DIAGNOSTICS: RECOVERY AND RENEWAL

OCTOBER 2020

FOREWORD

The need for radical investment and reform of diagnostic services was recognised at the time the NHS Long Term Plan was published in 2019.¹ This report, commissioned by NHS England at that time, alongside a review of adult screening services, was nearing publication before the Covid-19 pandemic struck. However, while the recommendations made pre-pandemic still stand, additional actions will be needed to deliver safe, high quality diagnostic services in an endemic phase of the disease and to support the recovery of diagnostic services.

The Covid-19 pandemic has further amplified the need for radical change in the provision of diagnostic services, but has also provided an opportunity for change. Many beneficial changes in relation to diagnostic pathways, such as increased use of virtual consultations and community services, have already been made. These changes must now be embedded. However, much more now needs to be done in the recovery period to establish new pathways to diagnosis, so that both patients and healthcare professionals can be assured that investigations will be done safely.

To deliver the increase in diagnostic activity required now and over the coming years, and to provide safe, patient-centred pathways for diagnostics, new service models are needed. Availability of Covid-19 virus testing for patients and healthcare professionals is likely to be critical, especially when community prevalence of the virus is high. Without such testing, patients will have to be considered as 'Covid-19 uncertain', which will slow throughput in imaging and particularly in endoscopy.

The following key actions can be defined:

- Acute and elective diagnostics should be separated wherever possible to increase efficiency.
- Acute diagnostic services (for A&E and inpatient care) should be improved so that patients who require CT scanning or ultrasound from A&E can be imaged without delay. Inpatients needing CT or MRI should be able to be scanned on the day of request.
- Community diagnostic hubs should be established away from acute hospital sites and kept as clear of Covid-19 as possible.
- Diagnostic services should be organised so that as far as possible patients only have to attend once and, where appropriate, they should be tested for Covid-19 before diagnostic tests are undertaken.
- Community phlebotomy services should be improved, so that all patients can have blood samples taken close to their homes, at least six days a week, without needing to come to acute hospitals.

These new services will require major investment in facilities, equipment and workforce, alongside replacement of obsolete equipment. Training of additional highly skilled staff will take time but should start as soon as possible. International recruitment should be prioritised

¹ NHS England. 2019. <u>The NHS Long Term Plan</u>

when possible but national workforce solutions will also be critical. Alongside this, skill-mix initiatives involving more apprenticeships and assistant practitioners, and using qualified staff at the top of their licence will be essential, as will learning lessons from staff flexibility and roles undertaken during the Covid-19 pandemic.

The radical changes recommended in this report will only become a reality if there is sufficient clinical and managerial leadership at national, regional and local levels. Full establishment of networks for imaging, pathology, endoscopy and cardiorespiratory diagnostics will be the driver for change at a local level, alongside those for genomics. At national level, data collections should be improved, commissioning arrangements to drive improvements in diagnostics should be considered and progress on implementation must be closely monitored and evaluated.

Implementation of the recommendations of this report will help drive improved outcomes in cancer, stroke, heart disease, respiratory diseases and other conditions in line with the NHS Long Term Plan commitments. Major efficiency gains will also be delivered through bulk buying of imaging equipment; reduced installation costs in non-acute sites; avoidance of duplication of imaging between hospitals; reductions in outsourcing of image acquisition and reporting; efficiencies of patient throughput; skill-mix initiatives; and significant reduction in acute admissions and lengths of stay.

Development of this report has been critically dependent on extensive discussions with experts in a wide range of relevant fields. These have included leaders of Royal Colleges and professional societies; national specialist advisors; leads of each of the diagnostic disciplines and national clinical directors in the specialties that are major users of diagnostics; charities and academics; Get It Right First Time (GIRFT) leads; senior managers in the diagnostics industry and independent sector providers. I would like to thank everybody involved for their contributions.

I am extremely grateful for input from colleagues within NHS England and NHS Improvement and Health Education England, and in particular to Sheila Dixon and Ashley Summerfield for their analysis, and to Sally Chapman and Daniel Gosling for their invaluable assistance with the development and drafting of the report.

Professor Sir Mike Richards CBE

Chair – Independent Review of Diagnostic Services for NHS England

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Case study 8: Building an artificial intelligence (AI) model to diagnose and referretinal disease

1. SUMMARY AND RECOMMENDATIONS

SUMMARY

- 1.1. Before the pandemic, the need for radical improvement in diagnostic services was already clear-cut. Demand had been rising rapidly over the past five years or more, driven by increases in hospital attendances, more direct requests for tests from GPs and broader clinical indications for existing technologies, such as CT scanning.
- 1.2. Diagnostic services in the NHS were reaching a tipping point, as shown by the marked increase in breaches of the six-week diagnostic standard in the past two years and by the substantial increase in outsourcing of imaging (including reporting) and endoscopy.
- 1.3. Without investment and reform in equipment, facilities and workforce, existing waiting time standards were very unlikely to be regained. Additionally, achievement of several NHS Long Term Plan commitments² including the ambition to diagnose 75% of people with cancer at an early stage would have been jeopardised, efficiencies not achieved and, most importantly, improvements in patient outcomes threatened.
- 1.4. The Covid-19 pandemic has exacerbated the pre-existing problems in diagnostics. The risk of infection to and from patients attending for diagnostic tests has slowed throughput in all aspects of diagnostics, but particularly in CT scanning and endoscopy. This is due to the need to deep clean equipment and facilities if a patient's Covid-19 status is positive or unknown. The backlog of patients waiting more than six weeks for diagnostics has increased very significantly since the start of the pandemic and now needs to be tackled as quickly as possible.
- 1.5. Major expansion and reform of diagnostic services is needed over the next five years to facilitate recovery from the Covid-19 pandemic and to meet rising demand across multiple aspects of diagnostics. New facilities and equipment will be needed, together with a significant increase in the diagnostic workforce, skill-mix initiatives and the establishment of new roles working across traditional boundaries.
- **1.6.** This expansion must start as soon as possible. In the meantime, use of independent sector facilities where possible should be maximised during the recovery phase.
- 1.7. Alongside expansion, new service delivery models are urgently needed to ensure safe pathways to diagnosis for patients in a Covid-19 endemic world and to drive efficiency in service delivery.
- 1.8. This report focuses on the most acute problems facing imaging, endoscopy, pathology, genomics and physiological measurement services (especially cardiorespiratory diagnostic services).

² NHS England. 2019. <u>The NHS Long Term Plan</u>

- 1.9. Implementation of the recommendations in this report has the potential to transform pathways to diagnosis. This will benefit wider aspects of service provision (including outpatients, same day emergency care, and primary and community care) and should help reduce inpatient lengths of stay, and also support access, including to more vulnerable groups, through more patient-centred local provision.
- 1.10. Collectively, the changes recommended in this report will provide safe environments and convenience for patients; support delivery of many NHS Long Term Plan commitments; and help save lives from major killers, including cancer, stroke, heart disease and respiratory diseases.
- 1.11. Alongside improvements in outcomes and convenience for patients, implementation of the recommendations in this report will deliver major efficiency gains. These include:
 - reductions in capital costs of CT and MRI scanners through bulk buying
 - reduced installation costs on non-acute sites
 - avoidance of duplication of imaging between hospitals through IT networking
 - reduced cost of outsourcing of image acquisition and reporting (estimated at over £160 million per annum)
 - improved patient throughput through separation of acute and elective imaging
 - skill-mix initiatives across all diagnostics
 - reduced length of stay through imaging always being undertaken on day of request
 - increased use of same day emergency care through improved access to diagnostics in A&E departments
 - efficiency gains through networking of pathology tests.

RECOMMENDATIONS

New service delivery models

- **Recommendation 1:** New pathways to diagnosis should be established, building on those already developed as part of the initial phase of the response to Covid-19, with virtual consultations and community diagnostics promoted to keep visits to acute hospital sites to a minimum. **[Page 18]**
- **Recommendation 2:** New pathways should separate emergency/acute and elective diagnostics wherever possible to improve efficiency and reduce delays for patients. **[Page 20]**

- **Recommendation 3:** Emergency/acute diagnostic services should enable patients to be imaged in A&E without delay and for inpatients to be imaged or to undergo endoscopy on the day of request. **[Page 20]**
- **Recommendation 4:** Community diagnostic hubs should be rapidly established to provide Covid-19 minimal, highly productive elective diagnostic centres for cancer, cardiac, respiratory and other conditions. For patients with suspected cancer, these should incorporate the rapid diagnostic centre service model. **[Page 23]**
- **Recommendation 5:** During recovery, triage tools should be used to prioritise patients according to likelihood of having serious disease. FIT levels for patients with possible bowel cancer and NT-proBNP for heart failure are examples. **[Page 24]**
- **Recommendation 6:** Commissioners working with acute trusts and pathology services should ensure that phlebotomy services are easily and safely accessible within the community six days a week. **[Page 24]**
- Recommendation 7: New diagnostic technologies should be rapidly evaluated e.g. nearpatient virus testing for Covid-19, advanced genomic technologies, artificial intelligence in imaging and endoscopy and wearables. The process for introducing these technologies should be further developed and communicated, with the roles of MHRA, NICE, CQC, the National Screening Committee, NHS Digital, NHSX and commissioners made clear. The Accelerated Access Collaborative could support coordination of this activity. **[Page 26]**

Equipment and facilities

- Recommendation 8: CT scanning capacity should be expanded by 100% over the next five years to meet increasing demand and to match other developed countries. In the Covid-19 recovery phase, priority should be given to ensuring each acute site with an A&E has access to a minimum of two CT scanners so that patients known to be Covid-19 negative can be kept separate from those who are Covid-19 uncertain or Covid-19 positive. Other additional scanners should be deployed to community diagnostic hubs. [Page 28]
- **Recommendation 9:** MRI, PET-CT, plain X-ray equipment (including mobile X-ray equipment) and ultrasound and DEXA scanning equipment should, as a minimum, be expanded in line with growth rates prior to the pandemic and all imaging equipment older than 10 years should be replaced. **[Page 29]**
- **Recommendation 10:** Equipment/facilities and staffing surveys should be urgently undertaken both for endoscopy and cardiorespiratory diagnostic services. These will

provide a baseline on which to plan for expansion/renewal where most needed. **[Page 29]**

Recommendation 11: Pathology and genomics equipment and facilities should be upgraded to facilitate the introduction of new technologies, to support Covid-19 testing and drive efficiency. **[Page 30]**

Workforce

- Recommendation 12: There should be a major expansion in the imaging workforce an additional 2,000 radiologists and 4,000 radiographers (including advanced practitioner radiographers, who undertake reporting) as well as other support staff and key 'navigator' roles. Additional training places should be provided for radiologists and radiographers and initiatives will be needed to meet demand, as well as expansion in assistant practitioner and support staff roles. [Page 33]
- Recommendation 13: There should be an increase in advanced practitioner radiographer roles, including for reporting of plain X-rays (to a minimum of 50%); and expansion of assistant practitioner roles to take on work currently undertaken by radiographers. [Page 33]
- Recommendation 14: Training academies for endoscopy should be established to enable expansion of screening colonoscopy and back-filling of symptomatic colonoscopy. More specialist practitioners and endoscopy nurses will also be needed. [Page 34]
- Recommendation 15: The number of echocardiographers and clinical scientists supporting cardiac arrythmia diagnosis, pulmonary function testing, sleep studies and blood gas analysis should be expanded. Diagnostic professionals who can 'multitask' are required to deliver spirometry, issue sleep studies, ambulatory ECG and blood pressure monitoring, phlebotomy and point of care testing. [Page 35]
- Recommendation 16: There should be a major drive to expand the pathology workforce, specifically histopathologists, advanced practitioners and other healthcare scientists, with an emphasis on skill mix. The establishment of training academies/schools should be considered. [Page 36]
- **Recommendation 17:** The number of genomic scientists and medics should be expanded and developed in line with the national genomic programme requirements, especially in cancer. The broader healthcare workforce should be developed to respond to the increased use of genomics. **[Page 36]**
- **Recommendation 18:** Alongside the necessary expansion of key professional groups, all relevant organisations should work together to deliver changes in the

diagnostics workforce. Particular emphasis should be given to driving skill-mix initiatives across the whole country. This will require concerted action at team, NHS trust and network levels. **[Page 37]**

Digitisation and connectivity

- **Recommendation 19:** Improving connectivity and digitisation across all aspects of diagnostics should be prioritised to drive efficiency, deliver seamless care across traditional boundaries and facilitate remote reporting. **[Page 38]**
- **Recommendation 20:** NHS Digital's work on developing and implementing a standardised universal test list across all diagnostic disciplines (pathology, imaging, endoscopy and cardiorespiratory services) should be accelerated, as has been done for the National Genomic Test Directory. **[Page 39]**

Delivering the change

- Recommendation 21: Clinical and managerial leadership should be put in place for all diagnostic disciplines at a national, regional and local/network level, to support implementation and to drive the change programme. Development programmes to support network leadership will be required. [Page 40]
- **Recommendation 22:** Regions should oversee work to complete the establishment of the imaging and pathology networks and to develop endoscopy networks and cardiorespiratory networks across the country. **[Page 41]**
- **Recommendation 23:** NHS England and NHS Improvement should review commissioning levers for diagnostics, to include tariffs, contracting arrangements, service specifications and quality requirements, to ensure that incentives are aligned with strategy. **[Page 42]**
- **Recommendation 24:** NHS England and NHS Improvement should ensure standardised data and information is collected across all diagnostic modalities to drive operational performance, improve business intelligence at a national and local level, and inform service improvement. **[Page 42]**

2. THE CASE FOR CHANGE

- 2.1. Major expansion of diagnostic capacity was already clearly identified as being needed before the pandemic. Without this expansion many of the NHS Long Term Plan commitments³ on cancer, heart disease, stroke, respiratory diseases and other conditions, and on the reform of same day emergency care and outpatient services, would be jeopardised.
- 2.2. The Covid-19 pandemic has highlighted the importance of diagnostic services and endemic Covid-19 has further increased the need for significantly more capacity.

RISING DEMAND FOR DIAGNOSTICS

- 2.3. Demand for almost all aspects of diagnostics has been rising year on year and for some diagnostic modalities demand was outstripping capacity before the pandemic. This was impacting on achievement of diagnostic waiting times standards, with knock-on effects on cancer and elective care. There is widespread consensus that demand will continue to rise.
- 2.4. The rise in demand has been driven partly by increases in activity across many aspects of acute hospital activity, with particular increases in demand from urgent referrals for cancer (10% p.a.) and from A&E for imaging. Wider indications for tests such as CT scanning are also fuelling demand.

GROWTH IN DIAGNOSTICS ACTIVITY

- 2.5. Activity has increased markedly across almost all aspects of diagnostics over the past five years with notable increases as follows (all growth based on projections from 2014/15 to 2018/19):
 - Imaging: CT scanning (6.8% p.a.), MRI scanning (5.6% p.a.), PET-CT (18.7% p.a.), non-obstetric ultrasound (3.8% p.a.) and DEXA (4% p.a.). Plain X-ray is an exception, where annual growth has been less than 1%.
 - Endoscopy: Colonoscopy (5.3% p.a.), flexible sigmoidoscopy (8.4% p.a.) and gastroscopy (3% p.a.).
 - Cardiorespiratory diagnostics: Echocardiography (5.7% p.a.).
 - **Pathology:** National figures for pathology are currently difficult to assess as laboratories have been changing their data collection processes, but at individual laboratory level there is no doubt that significant increases are being observed year on year in both numbers and complexity of tests.

³ NHS England. 2019. <u>The NHS Long Term Plan</u>

- **Genomics:** Activity is forecast to expand significantly over the next five years to meet the NHS Long Term Plan commitments, including more comprehensive cancer genomic testing and the introduction of whole genome sequencing (WGS).
- 2.6. The demand for diagnostics is rising faster than that for NHS services as a whole, which are typically rising at between 2.5% and 3.4% p.a. (**Table 1**).

	2014/15	2018/19	Average growth p.a.	Additional activity p.a.
A&E attendances (all types)	22.4m	24.8m	2.6%	603k
Emergency admissions	5.6m	6.4m	3.4%	203k
Outpatient referrals - GP referrals	19.0m 11.0m	21.0m 11.7m	2.5% 1.4%	502k 157k
- Non-GP referrals	7.9m	9.3m	4.1%	344k

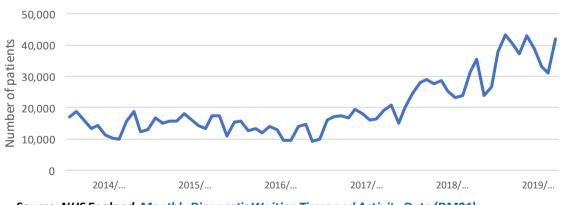
Table 1: Growth in hospital activity 2014/15 to 2018/19

Source: NHS Digital. <u>Hospital Episode Statistics</u> (HES)

REACHING A TIPPING POINT

2.7. The number of patients waiting more than six weeks for a diagnostic test increased markedly between 2017 and 2019, with particular deterioration in waits for gastrointestinal endoscopy procedures and urodynamics. The Care Quality Commission (CQC) also noted large backlogs in the reporting of some imaging tests. For example, median time to report MRI scans was three days, with wide variation across the country.

Figure 1: Number of patients waiting 6+ weeks at month end for a diagnostic test



Source: NHS England. Monthly Diagnostic Waiting Times and Activity Data (DM01)

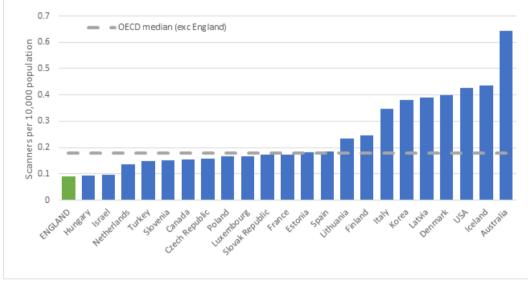
2.8. Many NHS trusts have had to outsource both imaging (acquisition and reporting) and endoscopy to independent providers in recent years, at substantial cost.

2.9. All of these factors indicate that diagnostic services were approaching a tipping point before the pandemic.

INTERNATIONAL COMPARISONS

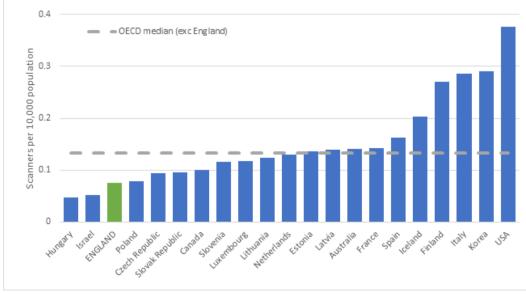
2.10. England lags far behind the OECD averages for scanners (CT, MRI and PET-CT) per million population, ranking lowest among 23 countries for CT scanner provision. Figures for scans per million population are marginally better than this, indicating that our low asset base is used better than that in some other countries.

