Diagnostic Services

Consultation on draft scope
Stakeholder comments table
05/10/2015-02/11/2015

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Alere	General	General	Diagnostic Services covers a large and diverse topic that impacts primary and secondary care and the quality of the service provided to the patient. In light of health policy move towards more community based diagnostic testing it may be appropriate to consider a separate guideline that specifically covers the diagnostic services of near-patient diagnostics and self-testing in the community.	Thank you for your comment. We agree it is a large and diverse topic, however, the intention is that this guideline will cover all settings including testing in the community.
Alere	3	50	Alere welcomes the production of NICE guidance on Diagnostic Services. We suggest that the key areas that will be covered need to be aligned where there is a likely shift in health policy, such as the drive to move towards more community-based diagnostic testing. The scope should 'future proof' the guideline in the light of the shift to the delivery of more services in the community.	Thank you for your comment. Location of services (has been identified as a key issue in the scope and will be covered in the guideline.
Alere	3	64 , 65	The draft scope currently excludes ambulatory monitoring of on-going therapies in the home as well as face to face tests that are carried out in the course of a clinical examination. This is inconsistent with high priority policy drivers e.g. the increased move towards self-management of individuals especially with long term conditions; the threat of Antimicrobial resistance (AMR) and secondary prevention will drive increased near patient diagnostics and self-testing. Examples include CRP point of care tests (CRP POCT) BNP, ultrasound, HbA1C and INR. Failure to organise and deliver these diagnostics in a systematic way could lead to varying clinical and patient outcomes, leading to further health inequalities.	Thank you for your comment. The intention of excluding 'ambulatory monitoring of on-going therapies in the home' was to cover those tests that patients can purchase over the counter (non NHS delivered service). The intention of excluding face-to-face tests was to exclude those undertaken in the course of routine clinical examination. We have amended section 1.3 'areas that will not be covered' to clarify this.
Alere	3	65	The draft scope currently excludes 'face to face tests that are	Thank you for your comment. Point of care testing is

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			carried out in the course of the clinical examination.' We feel this should be included because of the large number of point of care tests (POCT) in the community used by GPs, nurses, healthcare assistants and pharmacists. Many POCT are used near patient in the course of clinical examination. Examples of these include CRP, BNP, ultrasound, HbA1C, lipids, INR and HIV. A number of these are recommended in NICE guidance (eg. Pneumonia CG 191). It is important that guidelines are available to ensure consistency of service delivery for the near-patient tests.	included in the scope. We have amended section 1.3 'areas that will not be covered' to clarify this.
Alere	4	93 ,96,99, 101	It is unclear how the utility of POCT to improve patient outcomes in the community or in an out of hours service, can be evaluated without considering the specific clinical condition.	Thank you for your comment. It is beyond the scope of the guideline to focus on specific conditions, however, if subgroups require specific considerations for particular reviews, these will be discussed and agreed by the guideline committee when refining the protocols.
Alere	5	115	Not all patient results are needed in the same timeframe. An example is CRP where the result is needed at the point of consultation which could be primary care or out-of-hours clinic, (as per NICE Pneumonia CG 191), whereas other tests are less urgent, but can offer significant cost savings regarding clinical outcomes and patient convenience if delivered in the community (eg. BNP). Therefore urgency of the result needs to be considered according to the context in which the test has been ordered.	Thank you for your comment. It is beyond the scope of the guideline to focus on specific conditions, however, if subgroups require specific considerations for particular reviews, these will be discussed and agreed by the guideline committee when refining the protocols.
Alere	5	120	We suggest that the quality of reporting of results to patients by a Healthcare professional (HCP) should include guidance in the appropriate person feeding back on results to patients.	Thank you for your comment. Standardisation of communication and models of reporting have been identified as key areas within the scope. Details of the review questions will be refined by the guideline

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				committee when agreeing the protocols.
Alere	5	122	Appropriate use of healthcare resources should include number of visits to a GP (blood draw for test, return to get results etc) and the impact on cost and time. Cost analysis should include the appointments missed when patients have to attend for multiple visits such as phlebotomy followed by test results delivered at a subsequent visit and who do not attend (DNA) and miss an appointment.	Thank you for your comment. The impact on costs and resources of different service configurations will be included when assessing cost-effectiveness.
Barnsley Hospital NFT	General	General	Earlier access to diagnostics both via secondary and primary care with increased efficiency and report turnaround times across all of the modalities and more services delivered in the community where possible would certainly be desirable aspirations and ones which would benefit patients. However, the impact these recommendations will have on radiology departments will be felt throughout the UK as we are suffering from a chronic shortage of radiologists with many departments functioning routinely with locums and outsourcing of studies including on call work. This will inevitably deteriorate as the pressure put on departments is increasing year on year with little increase in training numbers and steady flow of radiologists out of the UK and also into retirement. NICE needs to recognise this as a problem as the clinical guidelines will inevitably place further pressure on departments and cost demands to trusts. I would hope that alongside the recommendations NICE would ask us to aspire to there will also be acknowledgement of the chronic shortfall in radiology capacity across the UK in terms of consultant staff, how this will affect integration of guidelines into under resourced departments	Thank you for your comment. How costs and resources will be impacted by the interventions being addressed is always considered when making recommendations for NICE guidelines. The cost impact of any potentially competing service alternatives will be considered as well as the cost effectiveness. And where there is anticipated to be a large cost impact from a recommendation, there will need to be strong evidence on cost effectiveness for this recommendation to be made. NICE's methods of appraising evidence and particularly work around cost effectiveness and resource impact/implementation help commissioners by providing them with information to be able to put forward a business case for commissioning the interventions/services recommended in NICE guidelines. As this is a guideline on service delivery, rather than a clinical guideline, the impact on staffing as a resource from different service configurations will be taken into account.

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			and assist in applying more pressure on what plans there are to address this within the national health service. Without addressing capacity the recommendations may well unwittingly adversely affect many departments and trusts. My greatest fear is that this shortfall in staffing across the UK will go unrecognised as it has done in previous NICE guidance which affects the imaging community.	
BNMS	4	90	Providers who are ISAS accredited (or other relevant standard for imaging recognised by NICE) and have ongoing audit and monitoring against the standards and plans in place for continual improvement. Providers who participate in NHS benchmarking and comply with any relevant guidance on workforce qualifications and staffing ratios. Providers who have clear benchmarked (nationally accepted standards) with (key performance indicators) for equipment quality control. Providers who have clearly defined benchmarked standards, audit and continual improvement plans for image optimisation as agreed by their Medical Physics Expert (MPE) and aligned to national benchmarking (diagnostic reference levels DRL) for acceptable radiation dose to patients from Radiology and Nuclear Medicine. Providers of Nuclear medicine services (including PET-CT services) who provide access during service operation for patient specific queries to the ARSAC holder for the service and access during service operation to their appointed MPE for	Thank you for your comment. This section lists key questions identified for further exploration. The guideline committee will work together to refine the questions and review the available published information in order to provide evidence-based recommendations on these areas.

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			patient dose and image optimisation queries and to ensure all potential incidents of "doses much greater than intended" are investigated and advice sought from the RPA if required and reported when required to the relevant organisation (CQC/Monitor) under the current legislation	
British Society for Antimicrobial Chemotherapy (BSAC)	General	General	Members of The British Society for Antimicrobial Chemotherapy (BSAC) have no comments for this **draft scope consultation – Diagnostic services.**	Thank you for your comment.
British Society of Gastroenterology	General	General	"The BSG recognises the variation in access to diagnostic services and the quality of services across the UK. The BSG have been proactive in leading quality improvement in diagnostic services and setting standards within gastroenterology and hepatology. Examples of this include the publication of peer reviewed clinical guidelines, the accreditation of endoscopic services in partnership with the Joint Advisory Group in Gastrointestinal Endoscopy, and the potential future accreditation of hepatology services via Liver Quest. We welcome NICE's interest in this important area, and the areas that are listed in the scoping document seem to adequately cover this large topic. Whilst one key consideration in the guidance is equality it is important that any barriers to access to diagnostic services outside of the traditionally commissioned	Thank you for your comment. We agree that access to services is important and it has been included as a key area within the scope, alongside considering different models of service delivery.

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			services such as primary care are addressed."	
British Thoracic Society	4	84 -85	Whilst multidisciplinary teams are useful to discuss results and plan care for patients such teams do not necessarily have the skill set to report detailed investigations e.g. an EEG in someone who may be being considered for surgery for a brain tumour. Clinicians in outpatients and on the wards will need results promptly and they cannot wait for MDT's. Results should be reported but then discussed, along with all the other results in an MDT. This does raise an issue about the availability of diagnostics being done off site. If biopsies are taken at a different hospital then MDT's need to see the actual tissue slides to discuss them. Similar information is required for imaging to prevent duplication.	Thank you for your comment. We believe that issues such as this will be captured in the questions that the guideline committee will develop around the topic of location of services as well as access to and communication between services. These sections are intended to capture communication between multiple people within one discipline or between multiple disciplines over multiple locations.
British Thoracic Society	4	86 -88	Co-location of services is important as in a "one-stop shop" to fast track patients through the system. Of course such carve out of diagnostics may mean other areas are inefficient because of the carve out. Again this is appropriate for selected clinical conditions and clinical pathways and diagnostics need to be considered as part of a pathway of care which can be planned for some conditions.	Thank you for your comment and this useful information.
British Thoracic Society	4	90	The indicators for a diagnostic service will depend whether this is life sciences, physiological measurement, imaging etc. Clearly an accurate diagnosis needs to be achieved using an appropriate diagnostic test which is reliable, reproducible with a prompt available report. It does not necessarily matter where you should deliver the services provided they fulfil set criteria and of course are accredited to ensure standards e.g. JAG.	Thank you for your comment. This section lists key questions identified for further exploration. The guideline committee will work to refine the questions and review the available published evidence in order to provide evidence-based recommendations. This guideline will be a broad overview of diagnostic

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				services as a whole, and will cover all of the diagnostic disciplines.
British Thoracic Society	4	93 -95	It is again difficult to be specific about where tests should be done as this will depend both on the disease and the nature of the test and the setting in which it can be performed. Irrespective, quality control of the result needs to take place. Point of care testing for example of anticoagulation in a nursing home may mean patients do not need to travel to hospital for an anticoagulant outpatient appointment. In contrast detailed imaging could not be provided readily and in a cost effective way in a nursing home. Unfortunately the question here is really too general.	Thank you for your comment. We believe there are considerations that are cross-cutting across conditions irrespective of the test that is used. If specific subgroups are thought to require separate considerations, these will be defined when the guideline committee agree the protocol for the review question.
British Thoracic Society	4	99	Whist it is difficult to formally document and confirm this, intuitively prompt results will allow changes in management which will hopefully improve patient outcome and reduce length of stay and therefore is beneficial from an organisational point of view. It is clear if someone has to wait a month for an imaging investigation then the disease may progress during this period.	Thank you for your comment. This section lists key questions identified for further exploration. The guideline committee will work together to refine the questions and review the available published information in order to provide an evidence-based recommendation.
British Thoracic Society	4	101 -102	Out of hours diagnostic services are likely to improve outcomes for people admitted acutely unwell though of course there needs to be the senior member of medical / nursing staff to interpret the result when it is available and act upon it. For example there is not much point doing a CT scan in the middle of the night of someone's chest if no one will take heed of the results. Again tailing the diagnostic test to the change in management and the timeliness needs to be factored in.	Thank you for your comment. We agree this is important to consider. The guideline will consider different models of service delivery. However, it is beyond the scope of this guideline to look at specific diagnostic tests or change in management after diagnosis.

