing and a reorientation towards the delivery of diagnostics in the community form part of the picture of how diagnostic pathways can be transformed in the drive to meet demand. However, these are not the only opportunities.

The redesign of diagnostic pathways could also make use of the improved links between primary and secondary care brought about through the Covid-19 pandemic, which saw strengthened advice and guidance systems providing access to specialist advice (NHS England 2022a). This shift enables GPs to access specialist advice, for example, which in some cases can negate the need for the patient to be referred to secondary care before a diagnostic procedure can be ordered. This means that patients can go 'straight to test' as primary care clinicians can request the most appropriate investigation at the point of care.

There is also potential for greater use of risk stratification tools to streamline diagnostic pathways, to direct capacity to those who most need further investigation and to reduce over-testing. An example of this is faecal immunochemical testing, which is done to identify possible signs of bowel disease and can be used as part of the assessment of patients presenting with lower abdominal symptoms, particularly in primary care. Faecal immunochemical testing acts as a screening tool and directs those with a 'detectable' faecal haemoglobin level to further investigation through a colonoscopy. There is also the opportunity to use risk stratification to insert diagnostics earlier in patient pathways.

Use of diagnostics earlier in the patient pathway – fibroscanners

A different model for the early diagnosis of chronic liver disease has been explored in Nottingham to address avoidable premature deaths from liver disease. This involved using population health analysis to screen practice lists in primary care for risk factors, including excessive alcohol consumption and type 2 diabetes. Patients with significant risk factors were then offered a fibroscan, on an adapted ultrasound scanner, which provides a more accurate diagnosis of liver disease than blood tests, and a quicker, less invasive test than a surgical biopsy (Collins 2018; El-Gohary *et al* 2018). This is an innovative use of diagnostics, which contrasts with when fibroscanners were first introduced, as hospital consultants used them as an adjunct to existing diagnostics and treatment pathways rather than developing new models.

Networked working

Some of the transformation in diagnostics is taking place by moving services to wherever it makes most sense for the population; however, alongside this there is still the need to have the test processed in a location that guarantees a timely, accurate result (Association of British HealthTech Industries 2022). Networks and alliances can play an important role in addressing this by bringing together individual diagnostic services, such as pathology units, into networks working across different boundaries (NHS England and NHS Improvement 2019). This follows the wider shift towards collaborative working throughout the health and care system, which is exploring the potential of more integrated working and effectively utilising scale (Mernin 2022).

Networked working – Cheshire and Merseyside Cancer Alliance Endoscopy Network

The nine trusts in the Cheshire and Merseyside Cancer Alliance have formed an endoscopy network, bringing together eight endoscopy services across twelve sites, serving a population of 2.75 million (Royal College of Physicians Joint Advisory Group on GI Endoscopy JAG 2020). The network's aims are to standardise practice and reduce unwarranted variation, making better use of resources and improving patient outcomes. This has involved developing and implementing strategies such as central scheduling so that complex cases are seen on a single site and patients are enabled to choose the site for endoscopy that is most convenient for them. Standardised pathways have been developed across the network for lower and upper gastrointestinal patients, which involves faecal immunochemical testing for each patient to establish their priority for endoscopy (Murray 2021).

There are 29 pathology networks now in place across England and diagnostic imaging networks are set to follow by 2023 (National Institute for Health and Care Excellence 2021). Endoscopy and cardiorespiratory services have also been earmarked as among the services that could benefit from working in this way. The rationale for this way of working is the potential for improvement through pooling resources and using the existing equipment, facilities and workforce more efficiently. Pathology networks demonstrated the benefits of this throughout the first year or two of the Covid-19 pandemic, keeping high throughput despite significant and sustained demand for both swab testing and antibody testing.

Challenges facing diagnostics

There are a number of challenges facing the diagnostics sector that may have an impact on how successfully the ambitions to expand diagnostic activity can be met. This follows significant underinvestment in diagnostics over many years, particularly equipment, facilities, the workforce and digital capability.