Figure 2: CT scanners per 10,000 population: international comparisons (2017)



Source: OECD. 2017. OECD diagnostic exams and population data

Figure 3: MRI scanners per 10,000 population: international comparisons (2017)



Source: OECD. 2017. OECD diagnostic exams and population data

THE IMPACT OF COVID-19 ON DIAGNOSTICS

- 2.11. The Covid-19 pandemic has further driven the need for change and demonstrated the importance of diagnostics in a modern, patient-centred health service. Some changes to diagnostic pathways previously considered too difficult have been made within weeks. Virtual consultations between patients and GPs have increased markedly and have been widely introduced between patients and specialists in secondary care.
- 2.12. However, during the peak of the Covid-19 pandemic A&E attendances for serious conditions such as heart attacks reduced markedly, as did urgent referrals for suspected cancer. Patients' fear of catching Covid-19 by coming to hospital is considered to be a major factor underlying these changes. These reductions in hospital activity were accompanied by a marked fall in CT and MRI activity, although significant recovery in activity levels has been observed in recent weeks (see **Figure 4**).
- 2.13. In addition, endoscopy procedures of all types almost ceased at the height of the pandemic because of justified concerns about aerosol generating procedures (e.g. bronchoscopy and gastroscopy) and the excretion of virus or viral particles in faeces (e.g. colonoscopy).

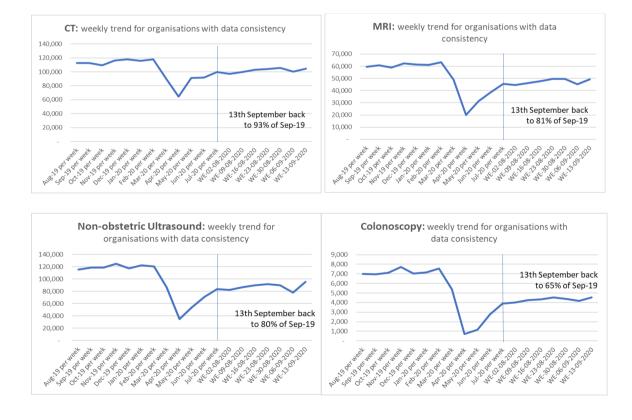


Figure 4: Impact of Covid-19 on diagnostic activity (August 2019 to September 2020)



Source: Diagnostic activity trends based on providers with consistent data relating to tests reported on DM01. NHS England. <u>Monthly Diagnostic Waiting Times and Activity Data (DM01)</u>

- 2.14. Activity levels are now increasing, but are still below pre-pandemic levels. For example, CT scanning activity from A&E was at 97% of pre-pandemic levels by May, while elective requests were only around half of pre-pandemic levels. By early June 2020, around 580,000 patients were waiting more than six weeks for a diagnostic test, compared with around 30,000 in February 2020.
- 2.15. Throughput in CT and MRI scanning was also markedly reduced at the peak of the pandemic, because of the need for deep cleaning if the patient was known to be Covid-19 positive or their Covid-19 status was uncertain. The Covid-19 pandemic has also placed an extraordinary burden on certain pathology services.
- 2.16. Staff sickness, self-isolation and shielding have further compounded the difficulties in delivering diagnostic services.
- 2.17. Cancer screening services largely ceased at the onset of the pandemic. As full screening services resume, these will drive increased demands in breast imaging, colonoscopy and colposcopy.
- 2.18. Patients recovering from Covid-19 are already being found to have respiratory and cardiac problems. These will place additional demands on a range of diagnostic services including chest X-ray, CT scanning, cardiac MRI, lung function tests and echocardiography.

- 2.19. Genomic testing will be important in the response to Covid-19. This will include sequencing the virus to support identification of Covid-19 outbreaks and to better understand its effects on different patient groups.
- 2.20. Taken together, these findings make a very strong case for investment and reform of diagnostic services.
- 2.21. Further details of the clinical case for change are given in **Appendix 1**.

3. NEW SERVICE DELIVERY MODELS – FOR RECOVERY AND THE FUTURE

- 3.1. Prior to Covid-19, standard diagnostic pathways had remained almost unchanged for decades, were wasteful of NHS resources and patients' time, and ignored opportunities offered by modern technology. Over the next 6 to 12 months and beyond, the NHS faces a challenge to resume diagnostic services, given the fall in activity during the peak of the pandemic and the impact of any further waves. However, there is also a unique opportunity to develop new models of service delivery as these services are resumed.
- 3.2. Elective diagnostics have very largely been provided on acute sites with patients typically referred by a GP to a hospital consultant, with a clinic visit on average four to five weeks later. The consultant then requested tests, for which the patient often needed to wait several weeks, and then saw the patient again to give results.
- 3.3. Since mid-March 2020, major changes have occurred and are continuing to occur in diagnostic pathways. Referrals to hospitals, including urgent referrals, decreased markedly at the peak, almost certainly because patients were afraid of catching Covid-19.
- 3.4. GPs reported that patients had not been contacting them (despite the availability of telephone consultations). Patients with serious illnesses including cancer were inevitably having their diagnoses delayed, which in some cases will have impacted on outcomes. Cancer screening programmes were (de facto) suspended and major backlogs developed.
- 3.5. There continues to be a need to create safe pathways to encourage patients to come forward if they have symptoms. These should maintain and build on some of the positive transformation that has already occurred: for example, telephone and virtual consultations between patients and GPs; the use of risk stratification tools; and patients being directed straight to test.
- 3.6. Recommendation 1: New pathways to diagnosis should be established, building on those already developed as part of the initial phase of the response to Covid-19, with virtual consultations and community diagnostics promoted to keep visits to acute hospital sites to a minimum.
- 3.7. Key components of the new service models are as follows:
 - separation of acute and elective diagnostics
 - establishment of community diagnostic hubs (CDHs)
 - new pathways with virtual consultations and access to expert advice and guidance
 - easy and safe access to blood tests, i.e. phlebotomy in the community
 - use of new diagnostic technologies supporting near-patient testing
 - infection control measures.

SEPARATION OF ACUTE AND ELECTIVE DIAGNOSTICS

- 3.8. Services for patients needing elective diagnostics have traditionally been provided on acute hospital sites. There is a strong case to be made for the separation of emergency/acute and elective diagnostics to provide quicker access to tests and greater convenience to patients, as well as to relieve pressure on acute sites and markedly reduce outpatient referrals and attendances. This case has been further strengthened by Covid-19.
- 3.9. The separation of acute and elective diagnostic services will improve efficiency of throughput in both areas and facilitate safe and efficient management of patients during an endemic phase of Covid-19. 'Acute' diagnostics are those relating to patients presenting to emergency departments and those for inpatients in acute hospitals. Typically, patients in A&E require tests and reports very rapidly (some within an hour) and those on inpatient wards on the day of request.
- 3.10. 'Elective' diagnostics are those requested directly by GPs and those requested as an outpatient by a specialist. Many of these tests will in future be requested following virtual consultations. A large proportion of elective diagnostic tests could be undertaken within the community.
- 3.11. The volumes of requests for imaging diagnostics by source are shown in **Table 2** below, based on activity levels in 2018/19. Almost half of plain X-rays are requested either from outpatient clinics or directly from GPs. Equivalent figures for ultrasound, CT and MRI are 85%, 59% and 86% respectively. While it may be appropriate for some of the tests requested from outpatient clinics to be done within an acute hospital, many could transfer to a CDH (see below). Elective diagnostic activity is likely to grow very substantially over the next five years.

	'Acute'			'Elective'		
	A&E	Inpatient	Total	Outpatient	GP	Total
Plain X-ray	7.8m	3.9m	11.7m	5.4m	5.7m	11.1m
Ultrasound	0.2m	1.3m	1.5m	5.2m	3.1m	8.3m
СТ	1.4m	1.5m	1.9m	2.4m	0.3m	2.7m
MRI	<0.1m	0.5m	0.5m	2.4m	0.6m	3.0m

Table 2: Volumes of acute and elective imaging activity (2018/19)

Source: NHS England. Diagnostic Imaging Dataset 2018/19 with figures rounded

Note: 75% of plain X-ray requested from outpatients are done on the day of request, but this proportion is much lower for other modalities (ultrasound = 27%; CT = 6%; MRI = 3%). Some same day requests might reasonably stay in acute hospitals.

- 3.12. Growth rates in acute and elective settings are the same for ultrasound (4% p.a.) and plain X-ray (1% p.a.). Growth in CT scanning is somewhat faster in the acute sector (9% p.a.) than in the elective sector (6% p.a.) and also for MRI (7% versus 5% p.a.). However, overall number of MRI scans done in the acute sector is much smaller.
- 3.13. A large majority of both endoscopy and echocardiography activity (well over 80%) is elective and could thus be undertaken in a CDH.
- 3.14. Recommendation 2: New pathways should separate emergency/acute and elective diagnostics wherever possible to improve efficiency and reduce delays for patients.
- 3.15. Recommendation 3: Emergency/acute diagnostic services should enable patients to be imaged in A&E without delay and for inpatients to be imaged or undergo endoscopy on the day of request.
- 3.16. The establishment of emergency/acute diagnostics will necessitate additional imaging equipment (plain X-ray, ultrasound and CT) in some hospitals. All acute hospitals with an A&E need to ensure provision of a co-located/adjacent CT scanner and X-ray facility.
- 3.17. Endoscopy services should be separated according to Covid-19 status, with endoscopies for patients who are known to be Covid-19 positive or who are Covid-19 uncertain being undertaken in facilities, e.g. operating theatres, with negative air pressure and with full personal protective equipment (PPE) and infection prevention and control (IPC) precautions.

COMMUNITY DIAGNOSTIC HUBS

- 3.18. Many countries provide elements of this new service model, in particular, many elective diagnostic services are provided outwith acute hospitals. The NHS has the opportunity to go further, by establishing a new service model which takes account of the impact of endemic Covid-19, is fit for the future and will be responsive to new innovations in diagnostics.
- 3.19. Community diagnostic hubs (CDHs) are needed to accommodate the major expansion in diagnostic services required over the next five years, as potential for expansion on acute hospital sites is very limited. The rationale for these has been further strengthened by the need to respond to the pandemic.
- 3.20. The aim will be to keep these hubs as free from Covid-19 as possible, by testing patients for the virus shortly before attendance. In future antibody testing may play a part in keeping these hubs free of Covid-19.
- 3.21. It is anticipated that three hubs per million population should be established in the first instance (broadly equivalent to the number of acute hospitals).

- 3.22. The exact configuration of services within a hub will be for local decision making. However, the objective should be to provide as broad a range of services as possible. Criteria for deciding on services to be located in a CDH will include:
 - the need to provide safe, Covid-19 minimal facilities and to maximise throughput
 - services for which demand is outstripping capacity
 - symptomatic presentations that may need multiple diagnostics, which can safely be undertaken off the acute site
 - scale of services needed to provide safe and efficient diagnosis and ongoing monitoring
 - convenience for patients.
- 3.23. Based on increasing demand and patient convenience, it is highly likely that as a minimum all CDHs will provide the following:
 - Imaging: CT, MRI, ultrasound, plain X-ray.
 - **Cardiorespiratory:** echocardiography, ECG and rhythm monitoring, spirometry and some lung function tests, support for sleep studies, blood pressure monitoring, oximetry, blood gas analysis.
 - Pathology: phlebotomy.
 - Endoscopy: additional facilities are undoubtedly needed and should be provided in Covid-19 minimal locations. However, these are likely to be better delivered at scale and may therefore only be provided in some CDHs. Some larger endoscopy facilities could also become training academies.
 - Consulting and reporting rooms.

3.24. Many other diagnostic services may well be located within CDHs. Examples include:

- mammography
- ophthalmology
- DEXA scan
- antenatal screening
- hysteroscopy and colposcopy
- cystoscopy
- urodynamics
- audiology
- fibroscan.

- 3.25. Consulting rooms may be valuable alongside diagnostic facilities for assessment of patients with a range of conditions and for explaining findings of investigations; for example, patients presenting with non-specific symptoms, which could be due to cancer; or with musculoskeletal problems requiring assessment to decide on appropriate use of imaging.
- 3.26. Mobile services may also be appropriate in some localities.
- 3.27. CDHs could potentially provide a range of maternity and gynaecology services. Ultrasound scanning for antenatal care is likely to increase as part of the drive to reduce still births. In addition, a range of gynaecological examinations investigations such as transvaginal scanning, hysteroscopy, colposcopy and urodynamics could be undertaken. Service users may prefer to be seen in a Covid-19 minimal hub.
- 3.28. The use of CDHs for children's investigations should also be considered. Children presenting with a range of symptoms such as lymphadenopathy, chronic abdominal pain and palpitations/syncope often require blood tests, ultrasound, plain X-ray and/or 24-hour ECG monitoring. All of these will be available in a CDH. However, if children's services are to be delivered, appropriate safeguarding and training of staff will be needed.
- 3.29. Outpatient referrals to urology are increasing significantly year on year with much of the workload relating to diagnosis or exclusion of cancer. Investigations for patients presenting with blood in the urine, a raised prostate-specific antigen or other urological symptoms could all be undertaken in a CDH, with urologists being supported by physician assistants or specialist nurses. Strengthening online advice and guidance has the potential to triage patients 'straight to test' or, in some cases, avoid onward referral.
- 3.30. A range of adult screening services could be provided within CDHs, such as mammography, colonoscopy, colposcopy, abdominal aortic aneurysm and diabetic eye screening.
- 3.31. Some complex diagnostic tests and interventions should clearly continue to be provided on acute hospital sites, e.g. complex endoscopies such as endoscopic retrograde cholangiopancreatography (ERCP) and CT coronary angiography.
- 3.32. CDHs could also support the delivery of some diagnostic tests (e.g. mobile X-ray) in patients' homes or in care homes and support home monitoring, including patients measuring their own blood pressure and oxygen saturation.
- 3.33. A range of digitally enabled home-based services are currently being piloted through NHS@home, with significant expansion envisaged in coming months. The aim is to give people connected, supported, personalised care to help them manage a range of long-term conditions, including chronic obstructive pulmonary disease (COPD), cystic fibrosis and type 1 diabetes within their own homes. Tests may include spirometry, blood pressure monitoring and glucose monitoring, reducing the need for hospital visits. Remote monitoring of people with symptoms of Covid-19 in care homes or at home

using oximetry is also being trialled to help identify early signs of deterioration and reduce mortality during local outbreaks or a second national peak.

- 3.34. In the immediate term, independent sector facilities should be used to reduce backlogs wherever possible. Alongside this, new facilities will need to be developed either on NHS sites (e.g. community hospitals) or in other locations (e.g. available space on high streets or retail parks).
- 3.35. Some cardiac and respiratory diagnostics (e.g. spirometry, some lung function tests and ECG) could also be provided at a more local level, such as for a primary care network serving a population of 50,000. The development of the larger CDHs proposed in this report should not preclude such developments where these make sense.
- 3.36. Diagnostics closer to home and fewer outpatient attendances should reduce patient journeys and thus improve sustainability, contributing to the NHS ambition to become Net Zero.
- 3.37. Selection of sites for CDHs should improve equity of access and support inclusion by considering physical, cultural and social needs of different/diverse population health groups, supporting the NHS Long Term Plan commitment to narrowing health inequalities.

3.38. Recommendation 4: Community diagnostic hubs should be rapidly established to provide Covid-19 minimal, highly productive elective diagnostic centres for cancer, cardiac, respiratory and other conditions. For patients with suspected cancer, these should incorporate the rapid diagnostic centre service model.

- 3.39. Rapid diagnostic centres (RDCs) were announced as part of the NHS Long Term Plan,⁴ recognising the need for the rapid assessment of patients with cancer symptoms or suspicious results.
- 3.40. Cancer alliances are already working to deliver the RDC service model for the management of all cancer pathways by 2023/24. The work to establish CDHs will need to be aligned with the delivery of RDCs and, for patients with suspected cancer, the hubs should incorporate the RDC service model as set out in the RDC specification.

NEW PATHWAYS TO DIAGNOSIS

3.41. New pathways, including telephone and virtual consultations, both between patients and GPs and between patients and specialists have been introduced at pace following the emergence of Covid-19. While the major driver for this has been patient safety, it has also promoted convenience for patients and reduced travel and hospital footfall. While there is a need to evaluate how virtual consultations can best be delivered and to which groups of patients, some aspects of this new model (in both primary and secondary care) should

⁴ NHS England. 2019. <u>The NHS Long Term Plan</u>

undoubtedly be maintained and built on for both new referrals and follow-up appointments.

- 3.42. Referrals to CDHs may come from primary or secondary care, including A&E. Prioritisation should be based on clinical need, ensuring that patients receive the right test(s), first time and, where possible, on the same day. Expert advice and guidance along with clinical decision aids should be available to GPs to ensure the most appropriate investigations are requested. This will result in faster diagnosis and reduced risk of Covid-19 infection through fewer visits.
- 3.43. Triage tools and algorithms can further support clinicians in making diagnostic assessments and in determining the most appropriate patient pathway.
- 3.44. Recommendation 5: During recovery, triage tools should be used to prioritise patients according to likelihood of having serious disease. FIT levels for patients with possible bowel cancer and NT-proBNP for heart failure are examples.

COMMUNITY PHLEBOTOMY SERVICES

- 3.45. Access to community phlebotomy services varies widely. In some CCGs these are available at GP practice level for five or six days a week with twice daily courier services, while in others they are only available once a week for very limited hours. Provision of easily accessible services which can take referrals for blood tests both from primary and secondary care will promote convenience for patients and avoid patients having to visit acute hospitals simply to have blood taken. It is essential that these services are provided in the community and outside hospital settings. These could also be provided in a range of locations, including GP practices, high street pharmacies and CDHs.
- 3.46. Phlebotomy staff need to be appropriately trained. Wherever the service is provided, phlebotomists need a dedicated room with the necessary equipment and access to PPE. Since the start of the pandemic, some GP practices or groups of practices have designated sites 'hot' or 'cold' depending on likelihood of Covid-19. As with other aspects of diagnostics, throughput in community phlebotomy services is considerably slower than before the pandemic. Consideration needs to be given to phlebotomists visiting patients in their homes or care homes to take blood samples, with proper precautions being taken.
- 3.47. Recommendation 6: Commissioners working with acute trusts and pathology services should ensure that phlebotomy services are easily and safely accessible within the community six days a week.

NEW DIAGNOSTIC TECHNOLOGIES

3.48. Multiple new innovations with the potential to diagnose serious illnesses earlier and improve outcomes, alongside the promise of driving efficiency, can be anticipated in the

field of diagnostics over the next five years. These innovations could potentially include new point of care tests, 'liquid biopsies' to diagnose cancer earlier and the use of artificial intelligence (AI) both to identify people at high risk of different conditions and to aid interpretation of images and complex diagnostic data.