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British Thoracic Society	4	104 -105	The referral pathway for services is important as people need to be on the "correct pathway" as this does speed up the management. This has been identified clearly in cancer services where a rapid progress through the diagnostic tests, perhaps in a protocoled way will facilitate an early diagnosis and earlier management.	Thank you for your comment. This section lists key questions identified for further exploration. The guideline committee will work to refine the questions and review the available published evidence in order to provide an evidence-based recommendation for how services are accessed.
Cancer Research UK	General	General	We welcome the introduction of a guideline on diagnostics, and look forward to the consultation. The importance of diagnostics to better cancer outcomes cannot be understated – as the earlier a person's cancer is diagnosed, the better their outcomes.	Thank you for your comment.
Cancer Research UK	general	general	The draft scope does not mention the introduction of innovative methods of service delivery. We feel that the introduction and promulgation of new models are important to ensure innovation and progress within diagnostics. The 'Accelerate, Coordinate and Evaluate (ACE)' programme is just one example where piloting innovation and service improvement could then be utilised and shared. (More information available here: http://www.cancerresearchuk.org/health-professional/early-diagnosis-activities/ace-programme)	Thank you for your comment and information. The guideline will cover different modalities of service delivery, including innovative methods where evidence is available.
Cancer Research UK	general	general	As diagnostic services are used by a very broad range of patients, it is important that conditions (such as cancer), where early diagnosis has a significant impact on mortality are given due weight.	Thank you for your comment. This guideline will not focus on condition or disease specific issues but instead the organisation of diagnostic services across the NHS. There may be specific questions where disease specific examples are provided at a high level, but this is to be discussed by the guideline committee when agreeing the protocols for each review question.

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Cancer Research UK	4	89	There is no mention about workforce in this document, including who is able to deliver services and safe staffing levels. Recent reports from Cancer Research UK, including 'Scoping the Future' and 'Horizon Scanning' have noted that the most significant barrier to delivering endoscopy and imaging diagnostics is workforce issues. (Both reports are available here: http://www.cancerresearchuk.org/about-us/we-develop-policy/our-policy-on-early-diagnosis/our-policy-on-gp-access-to-diagnostics)	Thank you for your comment and useful information. Costs and resources needed to deliver a service such as staff will be considered when assessing the cost-effectiveness of a service.
Cancer Research UK	4	92	There are several potential models of diagnostic service delivery which are not mentioned here, including patient self-referral, and nurse-triage 'straight to test'. We feel it could be made clear that all potential models of delivery should be included, to see what models and pathways may improve patient outcomes. This should also think about less common pathways, including referral to diagnostics from different parts of primary care (such as pharmacists or dentists).	Thank you for your comment. These service models are not excluded from the scope and comparison between models will be within the scope and considered by the guideline committee when agreeing protocols.
Cancer Research UK	4	103	It would be especially important to consider communication between primary and secondary care, as well as reporting between services - as noted in the Independent Cancer Taskforce report*, GPs need better access to specialist advice when making difficult referral decisions. (*'Achieving World-Class Cancer Outcomes: a strategy for England 2015 – 2020', 2015, Independent Cancer Taskforce – available here: http://www.cancerresearchuk.org/about-us/cancer-taskforce)	Thank you for your comment. We agree that communication between primary and secondary services is an important issue. This will be addressed within the guideline within the key areas listed in the scope of standardisation of r=communication and models of reporting.

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Cancer Research UK	4	86	Acknowledging that access to services varies is important, and may differ depending on the condition a patient has. The diagnostic services guidelines may also need to consider if an individual has several long term conditions or co-morbidities.	Thank you for your comment and for highlighting this. This guideline will cover diagnostic services across conditions and will not focus on condition specific issues. These may be covered within topic specific guidance.
Cancer Research UK	4	96	There could be some further refinement or clarification to ensure that 'point of care testing' is clearly understood. For example, should this include 'direct access' to tests from primary care? This may be understood differently from 'point of care' testing.	Thank you for your comment. The specific definition of what is included within this review question will be defined by the guideline committee when refining the protocol.
Cancer Research UK	5	127	There is no mention of NICE referral guidelines for suspected cancer [NG12], which have many links to diagnostics and may be worth mentioning as related. Quality standards for these guidelines are also currently in development.	Thank you for your comment. We will include NICE guideline 12, suspected cancer: recognition and referral to the list of related NICE guidance in the full guideline following development.
Cancer Research UK	5	115	Clinical outcomes including mortality are not mentioned as a main outcome, and this may be significant, especially when considering conditions such as cancer where timely diagnosis is crucial.	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed. This will include appropriate consideration of clinical outcomes; however, the focus of this guideline is delivery of services so the key outcomes are those related to quality and efficiency of the service.
Cancer Research UK	5	110	The draft scope currently flags information and support needs for people using diagnostic services. We feel this should be extended, so that people are more actively engaged (rather than just receiving information and support). This should also include	Thank you for your comment. The specific details of this review question will be agreed by the guideline committee and these factors will be taken into account when further detail is considered for this question.

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			consideration of how to ensure that consenting patients have their ability to access their test results (and other communications) online, as recommended by the Independent Cancer Taskforce.	
Cancer Research UK	7	150	The importance of diagnostic services for surveillance (when someone has a diagnosis but may need monitoring to check the progression of the disease) should be emphasised.	Thank you for your comment. All diagnostic services used at any stage in a patient pathway are within the scope for this guideline, however, we do not believe that surveillance requires specific emphasis.
Cancer Research UK	7	173	There are specific cancer waiting times for diagnosis which would be worth including here. The timeliness of diagnostic services is one of the most significant aspects of providing a quality service, and this must include the reporting of results to the referring clinician.	Thank you for this information, we have added detail as suggested.
Education for Health	General		We welcome this guideline but feel strongly that diagnostic quality assured spirometry should be included in the scope/ (Asthma diagnosis and monitoring – in progress NICE and draft COPD QS)	Thank you for your comment. This guideline will be an overview of diagnostic services as a whole, and will cover all of the diagnostic disciplines. While it is outside the scope of this guideline to provide guidance on individual tests for specific conditions, spirometry falls within physiological measurement and delivery of such services in general will be covered. As you have mentioned, topic specific clinical guidelines may cover guidance for individual diagnostic tests.
Education for Health	General		Diagnostic quality-assured spirometry is the recommended objective test performed to identify abnormalities in lung volumes and air flow1 It is the standardised measurement of a forced expiration (FE) into a calibrated measuring device or spirometer. In conjunction with physical assessment, history-taking, blood tests and X-rays,	Thank you for this information. As stated in the response to comment 168, it is beyond the remit of this guideline to make recommendations for specific diagnostic tools.

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			spirometry is used to exclude or confirm particular types of lung disease, including COPD. 1. National Institute for Health and Clinical Excellence. Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). 2010. www.nice.org.uk/CG101	
Education for Health	General		In the UK most of the management and diagnosis of people with COPD is provided in primary care sector. Unfortunately, spirometry is often performed inaccurately and consequently Most COPD is undiagnosed: around 835,000 people have been diagnosed in England, while 2.2 million people are living with COPD but do not know they have the condition. Over half those with moderate and severe disease and the vast majority of those with mild disease are undiagnosed. 2 Failure to diagnose matters because decline in lung function is faster in the earlier stages of COPD and undiagnosed patients do not receive the treatment that we know makes a big difference to outcomes. At the same time evidence suggests that around a quarter of people on general practice COPD registers do not meet the diagnostic criteria for COPD. This level of mis-diagnosis occurs because much of the spirometry currently performed fails to meet the essential quality standards 2 Department of Health (2011) An outcomes strategy for people with chronic obstructive pulmonary disease (COPD) and Asthma in England. http://www.dh.gov.uk/en/Publicationsandstatistics/ Publications/PublicationsPolicyAndGuidance/ DH_127974	Thank you for this information. This guideline will focus on the quality and efficiency of diagnostic services rather than addressing specific details of how to perform diagnostic tests for named conditions which will fall under the topic specific guidance for diagnosis of that condition.

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Education for Health	General		This occurs because diagnostic spirometry is often performed or interpreted incorrectly and fails to meet essential quality standards. Misdiagnosis matters because it results in people receiving inappropriate, expensive and potentially harmful therapies. It is therefore vital that all performing and interpreting spirometry should be competent in doing so, regardless of their professional qualification or experience	Thank you for your comment. As per the response to comment 170, it is beyond the remit of this guideline to make recommendations for specific diagnostic tests, however, the quality and efficiency of delivery diagnostic services will be covered.
Education for Health	General		Spirometry is one of the essential lung function investigations in the diagnosis, severity assessment and monitoring of a number of respiratory conditions. It may appear to be relatively simple to perform however, it relies on both the effort of the patient (or the person who is undergoing testing) and the technical skill of the operator to provide accurate and reproducible results for interpretation in combination with other clinical and technical information.	Thank you for your comment. As per the response to comment 170, it is beyond the remit of this guideline to make recommendations for specific diagnostic tests, however, the quality and efficiency of delivery of diagnostic services will be covered.
Education for Health	General		Although the investigation is now used widely, particularly in primary care, misdiagnosis is common so it is therefore vital that all performing and interpreting spirometry should be competent in doing so, regardless of their professional qualification or experience. 3. Primary Care Commissioning (2013) A Guide to Performing Quality Assured Diagnostic Spirometry.http://cdn.pcccic.org.uk/sites/default/files/articles/attachments/spirometry_e-guide_1-5-13_0.pdf	Thank you for your comment. As per the response to comment 170, it is beyond the remit of this guideline to make recommendations for specific diagnostic tests, however the quality and efficiency of delivery of diagnostic services will be covered.
Education for Health	Primary care		There are three distinct levels of competency required in performing and interpreting spirometry; (i) Competence at performing safe, accurate and reliable	Thank you for your comment. As per the response to comment 170, it is beyond the remit of this guideline to make recommendations for specific diagnostic tests,

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			spirometry. (ii) Competence of technically interpreting the results of spirometry in terms of physiological changes. (iii) Competence of interpreting the spirometry together with other clinical information to diagnose a respiratory disease. To ensure a valid diagnosis, quality diagnostic spirometry, in any clinical setting, should be quality-assured and only be performed by individuals who have been assessed to the standards established by the Association of Respiratory Technology and Physiology (ARTP) and the ARTP standards should be applied across the health system wherever the measurements are being made for quality and safety purposes. To assure quality the ARTP will maintain an up-to-date register of those practitioners who have been assessed as competent and who are "authorised" to perform and/or interpret spirometry. Registration will ensure that commissioners, employers of staff and individual practitioners are clear what the standards are and can verify which staff hold a current, assured qualification. Individuals undertaking diagnostic spirometry should be appropriately trained, assessed and certified by approved training organisations as being competent. (there are draft guidelines already developed: to be published) Spirometry measurement may be performed by a range of practitioners in the health system who are not necessarily qualified and regulated health care professionals, such as health care assistants. However, to maintain the quality of spirometry any practitioner performing spirometry should be able to demonstrate that they are trained and appropriately assessed as competent to perform the procedure and their details should be	however, the quality and efficiency of delivery of diagnostic services will be covered.

