NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Diagnostic services: organisation and delivery

Topic

The Department of Health in England and NHS England has asked NICE to develop service guidance on the organisation and delivery of diagnostic services.

For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the context section.

Who the guideline is for

- Healthcare professionals in primary, secondary and tertiary care who access, use or refer for diagnostics.
- Commissioners of diagnostic services.
- Secondary and tertiary care providers of diagnostic services.
- All settings in which NHS care is provided or commissioned.

It may also be relevant for:

- Private sector or voluntary organisations (for example community trusts) commissioned to provide services for the NHS.
- People using services, families and carers and the public.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to access to diagnostic service provision, for example for people living in remote geographical locations, people with physical and mental disabilities, non-English speaking populations and people from disadvantaged socioeconomic backgrounds.

1 What the guideline is about

A diagnostic service is a service that undertakes or provides diagnostic tests. These are procedures or measurements performed to confirm, or determine the presence or absence of, disease or abnormality or severity or progression of disease. Diagnostic tests are usually done after a person reports symptoms, or they can be based on the results of other medical tests, or carried out for people with risk factors for specific conditions. Such tests fall under the disciplines of imaging, pathology (including genetics, genomics and molecular testing), endoscopy and physiology.

1.1 Who is the focus?

Groups that will be covered

- People needing diagnostic tests.
- Staff who refer for, carry out, receive and/or interpret the results of diagnostic tests.
- No specific subgroups of people have been identified as needing specific consideration.

1.2 Settings

Settings that will be covered

- All settings in which NHS care is commissioned or provided including:

- primary care
- secondary care
- tertiary care
- the community (including in people's homes).

1.3 Activities, services or aspects of care

CommunicationbKey areas that will be covered

1 How services are delivered.
2 Where services are delivered.
3 Access to, and communication between services.
4 Information and support needs of people using services, their families and carers.

Areas that will not be covered

1 Which test to use to diagnose clinical conditions.
2 Subsequent changes in management following results of diagnostic tests.
3 Which screening services should be provided.
4 History taking or physical examination that is carried out in the course of the clinical consultation.

1.4 Economic aspects

We will take cost and efficiency as well as other economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective, as appropriate.

The preferred unit of effectiveness is the quality-adjusted life year (QALY). Further detail on the methods, including where NICE's standard health economic approaches may not apply, can be found in the interim methods

guide for developing service guidance and the manual on developing NICE guidelines.

1.5 Key issues

While writing this scope, we have identified the following key issues:

1 How services should be configured to improve i) cost efficiency, ii) accuracy, and iii) access. Service configuration will cover:

1.1 Where services are delivered, (e.g. location for services including centralisation, diagnostic and clinical adjacencies). The aspects to be examined include:

1.1.1 Booking systems

1.1.2 Timeliness (including availability of services)

1.1.3 Decision support systems

1.1.4 Specialist advice

1.1.5 Multidisciplinary communication

1.1.6 Standardisation of communication

1.1.7 Models of reporting

1.1.8 Information and support needs of people using diagnostic services, their families and carers.

Please see section 5 for example review questions.

1.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence:

1 Use of healthcare resources (such as; costs of repeated testing, costs of unnecessary tests, etc)

2 Cost and efficiency measures

3 Accuracy
4 Patient and carer views and satisfaction
5 Staff satisfaction among providers of diagnostic services.

2 Links with other NICE guidance, NICE quality standards, and NICE Pathways

2.1 NICE guidance

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to diagnostic services:

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136

NICE guidance in development that is closely related to this guideline

NICE is currently developing the following guidance that is closely related to this guideline:

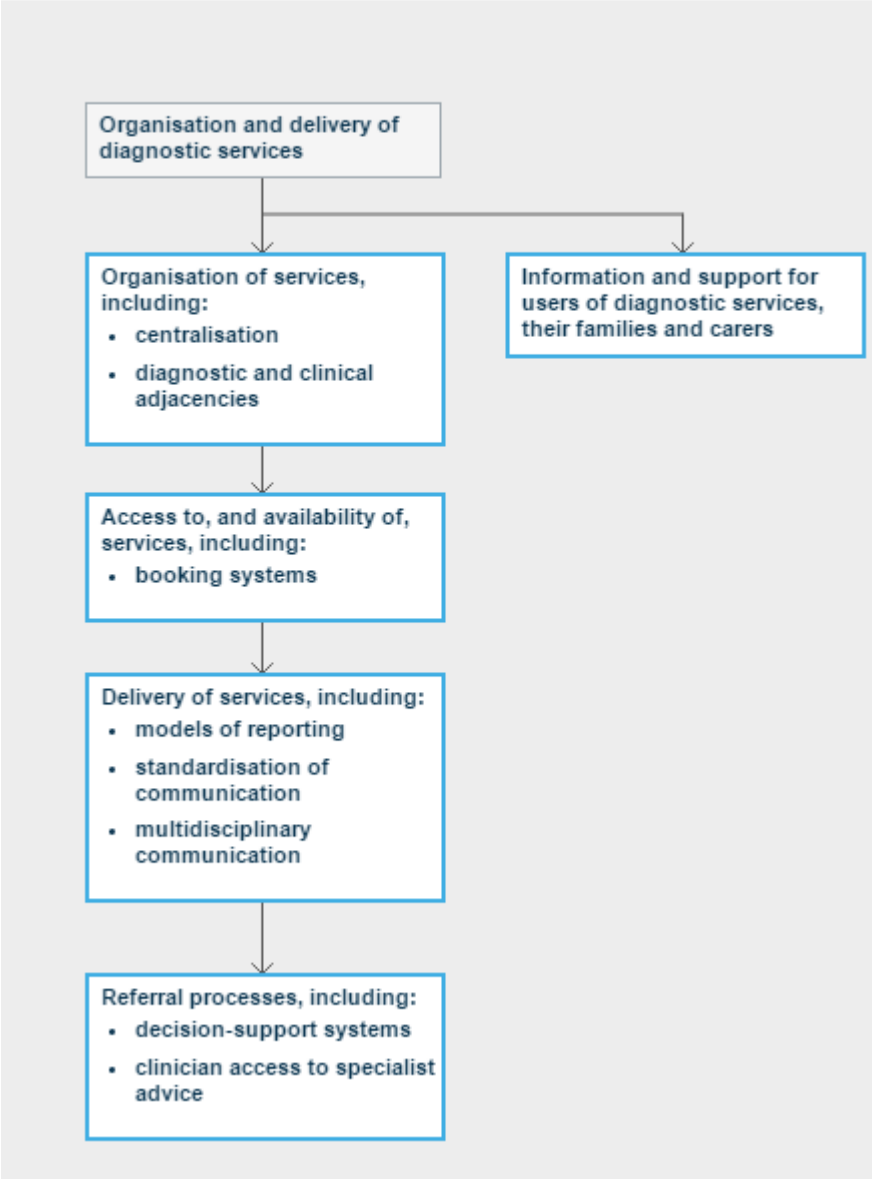
Service delivery and organisation for acute medical emergencies. NICE guideline. Publication expected November 2016.

2.2 NICE Pathways

NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

When this guideline is published, the recommendations will be added to a new NICE pathway. An outline of this pathway, based on the scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development.

Diagnostic services overview



3 Context

3.1 Key facts and figures

The demand for diagnostic services is increasing due to increased life expectancy, previously unrecognised unmet need, undiagnosed populations, newly introduced preventive strategies and advances in technology. According to NHS diagnostic waiting times and activity data (NHS England, May 2015), a total of 19 million 'key diagnostic tests' were undertaken in the

whole of 2014/15. This is a 5.9% increase from 2013/14. The above report also shows that monthly activity (the number of diagnostic tests undertaken during the month) increased over the 12 months prior to publication in March 2015, with an average monthly increase 0.7%.

The NHS Atlas of Variation in Diagnostic Services (November 2013) highlights significant variation in the quality and provision of diagnostic services across England. Unwarranted variation (that is, variation that is not explained by genuine differences in clinical need) is a significant concern, but in many cases is not currently understood. Unwarranted variation means that a patient's ability to access diagnostic services, and their ultimate health outcomes, could be affected by their postcode.

Waiting and reporting times are key issues for diagnostic services. The timeliness of diagnostic services is one of the most significant aspects of providing a quality service, but this must be considered alongside the quality of the result, and the interpretation and reporting of results to the referring clinician. The 2013/14 NHS Constitution pledges that patients should not be required to wait 6 weeks or longer for a diagnostic test. This is part of the legal right to treatment within 18 weeks of referral. NHS trusts face a financial penalty for non-delivery of this standard. For some conditions such as suspected cancer, there are additional waiting time targets such as the 'two week pathway' (the waiting time from initial GP referral to being seen by a specialist).

According to NHS diagnostic waiting times and activity data, the total number of patients waiting 6 weeks or longer from referral for one of 15 key diagnostic tests to be undertaken was 13,000 (at the end of March 2015). This was 1.5% of the total number of patients waiting at the end of the month. The estimated average (median) time that a patient had been waiting for a diagnostic test was 2.0 weeks at the end of March 2015. In the past 12 months (April 2014 to March 2015) the total number of patients waiting for a diagnostic test has continued to increase with an average monthly increase of 0.5%.

The move towards a 7-day NHS may have an impact on the provision of diagnostic services, which underpin clinical decision-making. Challenges and improvements in diagnostic services across seven days (NHS Improving Quality) identifies variation in the availability of diagnostic services outside normal working hours, which it is claimed can lead to delayed diagnosis, poorer clinical outcomes and poorer patient experience.