- 3.49. Point of care testing (POCT) has the potential to support the development of better care pathways and the delivery of care in a range of settings. Its use is set to grow as the effectiveness, quality and cost of devices improve. Key barriers to its safe and effective introduction will need to be addressed.
- 3.50. POCT will be important in supporting better care pathways for diagnostics, including in out-of-hospital settings and in settings where speed is vital, such as emergency departments. There are real opportunities for POCT to support clinical and shared decision making; make better use of the workforce; reduce unnecessary admissions; and support care in the community and at home (including self-monitoring), as well as to increase access for more marginalised groups and reduce health inequalities. It also has a role in more appropriate prescribing, such as of antibiotics. (See **Appendix 8**)
- 3.51. POCT for Covid-19 will be critical in managing safe access to services and patient throughput.
- 3.52. Real opportunities also exist with the use of AI. Horizon scanning undertaken by the Accelerated Access Collaborative (AAC) has identified five major areas under development: breast screening mammography; chest X-ray and chest CT interpretation; diabetic retinopathy screening; stroke imaging; and cardiac imaging. There are also interesting advances being made in endoscopy. (See **Appendix 9**)
- 3.53. However, it is important to recognise that, while all these areas show great promise, most are not yet ready for full implementation and are likely to support clinical practice as opposed to fully replacing the need for human interpretation of images.
- 3.54. The NHS provides an excellent testbed for assessing new innovations, but such assessments have not always been done as quickly as they could be. The NHS needs to prepare for implementation of these developments right now. The launch of the AI Health and Care Award run by the AAC in partnership with NHSX and the National Institute for Health Research (NIHR) is welcomed and will make £140 million available over three years to accelerate the testing and evaluation of the most promising AI technologies in the NHS. This includes supporting well-developed AI technologies that need more evidence for large-scale commissioning or deployment. The first round of the award is nearing completion with successful technologies to be announced in autumn 2020.
- 3.55. However, the roles of different organisations in evaluating safety, effectiveness and value of innovations are still being developed and may not be fully understood by people working outside those organisations, leading to a time lag between initial development of a product and its full evaluation. Coordination by the AAC to clarify roles for innovators

and to bring together the relevant organisations for evaluating and accelerating adoption of new diagnostic innovations could support earlier access.

3.56. Recommendation 7: New diagnostic technologies should be rapidly evaluated – e.g. near-patient virus testing for Covid-19, advanced genomic technologies, artificial intelligence in imaging and endoscopy and wearables. The process for introducing these technologies should be further developed and communicated, with the roles of MHRA, NICE, CQC, the National Screening Committee, NHS Digital, NHSX and commissioners made clear. The Accelerated Access Collaborative could support coordination of this activity.

4. EQUIPMENT AND FACILITIES

4.1. Major expansion and reform of diagnostic services is needed over the next five years to facilitate recovery from the Covid-19 pandemic and to meet rising demand across multiple aspects of diagnostics. New facilities and equipment will be needed if this demand is to be met.

IMAGING EQUIPMENT AND FACILITIES

- 4.2. There is broad clinical support for expansion of CT capacity being given the top priority within imaging. Demand for CT is likely to increase by at least 100% over the next five years. CT scanning has a wide range of uses across clinical specialties and settings and its use is increasing markedly for cancer, heart and respiratory disease. In light of Covid-19, this demand is only set to rise further.
- 4.3. CT scanner provision per million population in the UK is much lower than in other developed countries (see Figures 2 and 3 above). In 2017, the UK ranked lowest of 23 OECD countries in scanner provision. Comparison of CT scans per 10,000 population for 25 OECD countries in 2017 show that England's activity would need to increase by 77% to reach the OECD average. This would mean an additional 4.4 million scans p.a.
- 4.4. The increasing demand for imaging and especially CT combined with the reduced throughput related to Covid-19 is placing substantial demands on imaging services and therefore the available equipment.
- 4.5. As a consequence of Covid-19, imaging services on acute sites with an A&E have largely been separated into two channels. The first is for patients who are Covid-19 positive or Covid-19 uncertain. The second should be for those who are Covid-19 negative (e.g. following testing at the time of admission). In addition, trusts with two sites may choose to designate one as Covid-19 minimal.
- 4.6. Some small acute hospitals only have one site with one CT scanner and therefore should be given high priority for a second scanner. In general, the availability of plain X-ray, ultrasound and CT scanning close to an A&E department would be of great benefit.
- 4.7. The most urgent need is for scanners to support work in emergency departments and acute admissions units. This would enable a much higher proportion of stroke patients to be scanned within one hour. It would reduce breaches in the four-hour target and support same day emergency care (SDEC), in turn reducing inpatient admissions. Provision of additional scanners in or near emergency departments will also help release capacity for other urgent but not 'acute' patients, including patients receiving systemic treatments for cancer and patients with cardiac problems needing CT angiography.

- 4.8. The Covid-19 pandemic has led to a major increase in the use of mobile X-ray machines to avoid moving patients on intensive care units to X-ray departments. This has revealed that many mobile X-ray machines in use in the NHS are over 10 years old and in need of replacement.
- 4.9. Additional CT scanning capacity will clearly be needed in community diagnostic hubs. These could be used for patients referred directly by GPs (currently 300,000 p.a. across England, equivalent to around 30 scanners) and the nearly 2.5 million patients who are currently referred to CT scanning from outpatients (equivalent to around 250 CT scanners), including for some patients with suspected cancer to facilitate achievement of the Faster Diagnosis Standard.
- 4.10. Recommendation 8: CT scanning capacity should be expanded by 100% over the next five years to meet increasing demand and to match other developed countries. In the Covid-19 recovery phase, priority should be given to ensuring each acute site with an A&E has access to a minimum of two CT scanners so that patients known to be Covid-19 negative can be kept separate from those who are Covid-19 uncertain or Covid-19 positive. Other additional scanners should be deployed to community diagnostic hubs.
- 4.11. Over 43 million imaging tests were performed in the NHS in 2018/19. Plain X-rays (e.g. of the head, chest or limbs) account for over one half of all imaging tests (23.5 million), followed by non-obstetric ultrasound (7.6 million), CT scans (6.1 million) and MRI (3.6 million). Growth in activity is shown in **Table 3**. Highest percentage increases are seen in CT, MRI and PET-CT over the past five years.

	2014/15	2018/19	Average growth p.a.	Average additional activity
Plain X-ray (DID)	22.6m	23.5m	0.9%	208k
Non-obstetric ultrasound (DMOI)	6.6m	7.6m	3.8%	261k
CT (DMOI)	4.7m	6.1m	6.8%	352k
MRI (DMOI)	2.9m	3.6m	5.6%	176k
DEXA (DMOI)	389k	455k	4.0%	16k
PET-CT (DID)	89k	177k	18.7%	22k
Mammography*	2.7m	2.8m	1.2%	32k

Table 3: Growth in imaging activity 2014/15 to 2018/19

Source: NHS England. <u>Diagnostic Imaging Dataset</u> and <u>Monthly Diagnostic Waiting Times and Activity Data</u> (DM01)

* Mammography includes both screening and symptomatic services

Note: These figures are taken from DM01 where available, though this may underrepresent activity. For example, a single CT attendance may involve scanning of multiple areas of the body (e.g. chest, abdomen and pelvis).

4.12. Recommendation 9: *MRI, PET-CT, plain X-ray equipment (including mobile X-ray equipment) and ultrasound and DEXA scanning equipment should, as a minimum, be expanded in line with current growth rates and all imaging equipment older than 10 years be replaced.*

ENDOSCOPY EQUIPMENT AND FACILITIES

- 4.13. Endoscopy services, in particular those for colonoscopy, were already under considerable strain before the pandemic. This largely related to constraints on workforce, but the Get it Right First Time (GIRFT) programme also revealed inadequate facilities in a significant proportion of NHS trusts.⁵
- 4.14. Based on GIRFT visits to-date it is estimated that around 20 NHS trusts will require a complete rebuild of their endoscopy facilities (including endoscopy rooms, changing rooms, consultation rooms and decontamination facilities) and others need improvement works.⁵ It is already clear that around 200 new endoscopy rooms are needed in NHS trusts to cover current growth in endoscopy and enable the planned extensions to the bowel screening programme.
- 4.15. Unfortunately, there is no national asset register for endoscopy facilities (unlike that for imaging). Capacity and demand analysis in the Cheshire and Merseyside endoscopy network showed considerable potential to improve efficiency. (See **Appendix 3**, Case study 1).
- 4.16. Additional endoscopy equipment and facilities will be required to manage the reduced throughput related to Covid-19.

CARDIORESPIRATORY DIAGNOSTICS EQUIPMENT AND FACILITIES

- 4.17. As with endoscopy, there is no national asset register for physiological measurements comparable to that undertaken for imaging in 2019. This makes equipment and facilities planning extremely difficult.
- 4.18. Recommendation 10: Equipment/facilities and staffing surveys should be urgently undertaken both for endoscopy and cardiorespiratory diagnostic services. These will provide a baseline on which to plan for expansion/renewal where most needed.

⁵ Personal communication. GIRFT Gastroenterology workstream.

PATHOLOGY AND GENOMICS EQUIPMENT AND FACILITIES

- 4.19. One of the key drivers for establishing pathology networks is to use existing equipment and facilities (and workforce) more efficiently.
- 4.20. The advent of Covid-19 has introduced a need for both swab (direct viral detection) and antibody testing. This is clearly a rapidly developing field. It is anticipated that nearpatient testing and rapid testing will be available to the NHS as this will enable patients to be separated into Covid-19 positive and Covid-19 negative, increasing throughput. This should be in conjunction with further expansion of high throughput and high volume swab testing within the pathology networks.
- 4.21. Genomic laboratory hubs will require technology upgrades to increase throughput and to support consolidation of infrastructure.
- 4.22. Recommendation 11: Pathology and genomics equipment and facilities should be upgraded to facilitate the introduction of new technologies, to support Covid-19 testing and drive efficiency.

5. WORKFORCE

- 5.1. A wide range of health professionals is needed to provide a high quality, efficient diagnostic workforce. However, over recent years expansion of these professional groups has not kept pace with increases in demand and activity. As demand continues to rise over coming years it will be vital to increase recruitment and training in all these groups.
- 5.2. It will also be essential to do things differently in all the diagnostic disciplines, through skill mix and other initiatives, starting with the adoption of existing initiatives across all trusts. However, there is considerable scope to go further.
- 5.3. Throughout the Covid-19 response, diagnostic staff groups have been deployed with increased flexibility; this should now be harnessed and built on. There is now a unique opportunity to think differently about how to utilise the expansion of advanced clinical practice, apprenticeships and the development of new roles and new ways of working to redeploy our workforce to deliver diagnostic services. This should be based on a model of capability and skill mix rather than role definition.

THE IMAGING WORKFORCE

5.4. Radiologists, radiographers, physicists and nuclear medicine specialists are the key professional groups involved in imaging. To date, radiographers have principally been involved in image acquisition and radiologists in reporting images, participating in multidisciplinary teams and other duties. However, this is now changing with radiographers taking on advanced practitioner roles, including reporting, although there is wide variation in implementation of these roles between NHS trusts (see Figure 5). Radiologists are increasingly taking on a range of interventional procedures under imaging control.

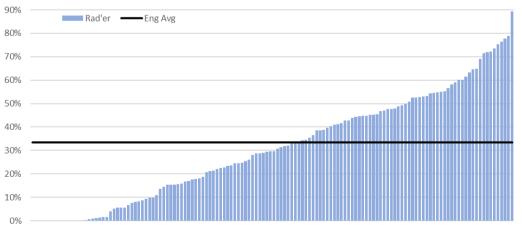


Figure 5: Variation in percentage of plain X-rays reported by advanced practitioner radiographers between NHS trusts

Source: NHS Improvement. 2019. <u>Transforming imaging services in England: a national strategy for imaging networks</u>

- 5.5. Assistant practitioner roles have been successfully introduced in some aspects of radiography, e.g. mammography and to a limited extent in other modalities. However, only around half of trusts use assistant practitioners in radiography. Imaging is a popular career within healthcare, but career pathways from apprenticeships upwards are poorly developed and educational institutions are not always reimbursed sufficiently to encourage them to deliver courses. Work is ongoing to support local systems to utilise the apprenticeship levy more effectively.
- 5.6. Expansion of the imaging workforce combined with a major drive to change ways of working will be vital in meeting the increasing demand, but will be very challenging to achieve.
- 5.7. Actions will be needed on multiple fronts and by several organisations, including NHS England and NHS Improvement, Health Education England (HEE), NHS Digital and higher education institutions and professional bodies.
- 5.8. Actions required include expansion of:
 - training numbers for radiologists
 - training places for radiographers
 - physicist posts
 - assistant practitioner radiographer posts
 - administrative and supporting roles with opportunities to progress to imaging roles
 - international recruitment of radiologists and radiographers when possible.
- 5.9. Alongside expansion, other initiatives are also urgently needed, including:
 - development of new ways of working, with a different balance of practitioners taking on different parts of the work (e.g. for acquisition of CT and MRI scans)
 - training for advanced practitioner radiographers to take on reporting of images with appropriate back filling of existing workloads
 - provision of imaging simulators to facilitate training of different staff groups
 - support for existing staff to take on additional responsibilities (e.g. micro credentialing)
 - recognition of sonographers as a regulated profession
 - full development of imaging networks with the connectivity to enable image sharing and flexible working, i.e. home reporting by radiologists/radiographers
 - introduction of artificial intelligence (AI) to support reporting as soon as it has been properly evaluated in different areas of imaging (e.g. screening mammography), thereby reducing radiologist/radiographer reporting time.

- 5.10. The overall estimated additional workforce requirements over five years (**Table 4**) are based on:
 - numbers of additional images (of different types)
 - staffing requirements to acquire these images (mainly radiographers and assistant practitioners)
 - staffing to maintain the new equipment (physicists)
 - staff to report the images (mainly radiologists with some advanced practice radiographers).

Table 4: Additional imaging workforce requirements

Imaging workforce	Additional requirement
Radiologists	2,000
Advanced practitioner/reporting radiographers	500
Radiographers	3,500
Assistant practitioners	2,500
Admin and support staff	2,670
Physicists	220

- 5.11. Recommendation 12: There should be a major expansion in the imaging workforce an additional 2,000 radiologists and 4,000 radiographers (including advanced practitioner radiographers, who undertake reporting) as well as other support staff and 'navigator' roles. Additional training places should be provided for radiologists and radiographers and initiatives will be needed to meet demand, as well as expansion in assistant practitioner and support staff roles.
- 5.12. Recommendation 13: There should be an increase in advanced practitioner radiographer roles, including for reporting of plain X-rays (to a minimum of 50%); and expansion of assistant practitioner roles to take on work currently undertaken by radiographers.

THE ENDOSCOPY WORKFORCE

- 5.13. Endoscopy services, in particular for colonoscopy, were already under very considerable strain before the pandemic. This largely related to constraints on workforce.
- 5.14. In 2019 a major change was introduced in the bowel screening programme, with faecal immunochemical testing (FIT) replacing the previous faecal occult blood test (FOBT). This is easier for patients, requiring only a single stool sample, and is quantitative, allowing different thresholds to be set. At present the screening programme covers men and women aged 60 to 74, with invitations sent every two years. The current threshold for further investigation is 120 μ g/G. The aim set out in the NHS Long Term Plan is to lower the starting age to 50, to contribute to the NHS Long Term Plan commitment to diagnose

75% of all cancer patients at stage 1 and 2 by 2028. Over time it is also hoped that the threshold for investigation will be lowered.

- 5.15. Both these improvements will increase the need for screening colonoscopy very considerably. Screening colonoscopy takes longer and requires more skill and training (related to recognition and removal of polyps) than standard colonoscopy.
- 5.16. Specialist screening practitioners (SSPs) provide a vital role in the initial management of patients who have positive findings on bowel screening. They assess whether a patient is fit for endoscopy and explain the procedure including the need for bowel preparation to patients. This reduces the number of patients who do not attend or who have an incomplete colonoscopy. The equivalent service has not generally been provided to patients presenting with symptoms, though this has been shown to be cost-effective. SSPs could undertake telephone triage of symptomatic patients, enabling appropriate patients to go straight to test.
- 5.17. The following workforce requirements relating to endoscopy will be needed:
 - Establishment of training academies both to accelerate the training of non-medical colonoscopists and to provide additional training to enable existing colonoscopists to take on screening colonoscopy. Unless existing screening colonoscopists can be freed to provide more screening sessions, around 50 colonoscopists will need to convert to screening colonoscopy in each of the next four years to deliver the additional screening colonoscopies p.a. in five years' time required to meet the NHS Long Term Plan commitment to reduce the starting age to 50. In addition, a similar number of additional screening colonoscopists would be needed to allow the FIT threshold to be reduced to 80 μg/G. If consultants currently undertaking symptomatic colonoscopy take on screening duties, non-medical endoscopists will need to be trained to back fill their current endoscopy activity.
 - Provision of virtual endoscopy training simulators.
 - Recruit and train a cadre of specialist practitioners to assess and support patients undergoing colonoscopy, thereby improving efficiency and patient well-being.
 - Recruit more endoscopy nurses to meet additional demand.

5.18. Recommendation 14: Training academies for endoscopy should be established to enable expansion of screening colonoscopy and back-filling of symptomatic colonoscopy. More specialist practitioners and endoscopy nurses will also be needed.

THE CARDIORESPIRATORY DIAGNOSTICS WORKFORCE

5.19. The cardiorespiratory diagnostics workforce has until now largely been part of cardiology and respiratory services within acute hospitals. In addition, some relatively simple diagnostic tests are undertaken in primary care. The numbers of people working in these areas is difficult to define as there is no national data collection. However, as with other diagnostic disciplines, it is clear that workforce capacity has not kept up with demand. This is particularly the case for echocardiography.

- 5.20. The establishment of community diagnostic hubs provides new opportunities to deliver high quality, efficient and patient-centred services for a range of patients with possible or known cardiac and respiratory conditions.
- 5.21. In addition to an increase in echocardiographers, new roles should be piloted, with expertise in a range of tests such as ECG, rhythm monitoring, spirometry and some other lung function tests. This will support the development of skills and different ways of working and encourage diversity in the diagnostic workforce.
- 5.22. Recommendation 15: The number of echocardiographers and clinical scientists supporting cardiac arrythmia diagnosis, pulmonary function testing, sleep studies and blood gas analysis should be expanded. Diagnostic professionals who can 'multitask' are required to deliver spirometry, issue sleep studies, ambulatory ECG and blood pressure monitoring, phlebotomy and point of care testing.