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			held on the central register. The interpretation of diagnostic spirometry should however, only be undertaken by a qualified and regulated health care professional or a clinical physiologist. The clinical diagnosis should be based not purely on the spirometry results but alongside a comprehensive clinical history and physical examination. It must be made by a qualified medical practitioner or an appropriately trained registered nurse or allied health care professional It is recognised that the performance and interpretation of diagnostic spirometry can be separate functions performed by different practitioners. For example in general practice, diagnostic spirometry may be performed by the nurse and interpreted by the GP. The responsibilities of each practitioner, and the process for acting on results, need to be clearly documented in a practice protocol.	
Education for Health	Primary care		In the NICE COPD Quality Standard it is recommended that diagnostic spirometry should be carried out on calibrated equipment by healthcare professionals competent in its performance and interpretation. 4 NICE (2011) Chronic obstructive pulmonary disease quality standard. http://www.nice.org.uk/guidance/qualitystandards/chronicobstructivepulmonarydisease/copdqualitystandard.jsp Primary care staff, not only frequently inadequately trained they frequently use poor-quality equipment.	Thank you for your comment. As per the response to comment 170, it is beyond the remit of this guideline to make recommendations for specific diagnostic tests, however, the quality and efficiency of delivery of diagnostic services will be covered.
Education for Health	General		To ensure that COPD is diagnosed and treated appropriately it is necessary to ensure that diagnostic spirometry in all local settings is only performed by professionals trained and certified	Thank you for your comment. As per the response to comment 170, it is beyond the remit of this guideline to make recommendations for specific diagnostic tests, however, the quality and efficiency of delivery of

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			as competent to Association for Respiratory Technology and Physiology (ARTP), or equivalent, standards. In addition, clinicians in primary care need to review the diagnosis of patients currently on the COPD register to identify those who may not have COPD	diagnostic services will be covered.
Genetic Alliance UK	**General**	General	Genetic Alliance UK is the national charity working to improve the lives of patients and families affected by all types of genetic conditions. We are an alliance of over 180 patient organisations. Our aim is to ensure that high quality services, information and support are provided to all who need them. We actively support research and innovation across the field of genetic medicine.	Thank you for your comments.
Genetic Alliance UK	2	41	Though these groups are certainly currently within scope of this guideline, it might be worth considering at least two subgroups: Those in the prenatal context: This subgroup has particular requirements with respect to speed of diagnosis; the diagnosis is not targeted at the patient; there is a special set of potential consequences following the delivery of results. Those with rare diseases: This subgroup will not be immediately visible at presentation, nevertheless they present a particular problem to the healthcare community, and it is one that has not been solved particularly well in the past. In a survey in 2010, Genetic Alliance UK found that more than a fifth of rare disease patients had to wait more than five years, and that the same proportion had more than five misdiagnoses on the way. (http://www.raredisease.org.uk/documents/RDUK-Family-	Thank you for your comment. The subgroups defined in the scope are those for whom separate recommendations are expected for all (or majority of) review questions. Specific subgroups per protocol will be discussed and agreed by the guideline committee when agreeing the review questions.

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			Report.pdf) A revisiting of this survey this year is underway, but is indicating that there has not been major progress over the past five years.	
Genetic Alliance UK	4	103	Suggested additional question: "Are there novel methods or tools that could prompt a more timely or more accurate diagnosis?"	Thank you for suggestion. Issues relating to accuracy of specific diagnostic tools are beyond the remit of this guidance. However, this guideline will look at different models of service delivery and their impact on quality and efficiency.
Genetic Alliance UK	5	115	Suggested additional main outcome "does the patient receive a conclusive diagnosis, or are further tests required?"	Thank you for your comment. The outcomes have been updated following consultation and now include costs of repeated testing and accuracy. Those listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed.
Genetic Alliance UK	9	219	Two additional suggested points for this section: The UK Strategy for Rare Diseases - https://www.gov.uk/government/publications/rare-diseases-strategy places great emphasis on the importance of diagnosis. The Genomic Laboratory Service Re-design is currently ongoing - https://www.engage.england.nhs.uk/consultation/genomic-laboratories	Thank you for this information. We have added these policy documents as suggested.
Genomic Health UK Ltd	7	152	The definition of diagnostic services included in the draft scope is restrictive in its focus ("to confirm, or determine the presence or absence of, disease or abnormality") and does not encompass diagnostic services designed to sub-classify patients following initial diagnosis, according to their severity of disease	Thank you for your comment. We have added a statement to state that severity or progression of disease may also be assessed.

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			(prognosis) or response to treatment (prediction). The Onco*type* DX® breast cancer test is an example of a diagnostic service designed to provide prognostic and predictive information following initial diagnosis and is recommended by NICE in the DG10 guidance. I would recommend that the definition should be broadened to the inclusion of prognostic and predictive diagnostic services. Such tests offer important value to patients, physicians and the healthcare payer, as they have the potential to improve patient outcomes, patient quality of life and safety, as well as efficient use of healthcare resources.	
Hywel Dda University Health Board	8	195	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	Thank you for your comment. We recognise that access to services is an issue and have included this as a key area that will be covered.
Institute of Biomedical Science	General	General	There is no reference to IT connectivity – interfacing direct recording of all results/reports from any location into the electronic patient record	Thank you for your comment. We agree that reporting between services is important to consider within the guideline. This will be covered within the key areas of standardisation of communication and models of reporting. Details of the review question will be refined with the guideline committee.
Institute of Biomedical Science	1	20 - 21	Shouldn't Private sector or voluntary organisations commissioned to provide services to NHS be included in line 18?	Thank you for your comment. Any service commissioned by the NHS is covered within this guidance.

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Institute of Biomedical Science	2	39 - 40	The text implies that the staff providing the diagnostic service do not also provide interpretation of the results to the referring staff member	Thank you for your comment. We have amended the point to make it clearer that these roles are not exclusive.
Institute of Biomedical Science	3	68	Define what economic aspects will be taken into account	Thank you for your comment. This will be discussed with the guideline committee and areas for economic analysis prioritised during development. The outcomes used to measure the effectiveness and cost effectiveness of services will also be discussed with the guideline committee when setting the specific review questions.
Institute of Biomedical Science	3	75	How will QALY measurement of effectiveness of treatment or intervention be applied to Diagnostic tests which are either a prelude to identifying treatment or intervention or monitoring progress of treatment or intervention	Thank you for your comment. It is correct that the benefit of a diagnostic test comes from the treatment the test indicates. A change in diagnostic services that leads to earlier management/treatment is likely to have an impact on quality of life. However, we will not be focusing on management following diagnosis within the guideline. The impact of treatment is also likely to be condition specific, and this guideline has a broad focus. There may, however, be a quality of life impact from the diagnosis itself in terms of there being a value in the patient having this information and this could reduce anxiety. It may be difficult to differentiate the quality of life of the undiagnosed condition from the quality of life of the diagnosed condition (pre-treatment), A literature search will be undertaken to try and identify this information.

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				It will also be discussed with the guideline committee whether quality of life is an appropriate outcome for this non condition specific guideline. However, this will be discussed further with the guideline committee when the review questions are being set, and when modelling priorities are being discussed.
Institute of Biomedical Science	3	53	What are the criteria for approval to provide and deliver services?	Thank you for your suggestion, however, it is beyond the remit of this guideline to cover approval for services.
Institute of Biomedical Science	3	65	The document needs to clarify what constitutes a "face-to-face" test. What is the difference between this and "point of care" or "near patient testing"?	Thank you for your comment. Face-to-face testing was intended to mean the history taking and physical examinations undertaken in the course of the clinical consultation (for example, not using any specific diagnostic tests, tools or equipment). This section has now been updated to clarify this.
Institute of Biomedical Science	4	83	All services covered by scope need to be named	Thank you for your comment. We have amended to include a definition of the diagnostic disciplines that fall within the scope of this guidance in section 1.
Institute of Biomedical Science	4	95	What is the definition of "improving patient outcomes" and how will this be measured? A "normal" results is just as important as an "abnormal" result.	Thank you for your comment. The specific patient outcomes that will be considered will be agreed by the guideline committee as each protocol is discussed.

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Institute of Biomedical Science	4	99	No reference to "urgent" tests and results. Rules for Emergency Department patient waiting times 4 hours – therefore for example Pathology turns round urgent core tests in 30 minutes	Thank you for your comment. When refining the review question, the guideline committee will consider whether separate considerations are required based on urgency of results. The acute medical emergencies guideline is also currently being developed by NICE and will address some of these issues. More information is available at https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0734
Institute of Biomedical Science	4	101	Acute hospitals with Emergency Department and Intense Care cannot operate without 24/7 cover which already exists for many Pathology Diagnostic tests	Thank you for this information.
Institute of Biomedical Science	4	104	No reference to existing "open access"	Thank you for your comment. We have amended this review question to cover different models of access to diagnostic services.
Institute of Biomedical Science	5	116	No reference to the "Waiting time from reporting the results to the referring clinician reading/acting on"	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed.
Institute of Biomedical	8	193	There is a variety in the way services are accessed. It may be appropriate for specialists in the field to determine the most appropriate investigations.	Thank you for your comment. We agree this may be appropriate in some cases.