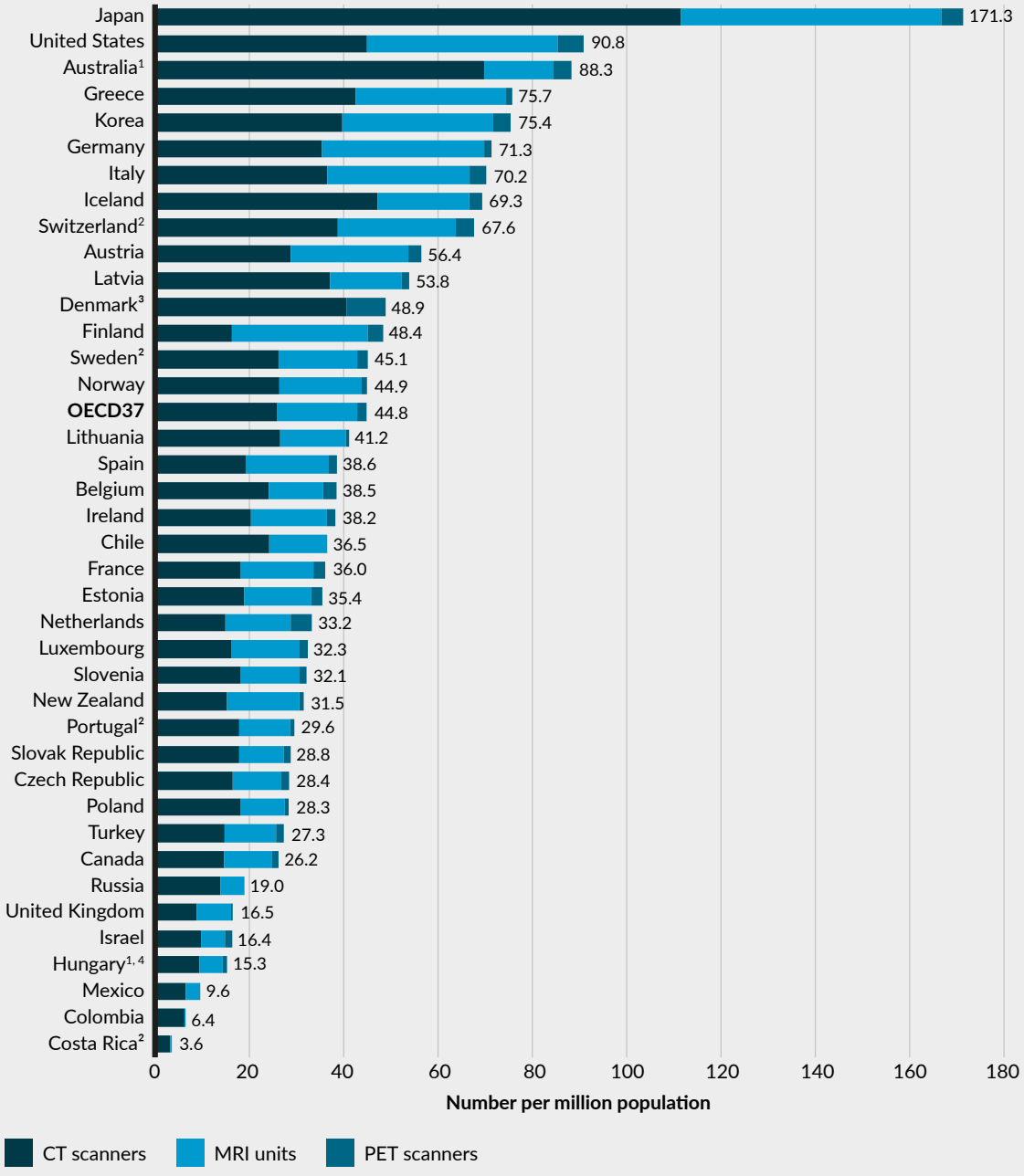
Equipment and facilities

The government's approach to capital budgets over the past decade has impacted diagnostic equipment and facilities, even though recently they have been the beneficiaries of discrete pots of funding: capital budgets have been redirected as recently as 2019/20 to boost day-to-day spending in the context of a prolonged financial squeeze on the NHS (**Anandaciva 2021a**). In this context, the condition of NHS buildings and equipment has worsened, some of which are diagnostic facilities and equipment (**NHS Digital 2021**).