THE PATHOLOGY WORKFORCE

- 5.23. Histopathology has been seriously challenged for several years due to the increasing numbers of samples (e.g. related to bowel and prostate cancer) and increasing complexity of testing. Perinatal pathology services, which are delivered by highly specialist paediatric post mortem centres and involve post mortems and histopathological examination, are under severe strain due to lack of trained pathologists. Genomic analysis is also increasingly being undertaken on cancer samples. This may necessitate taking of additional biopsies and will result in additional workload for histopathology laboratories.
- 5.24. A survey by the Royal College of Pathologists in 2018⁶ indicated that 45% of histopathology laboratories were having to outsource work and 50% of departments had to use locums. Workforce was the major constraint.
- 5.25. There is a clear need to expand the histopathology workforce. HEE recognises this specialty is in significant difficulty in relation to the growth needed to meet the NHS Long Term Plan commitments and that skill-mix initiatives will be vital.
- 5.26. The future pathology workforce will require more healthcare scientists, alongside more advanced practitioners and medically trained histopathologists. In addition, some of the pressure will be relieved once digitisation is fully implemented.

⁶ The Royal College of Pathologists. 2018. <u>Meeting pathology demand histopathology workforce census</u>

- 5.27. The Covid-19 pandemic has had a very major impact on pathology laboratories in relation to swab (virus) testing and increasingly to antibody testing. Testing capacity had to be expanded rapidly, requiring herculean efforts from the pathology workforce. At the peak of the pandemic, demand both for testing of patients presenting as emergencies and of staff working in Covid-19 positive environments was very high. Some of the laboratories designated for HPV testing for cervical screening and genomics were used to test for Covid-19. These laboratories are now needed to perform their original function.
- 5.28. Rapid, near-patient testing will be of particular value in keeping sites designated as 'Covid-19 minimal' free of disease.
- 5.29. Many other pathology services (e.g. blood sciences) observed reduced demand during the peak of the pandemic, as fewer patients attended GP surgeries and fewer were referred to outpatients. Demand is now rising again.
- 5.30. Recommendation 16: There should be a major drive to expand the pathology workforce, specifically histopathologists, advanced practitioners and other healthcare scientists, with an emphasis on skill mix. The establishment of training academies/schools should be considered.

THE GENOMICS WORKFORCE

- 5.31. Activity in genomics is set to increase over the next five years, particularly as whole genome sequencing is introduced into the NHS and cancer genomics is expanded, supporting new treatments that target genomic mutations. This will require a significant expansion in this specialist genomic workforce, including clinical geneticists, clinical scientists in cancer genomics and genomic counsellors, in line with the activity projections of the national genomics programme. The current genomic workforce is understaffed with vacancies in all professional groups.
- 5.32. Genomics will impact on many clinical specialties. There will therefore be a need to upskill the whole NHS workforce, beginning in those areas where genomics will be more rapidly deployed, e.g. oncology, cardiology and neurology.
- 5.33. Recommendation 17: The number of genomic scientists and medics should be expanded and developed in line with the national genomic programme requirements, especially in cancer. The broader healthcare workforce should be developed to respond to the increased use of genomics.

CHANGING THE SHAPE OF THE DIAGNOSTICS WORKFORCE

5.34. Throughout this review, the opportunities for changing the shape of the diagnostic workforce to meet the increasing demand and to deliver services efficiently have been clear. Some NHS organisations are already driving this change through the use of skill-mix initiatives and the establishment of new roles and hybrid teams to mitigate capacity gaps.

- 5.35. Skill mix should be central to the new diagnostics workforce, focusing on the competencies and the skills needed to deliver these services, rather than being restricted by professional group. Through the development of new roles, flexible working, changes to education and training and new ways of working, diagnostic services will be supported in meeting the needs of patients.
- 5.36. Delivering the changes required will be challenging. However, there has been rapid transformation in the way that staff have been deployed during the response to Covid-19. It will be important to consider lessons learned about supporting staff to work differently in terms of flexible working from home, variable working patterns and utilisation of competencies and skills in a different way, and the positive impact of this on recruitment and retention. For example, the diversification of roles and opportunities for the home reporting of images allowed the continuation of roles and supported retired professionals to return to work throughout the pandemic. This should continue as retired radiologists and advanced practitioner radiographers have much to offer.
- 5.37. Professional bodies, NHS England and NHS Improvement and other regulators, HEE and higher educational institutions will all have to work together to support the required transformation. Trusts should also be encouraged to think creatively, taking a competency-led approach to optimise the use of their diagnostics workforce throughout the Covid-19 recovery phase and beyond.
- 5.38. Recommendation 18: Alongside the necessary expansion of key professional groups, all relevant organisations should work together to deliver changes in the diagnostics workforce. Particular emphasis should be given to driving skill-mix initiatives across the whole country. This will require concerted action at team, NHS trust and network levels.

6. DIGITISATION AND CONNECTIVITY

- 6.1. Digitisation and IT connectivity across the NHS is currently variable, but will be vital for diagnostic networks to work efficiently. Full digitisation, IT connectivity and interoperability across the NHS from primary to secondary and tertiary care will need to be prioritised if the benefits of improved diagnostic services are to be realised.
- 6.2. For imaging services, IT connectivity will enable efficient use of radiology staff by allowing the workload of reporting to be shared across a network, and will provide access to specialist opinions when these are not available locally. It will allow home reporting of images and avoid duplication of diagnostic tests as patients move between hospitals. The same need for connectivity applies to cardiorespiratory diagnostics.
- 6.3. IT linkage between hospitals, diagnostic hubs and GP practices is also critical for effective pathology and genomic services. Currently, digitisation of cytology and histopathology is only available in a very limited number of hospitals in England. Full digitisation and IT connectivity of pathological specimens will allow workloads to be shared across networks and specialist opinions to be sought as in radiology. Development of informatics in genomic laboratory hubs and linkage to other services (particularly histopathology) are also needed and will support consolidation.
- 6.4. Community diagnostic hubs will also need to be linked effectively with primary care and with hospitals.
- 6.5. Digitisation is also a necessary precursor to large-scale use of artificial intelligence (AI) in diagnostics in the future, for sharing reporting workloads between hospitals and gaining access to specialist opinions.
- 6.6. The need for both AI and IT connectivity is well demonstrated for stroke patients where rapid assessment and treatment is of the essence. AI can rapidly identify patients who could benefit from thrombectomy, so that suitable patients can be transferred to thrombectomy centres. CT angiography images also need to be shared between hospitals without delay.

6.7. Recommendation 19: Improving connectivity and digitisation across all aspects of diagnostics should be prioritised to drive efficiency, deliver seamless care across traditional boundaries and facilitate remote reporting.

6.8. Across all the diagnostic disciplines (pathology, imaging, endoscopy and cardiorespiratory services) coding of tests needs to be standardised to compare like with like. The current lack of standardisation is seen particularly across pathology. Adoption of coding when it becomes available, as it is now for the majority of blood sciences, should be supported at pace.

- 6.9. Standardisation through the introduction of a universal test list will support patient safety, delivery of services across networks and more accurate collection of diagnostic data, and reduce the need for repeat testing.
- 6.10. Recommendation 20: NHS Digital's work on developing and implementing a standardised universal test list across all diagnostic disciplines (pathology, imaging, endoscopy and cardiorespiratory services) should be accelerated as has been done for the National Genomic Test Directory.

7. DELIVERING THE CHANGE

CLINICAL AND MANAGERIAL LEADERSHIP

- 7.1. Implementation of the recommendations of this report, if accepted, will involve a major programme of work at national, regional and local levels. This will need to be driven by highly skilled and committed managers and clinicians who will need to be supported by administrative and support staff. Without this, there is a real risk that the much needed changes will not be realised.
- 7.2. Recommendation 21: Clinical and managerial leadership should be put in place for all diagnostic disciplines at a national, regional and local/network level, to support implementation and to drive the change programme. Development programmes to support network leadership will be required.

DIAGNOSTIC NETWORKS

- 7.3. Networks and alliances bring together teams working in particular areas of healthcare, especially where some services cannot be delivered in all NHS trusts or where efficiencies can be achieved from cross-trust working. Examples include maternity and trauma networks and cancer alliances. Typically, they may serve populations of 1.5 to 3 million. They facilitate delivery of high quality, efficient and patient-centred care through:
 - development of efficient pathways between primary, secondary and tertiary care
 - development and monitoring of agreed protocols of care
 - workforce planning
 - equipment and facilities planning
 - facilitation of staff working across NHS boundaries (passports)
 - joint training programmes
 - centralisation of complex interventions in specific locations.
- 7.4. Networks have already been agreed as policy by NHS England and NHS Improvement for imaging and pathology, though as yet these have only been partially implemented. In genomics, a national network of genomic laboratory hubs has been established, consolidating provision across populations of between 5 and 10 million. During this review strong support has been indicated for extending the concept of networks to endoscopy and cardiorespiratory diagnostics.
- 7.5. It is important to recognise that in addition to the generic functions listed above, networks for individual service areas will have additional functions. For example:

- One of the key drivers for imaging networks is to facilitate sharing of images between providers. This will avoid duplication of imaging when a patient moves between hospitals and will also allow reporting to be done where there is spare capacity, including home reporting. In addition, complex interventional radiology may best be delivered in a small number of locations within a network.
- One of the key drivers for pathology networks is to use existing facilities and workforce more efficiently by reducing the number of laboratories within a network undertaking routine elective activity (as set out in the report by Lord Carter).⁷
- For endoscopy, a network established in Cheshire and Merseyside has demonstrated scope for significant efficiencies. (See **Appendix 3**, Case study 1). Nine NHS trusts are working together to assess capacity and demand; reduce the proportion of patients not attending or cancelling late; improve procurement; develop joint training; introduce centralised scheduling; offer patients choice of location for endoscopy; and centralise highly complex cases.
- Similar benefits are expected to be seen for cardiorespiratory networks, bringing together primary care, cardiac and respiratory services to plan and deliver optimal care.
- 7.6. The exact footprints for each of these networks should be agreed by regions working with integrated care systems and cancer alliances. Consideration should be given to establishing similar footprints for each of the diagnostic networks, unless there are sound reasons to the contrary.
- 7.7. Digitisation and IT connectivity will be vital for networks to work efficiently. IT linkage between hospitals, all diagnostic hubs and GP practices is vital for effective pathology and genomic services. Image sharing across networks will facilitate efficient use of radiology staff for reporting. This should include linkage to allow home reporting of images. Digitisation is a necessary precursor to large-scale use of artificial intelligence in diagnostics in the future.
- 7.8. Recommendation 22: Regions should oversee work to complete the establishment of the imaging and pathology networks and to develop endoscopy networks and cardiorespiratory networks across the country.

COMMISSIONING FOR DIAGNOSTICS

7.9. During this review, clinicians and managers working in NHS trusts frequently commented that the commissioning arrangements for different diagnostic tests can be a barrier to investment and reform of services. The costs of diagnostics are frequently bundled with outpatient or inpatient tariffs. This provides little incentive for trusts to invest in

⁷ Lord Carter of Coles for Department of Health. 2016. <u>Operational productivity and performance in English NHS</u> <u>acute hospitals: Unwarranted variations</u>

diagnostics or to replace ageing equipment. However, it is beyond the scope of this review to determine NHS commissioning arrangements. Separate commissioning arrangements are in place for genomics testing services and clinical genetics services.

7.10. Recommendation 23: NHS England and NHS Improvement should review commissioning levers for diagnostics, to include tariffs, contracting arrangements, service specifications and quality requirements, to ensure that incentives are aligned with strategy.

DATA AND INFORMATION FOR MONITORING OF PROGRESS

- 7.11. Throughout the work on this review the lack of consistent data and information on diagnostics has been evident. This hampers planning and monitoring at all levels. Definition of tests vary, especially in pathology; reasons for tests are not routinely collected and the outcome of a test is not recorded, even at the level of normal versus abnormal.
- 7.12. Information on imaging is relatively better than that for endoscopy, pathology and cardiorespiratory diagnostics. A new patient-level dataset has been developed for genomics and is currently being rolled out across the genomic laboratory hubs.
- 7.13. For imaging, there is both a routine data collection (the Diagnostic Imaging Dataset or DID) and the National Imaging Data Collection (NIDC) which provide an asset register and information on the workforce. Equivalent data collections need to be established urgently for the other diagnostic disciplines.
- 7.14. In endoscopy, the National Endoscopy Database (a collaboration between professional groups and NHS Digital) collects valuable information directly from IT systems for about 80% of NHS trusts. This needs to be extended to cover all NHS trusts and independent sector providers of NHS services as soon as possible.
- 7.15. As described in **Chapter 4** (equipment and facilities) no asset register of endoscopy facilities and workforce is held by NHS England and NHS Improvement, comparable to that for imaging. This needs to be rectified as soon as possible.
- 7.16. National data on pathology tests activity is particularly difficult to interpret, reflecting the lack of a standardised universal test list. Work being undertaken on this by NHS Digital should be accelerated. Standardised coding for imaging, including interventional radiology, should also be expedited. In addition, the Pathology Quality Assurance Dashboard should be embedded in national and local reporting structures.
- 7.17. Recommendation 24: NHS England and NHS Improvement should ensure standardised data and information is collected across all diagnostic modalities to drive operational performance, improve business intelligence at a national and local level and inform service improvement.

GLOSSARY

AAC	Accelerated Access Collaborative
A&E	Accident and emergency
AI	Artificial intelligence
AMR	Antimicrobial resistance
ARTP	Association for Respiratory Technology and Physiology
BNP	Brain natriuretic peptide
CDH	Community diagnostic hub
COPD	Chronic obstructive pulmonary disease
СРАР	Continuous positive airway pressure
CPET	Cardiopulmonary exercise testing
CQC	Care Quality Commission
CRP	C-reactive protein
СТ	Computerised tomography
CTCA	CT coronary angiography
СТРА	CT pulmonary angiography
DAC	Diagnostic and assessment centre
DEXA	Dual energy X-ray absorptiometry
DID	Diagnostic Imaging Dataset
DM01	Diagnostic Monitoring Dataset (waiting times)
DNA	Did not attend
ECG	Electrocardiogram
ERCP	Endoscopic retrograde cholangiopancreatography
FOBT	Faecal occult blood test
FIT	Faecal immunological test
GIRFT	Get it Right First Time programme
GMS	Genomic medicine service
HbA1c	Haemoglobin A1c (a measure of glycated haemoglobin used in diabetes)
HCG	Human chorionic gonadotrophin (used in pregnancy testing)
HEE	Health Education England
HES	Hospital Episode Statistics
HPV	Human papilloma virus
ICBP	International Cancer Benchmarking Partnership
ICS	Integrated care system
ILD	Interstitial lung disease
INR	International normalised ratio (for assessing anticoagulants)
IPC	Infection prevention and control
IT	Information technology
MRI	Magnetic resonance imaging
MHRA	Medicines and Healthcare products Regulatory Agency
NED	National Endoscopy Database
NHSD	NHS Digital
NHSE	NHS England
NHSI	NHS Improvement
NICE	National Institute for Health and Care Excellence

NIDC	National Imaging Data Collection
NIHR	National Institute for Health Research
NOU	Non-obstetric ultrasound
OCT	Optical coherence tomography
OECD	Organisation for Economic Co-operation and Development
PET-CT	Positron emission tomography linked to CT
POCT	Point of care testing
POCUS	Point of care ultrasound
PPE	Personal protective equipment
PSA	Prostate-specific antigen
RDC	Rapid diagnostic centre
RNIB	Royal National Institute for the Blind
SSP	Specialist screening practitioner
STP	Sustainability and transformation partnership
TIA	Transient ischemic attack
WGS	Whole genome sequencing

APPENDIX 1: THE CLINICAL CASE FOR CHANGE

1. CANCER

Increasing demand for diagnostics in relation to cancer is largely being driven by the following factors:

- The NHS Long Term Plan commitment to increase the proportion of cancers diagnosed at stage 1 or 2.
- A major increase in urgent referrals (around 10% p.a. over the past five years) of patients with possible cancer, who need to have cancer diagnosed or excluded as quickly as possible.⁸ Over 2 million such patients are now being referred each year a doubling since 2010. These patients almost all need one or more diagnostic tests depending on the tumour group. CT, endoscopy and biopsy (for cytology or histopathology) are the most frequently needed initial tests, with MRI for prostate cancer and for brain tumours, and mammography for possible breast cancer. Rapid access to all of these tests and to their results will be essential if the new 28-day Faster Diagnosis Standard is to be achieved. Optimal timed pathways have been developed for several cancers (e.g. lung and prostate).
- Expansion and improvement of existing screening services, including mammography for breast screening and endoscopy for bowel cancer screening (see Endoscopy section).
- Pilots of lung health checks to diagnose more lung cancers at a stage when they are curable. If fully rolled out, the demand for CT scans would increase by around 800,000 to 1 million p.a.
- Once a cancer has been diagnosed, MRI and PET-CT may be needed to assess the extent
 or spread of disease. Additional pathology and genetic tests on tumour samples are now
 needed for some cancer types (e.g. lung cancers) to identify subtypes that can benefit
 from specific treatments. All these additional tests help ensure that individual patients
 receive the most appropriate treatments and that patients who would be very unlikely
 to benefit can be spared any side effects.
- The use of chemotherapy and other systemic anticancer therapies is also increasing rapidly. Patients are receiving more different lines of treatment and treatments are being given for longer (e.g. until the disease progresses rather than for a fixed number of cycles). For each of these treatments it is necessary to establish a clear baseline and to monitor response to the relevant treatment at intervals (often every three to six months). This is most frequently done using CT scanning. Use of systemic therapies is increasing by around 7–8% p.a., with around 330,000 treatment regimens delivered in 2018/19.⁹ Each regimen currently involves an average of four CT scans. This suggests an increase in demand for CT scans of around 100,000 p.a.

⁸ NHS England. <u>Cancer waiting times</u>

⁹ Public Health England. <u>SACT Systematic Anti-Cancer Therapy Chemotherapy Dataset</u>

- The number of new cases of cancer is increasing by around 1% p.a., though by 3% in the most recent year. Other factors are dominating the increase in demand for diagnostics.
- Genomics: The NHS Long Term Plan set out a commitment to extend the use of molecular diagnostics so that over the next 10 years genomic testing will routinely be offered to all people with cancer for whom it would be of clinical benefit, and to extend participation in research. By 2023 over 100,000 patients newly diagnosed with cancer will be able to access these tests. It is important to recognise more tests will need to be undertaken by histopathology departments to identify patients who could benefit from genomic testing.

2. CARDIAC AND RESPIRATORY DISEASES

A wide range of diagnostic tests are needed for the accurate diagnosis of cardiac and respiratory diseases and for monitoring progress and response to treatment. Some of these can best be done in a community setting, while others need to be done in acute hospitals (e.g. for patients presenting with acute chest pain or breathlessness). Many of these tests are not currently counted within the NHS or are subsumed within other categories (e.g. specialist forms of CT within CT scanning).

Increases in the prevalence of both cardiac and respiratory diseases are raising demand for diagnostics. In addition, imaging tests such as CT coronary angiography (CTCA) to assess patency of coronary arteries and CT pulmonary angiography (CTPA) to assess possible pulmonary embolism are either much less invasive and/or have greater accuracy than previous tests, so demand is increasing.

Patients who have had severe Covid-19 are experiencing a growing range of problems, including ongoing respiratory and cardiac impairments. This is leading to an increased requirement for diagnostic and monitoring tests.