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Science				
Institute of Biomedical Science	8	199	There is no reference to highly trained specialist staff only equipment.	Thank you for your comment. We have amended this sentence to specify staff as well as equipment.
Institute of Biomedical Science	8	201	There is no clear definition or explanation of what constitutes a diagnostic test. It is not just a number or normal/abnormal. The reportable result is underpinned by knowledge, skills, training, competency and quality systems	Thank you for your comment. For the purpose of this guideline we feel the current definition of diagnostic tests is sufficient. Knowledge, skills, training, competency and quality systems are recognised as factors that impact on service quality.
Institute of Biomedical Science	8	179	Identify what are the 15 key diagnostic tests – this clearly would influence the focus of services covered by the guidance	Thank you for your comment. We will be covering all of the diagnostic disciplines within this guideline, which include the 15 key diagnostic tests referenced in the report and many others. Section 1 of the scope has been amended to clarify this.
Institute of Biomedical Science	10	246	What does the term "high value" mean?	Thank you for your comment. High value is intended to mean high quality so we have reworded the text to reflect this.
Institute of Biomedical Science	10	235	There is no reference to "State Registration" for professional staff to practice	Thank you for your comment. We have amended this section to reflect the requirements for state registration for practicing professionals.
Institute of Biomedic	10	235	There is no reference to internal and external quality assurance schemes	Thank you for your comment. We have amended this section to include a reference to internal and external quality assurance schemes.

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al Science				
Medtronic Limited]				
Medtronic Limited]	3 and 4	53 & 84-85	Continuous Remote Monitoring of Cardiac Monitors can be used for diagnostic purposes and have associated benefits highlighted below. An associated monitoring service providing analysis/decision support service to clinical teams may also be provided by manufacturers and 3rd party provider employing certified staff. In this multidisciplinary approach the patient is continuously followed-up remotely and doesn't need to travel to perform diagnostic tests to a specific healthcare facility. The results of the analysis define the urgency of reports which are sent according to priority to the clinical team in charge of the patient. More urgent results will be communicated more quickly in order to support decision making and quicker decisions by clinical staff as defined by the local service level agreement & clinical protocols.	Thank you for your comment. This guideline will be a broad overview of diagnostic services as a whole, and will cover all diagnostic disciplines While it is outside the scope of this guideline to provide guidance on individual tests for specific conditions, continuous remote monitoring of cardiac monitors falls within physiological measurement and delivery of such services in general will be covered.
Medtronic Limited]	4 and 5	98 -107	Remote Monitoring allows continuous (24/7) monitoring of the patient with timing for sending reports/alerts that can be customized by patient. Reports can be accessed online 24/7. The analysis/diagnosis/medical decision following a report depends on the organization of the medical team in charge of the patient. Decision support services could help the medical team to follow-up more efficiently monitored patients and react in a timelier manner.	Thank you for your comment. It is beyond the remit of this guideline to cover the subsequent medical management following a diagnosis, although reporting between services will be included within the guidance.
Medtronic Limited]	4 and 5	93 -95 & 119	Provision of a home monitoring system with a diagnostic implantable loop recorder compared to face to face hopsital follow up can significantly reduce the mean time to diagnosis by	Thank you for your comment and the information provided. This section lists key questions identified for further exploration. The guideline committee will work to

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			47% -78%, decrease unplanned visits and Emergency care in patients with unexplained syncope (Velu S, et al. Remote Monitoring of Implantable Loop Recorders Significantly Improves Diagnostic Outcomes. Europace. 2010; 14(supplement 4): iv22-iv27. Drak-Hernandez, et al. Effectiveness and Safety of Remote Monitoring of Patients With an Implantable Loop Recorder. Rev Esp Cardiol. 2013; 66(12):943-948.)	refine the questions and review the available published evidence in order to provide evidence-based recommendations.
Medtronic Limited]	4	101 -102	Using a Multidisciplinary approach involving a 3rd party service can provide out of hours diagnostic services	Thank you for this information.
Medtronic Limited]	5	108 -112	It is observed that clear upfront training and instructions on how to use technology at home and timely feedback (<24 hours) from the Care Provider on the receipt of information along the care pathway are both crucial for patients, families and carers in order to maintain good compliance and results. Based on feedback from 172 NHS Trusts in UK using the CareLink Network with over 35,000 Patients (Medtronic Data on File, August 2015)	Thank you for this information. This guideline will include the information and support that people using diagnostic services (and their families and carers) require.
Medtronic Limited]	5	120 & 123	A good reference of Patient Satisfaction and Quality of Life improvement in relation to Remote Monitoring can be seen in 2015 Heart Rhythm Society (HRS) Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Electronic Implantable Devices (http://www.hrsonline.org/Practice-Guidance/Clinical-Guidelines-Documents/Expert-Consensus-on-the-Monitoring-of-Cardiovascular-Implantable-Electronic-Devices/2015-Expert-Consensus-Statement-on-Remote-Interrogation-and-Monitoring-for-CIEDs#ixzz3pymrUmXA). Patients that use a home monitoring system have a favourable change in their health related quality of life (Landolina P, et al. Remote Monitoring Reduces Healthcare Use and Improves	Thank you for providing this useful information.

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			Quality of Care in Heart Failure Patients with Implantable Defibrillators: The EVOLVO Study. Circulation. 2012; 125: 2985-2992.) and high levels (92%-95%) of patient satisfaction (Petersen HH, et al. Patient Satisfaction and Suggestions for Improvement of Remote ICD Monitoring. Journal of Interventional Cardiac Electrophysiology. 2012; 34:317-324. Ricci R, et al. Long-Term Patient Acceptance of and Satisfaction with Implanted Device Remote Monitoring. Europace. 2010; 12: 674-679.)	
National Community Hearing Association (NCHA) and British Society of Hearing Aid Audiologists (BSHAA)	General	General (Summary)	**SUMMARY** The adult hearing service (audiology) includes hearing assessments which are classified as a physiological diagnostic service[i] and therefore fall under the scope of this guideline. We hope that the Committee working on this guideline will • find this evidence-based submission helpful and consider using adult hearing assessments as a clear example of a diagnostic service that should be delivered outside hospital, close-to-home in community-based facilities • take steps to ensure that the final guideline is not used to preserve an outdated hospital based model of care, where this is no longer justified on cost, access or outcome grounds. For example patient groups and the Department of Health	Thank you for your comments and helpful information. This guideline will cover diagnostic services across all disciplines. We would also like to highlight that NICE are also developing guidance on the assessment and management of hearing loss. Further information is available at the following website: https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0833 In respect to your specific comments, the evidence for each review question will be searched for and recommendations will be made based on the best available clinical and cost-effectiveness evidence. All recommendations including those for grouping of services will be based on evidence reviewed by the guideline committee. The outcomes for each review question will be defined by the guideline committee but will include patient related outcomes as well as service outcomes and cost-effectiveness.

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			have long supported calls to deliver diagnostics for adult hearing loss outside hospital[ii]. There is now a consensus that this can happen and that routine adult hearing assessments should be delivered in primary care settings[iii]. In 2015 Monitor added further evidence to support the case for change when it reported that where community-based hearing care has been commissioned, standards put in place are higher, prices lower by 20-25% per patient and access is improved – including for vulnerable groups[iv]. However there has also been longstanding and non-evidence-based opposition to this by entrenched hospital providers[v], this despite evidence that most hospital audiologists also agree that providing audiology closer to home benefits patients[vi]. The adult hearing service is, in our view, a good case study for why policy and evidence-based leadership is required alongside this guideline in order to tackle vested interests and ensure that optimal and cost-effective outcomes are achieved for all service users - i.e. that the final guideline is used to facilitate evidence-based change, not as a barrier against it. We therefore ask that the Committee consider the unintended consequences of making broad recommendations on diagnostics without service specificity and how this could impede rather than promote improvement. • ensure that particular care is taken when assessing the	

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			economic case for diagnostics because of the broad span of services involved. Any cost-effectiveness analysis (CEA) for diagnostics might therefore be very limited in terms of its usefulness, transferability and generalisability[1]. We would be happy to work with NICE on this guideline and to answer any questions linked to this submission. In particular we would be happy to meet NICE and discuss what lessons from audiology might be transferable to other areas of diagnostics in terms of cost-effectiveness and health quality management. ***Hearing loss and our recommendations*** Today, there are an estimated 3.8 million adults with undiagnosed hearing loss in England[vii]. The diagnostic service for adult hearing loss cannot be decoupled in a cost-effective way from the three-year patient pathway. Instead the NHS can diagnose more patients with hearing loss for any given budget by using the better value community-based three-year package of care, rather than non-mandated hospital activity based tariff (i.e. tackle undiagnosed hearing loss in a more cost-effective way)[viii].	

[1] At this stage it is not clear how analysts at NICE will control for multiple confounders – e.g. it is not clear how CEA will be useful given the broad scope of the guideline because variables such as where a diagnostic test takes place in the patient pathway can have an impact on patient outcomes and thus any ICER. Cost-benefit analysis on the other hand can be used to assess the cost per case diagnosed.

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			Despite the evidence showing that the vast majority of adults with hearing loss (90%) don't need to see a doctor, or attend ENT or hospital for their hearing loss[ix], hospitals continue to provide the vast majority of diagnostic tests for adults with hearing difficulties[x]. There is not only unacceptable variation in access to these diagnostic services[xi] but also variation in standards and prices[xii] and this, despite hospital audiology staff working beyond capacity, and feeling pressurised and overworked. We estimate that at least 450,000 adult hearing assessments - 1.8 and 2.3 million hospital contacts for audiology – each year should be commissioned out of hospital and delivered at lower cost in the community[xiii,xiv]. The evidence shows that this would reduce distance travelled (and hence travel costs) for service users (who are on average aged 70 and over)[xv], and save the NHS 20-25% per patient whilst improving standards and equity in access[xvi] - i.e. there is a clear economic and clinical case to transform hearing care. The longstanding resistance to moving diagnostic services for adult hearing out of hospital therefore needs to be challenged in an evidence-based way. Capacity in hospitals is scarce and comes at significant opportunity costs. In our view this is why NICE needs to consider adult hearing assessments alongside the entire adult hearing pathway and safeguard against general guidance on diagnostics which could be misused to frustrate much needed change in adult hearing care. It is based on the	

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			evidence provided in our submission that we provide the following overarching feedback: 1- *"What and how services are grouped together"* (line 51): We caution against non-evidenced based grouping, especially where this is done on the basis of provider convenience, system inertia, resistance to modernisation or to protect market share and revenue rather than improve patient outcomes and cost-effectiveness. There is a high risk that, unless NICE takes active steps to avoid this, non-evidence based grouping will continue to occur in audiology, as will the negative impact on patients (adults and children) which is well-documented. *2- "Where services are delivered" (line 54), "Who should provide and deliver services" (line 53) and "When services should be available" (line 55).* Diagnostics for hearing loss should be delivered in the community, and outside of hospital just as for GP, oral health and eye health diagnostics. We therefore invite NICE to ensure that patients and taxpayers are put first, and that providers are challenged if they make non-evidence based claims that shifting diagnostics into the community will harm other services – in audiology there is no evidence to support this. Based on NHS reference cost data, non-mandated hospital tariffs, community-based tariffs, available service	