In addition to the need for new diagnostic equipment, there is a backlog of diagnostic equipment that is more than 10 years old that needs to be replaced. The pandemic, which saw their greater use, has highlighted that many of the mobile X-ray machines in use in the NHS need replacement. Older equipment is likely to be more unreliable, which can lead to poorer patient care and lower productivity as, for example, an old scanner produces lower-quality images, is more likely to break down during a patient appointment and costs more to maintain (**Anandaciva 2021b**).

International comparison with countries of the Organisation for Economic Co-operation and Development (OECD), focusing on imaging equipment, shows that the UK has a below-average number of scanners (**Organisation for Economic Co-operation and Development 2021**). The UK has only 8.8 CT scanners per million population, compared with the OECD average of 25.9 and similarly for MRI units the numbers are 7.4 and 16.9, respectively (**Organisation for Economic Co-operation and Development 2021**). While it is important to note that there is no ideal number of scanners, the UK has lower numbers per million than the majority of OECD countries, including all of the European members aside from Hungary (*see* Figure 5).

Figure 5 CT scanners, MRI units and positron emission tomography (PET) scanners per million population, 2019 (or nearest year)

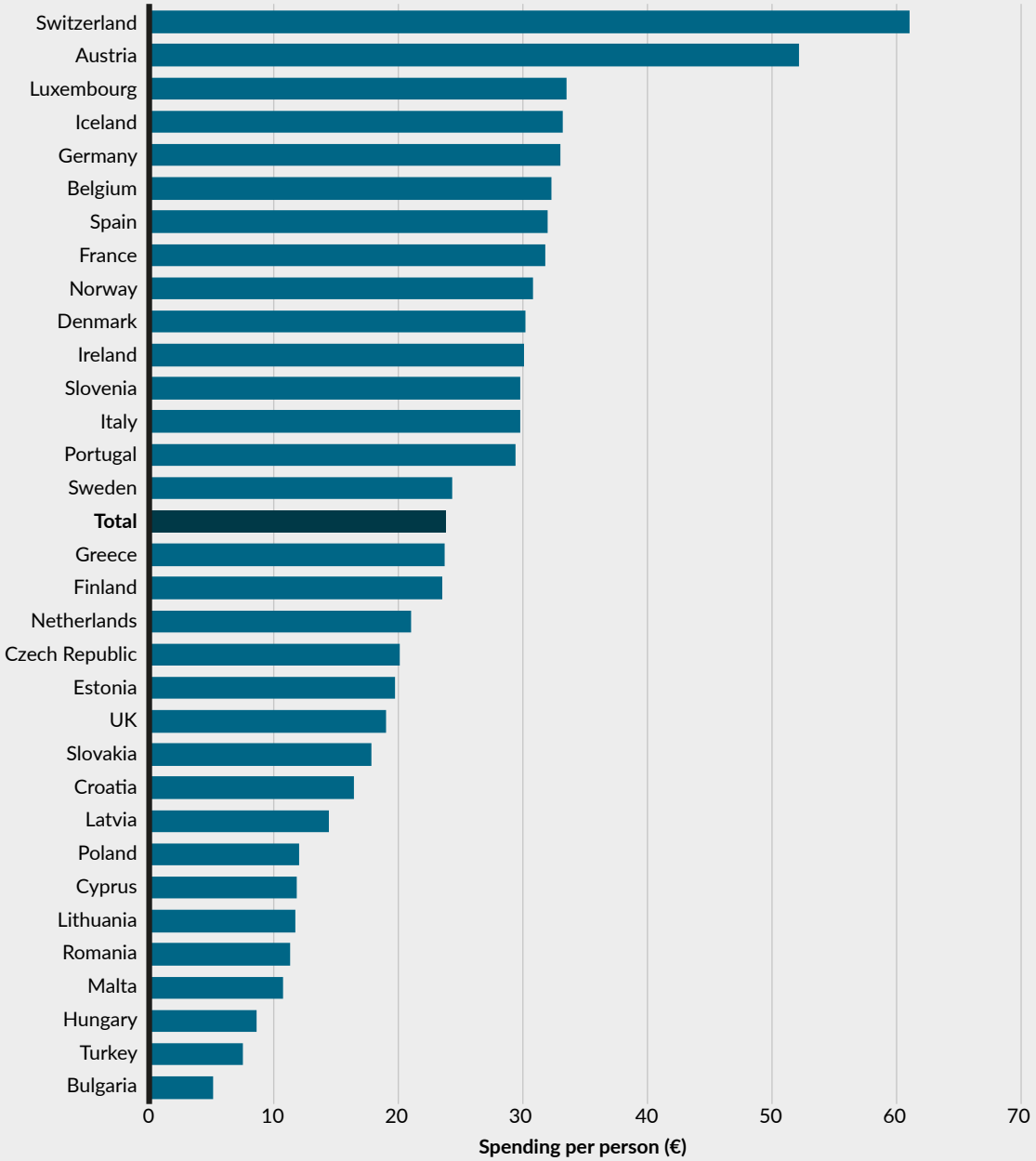


[1] Only equipment eligible for public reimbursement
[2] Equipment outside hospital excluded (only for MRI units in Switzerland)
[3] Data on MRI units not available
[4] Only equipment outside hospital included

Source: Organisation for Economic Co-operation and Development (2021)

Beyond large pieces of equipment such as scanners, the UK also has a lower-than-average spend per person on in vitro diagnostics, which are tests that can detect disease, conditions and infections and are typically conducted in test tubes and similar equipment (MedTech Europe 2021). The UK spends €19 per person on in vitro diagnostics, compared with an average of €23.80 among countries in the European Union, the European Free Trade Association (EFTA) and Turkey (*see* Figure 6). This equates to 1 per cent of total health expenditure – even though the