2.1 Cardiac diagnostics

Electrocardiograms (ECGs) and heart rhythm monitoring

ECGs and the set-up of monitoring of heart rhythm (Holter monitoring) can be done in any setting by trained healthcare assistants. Interpretation can be done by somewhat more senior staff, with access to remote advice where necessary. With appropriate governance in relation to reporting, these tests can therefore be done either within general practice or at a community diagnostic hub (CDH).

Artificial intelligence (AI) has been used to report ECGs. It has been found to 'over-report' abnormalities such as atrial fibrillation and inferior myocardial infarcts. It is therefore important that all such heart traces should be reported by a competent professional. However, if AI suggests a normal trace, this is very likely to be the case.

NT-proBNP

Brain natriuretic peptide (BNP) is secreted by the heart and is elevated in a wide range of cardiac abnormalities. NT-proBNP is a point of care blood test recommended by NICE (NG106).¹⁰

Echocardiography

Although this is an imaging test, it is usually undertaken under the direction of cardiology departments and is therefore considered alongside other physiological measurements. Echocardiography is central to diagnosing structural heart abnormalities (e.g. valve lesions) and for diagnosing and monitoring heart failure. It is also important in monitoring the impact of cancer treatments and drugs, such as chemotherapy, on cardiac function.

It is one of the tests reported in the DM01 dataset to monitor numbers of patients waiting more than six weeks. It is a high volume service with around 1.6 million tests annually. Activity levels are rising by around 5.7% p.a. Demand is outstripping capacity with considerable issues in achieving seven-day provision outside tertiary centres due to the need for on-call physiologists.

More than 90% of echocardiography examinations are undertaken by cardiac physiologists. However, examinations could undoubtedly be done within CDHs, with staff (independently reporting, experienced echocardiographers) rotating from acute hospitals. Images must be part of an NHS archive accessible from secondary care and transferrable to secondary care for further assessment if necessary within 24 hours.

2.2 Respiratory diagnostics

Spirometry

This is a NICE mandated test for confirming the diagnosis of chronic obstructive pulmonary disease (COPD), with the exhaled fraction of nitric oxide also important in the diagnostic asthma pathway. Performing accurate and reproducible spirometry is not easy and requires training to the Association for Respiratory Technology and Physiology (ARTP) certification to avoid potential misdiagnosis and inappropriate onward referral. With appropriate training, the test can be done by healthcare assistants who, with additional ARTP training, can also interpret the results in a community setting. Access to high quality spirometry should reduce the number of incorrect diagnoses of COPD in GP registries, currently estimated as up to one third. Reducing incorrect diagnoses is a commitment in the NHS Long Term Plan. Accurate spirometry may however lead to earlier requirement for more formal full pulmonary function tests with the advantage of earlier treatments.

Sleep studies

The importance of sleep disordered breathing (apnoea) as a risk factor for hypertension, atrial fibrillation, heart failure, diabetic retinopathy and transient ischaemic attacks (TIAs) is increasingly being recognised. In some organisations, referrals relating to sleep disorders account for a third of respiratory referrals. To adapt to the increasing workload, improve

¹⁰ NICE. 2018. Chronic heart failure in adults: diagnosis and management

efficiency and reduce patient journey, many organisations are adopting a straight to test approach.

Sleep tests are undertaken in the patient's own home and equipment can be issued by a practitioner grade before being interpreted by a trained physiologist (Band 5–6). Abnormalities can be successfully treated with continuous positive airways pressure (CPAP), which can lead to improved quality of life and productivity, improved cardiac output, lower blood pressure and reduced healthcare utilisation. Most hospitals have around 3,000 people on CPAP.

Chest X-ray

Chest X-ray (CXR) is one of the commonest imaging tests undertaken in the NHS (over 8 million X-rays per annum). Overall demand prior to Covid-19 was relatively stable, only increasing by 0.9% per annum. In 2018/19, A&E was the commonest source of requests for CXR (34%), followed by inpatients (31%), GP direct access (25%) and outpatients (9%).

During the peak of the Covid-19 pandemic many patients required monitoring with mobile CXR. This put a very considerable strain on existing equipment much of which is older than 10 years.

All CXRs should be reported by a competent person. This can be a radiologist, advanced practitioner radiographer or some physicians (e.g. respiratory physicians).

Ultrasound

Increasingly, chest physicians and acute medicine specialists are undertaking ultrasound examinations. This takes pressure off imaging departments and speeds up care, but needs to be done by trained professionals with appropriate equipment and quality assurance processes.

Lung CT

CT scanning is increasingly being used to detect lung cancer early (see Cancer section) and in follow-up of nodules that may be small cancers. This is an increasing problem as more thoracic CTs are performed for cardiac and other reasons. CT thorax is also essential for diagnosing other lung diseases, including bronchiectasis, and essential for diagnosing the type of interstitial lung disease (ILD) that may be amenable to NICE-approved antifibrotic drugs. There will be an increased demand for lung CT to follow up Covid-19 survivors, with up to 20% developing ILD as a consequence of the infection.

2.3 Cardiorespiratory diagnostics

Cardiopulmonary exercise testing

Cardiopulmonary exercise testing (CPET) is recommended by NICE¹¹ for patients undergoing cardiac, vascular and upper gastrointestinal surgery, and its use in exploring the reasons for unexplained breathlessness is growing rapidly. This involves simultaneously measuring ECG, blood pressure, oxygen saturation and ventilation during incremental exercise. These tests are currently undertaken in a hospital setting.

¹¹ NICE. 2016. <u>Preoperative Tests (Update) routine preoperative tests for elective surgery</u>

CT pulmonary angiography

CT pulmonary angiography (CTPA) is a very valuable test for patients presenting with acute breathlessness, where pulmonary embolism needs to be diagnosed or excluded.

Selection of patients for CTPA varies widely between hospitals. Get it Right First Time (GIRFT) findings indicate that the proportion of patients testing positive for pulmonary embolism is much lower in some hospitals than in others.¹² This should be monitored.

Covid-19 is also likely to increase demand for CTPA due to blood clotting problems leading to thromboembolic phenomena.

CT coronary angiography

CT coronary angiography (CTCA) is a minimally invasive test that shows the coronary arteries without the need for standard coronary angiography (which is more invasive as it involves a fine bore tube being inserted into the coronary arteries, usually via the radial artery). It requires modern high-resolution CT scanning equipment and staff with expertise in doing the test. It is predominantly used for patients with stable angina and demand for it is increasing rapidly.

It should be noted that both CTPA and CTCA may reveal nodules in the lungs that may then require follow-up for possible lung cancer. Surveillance may be amenable to an AI approach.

MRI

Although MRI is not currently extensively used for respiratory diseases, this may well change. For example, it may be used for monitoring chronic lung diseases and cystic fibrosis, especially as new and effective drugs come into use. MRI is increasingly being used in cardiac investigation with an estimated 2,400 scans per million population required. Cardiac MRI is a specialised technique requiring specific equipment and appropriately trained staff, and is currently under provided in most parts of the country.

PET-CT

PET-CT can be extremely useful in assessing some inflammatory cardiac conditions such as endocarditis related to prosthetic valves and other devices. This can inform clinical decisions on cardiac implant device removal, but is otherwise not currently widely used in cardiorespiratory diseases (other than staging of lung cancer).

3. STROKE AND TRANSIENT ISCHAEMIC ATTACK

Over 87,000 patients are diagnosed with stroke in England each year (SSNAP organisation audit report 2019).¹³ An additional 90,000 are likely assessed for potentially having suffered a stroke. While the incidence of stroke has fallen over the past two decades and death rates have fallen significantly, it remains the fourth largest killer in this country with around 35,000 deaths each year. It is also a major cause of adult long-term disability.

¹² Personal communication. GIRFT Cardiology and Respiratory workstreams

¹³ Sentinel Stroke National Audit Programme (SSNAP). 2019. <u>Acute Organisational Audit Report</u>

Rapid assessment and treatment are key to improvements in outcomes. This involves rapid transit to one of around 108 acute hospital stroke units and imaging within an hour of arrival. This enables early confirmation of a stroke and appropriate treatment planning.

However, at present only 55% of stroke patients get a brain scan (CT scan) within one hour of arrival at hospital. Patients who arrive between noon and early evening are less likely to get a timely scan. This limits the likelihood of patients being suitable for thrombolysis or thrombectomy.

AI has a strong evidence base in stroke care and appears to be as good as a neuroradiology opinion but has the benefit of providing interpretation within seconds, as opposed to up to 30 minutes when manual review of the images is undertaken remotely by a reporting doctor. The specificity and speed of interpretation means AI is likely to be of significant benefit in improving access to both thrombolytic therapy and mechanical thrombectomy in England, but requires national guidance, funding and implementation. Thrombectomy rates are 2% in England and are amongst the poorest in Western Europe¹⁴. The NHS Long Term Plan commitment is to reach at least 10%.

Patients presenting with TIAs or mini strokes also need rapid investigations, including MRI, CT angiography, carotid ultrasound, echocardiography and ambulatory cardiac and blood pressure monitoring. These investigations could in future be undertaken in CDHs.

4. MUSCULOSKELETAL CONDITIONS

There is widespread use of imaging, including plain X-ray, ultrasound and MRI, for musculoskeletal (MSK) conditions, with requests coming from both primary and secondary care. However, this is an area where concerns have been raised about the overuse of diagnostic tests.

Most patients with MSK symptoms are initially assessed in primary and community care settings. Anecdotally, MSK conditions use a lot of the available capacity for MRI and ultrasound. MRI is indicated for patients with 'red flag' symptoms suggesting possible cauda equina compression, metastases, infection or insufficiency fracture; where inflammatory disease is suspected; or where clinical symptoms and signs indicate a physical cause not responsive to conservative management. In some instances, ultrasound is also of use, especially to enable guided therapeutic procedures. Collectively, patients requiring such imaging are the minority. However, for other patient groups the findings from imaging correlate poorly with the clinical presentation and may not be helpful in planning care.

It is therefore recommended that assessments in the community are made by a specialist MSK practitioner who can determine whether imaging is indicated. These practitioners are mainly physiotherapists and GPs with a special interest, who can request and clinically correlate the results to inform effective decision making. They are either located within individual general practices as first contact practitioners or within community assessment service hubs.

¹⁴ Personal communication. GIRFT Stroke workstream

Although a lot of good MSK service provision exists, there is variability across the country. There is a need to align NICE approved diagnostic recommendations with the first contact practice agenda, community MSK assessment service provision and work being undertaken by Health Education England related to the capabilities and governance for MSK practitioners. This would support the quality requests to imaging departments, increasing the confidence of these departments in their need and could potentially free-up capacity.

5. MATERNITY AND GYNAECOLOGY

Maternity and gynaecological services are major users of diagnostics. Antenatal services are currently provided in a variety of locations, including hospital-based antenatal clinics and some community-based services, e.g. GP practices and community hospitals. During the peak of the pandemic some service users were reluctant to come to acute hospital sites. Ultrasound scanning in pregnancy is set to increase as part of the drive to reduce stillbirths.

Diagnostic services for gynaecology include transvaginal ultrasound scanning, hysteroscopy (e.g. for post-menopausal bleeding), colposcopy (e.g. as part of the cervical screening programme) and urodynamics (e.g. for stress incontinence). Although the number of urodynamic investigations reported on DM01 is relatively small (82,000 tests in 2018/19), the proportion breaching the six-week standard is higher than for other diagnostic tests. At the end of October 2019, 14.3% of patients had been waiting over six weeks, with wide variation in performance between providers.

Many of these services could potentially be provided in CDHs by trained nurses and midwives, providing convenience for patients in a Covid-19 minimal location.

Those with threatened miscarriages and possible ectopic pregnancies require emergency access to ultrasound scanning. This needs to be provided in close proximity to an A&E department. Improved provision of these services would reduce admissions.

6. CHILDREN'S SERVICES

Children may present as emergencies to an A&E department (e.g. with acute abdominal pain requiring urgent ultrasound) or with a range of sub-acute symptoms such as lymphadenopathy, chronic abdominal pain and palpitations/syncope. These often require blood tests, ultrasound, plain X-ray and/or 24-hour ECG monitoring. All these services will be available in a CDH for adults. However, if children's services are to be delivered, appropriate safe guarding and training of staff will be needed.

7. OPHTHALMOLOGY

Over 7.2 million attendances at NHS ophthalmology clinics were recorded in England in 2018/19, accounting for 11% of all outpatient attendances. A significant proportion of the current workload in hospital ophthalmology clinics relates to monitoring of patients with

conditions such as glaucoma, age-related macular degeneration or diabetic retinopathy. This could be done in CDHs.

A very high proportion of these patients can have clinical decisions made based on clinical data including some form of imaging, by either digital photography or optical coherence tomography (OCT), which is a form of high-resolution imaging of the eye tissues. Attendances are rising by 2.2% p.a. The current service model is under huge strain, with patients not being seen at the optimal intervals and reports of patients going blind while waiting to be seen. Ophthalmology has been identified as the first service to be redesigned as part of the NHS Long Term Plan outpatient reform programme.

Many patients with both acute and non-acute eye problems are initially assessed by high street optometrists. These provide a very valuable role in case finding and many now provide both digital imaging and OCT services, and can also collect other key clinical information such as eye pressures. However, they are currently poorly linked to NHS ophthalmology services. Patients with possible abnormalities are therefore generally referred to an ophthalmology clinic. If IT links and consistency of equipment and training were better, many of these patients could be assessed by ophthalmologists through virtual clinics, based on data collected by optometrists. Some optometrists could also be upskilled or their existing skills better utilised to make decisions under hospital guidance and governance.

A three-tier model can therefore be envisaged: high street optometrists for case finding and some ongoing low risk virtual and face-to-face care; CDHs for high flow, rapid throughput ongoing monitoring of patients with established conditions; and hospital clinics largely reserved for those who need treatment or very high risk/complex cases. Effective IT connectivity between these tiers will be essential.

Al is also likely to play an important role in the diagnosis and monitoring of several common ophthalmological conditions. This includes screening for diabetic retinopathy and macular oedema as well as detection and monitoring of age-related macular degeneration and glaucoma. While many AI products outperform clinicians in studies, none are ready for widespread implementation across the NHS. Creating imaging-only pathways with IT connectivity will however pave the way for these solutions to be embedded quickly as they become available.

8. UROLOGY

Referrals to urology outpatient services have increased significantly over recent years with much of the workload relating to the diagnosis or exclusion of kidney, bladder or prostate cancer (in addition to significant investigation and treatment of benign urinary symptoms). Patients typically present with haematuria (blood in urine), a raised prostate-specific antigen (PSA) measured in primary care or other lower urinary tract symptoms.

Key investigations for haematuria are ultrasound, CT and flexible cystoscopy. Raised PSA levels are now primarily investigated with MRI. This may be followed by a transperineal biopsy, which

can be undertaken under local anaesthetic. Patients presenting with other lower urinary tract symptoms may need investigation with urodynamics.

Flexible cystoscopy was previously often undertaken in endoscopy suites, but is now increasingly undertaken in outpatient settings. A significant proportion of the cystoscopy workload relates to repeat examinations with or without intravesical treatments (e.g. following a diagnosis of bladder cancer).

The majority of the urological outpatient workload could be done in CDHs, with new pathways between primary and secondary care. GPs should have access to online advice and guidance, following which some patients may be suitable for straight to test investigation or may in fact not require onward referral. Non-medical physician associates or specialist nurses are now increasingly undertaking urological assessment and investigations under the supervision of urologists. This should be increased to relieve known pressures on the urology workforce.

9. LIVER DISEASE

Liver disease is on the increase due to lifestyle changes in the population. This includes both alcohol associated liver disease and non-alcoholic fatty liver disease. Between 2014/15 and 2018/19 hospital admissions for liver disease increased by 25%. Mortality from liver disease has also increased over the last few decades and is now amongst the commonest cause of premature mortality in men in the UK.

Liver disease often leads to multiple hospital admissions and sometimes long hospital stays. Effective pro-active management of patients at risk and at earlier stages of the disease course can improve outcomes for patients and lower costs for the NHS.

Fibroscan (transient elastography) alongside blood tests can help non-invasively identify disease at an earlier stage, before it progresses to cirrhosis.

APPENDIX 2: IMAGING

INTRODUCTION

The term imaging covers a wide range of modalities, including plain X-ray (fixed and mobile), ultrasound (obstetric and non-obstetric), CT scanning, MRI, PET-CT, DEXA scanning, fluoroscopy, mammography and nuclear medicine imaging. These are used for diagnosis and monitoring of a very wide range of conditions, including cancer, heart disease, stroke, respiratory diseases, trauma, musculoskeletal diseases, neurology and, most recently, Covid-19. Demand has been increasing by around 4% p.a. for most modalities, but at a considerably higher rate for CT, MRI and PET-CT. These increases are substantially higher than those for A&E attendances, emergency admissions and outpatient referrals (see Chapter 2). The overall growth in imaging activity is in part due to the growth in activity across all sectors of healthcare, but also to new indications for some modalities.

DEMAND ESTIMATES FOR IMAGING PRIOR TO THE PANDEMIC

There is no sign that the increases in demand observed in recent years will slow. As a minimum, therefore, England needs to plan for growth to continue at current levels over the next five years for most modalities.

Demand for CT scanning is currently growing at around 7% p.a. Demand is likely to rise even faster in the next five years with increasing use for cancer (both primary diagnosis/staging and ongoing monitoring), heart disease (CT angiography), stroke and respiratory disease (including use for monitoring patients recovering from Covid-19), and increasing requests from A&E departments. Lung cancer screening may further increase demand if fully rolled out. Taking all these factors together, demand for CT is likely to increase by at least 100% over the next five years.

Demand for PET-CT scanning has been growing at an exceptional rate (18.7% p.a.), having started from a low base. Continuation at this rate may not be needed, but it is important to recognise that England still lags well behind other countries, with an extra 57% growth needed to meet the OECD average in 2017. Expansion by at least 10% p.a. over the next five years is therefore likely to be needed.

IMPACT OF COVID-19 ON DEMAND AND THROUGHPUT FOR IMAGING

In the initial phase of Covid-19, A&E and outpatient attendances fell markedly with a corresponding fall in activity for most imaging modalities. For example, at its lowest, CT scanning activity fell by almost two thirds and MRI scanning to about one sixth of normal levels. In contrast, use of mobile plain X-ray machines on intensive care units increased. The decrease in CT and MRI activity allowed backlogs in reporting of scans to be cleared.

Now that the initial peak of the pandemic has passed, hospital activity is rising again. However, the Covid-19 is still impacting on imaging and in particular on CT and MRI. If patients are Covid-

19 positive or their status is unknown, throughput for CT and MRI is reduced due to the need for deep cleaning between patients. However, if 'Covid-19 minimal' sites can be established (with both patients and staff being known to be free of Covid-19), throughput would be improved markedly with only around a 10% reduction in throughput from the pre-Covid-19 era.