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			specifications, Monitor's review of the adult hearing service, and the Department of Health and NHS England Action Plan on Hearing Loss, the consensus of evidence is that diagnostics for adults with hearing loss should be provided in the community and outside of hospital. Patient groups since the 1980s, the Department of Health since 2007, and the NHS most recently have all supported this aim[xvii]. The type of provider is not relevant. There is no credible evidence that any particular type of provider should or should not provide diagnostics for adult hearing loss. Rather an evidence and risk based approach favours community provision irrespective of provider (traditional NHS, ISP). Here we feel that lessons from hearing care will be transferable to other diagnostic services. It is helpful then that Monitor has reviewed the Department of Health's Any Qualified Provider (AQP) policy and shown that it is an efficient way to commission diagnostic services outside of hospital from the most suitable, qualified and accessible providers. Services should be available based on clinical need and/or patient preferences – in our view, as with eye care today, diagnostic services for hearing loss should be available close to home and when patients want to access them. In many cases people will demand access to hearing care at least six days a week. If NHS England and the Department of Health provide community providers with some assurance that NHS commissioners will make evidence-based	

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			decisions and fair playing field guidance will be enforced, then community-based providers will be able to invest in additional weekend and evening clinics without increasing the marginal cost per patient for the NHS.	
National Community Hearing Association (NCHA) and British Society of Hearing Aid Audiologists (BSHAA)	4	84 -85	Diagnostics services include, and are linked to, many disparate services and therefore in our view there are no universal principles that apply to all diagnostics. To conclude otherwise would be a false syllogism. We are concerned therefore that that the scope of the current guideline is too ambitious and there is a moderate to significant risk that it will end up confusing rather than helping the groups listed (lines 37-42 p.2). Nevertheless, in order to support NICE in this ambitious work programme, we focus our submission on audiology, which falls under physiological diagnostic services[xviii]. ***Physiological diagnostic services – audiology*** NICE refers to the NHS Atlas of Variation (line 166, page 7). Adult hearing assessments are reported in the Atlas of Variation[xix]. We agree with NICE that not all stakeholders understand the causes of variation in quality of diagnostic services (lines 166-173, page 7). However we also believe that few stakeholders have been able to take the time to explore possible causes of variation. We therefore caution against using current fashionable words like "multidisciplinary" and "integrated" when discussing adult hearing services. Instead we ask the Committee to consider the	Thank you for your comment. We acknowledge that it is a broad topic, although believe that there are principles of the organisation and delivery of diagnostic services that are cross-cutting. Thank you for the additional information provided. The guidance will be produced using best practice evidence based methodology according to the NICE process and methods guide for developing NICE guidelines. This includes ensuring surveillance for future guideline updates and that recommendations are based on robust evidence incorporating cost effectiveness evidence.

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			root cause of the current system-wide challenges – i.e. the causes of variation in hearing assessments and quality of services. In our view this will be critical to ensure that the guideline on "Diagnostic services: organisation and delivery" is fit for purpose and genuinely helps the NHS and patient care. To assist with this we hope that the following examples will be useful to the Committee • in audiology the person performing the diagnostic test is often the same person who provides rehabilitative intervention and support (e.g. hearing aids)[2]. Consequently how diagnostics are commissioned for audiology can restrict patient choice – e.g. if commissioners only commission diagnostics from hospitals on the unfounded assumption this offers an integrated model of care, then people with non-medical hearing loss (the vast majority) will have to visit hospital for life to get support for their age-related hearing loss. This can cost patients and the NHS more than a community-based model of care (see below) • individual audiologists can and do provide the entire diagnostic and care pathway and current growth in demand is unsustainable for a purely hospital-based model of care. In the last 10 years activity reported by audiology services	

[2] This is not the case in many areas of diagnostics and therefore we do not believe our example can be generalised.

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			has increased by 142%[xx] and there are still an estimated 3.8 million people with unmet hearing needs in England[xxi]. Therefore if the final guideline is used to support a hospital model of care for diagnostics on the unfounded assumption that multidisciplinary teams will be delivering integrated care, then the guideline risks causing systems failure in hospital audiology departments. This is why understanding roles within each subspecialty and current capacity are important aspects of developing this guideline. (Alternatively NICE could provide case studies for commissioners which we would be happy to co-produce e.g. an evidence-based case study for diagnostic hearing services for adults). • many of the challenges in NHS hearing care today flow from failures by commissioners and traditional providers to follow existing guidance. For example NHS Improvement notes that one key part of delivering quality services is that, *"capital planning, room capacity and equipment need to be aligned to service need and demand"*[xxii]. If commissioners and hospitals were utilising hospital capacity to its full, it is unlikely they would be delivering hearing assessments for adults in acute hospitals given this area of diagnostics is very low risk, delivered by technicians and is no more complex than sight tests (which occur in primary care). It is therefore our view that one driver of variation in audiology	

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			assessments in the Atlas of Variation is that there is a capacity constraint and this is because diagnostic services are commissioned, wrongly, based on historical activity rather than, correctly, on modelled local need (e.g. Joint Strategic Needs Assessments). We therefore hope that in taking on this ambitious project, NICE will control for complex variables and do all that it can to ensure that its final guidance is not misused to protect out-dated, costly and unsustainable models of care.	
National Community Hearing Association (NCHA) and British Society of Hearing Aid Audiologists (BSHAA)	4	86 -88	Again, there are no universal principles that apply to all diagnostics. ***Diagnostics – hearing assessments*** In hearing care many seemingly logical arguments for co-location do not withstand scrutiny. For example hospitals sometimes argue that it is important that children's and adult hearing assessments are co-located. We believe that there is sufficient evidence to support ***not*** co-locating adult and children's hearing assessments – including for example that the peer-reviewed literature on health care quality acknowledges that capacity management is a key factor in patient outcomes, therefore when hospital departments are at capacity because of	Thank you for your comments. The review is intending to identify areas where there is evidence for co-location of services, and will make recommendations accordingly.

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			demand for adult hearing care, there is a significant risk that providers - no matter how hard they try[3] – will not be able to maintain quality for either children or adults (see below). One argument in favour of co-location is that clinics need a steady stream of adult patients in order to train audiologists who, once trained, can move on to assessing children. In our view this is misguided. There is no logical reason that millions of older people with a hearing loss should have to travel to hospitals to access a non-medical service simply in order to help train 1,900 non-medical audiologists to a standard that allows some of them to perform diagnostic tests on the far smaller number (thousands) of children who have a hearing loss. Instead, as in eye care, it is possible for audiologists to train in the community and for fewer audiologists to specialise and work in hospitals – this in our view will also help address gaps in quality and reduce costs whilst maintaining career options for audiologists to safeguard future workforce supply. Based on annual reference cost data we estimate that by delivering adult hearing services (including diagnostics) in the community, over 1.8-2.3 million hospital contacts for audiology can be delivered outside hospital each year[xxiii]. If the NHS switches from the non-mandated activity-based tariff to the community-based package of care in the long run costs can also	

[3] NB. For avoidance of doubt, hospital audiologists are capable of providing high quality care to all age groups, the system however does not always facilitate this – e.g. it does not always consider how many patients can be seen by any single department. In fact most failures in audiology have been because of systems, rather than staff, failures.

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			be reduced by c.£30 million per annum. This liberated capacity and cost savings could then be used to ease pressure on hard-pressed hospital services[xxiv] and enable them, for example, to address concerns raised by the National Deaf Children's Society about variation in quality of diagnostics in paediatric audiology across the NHS in England - e.g. where 1 in 3 departments are failing basic quality standards[xxv]. Another argument that has been made is that co-location of the adult hearing services (audiologists) with medical doctors is important in order to rule out serious pathology as the cause of hearing loss in adults. In our view the decision on whether services should be co-located depends on a range of variables – including prevalence of the underlying condition, risk of differential diagnosis and risks associated with diagnostics themselves, workforce, cost-effectiveness of interventions etc. With respect to diagnostics for adult hearing loss we have been able to find no evidence at all to support the case for co-location with medical teams. This is because the vast majority of hearing assessments performed by audiologists will result in a diagnosis of age-related hearing loss[xxvi]. Age-related hearing loss is a long-term condition and in almost all cases there is no medical or surgical treatment[xxvii]. People that meet nationally agreed referral criteria – the vast majority of people with adult hearing loss – can access NHS hearing care from a non-medically qualified audiologist and do not have to see an Ear, Nose and Throat (ENT) doctor[xxviii]. Moreover, referable conditions are readily	

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			detected and form part of all community-based audiologists' training with screening tools and can then be referred on more appropriately if required[xxix]. Such referrals are seldom so urgent that co-location is a necessity. Therefore, arguments that adult hearing assessments should be provided in hospital to out rule tumours etc. have no merit based on the epidemiology of disease, differential diagnosis, risk, clinical ability, or cost-benefit analysis[xxx]. There are also clear benefits for patients with hearing loss when community-based services increase capacity. For example Monitor recently reviewed adult hearing services and found that where community-based providers delivered NHS hearing care Clinical Commissioning Groups (CCGs) had been able to • *"treat more patients for the same spend"* [xxxi] • lower prices by more than 20-25% per patient • improve standards by introducing more robust service specifications since extending choice of provider[xxxii]. This in our view provides an important example of how diagnostic services need to be organised and delivered by taking a systems and an evidence-based approach. It is far too easy for example to • assume co-locating adult and children hearing services is logical when in fact demand for adult hearing care has increased by 142%[xxxiii] in the last 10 years and there is good reason to believe that this – based on capacity constraints	

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			and the peer-reviewed literature on health care quality management – has had a detrimental impact both on patients with age-related hearing loss services and on quality in other areas (such as children's services) • believe that there is logic to co-locating services based on the training needs of audiologists, when in fact the vast majority of adults with hearing loss can be diagnosed and managed by a single provider in the community and there is a stronger case to train all audiologists in the community with some specialising in hospital based clinics rather than vice versa • not examine the risk of differential diagnosis and the cost per additional case detected and thus risk misallocating NHS resources due to risk aversion or protectionism In summary, we think the key to achieving successful diagnostic services for hearing loss is to ensure adults are managed outside hospital whenever possible, and in doing so – as the health quality management literature supports –liberate capacity and allow hospital audiology the capacity and time to improve diagnostics for children with hearing loss where 1 in 3 of services currently fail basic quality standards[xxxiv].	
National Community Hearing Association (NCHA)	4	90 -91	We think it is important that indicators do not create perverse incentives. For example by focussing on waiting times in audiology, there is an incentive to diagnose and then 'fit and forget' patients – especially when providers reach (or exceed) 100% utilisation and have limited capacity to follow-up patients	Thank you for your comment and this useful information. When refining the review protocol, the guideline committee will consider the patient pathway and consider all outcomes that should be included as relevant for decision making. The key outcomes have

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and British Society of Hearing Aid Audiologists (BSHAA)			(which we have reason to believe is the case already in 2015 and will worsen as the population ages, austerity tightens and demand for this service increases). It is on this basis we recommend that, when designing diagnostic indicators, the impact these indicators might have on the entire patient pathway should be considered. A good example of how to do this is well is the Department of Health's 2012 Any Qualified Provider (AQP) implementation pack for adult hearing services. This is because it included multiple indicators to measure the quality of the entire service (including diagnostics). These include • 90% of patients referred should be assessed within 16 working days of receipt of referral • 90% of patients requiring a hearing aid should be seen within 20 working days of the assessment • 90% of follow-up appointments should be within 10 weeks of fitting • 90% of patients should be able to access aftercare within 2 working days of a request • 95% of responses received from patients sampled should report overall satisfaction[xxxv]. Since then, Monitor has reviewed this 2012 policy and found that • "*Commissioners and providers told us that the specifications*	been updated since consultation and waiting time is no longer stated as a main outcome. The impact that recommendations will have will be taken into account by the guideline committee.