Figure 6 In vitro diagnostic spending per person, 2020 (EU27, EFTA, UK, Turkey)



Source: MedTech Europe (2021)

results of in vitro diagnostic tests influence many clinical decisions (Association of British HealthTech Industries 2020). In vitro diagnostics are also key to point-of-care testing as they include tests that health care professionals can perform outside of a laboratory setting, and so a lack of investment in these tests could limit the ability to introduce point-of-care testing into care pathways.

Workforce

Alongside sufficient diagnostic equipment and facilities, which may not necessarily be in place, a further rate-limiting factor is having enough staff trained to use them and deliver services (NHS England 2021).

The diagnostic workforce draws on a wide range of health professionals, ranging from radiologists to nuclear medicine specialists, and histopathologists to endoscopists. Each category of diagnostic test has a large and diverse workforce that underpins it, who often work together in a multidisciplinary way throughout the course of the diagnostic process.

However, years of poor workforce planning and inadequate funding across the health and care system have resulted in chronic staff shortages (The King's Fund 2022b). The impact of this is being felt in diagnostics as the growth in the diagnostic workforce has not kept pace with demand and activity and now there are significant vacancies impacting all specialities – with imaging, radiology, pathology and endoscopy notably under strain. Shortages are increasingly creating pinch points in the parts of the diagnostic pathways that are reliant on human intervention.

According to the Royal College of Radiologists, the NHS radiologist workforce is now short-staffed by 43 per cent and needs at least another 1,939 consultants just to keep up with pre-Covid-19 levels of demand for scans and image-guided surgery (Royal College of Radiologists 2021; Association of British HealthTech Industries 2020). Similarly, only 3 per cent of histopathology departments, which examine biopsies or surgical specimens under a microscope, said they had enough staff to meet clinical demand, leading to a concurrent increase in the number of laboratories outsourcing work and using locum staff (Association of British HealthTech Industries 2022; Royal College of Pathologists 2021).