The ongoing healthcare needs of patients who have recovered from Covid-19 will also impact on imaging (and on other cardiorespiratory diagnostics). They are very likely to need chest CT scans at intervals. It will be important to define when these patients can be designated as being free of Covid-19, so that they can be imaged in community diagnostic hubs (CDHs).

RECOVERY PHASE REQUIREMENTS

The increasing demand for imaging, especially CT, combined with the reduced throughput related to Covid-19 is placing severe demands on imaging services. Establishment of protocols for virus testing procedures for patients undergoing CT, MRI and PET-CT should be given high priority, alongside the development of Covid-19 minimal CDHs. Ongoing use of independent sector facilities during this period will be of great value.

Within acute hospitals imaging services should be separated into two channels. The first should be for patients who are Covid-19 positive or Covid-19 uncertain. The second should be for those who are Covid-19 negative (e.g. following testing at the time of admission). Some acute hospitals only have one CT scanner. They should be given very high priority for getting a second. In general, the availability of plain X-ray, ultrasound and CT scanning close to an A&E department would be of great benefit.

LONGER TERM REQUIREMENTS

Expansion of imaging equipment and facilities to meet anticipated demand combined with replacement of old machines is clearly much needed. A large proportion of current activity relates to requests from outpatient clinics and direct requests from GPs. These requests account for nearly half (2.76 million) of all current CT scans and more than half (2.84 million) of all current MRI scans. Much of the future growth is likely to come from these elective requests. This highlights the potential for future activity to be undertaken within Covid-19 minimal CDHs.

The overall estimated requirement for additional and replacement equipment over the next five years is as follows:

	Additional	Replacement
CT scanners	777	256
MRI scanners	273	193
Ultrasound	1,298	1,331
Mobile X-ray	300	749
Mammography	195 (screening +	695 (screening +
	symptomatic)	symptomatic)

Table A2.1: Estimated requirement for imaging equipment over five years

	Additional	Replacement
DEXA scanners	25	80
Fluoroscopy	263	860
Nuclear medicine	0	211
PET-CT	45	10 mobile, 6 fixed

Note: Numbers of additional scanners are based on predicted growth in activity. Throughput is based on 14 hours per day, six days per week. Numbers of replacement scanners are based on the known ages of all equipment and the need to replace after 10 years.

Expansion of the imaging workforce (e.g. radiographers, radiologists and physicists) combined with improvements in productivity will be vital in meeting the increasing demand, but very challenging. Actions will be needed on multiple fronts and by several organisations, including NHS England and NHS Improvement, Health Education England (HEE), NHS Digital, and higher education institutions and professional bodies.

Actions required include expansion of:

- training numbers for radiologists
- training places for radiographers
- physicist posts
- assistant practitioner radiographer posts
- administrative and supporting roles with opportunities to progress to imaging roles
- international recruitment of radiologists and radiographers when possible.

Alongside expansion, other initiatives are also urgently needed, including:

- development of new ways of working, with a different balance of practitioners taking on different parts of the work (e.g. for acquisition of CT and MRI scans)
- training for advanced practitioner radiographers to take on reporting of images with appropriate back filling of existing workloads
- provision of imaging simulators to facilitate training of different staff groups
- support for existing staff to take on additional responsibilities (e.g. micro credentialing)
- recognition of sonographers as a regulated profession
- full development of imaging networks with the connectivity to enable image sharing and flexible working, i.e. home reporting by radiologists/radiographers
- introduction of artificial intelligence (AI) to support reporting as soon as it has been properly evaluated in different areas of imaging (e.g. screening mammography), thereby reducing radiologist/radiographer reporting time.

Estimates of numbers required in each profession have been based on numbers of additional images (of different types); staffing requirements to acquire these images (mainly

radiographers and assistant practitioners); staffing to maintain the new equipment (physicists); and staff to report the images (mainly radiologists with some radiographers).

The overall estimated requirements for additional personnel over five years are as follows:

Table A2.2: Estimated requirement for additional imaging workforce over five years

Imaging workforce	Additional workforce required
Radiographers	3,500
Assistant practitioners	2,500
Admin and support staff	2,670
Advanced practitioner/reporting radiographers	500
Radiologists	2,000
Physicists	220

APPENDIX 3: ENDOSCOPY

INTRODUCTION

Endoscopy is the inspection of any internal hollow organ using a thin tube with a light source. Examples include inspection of upper airways (e.g. nasendoscopy), trachea and lungs (bronchoscopy) and bladder (cystoscopy). This appendix focuses on endoscopy of the upper gastrointestinal tract (gastroscopy) and the lower gastrointestinal tract (colonoscopy) and flexible sigmoidoscopy.

In 2018/19, over 2 million gastrointestinal (GI) procedures were undertaken in England, comprising around 900,000 upper GI endoscopies (mainly gastroscopies), 430,000 flexible sigmoidoscopies and 700,000 colonoscopies. Most of the colonoscopies (estimated at around 530,000) were undertaken on symptomatic patients, of whom the largest proportion presented via the urgent cancer referral route. An estimated 112,000 colonoscopies were undertaken for surveillance (i.e. in people who had previously had a colonoscopy but were considered at high risk of developing cancer) and around 55,000 were done following screening – either faecal occult blood testing (FOBT) or bowelscope.

Overall numbers of endoscopy procedures have been increasing over the past five years, with an average growth of 3% p.a. in gastroscopy; 8.4% in flexible sigmoidoscopy (with growth relating largely to the roll out of the bowelscope screening programme); and 5.3% for colonoscopy.

In 2019, a major change was introduced in the bowel screening programme, with faecal immunochemical testing (FIT) replacing the previous FOBT. This is easier for patients, requiring only a single stool sample, and is quantitative, allowing different thresholds to be set. At present the screening programme covers men and women aged 60 to 74, with invitations sent every two years. The current threshold for further investigation is 120 μ g/G. The aim set out in the NHS Long Term Plan is to lower the starting age to 50. Over time it is also hoped that the threshold for investigation will be lowered. Both of these improvements will increase the need for screening colonoscopy very considerably. Screening colonoscopy takes longer and requires more skill and training (related to recognition and removal of polyps) than standard colonoscopy.

The use of FIT for patients presenting with bowel symptoms offers hope that patients with very low FIT levels may have such a low risk of having bowel cancer that they do not need a colonoscopy. Early trial results are encouraging, but FIT was not being widely used pre-Covid-19.^{15,16}

¹⁵ Mole G, Withington J, Logan R. 2019. <u>From FOBt to FIT: making it work for patients and populations</u>. *Clin Med (Lond)* 19(3): 196-199.

¹⁶ Westood M, Corro Ramos I, Lang S, Luyendijk M, Zaim R, Stirk L, et al. 2017. <u>Faecal immunochemical tests to</u> <u>triage patients with lower abdominal symptoms for suspected colorectal cancer referrals in primary care: a</u> <u>systematic review and cost-effectiveness analysis</u>. *Health Technol Assess* 21(33): 1-234.

Endoscopy services, particularly those for colonoscopy, were already under very considerable strain before the pandemic. This largely related to constraints on workforce, but the Get it Right First Time (GIRFT) programme also revealed inadequate facilities in a significant proportion of NHS trusts.¹⁷ Unfortunately, there is no national asset register for endoscopy facilities (unlike that for imaging). Capacity and demand analysis in one endoscopy network showed considerable potential to improve efficiency (see Appendix 3, Case study 1).

Specialist screening practitioners provide a vital role in the initial management of patients who have positive findings on bowel screening. They assess whether a patient is fit for endoscopy and explain the procedure including the need for bowel preparation to patients. This reduces the number of patients who do not attend or who have an incomplete colonoscopy. The equivalent service has not generally been provided to patients presenting with symptoms, though this has been shown to be cost-effective.

DEMAND ESTIMATES FOR ENDOSCOPY PRIOR TO THE PANDEMIC

Demand for gastroscopy was estimated to continue to grow by around 3% p.a. prior to the pandemic. As yet there is no non-invasive test to replace gastroscopy for patients with symptoms related to the upper gastrointestinal tract. However, a new technique (Cytosponge) is being trialled and may offer hope for the future. Some gastroenterologists believe that demand for gastroscopy could be limited by better patient selection, though in practice this has proved very difficult to achieve.

At least half of all flexible sigmoidoscopy relates to the bowelscope screening programme which is aimed at men and women aged 55 years. Although final decisions had yet to be made prior to the pandemic, this programme may not be needed when the age range for FIT screening is lowered.

Future overall demand for colonoscopy was very difficult to estimate prior to the pandemic, as the impact of using FIT for triage of symptomatic patients on colonoscopy rates and patient outcomes had not been fully evaluated. However, it was clear that screening colonoscopy needed to increase very substantially, with around a three-fold increase depending on the final threshold for FIT. This will require additional training of colonoscopists. Initially this should be aimed at colonoscopists (medical or non-medical) who are already undertaking procedures on symptomatic patients.

IMPACT OF COVID-19 ON DEMAND AND THROUGHPUT FOR ENDOSCOPY

The numbers of all types of endoscopic procedures reduced by over 90% at the peak of the pandemic. Gastroscopy was designated as an aerosol generating procedure (AGP) and

 $^{^{\}rm 17}$ Personal communication. GIRFT Gastroenterology works tream

therefore carries a risk to endoscopists if patients are Covid-19 positive or Covid-19 uncertain. The current advice from Public Health England is that gastroscopy is no longer an AGP.¹⁸

Viral particles are also found in faeces, making colonoscopy potentially risky too. Emergency procedures at the peak of the pandemic were wherever possible undertaken in operating theatres with negative air pressure and with full personal protective equipment (PPE) and infection prevention and control (IPC) procedures.

A very significant backlog of patients requiring endoscopies therefore built up. This comprised both patients with known high FIT levels following screening and patients with symptoms. This backlog is now being tackled. Throughput in endoscopy suites has also reduced markedly, because of the need to deep clean endoscopy rooms between patients in case of Covid-19.

RECOVERY PHASE REQUIREMENTS

There is an urgent need to establish Covid-19 minimal endoscopy facilities to aid recovery. Testing of both patients and staff will facilitate this. If this can be achieved, the need for deep cleaning between patients will be greatly reduced, allowing throughput to increase nearer to normal levels.

A full asset register of endoscopy facilities and workforce should be established as a matter of urgency by NHS England and NHS Improvement, working with relevant professional groups. This will facilitate both short- and longer-term planning.

Patients who are Covid-19 positive and those who need an emergency endoscopy before Covid-19 status can be determined should continue to have their procedures done in facilities with negative air pressure (usually operating theatres) with full PPE and IPC. Procedures on these patients should not be undertaken in a Covid-19 minimal environment.

Prioritisation of patients for colonoscopy will be needed at least while backlogs are being tackled. There is a broad consensus amongst clinicians working in this area that FIT levels should be used to select patients who most need colonoscopy, whether following screening or symptomatic investigation. Highest priority should be given to those with FIT >100. Symptomatic patients with FIT <10 may be observed for the time being without colonoscopy but should have a repeat test in three months. Patients with FIT 10–100 should be considered for alternative diagnostic procedures where available. These include CT colonography (though CT scanning facilities are also very stretched) and capsule colon endoscopy.

Additional endoscopy facilities will undoubtedly be needed both to reduce the backlogs and to manage slower throughput. In the short to medium term use of independent sector facilities would seem the only way to achieve this.

¹⁸ Public Health England. 2020. <u>Guidance: COVID-19 infection prevention and control guidance: low risk pathway-key principles</u>

Existing endoscopy facilities in acute hospitals will almost certainly continue to be needed during the recovery phase. Wherever possible, patients should access these facilities without having to go through areas with Covid-19 positive patients or staff. Endoscopists working in Covid-19 minimal facilities should wherever possible not also work in Covid-19 positive areas. Rotations of staff may be needed, with virus testing for staff moving from a Covid-19 positive area to a Covid-19 minimal facility.

LONGER-TERM REQUIREMENTS

The following longer-term requirements can be identified:

- Establishment of endoscopy networks across the country.
- Close monitoring of the impact of the use of FIT for symptomatic patients, as this will help determine longer-term capacity requirements.
- Mandating participation in the National Endoscopy Database (NED) by the 20% of NHS trusts that are not already doing so.
- Planning for endoscopy facilities within community diagnostic hubs (CDHs), where needed. These are better delivered at scale and may therefore only be provided in some CDHs. These will need both endoscopy rooms and decontamination facilities as well as changing and waiting areas. Consideration will need to be given to air pressure requirements as a consequence of Covid-19.
- Establishment of training academies both to accelerate the training of non-medical colonoscopists and to provide additional training to enable existing colonoscopists to take on screening colonoscopy. It can be estimated that around 50 colonoscopists will need to convert to screening colonoscopy in each of the next four years (each undertaking around 240 screening colonoscopies p.a.) to deliver an additional 50,000 screening colonoscopies p.a. in five years' time. Non-medical endoscopists will need to be trained to back fill their current endoscopy activity. If the threshold for colonoscopy following a FIT test is to be lowered, further screening colonoscopists will need to be trained.
- Recruit and train a cadre of specialist practitioners to assess and support patients undergoing colonoscopy, thereby improving efficiency and patient well-being.
- Recruit more endoscopy nurses to meet additional demand.

Case study 1: Cheshire and Merseyside endoscopy network

The nine trusts in the Cheshire and Merseyside Cancer Alliance have formed an endoscopy network, serving a population of 2.75 million. In 2016/17 the network had a total of 47 endoscopy rooms and undertook around 124,000 endoscopies p.a. (upper GI, flexible sigmoidoscopies and colonoscopies).

Working together, network leaders have assessed capacity and demand and usage of existing facilities. Using a points system, they looked at usage of endoscopy lists and identified a potential 25% efficiency gain. They compared did not attend (DNA) rates across sites (range 3–12%), late patient cancellation rates (1–8%) and turnaround times between patients (10–17 minutes). By working as a network they have reduced costs of procurement and developed a joint training programme for nurses and administrative and clerical staff. The aim is to develop a passport system so that staff can work across sites. Central scheduling will be introduced so that complex cases are undertaken on a single site and patients enabled to choose the site for endoscopy that is convenient for them. A surveillance database has been established to maximise the beneficial impact of new guidelines and allow network-wide genetic clinics to be introduced.

The network has piloted and evaluated the role of a nurse practitioner who undertakes pre-assessment of patients' medical suitability for colonoscopy and advises on bowel preparation (similar to that already provided within the bowel screening programme). This has been shown to be highly cost-effective by reducing DNA and cancellation rates. Although initially undertaken face to face by a Band 7 nurse, network leads believe this could potentially be done by phone and by a Band 5 nurse.

APPENDIX 4: CARDIORESPIRATORY DIAGNOSTICS

INTRODUCTION

A wide range of tests are needed to assess and monitor patients with cardiac and/or respiratory problems. These are critical for delivery of the NHS Long Term Plan commitments. The increasing uses of CT cardiac angiography (CTCA) to assess coronary arteries and CT pulmonary angiography (CTPA) to diagnose or exclude pulmonary embolism and the increasing use of MRI for cardiac and respiratory problems are covered in Appendix 2 on imaging, as these investigations are very largely undertaken in imaging departments.

This appendix therefore focuses on tests including:

- electrocardiography (ECG)
- monitoring of heart rhythm (where patients may be asked to wear a monitor at home for a week or longer)
- echocardiography
- ambulatory monitoring for ECG and blood pressure
- spirometry to measure the volume in and/or speed at which air can be exhaled
- measures of airway inflammation by FeNO
- oximetry and blood gas analysis to determine patients' requirements for supplemental oxygen
- full pulmonary function tests (lung volumes, gas transfer)
- sleep studies and treatment with CPAP.

Some of these tests can be undertaken within either primary or secondary care. Historically, monitoring of both quality and quantity of these tests has been lacking. Concerns have, for example, been raised regarding both the quality of spirometry and the accuracy of recorded results. Quality assured spirometry services are recommended by NICE to ensure accurate diagnosis of asthma and chronic obstructive pulmonary disease (COPD) and to ensure appropriate treatment.

Many, if not all, of these tests could be undertaken efficiently and effectively in a community diagnostic hub, with IT links to cardiac and respiratory services in acute hospitals for some reporting. Some of the simpler tests may also be provided more locally at a primary care network level. This will be for local decision making.

Particular concerns have been raised about echocardiography. Activity has been growing at 5.7% p.a. with over 1.6 million tests being undertaken in 2018/19. Waiting times are increasing, with over 4% waiting more than six weeks prior to the pandemic. Inadequate workforce numbers has been the primary constraint.

IMPACT OF COVID-19 ON CARDIORESPIRATORY DIAGNOSTICS

As Covid-19 primarily affects the lungs it is not surprising that the pandemic has had a major impact on respiratory services. At the peak of the pandemic there was increased demand for mobile X-ray imaging and CT scanning. In addition, some patients have developed cardiac problems related to Covid-19 requiring echocardiography.

Patients may be left with significant respiratory and cardiac problems for months and possibly years following Covid-19 infection. In addition, the number of patients who presented to A&E with cardiac problems during the peak of the pandemic was markedly reduced. Some of these are likely to have developed extra complications including heart failure as a result of not being investigated and treated promptly.

Taken together, Covid-19 will increase demand both directly and indirectly for CT chest scans, cardiac MRI, lung function tests and echocardiography for months or years to come, to monitor recovery and rehabilitation. It will be very important to determine at what point a patient who has tested Covid-19 positive is no longer infectious and can thus be investigated in a Covid-19 minimal environment. At present it is difficult to quantify the number of additional investigations likely to be required.

LONGER-TERM REQUIREMENTS

Demand for cardiac and respiratory diagnostics is set to increase over coming years because of : changes in the prevalence of relevant diseases; the introduction of more effective treatments requiring close monitoring; and the introduction of less invasive procedures which can be of benefit to a wider population of patients.

The establishment of CDHs provides the opportunity to revolutionise cardiorespiratory diagnostics, improving quality and accuracy of tests, efficiency and convenience for patients, while minimising any risks related to Covid-19.

The following actions are therefore needed:

- ensure that planning for cardiorespiratory diagnostics is considered in the design of CDHs
- establish cardiorespiratory networks bringing together primary and secondary care diagnostics across integrated care system or other populations
- undertake national baseline surveys of echocardiography, sleep and pulmonary function respiratory equipment, together with the cardiorespiratory diagnostic workforce
- develop additional training programmes so that echocardiographers can meet predicted demand
- develop new advanced practitioner roles to undertake a range of cardiorespiratory and other diagnostics (e.g. spirometry, ECG, rhythm monitoring and phlebotomy), predominantly within a CDH.

APPENDIX 5: PATHOLOGY

INTRODUCTION

The term pathology covers a wide range of subspecialties and an even wider number of individual tests. These can be grouped as:

- blood sciences blood transfusion; haematology; clinical biochemistry; immunology
- cellular pathology cytology and histopathology (and mortuary services)
- microbiology bacteriology; virology
- genetics cytogenetics; cancer genetics and rare disease genetics.