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			put in place [for AQP] set out higher requirements for providers or were more explicit than the arrangements previously in place. Before, service specifications were not always in place or when in place, they often lacked clarity. For example, the new specifications clarified obligations to provide follow-up appointments and aftercare services" and • *"in our view, the service specifications, combined with regular reporting of outcome measures and penalties for underperformance, create incentives for providers to ensure the desired quality. They can also help commissioners ensure that adult hearing services offer good value for money and that the needs of patients are met*"[xxxvi] In our view this provides a good case study for diagnostic services. Whilst audiology assessments are diagnostic tests, the *service* KPIs provide strong incentives for providers to diagnose, treat and then offer ***on-going support*** – this latter addressing the problem of gaps in follow-up care in adult hearing services (with serious risk of unacceptably poor outcomes) which had previously been unaddressed by the NHS for 30 years[xxxvii].	
National Community Hearing Association (NCHA)	4	93 -95	Yes The main advantage of providing diagnostics for adult hearing loss outside of hospital is to improve quality of care (access, ongoing care and compliance with treatment). The reason why	Thank you for your comment and the information provided. This section lists key questions identified for further exploration. The guideline committee will work together to refine the questions and review the available published evidence in order to provide evidence based

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and British Society of Hearing Aid Audiologists (BSHAA)			delivering this service outside hospital has advantages is complex but, briefly, according to the Department of Health it includes the fact that increasing capacity in the community reduces the monopoly power held by incumbent providers (i.e. secondary care) and this improves (previously weak) incentives to invest in audiology and respond to the needs of service users[xxxviii]. As noted above the vast majority of people with age-related hearing loss still have to attend secondary care for a simple diagnostic test. They then remain trapped in the secondary care system which can have an impact on their hearing outcomes – e.g. lack of follow-up care due to capacity constraints and weak incentives (a chronic problem in the NHS hearing service[xxxix]). Commissioners therefore find they have greater power when they commission services from several providers and that this can improve standards and lower the cost per case. For example Monitor, it its review of audiology found that in areas where community-based providers were active, commissioners were able to commission higher standards[xl], for 20-25% lower price than than the national hospital non-mandated tariff[xli] and increase access for service users[xlii].	recommendations for delivery of diagnostic services, including issues relating to location.
National Community Hearing Association (NCHA)	4	96 -97	Yes. As explained above, delivering hearing care in the community (primary care) can improve outcomes. For example Monitor notes that since allowing primary care providers to offer NHS	Thank you for your comment and the information provided. This section lists key questions identified for further exploration. The guideline committee will work together to refine the questions and review the available published information in order to provide evidence-

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and British Society of Hearing Aid Audiologists (BSHAA)			hearing assessments • "*new options for people who may have found it difficult to access care have also emerged, such as providers that specialise in home visits or organisations setting up in areas where patients had previously had to travel long distances to reach the service. These aspects make services easier to access*"[xliii] This is important because people on average delay seeking help for their hearing loss by up to 10 years and this wait can reduce their ability to adapt to hearing aids and hence have a negative impact on long-term hearing outcomes[xliv]. Accessing hearing care in the community has also been a longstanding goal for patient groups and they have long argued that providing care in the community would improve outcomes and the quality of care: • *"The current structure, where audiology services are hospital-based [is inappropriate for a technical procedure]. It is also inappropriate for a service that requires continuing patient support [...]. A locally-based service would be more convenient [for the elderly to access follow-up advice]. It is estimated that a lack of back-up support under the current system is responsible for as many as 20 per cent of patients not using their hearing aid after the first fitting"* RNID 1999[xlv]	based recommendations including where diagnostic services should be delivered.

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			• *"The hospital care model is not appropriate for an ageing population – we are calling for a radical approach to redesign and de-medicalise hearing services to widen access and choice"* Action on Hearing Loss 2011[xlvi] Moreover, in 1997, in a Department of Health sponsored study, heads of NHS audiology departments supported these positions with a response rate of 87%[xlvii]. **Table one** in endnote number six shows that, according to hospital providers themselves, care closer to home had considerable advantages for patients; including improved access and the potential to improve hearing aid compliance. It also shows there was strong agreement on the benefits of care closer to home.	
National Community Hearing Association (NCHA) and British Society of Hearing Aid Audiologists (BSHAA)	4	99 -100	Adults referred for a hearing assessment in the community are provided with results on the same day - this is routine.	Thank you for this information. This section lists key questions identified for further exploration. The guideline committee will work together to refine the questions and review the available published information in order to provide an evidence-based recommendation.
National	4	101	Yes.	Thank you for your comment. This section lists key

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Community Hearing Association (NCHA) and British Society of Hearing Aid Audiologists (BSHAA)		-102	In regions where community-based providers operate, more NHS patients can access hearing assessments at weekends (including domiciliary care) at no extra cost to the NHS. This improves access and allows people more flexibility, reduces barriers to getting their hearing loss diagnosed and improves uptake of interventions[xlviii]. There is also access to seven day aftercare – something the traditional NHS hearing care service did not offer before the introduction of community-based providers. This is important because people on average delay seeking help for their hearing loss by up to 10 years and this wait can reduce their ability to adapt to hearing aids and hence have a negative impact on long-term patient outcomes[xlix]; and aftercare is a key factor (as noted above) to ensuring people continue to use and benefit from their hearing aids.	questions identified for further exploration. The guideline committee will work to refine the questions and review the available published information in order to provide an evidence-based recommendation for when services should be available.
National Community Hearing Association (NCHA) and British Society of Hearing Aid Audiologists	4	104 -105	In our view the simple answer is yes. This is because in hearing care the diagnostic test occurs at the start of the pathway and the provider that is chosen by the patient to carry out the diagnostic test is also the provider that will care for the patient for the (at least) next three years. This matters, because if the diagnostic test is only accessible in hospitals and hospitals are at capacity, then aftercare and follow-up care is less likely to be provided and hence hearing outcomes are likely to suffer[l]. It is also important to note that in audiology, as noted above, the	Thank you for this information. These questions have now been updated following consultation. However, the guideline committee will work to refine the questions and review the available published evidence in order to provide evidence-based recommendations.

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(BSHAA)			vast majority of older people with age-related hearing loss are referred to hospital for a non-medical diagnostic test and then have to remain under the care of the hospital in order to access a non-medical intervention (hearing aid). To the best of our knowledge this does not happen in any other advanced country (i.e. it only happens in the UK and this appears to be solely because of NHS inertia or as an expensive demand management device, with no evidence basis or economic or public health case to support it). Over a patient's lifetime the main reason that they will then have to visit audiology is for hearing aid repairs[li]. This means people aged 70 and older are having to make multiple visits each year to hospital for minor and routine hearing aid repairs (tubes replacements etc.). This imposes an unfair and unnecessary cost on service users (e.g. distance travelled, hospital car parking and time lost compared to accessing simple services closer to home). If the same patients were able to get their diagnosis (and thus treatment) in the community, as 50% of England now allows (and all private patients have always been able to access), then patients would be more likely to attend follow-up appointments[lii], walk in for hearing aid repairs (as they walk in for spectacle repairs today) and have better hearing outcomes. Community providers for example report record compliance rates at 90% or higher and they attribute this to accessibility of inclusive NHS follow-up and aftercare on demand[liii].	
National Communit	4	106 -107	With adult hearing assessments adhering to the agreed booking time is part of good service user care. For example, we think that	Thank you for your comment. One of the key areas identified in the scope is access to services. Subgroups

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y Hearing Association (NCHA) and British Society of Hearing Aid Audiologists (BSHAA)			it is unacceptable that the NHS has a system in place for people with sight problems where they can access diagnostics in primary care at a fixed time, but for hearing care people are forced get a GP referral, 90% are denied a choice even in regions where one exists[liv], and then have to attend hospitals and have appointment times overrun. It highlights, as do many parts of the NHS hearing service, that the NHS treats people with hearing sensory impairment as second class citizens when compared with to those with visual sensory impairment (a bias rather than evidence-based differentiation). We think there is a need to respect service user's time and providers that are at capacity, need to be more transparent with their commissioners so that sufficient capacity is planned to deliver quality care and therefore maximise the changes of good hearing outcomes. In this sense we feel not being able to adhere to appointment times for routine diagnostics like adult hearing assessments is a sign of a system under pressure and this in intrinsically linked to poorer outcomes.	that require special consideration will be discussed and agreed by the committee when agreeing the review protocols.
National Community Hearing Association (NCHA) and British Society of Hearing	4	110 -112	As noted above, there are far too many people with undiagnosed age-related hearing loss in England. Increasing awareness about hearing loss is highlighted as a priority in NHS England and Department of Health's Action Plan on Hearing Loss[lv] and this should be the primary focus with respect to information and support for people thinking about accessing diagnostic services for their hearing loss.	Thank you for your comment. It is beyond the scope of this guideline to make recommendations specific to certain conditions. However, NICE are also in process of developing a clinical guideline on adult onset hearing loss. Further information is available at https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0833