Staff shortages have a clear impact on the ability of diagnostics services to deliver timely access and results. Imaging is an example of a diagnostic discipline that requires specialist equipment and staff to administer it, often in a one-to-one scenario with a patient, and then specialist staff to report the findings. The lack of staff directly restricts the ability to deliver services, irrespective of the equipment

available. The shortfall in the imaging workforce is now particularly acute, with the Independent Review of Diagnostic Services for NHS England (2020) highlighting the urgent need for additional people in this field. Table 1 shows the estimated extra numbers of the different types of imaging roles needed.

Table 1 Estimated requirements for the additional imaging workforce over five years

Roles	Additional workforce required
Physicists	200
Advanced practitioners/reporting radiographers	500
Radiologists	2,000
Assistant practitioners	2,500
Administration and support staff	2,670
Radiographers	3,500

Source: Independent Review of Diagnostic Services for NHS England (2020)

A workforce shortfall also has implications for service budgets as costs to deliver the service go up to accommodate the need to use outsourcing and locums. The Royal College of Radiologists (2021) found that NHS trusts are using a variety of work-arounds to compensate for shortages, including outsourcing, and 41 per cent of trusts are leaving imaging examinations unreported or auto-reported, which is an automatic response sent to referring clinicians, stating it is their responsibility to either provide a formal imaging report or to request one from the radiology department. Expenditure on outsourcing and ad-hoc locums in radiology departments rose from £90 million in 2019 to £122 million in 2021 (Royal College of Radiologists 2021). The same report also found that while the use of imaging networks has been a useful way of managing reporting needs, it still entails redistributing workload across the same stretched workforce (Royal College of Radiologists 2021).

The impact of this for patients is delayed access coupled with additional time spent waiting for their results to become available. This contrasts with policy-makers' expectation that innovations or changes such as the set-up of community diagnostic centres will enable tests to be done anywhere, with results that are available quickly and directly (Department of Health and Social Care 2022b).

The rising demand for diagnostic tests means that investment is needed to recruit new staff and retain current staff to ensure that vacancy rates do not continue to rise (McCaughey and Powis 2020). However, new ways of working will also be key to delivering services within current workforce capacity. This entails thinking differently, particularly focusing on skill mix, so that the skills and competencies needed to deliver services are the focus, rather than the specific job role or title, for example radiologist.

There is potential for health care assistant roles to be upskilled, for example given Association for Respiratory Technology and Physiology (ARTP) certification to perform spirometry, used to diagnose chronic obstructive pulmonary disease (COPD), to relieve pressure on the diagnostic workforce. Support roles can be used effectively to streamline pathways and reduce demands on the time of health professionals performing diagnostic tests. Examples of this include screening practitioners, who assess whether a patient is fit for an endoscopy and explain what preparation is needed for the test, and assistant radiographers and imaging support workers, who process images and help with biopsy procedures (Brown *et al* 2015; Health Careers undated).

To deliver services and results efficiently, there is also a need to retain and build on the flexibilities introduced during the Covid-19 pandemic. During the pandemic, staff were able to work from home, which enabled the return of retired radiologists and radiographers to the workforce. This could be built on to explore the potential of outsourced reporting, possibly to other countries, to address capacity gaps (The Health Foundation 2018).

Digital and information-sharing infrastructure

The context of needing to use stretched capacity in diagnostics as efficiently as possible, and the desire to transform and innovate, puts a premium on services and organisations being able to share information with each other and with patients (Craven 2021). Digital and information-sharing infrastructure is a key enabler to the delivery of diagnostic services, the success of networked working and 'virtual' wards. The Independent Review of Diagnostic Services for NHS England (2020) stresses the importance of full digitisation and information technology connectivity as a means of sharing workloads across networks and regions (Roche Diagnostics Limited 2021). However, currently this is not a seamless experience – instead, sharing data, including diagnostic images and pathology records, is often difficult, meaning that diagnostic tests are often repeated to obtain the result in a timely way or when the patient moves between care settings (Javid 2022).