Huge numbers of individual pathology tests are done each year (an estimated 1.2 billion p.a.). Around 44% of these originate from primary care. Year on year increases are being observed by individual laboratories, though variations in counting make national aggregates difficult.

A key recommendation of Lord Carter's report on pathology¹⁹ was that a large proportion of non-acute pathology services should be centralised within network hubs to promote efficient use of resources, especially workforce. Twenty-nine pathology networks are being established. Some essential laboratory services will still be needed on acute hospital sites.

Phlebotomy (blood taking) services are clearly critical to blood sciences but are currently patchy across primary care and the community.

Cytology services underwent a major transformation in 2019 to accommodate the change from primary cytology testing to primary HPV testing within the cervical screening programme. HPV testing is fully automated. The number of laboratories undertaking cervical screening testing has reduced from 46 to eight.²⁰

Histopathology has been under increasing strain for several years due to increasing numbers of samples (e.g. related to bowel and prostate cancer) and increasing complexity of testing. Genomic analysis is also increasingly being undertaken on cancer samples. This may necessitate additional biopsies to be taken and will increase the workload for histopathology laboratories.

A survey undertaken by the Royal College of Pathologists in 2018²¹ indicated that 45% of histopathology laboratories were having to outsource work and 50% of departments had to use locums prior to the pandemic. Workforce was the major constraint.

¹⁹ Lord Carter of Coles for Department of Health. 2016. <u>Operational productivity and performance in English NHS</u> <u>acute hospitals: Unwarranted variations</u>

²⁰ Professor Sir Mike Richards independent review. 2019 <u>Report of the independent review of adult screening</u> programmes in England

²¹ Royal College of Pathologists. 2018. <u>Meeting pathology demand histopathology workforce census</u>

There is a clear need to expand the histopathology workforce significantly. HEE recognises this specialty is in significant difficulty in relation to the growth needed to meet NHS Long Term Plan commitments and that skill-mix initiatives will be vital.

IMPACT OF COVID-19 ON PATHOLOGY

The Covid-19 pandemic has had a very major impact on pathology networks in relation to swab testing for the virus and increasingly to antibody testing. At the peak of the pandemic demand – both for testing of patients presenting as emergencies and of staff working in Covid-19 positive environments – was very high, placing substantial pressure on the networks. As the peak has receded, the need to test patients attending for diagnostic procedures, elective and urgent surgery and for other procedures has risen. Unless this demand can be met, recovery of services will be jeopardised. Rapid, near-patient testing will be of particular value in keeping designated sites Covid-19 minimal.

During the peak of the pandemic some of the laboratories designated for HPV testing for cervical screening were used to test for Covid-19. These laboratories now need to perform their original function as soon as reasonably possible.

Many other pathology services (e.g. blood sciences) observed reduced demand during the peak of the pandemic as fewer patients attended GP surgeries and fewer were referred to outpatients.

RECOVERY PHASE REQUIREMENTS FOR PATHOLOGY

Testing for Covid-19: The key requirement for pathology services across the country during the recovery phase is to establish effective testing for the very wide range of NHS patients and staff, social care residents and staff and other key workers who need it. The full scope of a testing strategy for the country is clearly beyond this report. However, from an NHS recovery perspective, rapid near-patient testing in hospitals and community diagnostic hubs (CDHs) is clearly of vital importance, especially when prevalence of Covid-19 in the community is high. This should be in conjunction with further expansion of high throughput and high-volume swab testing within the pathology networks. This is needed to improve timely access to COVID-19 testing alongside usual testing requirements, including HPV, seasonal flu and other molecular diagnostics.

Phlebotomy: Alongside this, effective phlebotomy services need to be established that avoid the need for non-emergency patients to attend acute hospitals to have their blood taken. At present, the provision of community phlebotomy services is highly variable. In some CCGs, GP surgeries are able to provide this on five or six days a week. This level of provision should be the norm for all patients, with services being provided within primary care or other locations if more appropriate.

If these services are to be provided in CDHs, patients who have not been tested for Covid-19 will need to be kept separate from others. Within primary care networks it may be appropriate to designate one GP surgery for such tests.

LONGER-TERM REQUIREMENTS

For pathology services to be fully effective in the medium to longer term the following requirements can be identified:

- Full establishment of the designated pathology networks to drive efficiencies across a range of pathology disciplines.
- Full digitisation and IT connectivity within networks enabling ordering of tests and reporting of results between GP practices, acute hospitals and CDHs and pathology hubs. This will also allow sharing of reporting and access to highly specialised opinions, e.g. in histopathology.
- Expansion of the histopathology workforce with more healthcare scientists as well as medical histopathologists.

APPENDIX 6: GENOMICS

INTRODUCTION

Genomics is the study of the whole genome (made up of genes). A person's genome holds the information needed to build the human body and keep it healthy. By looking at specific parts of the genome we can find out whether a person is carrying a specific gene variation (altered gene) that causes a specific medical condition such as rare or inherited disease or certain cancers. This allows diagnosis and treatment to be tailored to individual patients.

Technological and scientific advances are continuing to drive developments in medical practice, enhancing the ability to diagnose illness more precisely and target treatment of disease. Genomic technologies, applied at the level of the whole genome, coupled with an increasing ability to link and interrogate large amounts of clinical and diagnostic data at a relatively low cost, offer significant clinical, patient and system benefits including:

- enabling a quicker diagnosis for patients with a rare disease, rather than years of uncertainty, referred to as the 'diagnostic odyssey'
- matching people to the most effective medications and interventions, reducing the likelihood of an adverse drug reaction
- increasing the number of people surviving cancer each year because of more accurate diagnosis and more effective use of therapies.

The NHS has been delivering genomic testing for many years; however, there have been significant issues, including inequity in access to testing; variability in the quality and outcomes of testing; poor data collection; gaps in the workforce and outdated ways of working; an unstructured approach to the uptake of new technologies; and variability in commissioning approaches.

To overcome these challenges the NHS Genomic Medicine Service (NHS GMS) was launched in October 2018 with the aim of providing a high quality, equitable service able to respond to new technological developments.

The NHS GMS builds on the existing NHS infrastructure and NHS contribution to the 100,000 Genomes Project.

It comprises the following elements:

- 1. A national genomic laboratory service delivered through a network of seven genomic laboratory hubs.
- 2. A National Genomic Test Directory defining the testing available within the NHS in England and the technology by which it should be delivered.
- 3. National whole genome sequencing (WGS) provision and a supporting informatics infrastructure developed in partnership with Genomics England.

- 4. An integrated clinical genetics service inclusive of genomic counselling for rare and inherited diseases and cancer.
- GMS alliances, built on the NHS Genomic Medicine Centre infrastructure, developed as part of the 100,000 Genomes Project. The alliances aim to support the systematic embedding of genomic medicine to ensure all eligible patients can access high quality services.

NHS GENOMIC MEDICINE SERVICE

Transition to the national genomic laboratory service began in October 2018. This includes:

- consolidating the existing laboratory infrastructure
- establishing capability to deliver all the tests identified in the National Genomic Test Directory to support equitable access to testing nationally
- moving specialist testing to designated specialist test providers
- consolidating next generation sequencing panel testing for cancer into a small number of NHS laboratories, with the aim of reducing turn-around times and increasing access
- mapping of all non-WGS testing to laboratory information management systems (LIMS) to facilitate the introduction of a new national pricing model and standardise the integrated reporting of results (enabling genomic findings to be integrated with other diagnostics).

IMPACT OF COVID-19 ON GENOMIC SERVICES

The pandemic has had a major impact on the genomic testing service with equipment and staff being redeployed to support Covid-19 testing. Genomics services played an important role in ensuring testing capacity for patients presenting as emergencies and relevant staff were delivered.

RECOVERY PHASE REQUIREMENTS

Long-term planning for the recovery of genomic services is now underway. It will be important to ensure that these laboratories can perform their original function as soon as reasonably possible. Laboratories are now putting in place working arrangements which take account of social distancing measures, including additional shift patterns and workflows.

Genomic testing will continue to be important in the response to Covid-19. This will include sequencing the virus to support identification of Covid-19 outbreaks and to better understand its effects on different patient groups.

FORWARD LOOK FOR GENOMICS

The NHS Long Term Plan has committed to:

- Sequencing 500,000 whole genomes by 2023/24, initially for:
 - o seriously ill children likely to have a rare genetic disorder
 - people with one of 21 rare conditions where current evidence supports early adoption of WGS as a diagnostic test
 - people with specific types of cancer for which there is likely to be the greatest patient benefit from using WGS – children with cancer, sarcoma and acute myeloid leukaemia.
- Extending access to molecular diagnostics to enable genomic testing to be routinely offered to all people with cancer.
- Expanding access to genomic testing for familial hypercholesterolaemia.
- Linking and correlating genomic, clinical data and patient data to provide routes to new treatments, diagnostic patterns and help patients make informed decisions about their care

To achieve the Long Term Plan commitments and harness the potential of the NHS GMS, further investment will be required. This includes capital requirements for high throughput machines to achieve the efficiencies needed to establish a sustainable service. This will enable the increasing demand to be met. Improvements to laboratory IT systems will also be important to enable reporting and requesting of genomic tests across the system and to support cancer genomics and links with pathology.

To manage the increasing demand and complexity of genomic testing there also needs to be a significant expansion in the specialist genomic workforce. The demand for clinical geneticists and genomic counsellors is set to exceed supply. There needs to be a concerted effort to train additional clinical geneticists and genomic counsellors to meet this demand. Training is also required for clinical scientists and bioinformaticians to support the increasing complexity of the analysis of genomic tests.

In recognition of the impact that genomics will have across most clinical specialties and in embedding the use of WGS, there is also a need to increase understanding of genomics within the wider NHS workforce. This should begin in those areas where genomics will be most rapidly deployed, e.g. in oncology, cardiology and neurology.

APPENDIX 7: GUIDANCE FOR COMMUNITY DIAGNOSTICS HUBS

1. INTRODUCTION

- 1.1. Demand for diagnostics was rising markedly before the pandemic and for some tests this was outstripping capacity. During the peak of the Covid-19 pandemic, requests for diagnostics decreased. However, requests for diagnostics are now increasing again with throughput being reduced because of the additional infection prevention and control (IPC) measures.
- 1.2. There is a clear need for increased capacity both in terms of equipment/facilities and workforce. In addition, a major drive on efficiency is required. A key component of that will be to streamline diagnostic services. Acute (A&E and inpatient) and elective (GP and outpatient) diagnostics should be separated wherever possible. Streamlining will help address the current backlog and aid the longer-term recovery of services.
- 1.3. In general, acute hospital sites have very limited spare capacity (including for parking) and are difficult to keep Covid-19 minimal. Therefore, to deliver safe, patient-centred and efficient elective diagnostic services and to prepare for much needed expansion of capacity, community diagnostic hubs (CDHs) should be rapidly established. These will enable the provision of Covid-19 minimal, highly productive elective diagnostic services to meet demand for NHS Long Term Plan priorities, including cancer, cardiac, respiratory and other conditions. CDHs are recommended as part of new service models for diagnostics in this review.
- 1.4. CDHs will also play an important role in providing diagnostics for the ongoing monitoring of long-term conditions.
- 1.5. Development of integrated symptom-based pathways to diagnosis agreed between primary and secondary care will be vital alongside the establishment of new facilities. These should incorporate lessons learned from changes made at the peak of the pandemic and should encompass referral criteria, advice and guidance, clinical decision making and communication of diagnostic findings. This should be underpinned by IT connectivity.
- 1.6. These hubs should be kept separate from locations serving patients known to have Covid-19. Speed of mobilisation should be a key factor in site identification.
- 1.7. From June 2020 to March 2021, systems should maximise use of existing facilities, including diagnostic facilities on 'cold' NHS sites and in the independent sector.
- 1.8. Regions working with ICS/STPs, cancer alliances and existing local diagnostic services and networks (imaging and pathology) should develop long-term plans for the sustainable

development of CDHs for implementation from April 2021.

2. PURPOSE

- 2.1. The aim of the CDHs will be to:
 - Minimise risks of transmission of Covid-19 between patients, visitors and staff during the diagnostic process, thereby providing a safe environment for patients and staff for the conduct of diagnostics for all disease pathways during the period in which Covid-19 is endemic.
 - Increase and optimise diagnostic capacity in the longer term through the separation of acute and elective diagnostic provision providing benefits in terms of efficiency and quicker access to testing and convenience for patients.
 - Improve patient experience of the diagnostic process and facilitate earlier diagnosis of a range of conditions, where possible providing a suite of tests in one day in a single location.

3. PROPOSED NUMBER

3.1. It is anticipated that three hubs per million population should be established in the first instance (broadly equivalent to the number of acute hospitals).

4. LOCATION

- 4.1. The CDHs will usually be sited away from acute hospitals, with adequate public transport links and car parking. NHS community hospitals, retail parks or high street shopping centres may provide suitable locations with decisions being made based on local need.
- 4.2. Selection of sites for CDHs should improve equity of access and support inclusion by considering physical, cultural and social needs of different/diverse population health groups, supporting the NHS Long Term Plan commitment to narrowing health inequalities.
- 4.3. If co-located with an acute hospital, there should be a separate entrance such that neither staff nor patients attending the hub are required to enter the main hospital building.
- 4.4. Diagnostics closer to home and fewer outpatient attendances should reduce patient journeys and thus improve sustainability, contributing to the NHS ambition to become Net Zero.

5. RANGE OF SERVICES

- 5.1. The exact configuration of services within a hub will be for local decision making. However, the objective should be to provide as broad a range of services as possible. Criteria for deciding on services to be located in a CDH will include:
 - need to provide safe, Covid-19 minimal facilities and to maximise throughput
 - services for which demand is outstripping capacity
 - symptomatic presentations that may need multiple diagnostics, which can safely be undertaken off the acute site
 - scale of services needed to provide safety and efficient diagnosis and ongoing monitoring
 - convenience for patients.
- 5.2. Based on increasing demand and patient convenience, it is highly likely that as a minimum all CDHs will provide the following:
 - Imaging: CT, MRI, ultrasound, plain X-ray.
 - **Cardiorespiratory:** echocardiography, ECG and rhythm monitoring, spirometry and some lung function tests, support for sleep studies, blood pressure monitoring, oximetry, blood gas analysis.
 - Pathology: phlebotomy.
 - Endoscopy: facilities are undoubtedly needed and should be provided in Covid-19 minimal locations. However, these are likely to be better delivered at scale and may therefore only be provided in some CDHs. Some larger endoscopy facilities could also become training academies.
 - Consulting and reporting rooms.
- 5.3. Many other diagnostic services may very well be located within CDHs, e.g.:
 - mammography
 - ophthalmology
 - DEXA scan
 - antenatal screening
 - hysteroscopy and colposcopy
 - cystoscopy
 - urodynamics
 - audiology
 - fibroscan.

- 5.4. Consulting rooms may be valuable alongside diagnostic facilities for assessment of patients with a range of conditions and for explaining findings of investigations; for example, patients presenting with non-specific symptoms, which could be due to cancer; or with musculoskeletal problems requiring assessment to decide on appropriate use of imaging.
- 5.5. Mobile services may also be appropriate in some localities.
- 5.6. CDHs could potentially provide a range of maternity and gynaecology services. Ultrasound scanning for antenatal care is likely to increase as part of the drive to reduce still births. A range of gynaecological examinations investigations such as transvaginal scanning, hysteroscopy, colposcopy and urodynamics could be undertaken. Service users may prefer to be seen in a Covid-19 minimal hub.
- 5.7. The use of CDHs for children's investigations should also be considered. Children presenting with a range of symptoms such as lymphadenopathy, chronic abdominal pain and palpitations/syncope often require blood tests, ultrasound, plain X-ray and/or 24-hour ECG monitoring. All of these will be available in a CDH. However, if children's services are to be delivered, appropriate safe guarding and training of staff will be needed.
- 5.8. Outpatient referrals to urology are increasing significantly year on year with much of the workload relating to diagnosis or exclusion of cancer. Investigations for patients presenting with blood in the urine, a raised prostate-specific antigen or other urological symptoms could all be undertaken in a CDH, with urologists being supported by physician assistants or specialist nurses. Strengthening online advice and guidance has the potential to triage patient 'straight to test' or, in some cases, avoid onward referral.
- 5.9. A range of adult screening services could be provided within CDHs, such as mammography, colonoscopy, colposcopy, abdominal aortic aneurysm and diabetic eye screening.
- 5.10. Some complex diagnostic tests and interventions should clearly continue to be provided on acute hospital sites, e.g. complex endoscopies such as endoscopic retrograde cholangiopancreatography (ERCP) and CT coronary angiography.
- 5.11. CDHs could also support the delivery of some diagnostic tests (e.g. mobile X-ray) in patients' homes or in care homes and support home monitoring, including patients measuring their own blood pressure and oxygen saturation.
- 5.12. A range of digitally enabled home-based services are currently being piloted through NHS@home, with significant expansion envisaged in coming months. The aim is to give people connected, supported, personalised care to help them manage a range of long-term conditions within their own homes. Pilots include COPD, cystic fibrosis, type 1 diabetes through spirometry, blood pressure monitoring and glucose monitoring, thereby reducing their need for hospital visits. Remote monitoring of people with symptoms of

Covid-19 using oximetry in care homes or at home is also being trialled to help identify early signs of deterioration and reduce mortality during local outbreaks or a second national peak.

6. HOURS OF OPERATION

6.1. Ideally, CDHs should operate for 14 hours a day, seven days per week. However, workforce constraints may make this unachievable in the short term.

7. RAPID DIAGNOSTIC CENTRES AND COMMUNITY DIAGNOSTIC HUBS

- 7.1. Rapid diagnostic centres (RDCs) were announced as part of the NHS Long Term Plan, recognising the need for the rapid assessment of patients with cancer symptoms or suspicious results.
- 7.2. Cancer alliances are already working to deliver the RDC service model for the management of all cancer pathways by 2023/24. As diagnostic services are reshaped by the response to Covid-19, it is essential there is a clear relationship between RDCs and CDHs.
- 7.3. The work to establish CDHs will need to be aligned with the delivery of RDCs and, for patients with suspected cancer, the hubs should incorporate the RDC service model as set out in the RDC specification.

8. CLINICAL PATHWAYS

- 8.1. Requests for diagnostics may come from primary or secondary care, including A&E. Prioritisation should be based on clinical need, ensuring that patients receive the right test(s), first time and where possible on the same day. Expert advice and guidance along with clinical decision aids should be available to GPs to ensure the most appropriate investigations are requested. This will result in faster diagnosis and reduced risk of Covid-19 infection through fewer visits.
- 8.2. Bookings should be by appointment, where possible allowing patients to choose times. Patients should be able to answer pre-appointment questions relating to the specific tests (e.g. MRI safety checks) and their general health prior to their appointment.
- 8.3. Clear protocols should be established for communicating results of investigations to patients and to the requesting clinician. In some cases, it will be important to have an appropriate clinician (medical or non-medical) within the CDH to communicate information immediately. In other cases, reporting on investigations will be done remotely. In all cases, requesting clinicians should have access to advice on the interpretation of results.