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Aid Audiologists (BSHAA)			For example people are more likely to access diagnostic services for their hearing loss if they understand that early hearing intervention and on-going support can improve their quality of life by reducing the psychological and social effects associated with age-related hearing loss[lvi]. NHS England and Age UK recently published a practical guide to ageing which also advises people to get their hearing tested early on to reduce the risk of functional decline[lvii], and NICE also advises that hearing tests are important part of ensuring wellbeing of older people living in care homes[lviii]. In our view undiagnosed hearing loss would be less of a challenge if CCGs and GPs encouraged, rather than blocked[lix], informing people about the benefits of getting hearing loss diagnosed and addressed. Therefore in our view the root cause of problems in diagnostics for adult hearing loss is not that providers do not know what information service users want and need, but rather that not all CCGs and GPs are keen to invest in the public health interventions required once hearing loss has been diagnosed. This of course creates health inequalities for older people because 96% of people with hearing loss are aged 41 and over but, despite the Equality Act 2010, there is still a cultural challenge in parts of the NHS with respect to age-related conditions.	
NHS England	general		It does not define what the term 'diagnostic services' includes/excludes, maybe this is the initial part of the work?	Thank you for your comment. We have added clarification of the definition of diagnostic services being

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				used for this guideline to section 1 of the scope.
NHS England	general		No mention of 'skill mix' or anything about barriers to changes to allow staff to take on new roles.	Thank you for your comment. The focus of this guideline will be on quality and efficiency of diagnostic service delivery. Barriers to implementation of any of the recommendations that are developed will be considered by the committee.
NHS England	general		This scoping document says no special sub-groups have been identified. In fact I believe there do need to be special arrangements to facilitate people with visual or hearing loss, and those who lack competent decision making in order for them not to be disadvantaged regarding access to diagnostic tests	Thank you for your comment. These groups will be considered in all review questions in terms of equality considerations, and will be highlighted within the equalities monitoring form. However, the intention is that reviews will not be carried out separately for these groups for all questions, as in many cases the same principles would apply for all and therefore they are not listed as specific subgroups to be considered. If relevant for specific questions, these will be indicated in each protocol as advised by the guideline committee.
NHS England	general		In terms of organisation of services there may be an issue regarding sub-specialisation of reporting. For example common for cancer staging CTs to be reported by a general radiologist then reviewed and re-reported by a specialist radiologist for a cancer MDT	Thank you for your comment. Standardisation of communication, models of reporting and multidisciplinary communication are all now highlighted as key areas within the scope and will be considered within the guideline.
NHS England	general		There may be quality assurance issues in relation to outsourcing of reporting e.g. overnight imaging reporting from other parts of the world.	Thank you for your comment. Models of reporting is now highlighted as a key area within the scope and will be considered within the guideline.
NHS England	4	103	This line doesn't seem to make sense - ? how services are accessed and reporting between services.	Thank you for your comment. We have reworded this to 'access to, and communication between services'.
NHS England	4	86	A specific helpful co-location between endoscopy and CT for diagnosis and prompt staging of lower GI cancers	Thank you for highlighting this.
NHS	4	93	Specific issue regarding quality assurance of spirometry in	Thank you for your comment. This guideline will cover

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England			primary care to diagnose COPD.	quality and efficiency of diagnostic services. However, it is beyond the scope to address specific details of how to perform diagnostic tests for named conditions which will fall under the topic specific guidance for diagnosis of that condition.
NHS England	4	99	Same day result needs to refer not just to reporting but also consider how the result reaches the requesting clinician and the patient in a timely manner (very relevant for new 4 week cancer test strategy)	Thank you for your comment. Standardisation of and models of communication have been identified as key issues in the scope and these issues will be covered.
NHS England	4	104	As part of looking at agreed patient bookings please also cover patients (with clinical agreement) booking into their own diagnostic test appointments on-line	Thank you for your comment. The review questions have been updated, details of the protocol will be reined and agreed with the guideline committee, but it is intended that this will cover a range of booking methods.
Primary Care Respiratory Society UK	General		We welcome this guideline and would like to ensure that relevant aspects of diagnosing respiratory disease are included here. There is considerable evidence that the quality of diagnosis in respiratory disease needs improving, and examination of the configuration of and different models of providing diagnostic services for respiratory diseases would be extremely worthwhile, in order to find out what delivers best outcomes for patients and value for the NHS.	Thank you for your comment. This guideline will cover diagnostic services as a whole, across all disciplines. There may be specific questions where disease specific examples are provided at a high level, but this is to be discussed by the guideline committee when agreeing the protocols for each review question.
Primary Care Respiratory Society UK	General		The Department of Health highlighted poor diagnosis of COPD in The Outcomes Strategy for COPD and asthma. (2011) Ch 5. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216139/dh_128428.pdf https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213840/dh_113279.pdf	Thank you for your comment and useful information. This guideline will however focus on the delivery of diagnostic services and will be unable to address specific details of how to perform diagnostic tests for named conditions which will fall under the topic specific guidance for diagnosis of that condition.

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			The NICE quality standard for COPD also emphasises the importance of an accurate diagnosis. https://www.nice.org.uk/guidance/QS10/chapter/Quality-statement-1-Diagnosis See also: Partridge MR, 2014, Enhancing the diagnosis and management of COPD in Primary care., *Multidiscip Respir Med*, Vol: 9, ISSN: 1828-695X	
Primary Care Respiratory Society UK	General		The National review of asthma deaths (2014) exposed significant issues with poor diagnosis in asthma, since many of those deemed to have died from asthma had questionable diagnosis of asthma. https://www.rcplondon.ac.uk/projects/outputs/why-asthma-still-kills	Thank you for your comment and useful information. This guideline will however focus on the delivery of diagnostic services and will be unable to address specific details of how to perform diagnostic tests for named conditions which will fall under the topic specific guidance for diagnosis of that condition. NICE are also developing guidance for the diagnosis of asthma. Further information is available at: https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0640
Primary Care Respiratory Society UK	General		Aspects of respiratory disease diagnosis which warrant inclusion include: - Fractional inhaled nitric oxide (see delayed NICE draft asthma diagnosis and monitoring guideline) - Spirometry (see delayed NICE draft asthma diagnosis and monitoring guideline, and draft COPD QS) Both these have been identified as important tools to improve	Thank you for your comment and this useful information. However, as per response to comment 159, this guideline will focus on the delivery of diagnostic services and will be unable to address specific details of how to perform diagnostic tests for named conditions which will fall under the topic specific guidance for diagnosis of that condition.

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			the diagnosis of respiratory disease. Peak flow monitoring in asthma diagnosis has arguably been under studied and under emphasised in guidelines on asthma diagnosis despite its ready availability, simplicity low cost and high specificity. There is a tendency to concentrate on newer and more expensive technologies and neglect research and training in the use of older but valuable diagnostic techniques.	
Primary Care Respiratory Society UK	General		The following references may be particularly useful in relation to the availability of lung function testing to primary care; Hassett R, Meade K, Partridge MR, 2006, Enhancing the accuracy of respiratory diagnoses in primary care: a report on the establishment of a Community Respiratory Assessment Unit., Prim Care Respir J, Vol: 15, Pages: 354-361, ISSN: 1471-4418 Starren ES, Roberts NJ, Tahir M, O'Byrne L, Haffenden R, Patel IS, Partridge MRet al., 2012, A centralised respiratory diagnostic service for primary care: a 4-year audit, PRIMARY CARE RESPIRATORY JOURNAL, Vol: 21, Pages: 180-186, ISSN: 1471-4418	Thank you for this information.
Primary Care Respiratory Society UK	General		Will this guideline consider the support that a patient may need after receiving a diagnosis? In some disease areas, this is better developed than others – such as breast cancer. Patients with COPD often feel that they are delivered the bombshell of a diagnosis but without the support to come to terms with it, and to learn how to live with it. How a patient manages their condition may be influenced by the way that they receive the news of	Thank you for your comment. This guideline will cover information needs of people using diagnostic services. However, it is beyond the remit of this guideline to cover support following diagnosis for specific disease areas.

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			diagnosis and the support that is available to them immediately after a diagnosis.	
Primary Care Respiratory Society UK	3	51	This section seems to focus on diagnostic services that are already available. We are interested to know how NICE will address diagnostic approaches that are so new that there is little/no published evidence. Eg. Fractional inhaled nitric oxide measurement to diagnose asthma in primary care (See delayed NICE draft guidance on asthma diagnosis and monitoring)	Thank you for your comment. The guidance will cover diagnostic service models where evidence is identified. However, it is beyond the scope of this guideline to make recommendations on disease specific diagnostic tools, which will be covered within the relevant disease specific guideline or NICE diagnostic assessment programme.
Primary Care Respiratory Society UK	3	65	Not to be included: Face-to-face tests that are carried out in the course of the clinical examination. Some tests may currently be carried out as face-to-face tests but may be more suitable to be delivered on a hub and spoke model. Likewise, others may be delivered from a central location that patients must access, when they potentially could be moved to take place in the course of a clinical consultation. We suggest that a diagnostic intervention should be considered for inclusion in the guideline if there is evidence that diagnosis is poor in that disease area. The fact that a test is currently delivered face-to-face in the course of a clinical consultation is too simplistic a basis on which to exclude a useful test that is being done poorly – if making such a test available on a different basis would lead to it being done more effectively. Spirometry is a case in point, since many nurses and GPs performing spirometry have not received the necessary training to do this competently. It could be that a different model of delivery of this investigation would deliver a better outcome.	Thank you for your comment. Face-to-face testing was intended to mean the history taking and physical examinations undertaken in the course of the clinical consultation (for example, not using any specific diagnostic tests, tools or equipment). This section has now been updated to clarify this. The question of where diagnostic services are delivered has been identified as a key issue to be covered in the scope under section 1.5. The guideline will focus on quality and efficiency of diagnostic service delivery, as measured by the outcomes defined in the individual review questions which will be refined by the guideline committee.