3.2 Current practice

There is inconsistency in how diagnostics services are accessed. Some services can be accessed directly from primary care and others only by a secondary care referral. Access by secondary care referral can increase patient waiting times because the patient has to first wait to be seen in the secondary clinic, then wait for the diagnostics tests. Conversely, access from primary care for complex modalities has the potential to increase unnecessary referrals that would not be requested by a specialist secondary care clinician.

Some diagnostic tests are available at the point of care, whereas others require the involvement of laboratories, highly trained staff and highly specialised equipment. Factors such as the portability of equipment mean that an increasing variety of tests can be provided in the community.

Some diagnostic services are provided locally, whereas others are centralised in large hubs (or are in the process of being centralised). Some services are co-located with the relevant clinical specialty, even though the service may provide investigations for a broader range of specialties.

The number of tests passing through diagnostic services may be higher if they are also used for population-based screening, and tests relating to the ongoing management of chronic disease.

Some populations find it more difficult to access diagnostic services. These include older people, people with multiple comorbidities or chronic conditions who may need their condition to be monitored frequently, people who live in remote geographical locations, people in travelling communities and others of no fixed abode, such as homeless people.

Having diagnostic services in a variety of geographical locations may mean that patients need to travel significant distances between sites. This could result in costly transport, as well as time off work and school for families or carers. Patients may also need to attend several different units for tests if these are not co-located or provided as a 'one-stop shop'.

3.3 Policy, legislation, regulation and commissioning

Policy

The availability of safe effective services over 7 days a week is a current NHS priority. Delivery of diagnostic services is central to any service transformation. Ensuring high quality care for all and managing an increasing demand for services requires innovative transformation in the delivery of services as discussed in NHS England's framework for planning for people.

Relevant published policy documents include:

- Equality for all – delivering safe care seven days a week – case studies (NHS Improvement Quality)
- NHS services – open seven days a week: every day counts (NHS Improvement Quality)
- NHS services, seven days a week forum
- Everyone counts: planning for patients 2014/15 to 2018/19 (NHS England)
- Challenges and improvements in diagnostic services across seven days (NHS Improvement Quality).

The UK Strategy for Rare Diseases places great emphasis on the importance of diagnosis: https://www.gov.uk/government/publications/rare-diseases-strategy

The Genomic Laboratory Service re-design is currently ongoing: https://www.engage.england.nhs.uk/consultation/genomic-laboratories

Legislation, regulation and guidance

Best practice guidance is produced by the medical Royal Colleges and other professional bodies.

The National Screening Committee produces recommendations on screening programmes across the UK.

State registration with the Health and Care Professions Council is a requirement for some professions involved in providing diagnostic services, for example biomedical scientists, clinical scientists and radiographers.

Accreditation schemes exist for most diagnostic disciplines (imaging, pathology and genetic testing, endoscopy and physiological services) and there are also internal and external quality assurance schemes in existence.

Regulations are in place for:

- Imaging - including IR(ME)R 2000, IR(ME) Amendment Regulations 2006, IR(ME) Amendment Regulations 2011, The Ionising Radiations Regulations 1999 (IRR'99)
- Pathology and genetic testing - including The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004, The Good Laboratory Practice Regulations 1999, The Good Laboratory Practice Regulations 1997, UK Standards for Microbiology Investigations (SMI): quality and consistency in clinical laboratories (2014)

Commissioning

Commissioning of diagnostic services is recognised as a particular challenge, particularly ensuring that the services delivered are of high quality, effective and timely to support all clinical pathways. Clarity and harmonisation of practice across the NHS is needed to address variation in practice and diagnostic testing rates. Information has been produced by NHS improvement with a view to aiding commissioners and service providers in meeting the commissioning challenge:

- Top tips to overcome the challenge of commissioning diagnostic services
- Directory of diagnostic services for commissioning organisations.

4 Further information

This is the final scope.

The guideline is expected to be published in November 2017.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.

5 Draft review questions

The following questions have been drafted in relation to the key issues. These will form the basis of more detailed review questions developed with the help of the guideline committee to guide the systematic review of the literature. We are aware that most of the key issues are strongly linked, and therefore some of the questions may overlap between areas (such as where services are delivered and communication between services).

1 What model of access to diagnostic tests improves outcomes?

2 What is the best arrangement of diagnostic services to most efficiently take, analyse and report diagnostic tests?

3 Does co-location of diagnostic services improve outcomes?

4 Does co-location of diagnostic services with clinical/therapeutic management services improve outcomes?

5 Do decision-support systems prior to referral improve outcomes?

6 What method of arranging appointments improves outcomes?

7 Does clinician access to specialist advice prior to referral and following results improve outcomes?

8 What model of multi-disciplinary communication improves outcomes?

9 Does standardisation of test requests and reporting improve outcomes?

10 What models of reporting improve outcomes?

11 What information and support do people using diagnostic services and their families and carers want (before the test and following reporting of the results)?