8.4. Diagnostic images and results of other investigations should in all cases be available for review by multidisciplinary teams.

9. MEASURES TO PROTECT PATIENTS AND STAFF

- 9.1. All services must comply with guidance to ensure they are Covid-19 minimal for staff and patients. IPC should be the guiding principle as follows:
 - Patients should be virus tested where possible prior to attendance, especially for certain procedures, e.g. endoscopy, lung function tests and imaging tests, where lengthy deep cleaning of equipment would otherwise be required.
 - Patients' symptoms should be assessed and temperatures taken on attendance, and face masks provided.
 - Clinical staff should be virus tested where possible at least weekly. Staff should move as infrequently as possible between sites treating patients with known Covid-19 and CDHs.
 - Adequate PPE should be provided, depending on the procedure to be undertaken. Rigorous cleaning regimens (including for equipment) should be in place.
- 9.2. Investigations for patients who have active Covid-19, or those who require urgent diagnostics, should not be undertaken in these hubs.

10. GOVERNANCE AND INTEGRATED CARE

- 10.1. Regional oversight of the establishment of CDHs will be critical. Regions will need to work with ICSs/STPs, diagnostic networks and primary care services to determine the location and configuration of services. Ultimately, it is likely that a single trust will need to take lead responsibility for a CDH.
- 10.2. It will be important that the workforce is integrated between the acute sector and CDHs with the rotation of staff being the norm. Passports to allow staff to move easily between sites should be encouraged.
- 10.3. CDHs will form a key component of diagnostic networks and therefore must wherever possible be integrated with NHS IT systems (e.g. EPR, PACS/RIS, LIMS, Order Comms). This will facilitate sharing of images and availability of test results across primary and secondary care.
- 10.4. The quality and safety of diagnostics delivered in a CDH should be rigorously monitored. This will include the number of patients being referred and investigated and the timeliness of investigations and results reported to requesting clinicians and patients.

10.5. As experience with CDHs increases, it will be important to share learning both regionally and nationally.

11. POTENTIAL VOLUMES OF ELECTIVE ACTIVITY

11.1. The volumes of requests for imaging diagnostics by source are shown in Table A7.1 below, based on activity levels in 2018/19. Almost half of plain X-rays are requested either from outpatient clinics or directly from GPs. Equivalent figures for ultrasound, CT and MRI are 85%, 59% and 86% respectively. While it may be appropriate for some of the tests requested from outpatient clinics to be done within an acute hospital, many could transfer to a CDH. Elective diagnostic activity is likely to grow very substantially over the next five years.

	'Acute'			'Elective'		
	A&E	Inpatient	Total	Outpatient	GP	Total
Plain X-ray	7.8m	3.9m	11.7m	5.4m	5.7m	11.1m
Ultrasound	0.2m	1.3m	1.5m	5.2m	3.1m	8.3m
СТ	1.4m	1.5m	1.9m	2.4m	0.3m	2.7m
MRI	<0.1m	0.5m	0.5m	2.4m	0.6m	3.0m

Table A7.1: Volumes of acute and elective imaging activity (2018/19)

Source: NHS England. <u>Diagnostic Imaging Dataset</u> 2018/19 with figures rounded Note: 75% of plain X-ray requested from outpatients are done on the day of request, but this proportion is much lower for other modalities (ultrasound = 27%; CT = 6%; MRI = 3%). Some same day requests might reasonably stay in acute hospitals.

- 11.2. It should be noted that the elective activity for CT is equivalent to the capacity of around 250 CT scanners (5 per million). While it is unlikely that all elective activity will move from acute hospitals, it is anticipated that CT activity could double over the next five years. Much of this activity could be undertaken in CDHs. A similar case can be made for MRI.
- 11.3. The large majority (probably around 80%) of endoscopy activity is elective and could thus be undertaken in a CDH.

Case study 2: Diagnostic and assessment centre, the Norfolk and Waveney STP proposal

The three NHS foundation trusts within the Norfolk and Waveney STP serve a combined population of 1.4 million people. Rapidly increasing demand for imaging means that services across all three trusts are under huge strain. Inadequate NHS imaging capacity means that the trusts are spending around £2 million p.a. renting mobile imaging capacity. Outsourcing of scanning and reporting for ultrasound and MRI is costing £1 million p.a. and outsourcing of reporting for other imaging is costing £1 million p.a. Several of the trusts' machines are more than 10 years old and there is a lack of

connectivity between sites. In consequence of these problems all three trusts are having difficulty meeting targets.

In response, the STP is proposing to develop diagnostic and assessment centres on all three sites. These centres will comprise both imaging (MRI, CT, ultrasound and plain X-ray) and outpatient consultation rooms. On the Norfolk and Norwich University Hospital campus, the new facilities will be co-located near a large, recently built modern endoscopy facility and the existing radiology academy will relocate to the new Diagnostic and Assessment Centre. Across the three sites the proposal will provide six CT, nine MRI, two ultrasound and two plain X-ray units, as well as 46 outpatient consultation rooms and IT connectivity, at a cost of £70 million overfour years.

The new centres will enable elective diagnostic services and considerable outpatient activity to be separated from acute services (e.g. A&E and inpatient services). This will improve flow in both patient groups and will facilitate one stop outpatient assessment and imaging.

Case study 3: Community diagnostic centre, Ealing

InHealth's diagnostic centre in Ealing, London is located on the high street (Uxbridge Road). This location affords patients great accessibility with good public transport links and on-site parking. The centre is open 14 hours per day, seven days per week, 363 days per year. In the last 12 months it has been used by more than 30,000 NHS patients alongside a small number of private patients. The NHS patients are typically referred by their GP under contracts commissioned by CCGs.

This multimodality diagnostic centre offers the following services:

- MRI
- ultrasound
- X-ray
- DEXA scans
- blood pressure monitoring
- echocardiograms
- ECGs
- audiology
- endoscopy.

The centre is extremely well utilised with 100% of appointment slots booked each day. On average 92% of all appointment slots are attended after accounting for did not attends (DNAs), staff sickness and equipment breakdowns.

For most modalities, patients are usually offered the first available appointments within 7 to 10 days. The timeliness of appointments and the levels of productivity have been achieved through investment in a patient referral centre (based in Manchester), together with the associated processes and IT infrastructure that closely links the booking and scheduling process with the operating teams at each centre.

Case study 4: Respiratory diagnostic hub, Birmingham and Solihull

University Hospital Birmingham (UHB), local commissioners and Astra Zeneca are working together to pilot a respiratory diagnostic hub, with the aim of correctly diagnosing asthma and chronic obstructive pulmonary disease (COPD) and other respiratory conditions.

The service is delivered weekly in a primary care centre and provides peak flow monitoring, spirometry, gas transfer, expired nitric oxide (FeNO), oximetry (SpO₂) and six-minute walking tests. Further respiratory tests and some sleep tests are planned.

The service is delivered by a Band 6 clinical physiologist (rotating from UHB), a Band 7 respiratory specialist nurse and an assistant practitioner (Band 4). They are supported by a GP with a special interest and a consultant respiratory physician.

Early results show changes to the originally suspected diagnosis in a significant number of patients, leading to changes in treatment and avoidance of hospital referrals.

Further development of the service might involve extending it to other GP practices or to mobile services delivered from a 'diagnostics truck'. Smoking cessation advice and advice on inhaler technique could be provided and the service could be extended beyond respiratory tests.

APPENDIX 8: POINT OF CARE TESTING

Although point of care testing (POCT) has been used in specific areas of healthcare for decades (e.g. blood gas measurement in intensive care units), it is a relatively new development in other areas. However, it is set to grow as the effectiveness, quality and cost of devices improves. It can:

- provide convenience and speedy results for patients
- support rapid clinical and shared decision making and the diversification of the workforce
- reduce unnecessary admissions to hospital and support care in the community and at home, important to ageing well
- help reach marginalised groups, including those with mental health problems, reducing health inequalities and variation in access to services
- support the development of better care pathways and appropriate prescribing.

POCT has the potential to support the development of better care pathways and is being introduced and evaluated in a range of settings, including:

- acute ambulatory care units
- acute hospital at home services
- GP practices
- out-of-hours primary care and paramedic services
- care homes
- community diagnostic hubs
- emergency departments
- acute medical units
- imaging departments.

POCT has potential uses for local monitoring of chronic diseases, self-monitoring of anticoagulation or renal function, undertaking health checks and assessing patients who are deteriorating or acutely unwell. COVID-19 specific POC tests are being evaluated through the NIHR CONDOR programme.²²

Pulse oximetry has been used for many years in acute hospital settings, but has recently been found to be of particular value in the assessment of patients with possible or definite Covid-19. It is now increasingly being used in community settings.

²² Condor. NIHR. <u>Covid-19 National Diagnostic Research and Evaluation Platform</u>

POCT blood tests can often be done on finger prick samples, thereby avoiding the need for phlebotomists. Some tests can be done by patients themselves at home (e.g. some renal transplant patients). Analysers are often about the size of a shoebox or smaller.

Blood tests currently include:

- C-reactive protein (CRP): high values in patients with cough suggest a bacterial origin, important in antibiotic stewardship
- D-dimer to assess for possible deep vein thrombosis or pulmonary embolism
- renal function including electrolytes to support acute care at home or safety of contrast injections prior to CT scanning
- lactate as part of early recognition of sepsis
- B type natriuretic protein (NT-proBNP) for detection of heart failure
- high sensitivity troponin to assess for acute cardiac ischaemia or cardiac muscle damage
- lipids to establish cardiovascular risk
- HCG to assess progress of early pregnancies
- flu (A and B) tests
- glucose
- INR to monitor warfarin levels.

Urine tests to assess possible urinary tract infections are in development. As these tests form 40% of microbiological tests in primary care, there is a real opportunity to support appropriate prescribing.

Imaging POCT is a growth area with real potential. Point of care ultrasound (POCUS) is now being used in some emergency departments and access to an ultrasound machine is available on more than half of acute medical units. However, use is currently limited by the number of individuals who are trained in its use. Pocket sized ultrasound machines can be used for POC echocardiography (e.g. for detection of pericardial effusion, ventricular systolic dysfunction), lungs (e.g. for signs of COVID-19 which may also be prognostic, pleural effusion, pneumothorax or consolidation), abdomen (for biliary tree dilatation, hydronephrosis, ascites) and limbs (for possible deep vein thrombosis). Hand-held devices plug into a smartphone/tablet and can send images to Cloud-based systems for training, governance and audit purposes.

POC X-ray machines have recently been developed which are portable and may prove to be useful in care homes and for patients who are unable to leave home.

Offering both bloods and imaging could support differentiation of acute illness syndromes at home or in care homes and is being implemented by a small number of acute hospital at home services.

POC breath tests are also in development but as yet not validated in clinical settings, including tests to distinguish viral from bacterial infections, to detect markers of cancer and to measure blood gas concentrations and offer a simpler diagnostic alternative for respiratory conditions or to detect asthma exacerbations earlier.

Key barriers to the uptake and effective use of POCT include:

- determining what evidence is necessary before a particular test is introduced
- appropriate governance for quality control, including:
 - staff training
 - o calibration of equipment
 - o specification of individual tests
- connectivity of results or images with medical records
- reimbursement issues (e.g. in primary care) and difficulties in achieving economies of scale.

Whenever new tests are being considered in specific clinical areas, discussion with local pathology laboratories is strongly recommended.

Case study 5: Point of care testing to broaden access to cardiovascular screening in patients with severe mental illness

People with severe mental illness experience a mortality gap of 15 to 20 years compared to the general population. In community mental health team (CMHT) caseloads, there is poor completion of annual physical health check in these at-risk service users. Typically, mandatory HbA1c and lipid panel blood tests are not performed, due to illness-related factors, lack of clinical resource and care fragmentation between primary and secondary care.

The CARdiovascular monitoring in MENtal health (CARMEN) project aimed to improve physical health check completion by implementing and evaluating the 'Afinion' POC device in an early intervention in psychosis service (EIS) in Oxfordshire. Over a six-month intervention period, staff were trained to use the device to perform, analyse and interpret HbA1c and lipid panel blood tests.

In the six-month implementation period, 40.3% of eligible service users in the Oxfordshire EIS service received a full physical health check. In the same period, the matched-control Buckinghamshire EIS team had 7.8% of its caseload receiving a full physical health check. Service users were universally positive about POC, and reported reduced anxiety, better care and increased engagement with their physical health. Clinicians felt that POC could enhance the therapeutic relationship and enjoyed the increased autonomy and self-efficacy.

Case study 6: Point of care CRP testing in general practice safely reduces antibiotic use for COPD exacerbations

The NIHR-funded PACE trial, which recruited 653 participants from UK primary care, provides strong evidence that a rapid test for raised CRP levels, which occur with serious infection, could help prescribers in primary care make better decisions about who needs antibiotics to treat a chronic obstructive pulmonary disease (COPD) exacerbation and who does not.

Flare-ups of COPD can be caused by infections of the airways or environmental triggers, and cause about 115,000 admissions to hospital every year. Determining whether a flareup is due to infection is difficult in primary care, and currently around 80% of those presenting in primary care with moderate exacerbations of COPD are treated with antibiotics.

Use of a rapid CRP blood test in general practice for people with COPD exacerbations has been shown to reduce the proportion who take antibiotics over the next month by about 20% compared with usual care alone. The reduction in antibiotic use does not lead to worse health, more visits to the doctor or greater need for antibiotics later on.

APPENDIX 9: ARTIFICIAL INTELLIGENCE

Numerous artificial intelligence (AI) products are currently being developed, many of which relate to imaging for diagnostics and screening. Horizon scanning undertaken by the Accelerated Access Collaborative (AAC) and NHSX has identified five major areas under development:

- breast screening mammography
- chest X-ray and chest CT interpretation
- diabetic retinopathy screening
- stroke imaging
- cardiac imaging.

It is important to recognise that while all these areas show great promise, they are not yet ready for full implementation. Several of these products have been evaluated on retrospective image samples and now need to be tested prospectively. Some are being designed as triage tools to help prioritise images for urgent reporting (e.g. for chest X-rays). In the case of screening mammography, it is envisaged that AI may replace one of the two current radiologists or reporting radiographers, but not replace assessment by both readers at least for the foreseeable future. For chest CT scans, AI may have valuable roles in identifying and measuring nodules, reducing the time taken for a radiologist to report a scan. However, as with screening mammography, AI will not replace a human reader in the foreseeable future.

The launch of the AI Health and Care Award run by the AAC in partnership with NHSX and NIHR is very welcome. This will make £140 million available over three years to accelerate the testing and evaluation of the most promising AI technologies, including supporting well-developed AI technologies that need more evidence to support large-scale commissioning or deployment. This forms part of the wider NHS AI Lab overseen by NHSX.

Case Study 7: Kheiron/East Midlands Radiology Consortium

The East Midlands Radiology Consortium (EMRAD) was launched in 2013 to create a common digital radiology system. Pioneering work led to the development of a Cloudbased image-sharing system through which the seven NHS trusts involved in the partnership could share diagnostic images, such as X-rays and scans.

In 2018, EMRAD formed a partnership with two UK-based AI companies, Faculty and Kheiron Medical, to help develop and test AI tools in the breast cancer screening programme in the East Midlands. The project is one of seven 'wave two' NHS test beds and aims to develop and test both clinical and non-clinical (operational) AI tools. Realising the opportunities presented by AI will depend on the availability (and accessibility) of data to 'train' such tools. As part of their role in the test bed, Kheiron, are conducting a large-scale retrospective study on mammograms from two NHS sites within the EMRAD. The aim is to test whether its deep learning mammography software, 'Mia', can be considered as an independent second reader in double-read screening programmes. This has the potential to support the screening workforce.

The test bed project is also assessing whether AI tools can help run operational and administrative aspects of the breast screening programme. Faculty's 'Platform' software is being evaluated to see where it can optimise operational processes such as clinic scheduling and staff resourcing. For example, AI tools could be used to accurately predict whether people will or will not attend their screening appointment, thereby allowing over-booking of clinics without impacting service quality.

Case study 8: Building an AI model to diagnose and refer retinal disease

Working in close partnership with world-leading experts from Moorfields Eye Hospital NHS Foundation Trust, DeepMind Health (now Google Health) developed AI technology which could improve the way eye diseases are diagnosed and treated. In the future, this technology could help the millions of people across the globe who are affected by preventable or curable sight loss and support eye doctors to deal with increasing demands.

In the UK more than 2 million people suffer from some form of visual impairment or blindness. At least half of these UK cases are avoidable with early detection and proper treatment, according to the RNIB. Eyecare professionals use optical coherence tomography (OCT) scans to help diagnose eye conditions. These 3D images provide a detailed map of the back of the eye, but they are hard to read and need expert analysis to interpret. The time it takes to analyse these scans, combined with the large number of scans (over 1,000 a day at Moorfields alone) and a shortage of ophthalmologists can lead to lengthy delays between scan and treatment. If a patient develops a sudden problem, such as a bleed at the back of the eye, these delays could even cost patients their sight.

The AI model can quickly interpret eye scans from routine clinical practice with 94.5% accuracy – surpassing many experts. This is despite the fact that the experts that Google compared its model with had access to both the OCT scans and a range of other clinical information that would normally be provided in routine clinical practice, while the AI only had access to the scans.

The model was able to identify signs of disease from a dataset which included over 50 different retinal pathologies and make recommendations for how patients should be referred for treatment. A novel two-stage model design provided detailed 3D segmentations to help the clinician understand the basis for each decision. In the future, this could make it easier for clinicians to fast-track patients with the most serious eye diseases, such as age-related macular degeneration and diabetic eye disease, before irreversible damage sets in.

Google Health is currently working with Moorfields to develop this research into a deployable prototype that could improve patient care. This will involve prospective trials followed by the necessary regulatory approvals.

The AI technology is designed to be a tool for doctors, ophthalmologists and other eye care professionals to help them prioritise patients in most urgent need of treatment, and free up their time to concentrate on what matters most – treating patients. Final responsibility for diagnosis and treatment will always rest with expert clinicians.

These applications will bring major benefits in radiology, both in terms of timeliness of interpretation of images and in reducing the need for increases in the workforce needed for reporting. However, it would be wrong to assume that AI will reduce the need for radiologists. Their skills will be needed for interpretation of complex images for the foreseeable future. It is also important to recognise that radiologists undertake many other functions, including taking biopsies under imaging control, performing interventional radiological procedures, participating in multidisciplinary team meetings and providing advice to other clinicians.

Al is also likely to have an important role in the interpretation of histopathological specimens. However, this area is less well advanced than Al for radiology.

AI may also have uses in colonoscopy both by aiding detection of polyps and in predicting the risk of malignancy. However, these applications need further evaluation.