The government has recognised this and set out £248 million of investment in the digitisation of diagnostic services, which 'means that hospital labs will be able to share patient results, tests and scans with clinicians, wherever they are' (Department of Health and Social Care 2021). This investment may not be sufficient to achieve this aim, given the scale of the challenge in digitising NHS diagnostics, with the digitisation of cytology and histopathology only available in a very limited number of hospitals. Furthermore, NHS England is now expected to fund the uplift in pay for NHS staff out of existing budgets and it has been clear that this will require the 'release of money from existing programmes', with technology and diagnostic capacity singled out as two areas that will see the impact of this (McLellan and Kituno 2022).

Virtual wards

A 'virtual' ward is a way of delivering care that means that patients receive care at home rather than in hospital, while being supported through the remote monitoring of physiological variables with the use of technology platforms and diagnostic medical devices such as pulse oximeters. Virtual wards are currently being used to support patients with Covid-19, acute respiratory infections, urinary tract infections and chronic obstructive pulmonary disease, but the ambition expressed in the 2022/23 operational planning guidance is for all integrated care systems to have 40 to 50 virtual beds per 100,000 population by the end of 2023 (Illman 2022).

While the ambition, and the technology, exist to make greater use of virtual wards, the pathways and underpinning financial agreements to fund them are not in place, or developed enough, for routine physiological monitoring in either primary care or secondary/community care. This will be an issue for integrated care boards to consider as they seek to meet the targets for virtual bed numbers.

There is also a wider question about the state of digital capacity and readiness in the NHS, with the National Audit Office finding in 2020 that digital capability (the use of technology to deliver care) remains a significant challenge, with 16 per cent of trusts assessing their capability as 'low' (National Audit Office 2020). Achieving the interoperability of data and information technology systems has been a longstanding aim in the NHS – first recognised as important in 1998 – but progress towards it has been patchy and remains very challenging (National Audit Office 2020). Even now only 54 per cent of NHS trusts report that staff can rely on digital records for the information they need when they need it and it will be a further three years before all integrated care systems and NHS trusts will be

required to have core digital capabilities in place, including electronic health records (Javid 2022; National Audit Office 2020). In this context, with widespread variation in starting points, it is difficult to see that all diagnostic services in England will be able to quickly make use of digital means to boost capacity in the short term. This risks compounding pre-existing inequalities in access.

Conclusion: the future of diagnostics

The centrality of diagnostics to the NHS's ability to deliver patient services cannot be understated (McCaughey and Powis 2020). They are fundamental to clinical decision-making. There is huge potential for diagnostics to play an even greater role in driving improved outcomes through transformation and innovation, particularly via the redesign of patient pathways and the introduction of new technology. This is being realised through a shift to community settings and community diagnostic centres, which has been recognised as an important opportunity to widen access and improve uptake by giving people more choice around when, where and how to access diagnostic services (Roche Diagnostics Limited 2021). While this is cause for optimism, there is also a need for realism.

While the temptation may be to consider community diagnostic centres or community diagnostics as the solution to all questions about diagnostic capacity, this is not the only answer. Concerted policy focus and investment will be needed to address the historic underinvestment in diagnostics over many years, particularly in terms of infrastructure and the workforce, if the major expansion of diagnostic capacity that is needed in the NHS is to be realised (Association of British HealthTech Industries 2020).

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Charlotte Wickens is a policy adviser at The King's Fund. She sits within the responsive policy team and her work at the Fund is primarily external facing, identifying, analysing and communicating emerging policy issues.

Charlotte previously worked at Anthony Nolan, where she led work on access to treatments, with a focus on understanding the changes to the access landscape resulting from the review of National Institute for Health and Care Excellence's (NICE) methods. She also conducted focused policy work on blood cancer data, a strategy for the next 10 years of stem cell transplantation and patient experience of the Covid-19 pandemic. Before this she held roles at Macmillan Cancer Support and the Office of the Children's Commissioner for England. She has a Masters in international security from the University of Sussex.

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