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Primary Care Respiratory Society UK	4	96	3.2 Does providing point of care testing in primary care improve patient outcomes? A key consideration in respiratory diagnosis is that objective diagnostic measures need to be considered alongside patient examination and taking a full history. It is therefore potentially problematic if the testing is undertaken in a separate location or at a different time and by different people from the clinician who must consider the whole picture in order to make a diagnosis.	Thank you for your comment. These questions have now been updated and specific details will be refined by the committee when agreeing the protocols.
Prostate Cancer UK	general	general	We think the proposed *Diagnostic services: organisation and delivery guideline* should signpost health professionals to NICE guideline 12, *Suspected cancer: recognition and referral* and the associated Quality Standard, so that best practice diagnostic pathways can be followed by cancer type. This would contribute to the proposed guideline's aim to reduce variations in access to diagnostic tests.	Thank you for your comment. We will include NICE guideline 12, suspected cancer: recognition and referral within the list of related NICE guidance in the full guideline following development.
Prostate Cancer UK	5	115	We suggest including a seventh main outcome for consideration when searching for and assessing the evidence that relates to the provision of patient information. We believe this research question will be key to informing proposed review question 6.1, 'what information and support do people using diagnostic services (and their families and carers) want at different points during their pathway within diagnostic services?'.	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed.
Prostate Cancer UK	5	118 -119	We support the inclusion of waiting times as an outcome measure because they are important to the early detection of cancer. However, waiting time targets should not supersede the NHS' duty to ensure patients are fully informed about their	Thank you for your comment. These outcomes are intended to inform the recommendations that will arise from this guideline and will be finalised and agreed per review protocol by the guideline committee. The priority

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			choice of diagnostic test. For example, providing information to men referred for suspected prostate cancer on the associated risks and benefits of undergoing a prostate biopsy should be prioritised above waiting time targets that may not take account of the decision-making time men may need.	of relevant outcomes will be agreed separately for each review, and we agree that waiting time will not be a critical outcome for all review questions.
Prostate Cancer UK	5	118 -119	We would like the term 'presentation' to be defined and to include the identification of 'at risk' groups. This is because many men enter the prostate cancer diagnostic pathway without presenting with symptoms associated with prostate cancer. Instead, they are referred for suspected cancer following their decision to have a prostate specific antigen (PSA) test. These men will have either self-identified, or been proactively identified by their GP as being at risk of prostate cancer (e.g. men aged 50 and over, Black African or African Caribbean men and those with a family history of the disease).	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed. Any guideline specific definitions of time points that are determined by the committee for the purposes of the review will be defined in the guideline when it is written.
Prostate Cancer UK	5	118 -119	We think that outcome 1, 'waiting time from presentation to diagnostic test' could either be amalgamated into outcome 2, or remain the same with changes made to outcome 2 so that it reads: 'waiting time from diagnostic test to reporting of results'. This is to ensure that the specific data – i.e. both time from presentation to diagnostic test and time from diagnostic test to reporting of results – are collected to inform proposed review question 4.1, which asks whether the provision of same day results from diagnostic services improve patient outcomes.	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed to ensure specific data relevant to each review question is captured.
Royal College of General Practitioners	General	General	The advent of tele-consultations needs to be seen within this context where the patient may then access diagnostic services direct for diagnosis or monitoring of a chronic condition. Some patients may have home monitoring e.g. INR and may need advice requiring interpretation and action.	Thank you for your comment. Access to services is identified as a key area within the scope, and different models will be considered within the guideline.

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			Some patients might be encouraged to access diagnostic services direct where they have a chronic condition and where they wish to be much more partners in their own care or in that of dependants e.g. drug levels (lithium, anti-epileptics) or renal function in patients on home dialysis. (PS).	
Royal College of General Practitioners	General	General	Quality control of diagnostics becomes more important where there are multiple providers. (PS).	Thank you for your comment. It is intended that this guidance will look at quality and efficiency within diagnostic service delivery models. Issues such as multiple providers may be explored within the relevant review questions.
Royal College of General Practitioners	General	General	It is crucial to see this work within the wider context of shifting control from hospitals to community with primary care and the registered list being the key foundation. A document signed off by the RCCP and Royal College of Radiologists set out minimum access targets and the need to build in a clinical relationship between primary care and the commissioned service - this may be of value to the scope. This document reflected the fact that most diagnostic services faced into hospitals as the key customer and not primary care. A member used it locally to commission a primary care facing diagnostic service which now gives us direct access to MRI etc. There are a key set of principles which should apply to any diagnostic services which need to be agreed beforehand. That would include a wider definition of "value" rather than just cost. (DP)	Thank you for your comment and useful information. The guideline will take into account cost impact as well as cost effectiveness. In cost effectiveness, trade-offs are considered that include cost, for example, the trade-off between cost and effects, such as cost and quality of a service in this particular guideline. As this is a service delivery guideline, it is anticipated that there will be large cost implications of recommendations made which is why it is even more important to identify the benefits that any additional costs will bring and whether a recommendation is 'value for money'. In these difficult times for the NHS, we also want to identify service configurations that could lead to efficiency savings without detriment to the quality of a service. Therefore, cost is an important factor but should always be considered as part of a trade-off and not the sole factor for decision making. Outcomes for each review (including how cost

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				effectiveness will be measured) will be confirmed with the guideline committee when each protocol is agreed.
Royal College of General Practitioners	3	67	The economic evaluations appears limited in nature. The real economic aspects of community diagnostics are highly dependent on the size of population the tests are servicing, their usage, the capital and consumable costs and training costs. The organisation of GPs into larger federations needs to be considered as well as providing some diagnostics in mobile vans. (MH)	Thank you for your comment. The 'economic aspects' section of the scope only gives a brief introduction into how NICE assesses cost effectiveness. We agree that factors that can impact the cost effectiveness of providing a service include the population that is using that service, and the costs involved in setting up and managing the service. All of these factors will be considered when assessing cost effectiveness.
Royal College of General Practitioners	3	56	This line askes how the services are accessed and reported between services. It is important that results from diagnostic tests produce structured messages that can be exchanged by EDI (Electronic Date interchange) between the diagnostic service, the requestor and eventually the patient. We should also consider that patients may want to access their results directly and download them directly into their own personal health records that they may hold. (MH)	Thank you for your comment. Access to services, standardisation of and models of reporting have been identified as key issues to be covered by the guideline.
Royal College of General Practitioners	11	3	Consider inserting an extra question. Can the provision of diagnostic services in primary urgent care settings allow for safe and effective care of patient groups who would otherwise be triaged to secondary care? E.g. rule out myocardial infarction or deep venous thrombosis in ambulatory patients presenting with chest pain or leg swelling. (DA)	Thank you for this suggestion. We believe this will be covered by the review questions relating to where services are delivered and access to and communication between services. Specific details of the review questions will be refined by the committee when the protocols are agreed.
Royal College of Paediatrics and	General	General	The scope should be explicit that age appropriateness of diagnostic services and where they are delivered must be in scope, older people are mentioned but services to meet the needs of babies and children are not.	Thank you for your comment. This guidance will be for people of all ages, including diagnostic services for babies and children.

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Child Health				
Royal College of Paediatrics and Child Health	4	96 -97	It is not clear whether point of care testing outside of the home is in or out of scope.	Thank you for your comment. Point of care testing provided by NHS services in the home is within the scope.
Royal College of Pathologist	10	244	Commissioning of diagnostics is indeed a challenge. Clarity and harmonisation of practice across the NHS is needed to address variation in practice and diagnostic testing rates.	Thank you for your comment. We have amended the text to highlight this issue.
Royal College of Pathologists				
Royal College of Pathologists			I feel that it the paper would have more relevance and make more sense if it gave examples relating to maybe the top 5 diagnoses made in medicine, rather than using such a broad brush approach.	Thank you for your comment. We agree that the remit is broad, however, this guideline will not cover specific diagnosis as the intention is to make recommendations for the delivery of all services across the NHS. Limiting to specific diagnoses may lack generalisability across the spectrum. There may be specific questions where disease specific examples are provided at a high level, to be discussed by the guideline committee when agreeing the protocols for each review question.
Royal College of Pathologists	2	41	There is a subgroup of people who have variants of uncertain clinical significance identified by genetic testing and others who have had predicted test results. The may be considered the 'worried well'. Are these people included in further testing?	All people using diagnostic services will be included within the guidance. The guideline will not cover the management of people following their diagnosis. However, continued monitoring using diagnostic

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				services is within the scope of this guidance.
Royal College of Pathologists	3	68	Economic evaluation will be influenced by providing the test at the optimal part of the diagnostic pathway that relates to comment 2, 3, 4 and 5 above.	Thank you for your comment. The focus of this guideline is broad in order to encompass all diagnostic services and not focus on specific conditions. Therefore, the impact of a diagnostic service on other parts of the patient pathway, such as management, is outside of the scope as this is likely to be condition specific. We agree that there are many factors that influence the cost-effectiveness of how a diagnostic service is configured, however, given the breadth of the guideline, the 'optimal' part of the pathway may not be the same for different conditions. The outcomes used to measure the effectiveness and cost-effectiveness of services will also be discussed with the guideline committee when setting the specific review questions. We agree it will be a challenge to look at diagnostic services across the NHS without being condition specific. However, we want to focus on services as a whole and not only on the services for a specific condition. There may, however, be specific questions where disease specific examples are provided at a high level, but this is to be discussed by the guideline committee when agreeing the protocols for each review question. It is possible that index conditions may be used in economic modelling which may allow a more standardised approach of assessing cost-effectiveness

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				(cost per QALY) as epidemiology and data on outcomes around a particular condition may be used. Modelling feasibility is dependent on data, however, this may be one approach to deriving long term outcomes from competing diagnostic service configurations, and therefore assessing the impact of the service on the other parts of the pathway. It may also be the case that the pathway for different conditions within some diagnostic disciplines may be very similar or the same (for example, genetic testing), and therefore, even without being condition specific, assumptions might be made about the benefits that a particular service configuration may have further down the pathway.
Royal College of Pathologists	3	75	It is unclear how QALY will reflect the benefit of a significant proportion of genetic tests where the outcome may be more about empowerment.	Thank you for your comment. We agree that there are scenarios where quality of life measures are not sensitive enough. The outcomes used to measure the effectiveness and cost effectiveness of services will also be discussed with the guideline committee when setting the specific review questions.
Royal College of Pathologists	3	52	Which services are grouped together is likely to be a dynamic arrangement. For example the real benefits of genetic testing will only be realised if the testing occurs much earlier in the pathway than happens now. It is unclear how such optimal arrangements will be modelled and made future proof.	Thank you for your comment. We agree this will be a challenging area to consider when addressing the review of grouping of services. Priorities for economic analysis and the outcomes used to measure cost effectiveness will be discussed with the guideline committee.
Royal College of Pathologists	3	60	It is unclear how recommendations can be provided on what and how services are grouped together without confirming which tests should be used to diagnose clinical condition. There is wide variation in practice that should be harmonised and aligned	Thank you for your comment. The tests that should be used to diagnose conditions are beyond the remit of this guideline, and are covered within topic specific guidance where best practice is defined.

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			to best practice	
Royal College of Pathologists	3	63	Screening services are an integral part of the diagnostic pathway and need to be included. The provision of screening services impacts on what and how services should be grouped.	Thank you for your comment. The UK National Screening Committee provides guidance on which screening programmes should be provided; therefore, this is beyond the remit of this guidance. However, it is acknowledged that some screening services use the same facilities as diagnostic services and therefore may be within the diagnostic services pathway.
Royal College of Pathologists	3	65	Face to face tests should be included for the same reason as above, they are and need to be integral to the diagnostic pathway.	Thank you for your comment. Face-to-face testing was intended to mean the history taking and physical examinations undertaken in the course of the clinical consultation (for example, not using any specific diagnostic tests, tools or equipment). This section has now been updated to clarify this.
Royal College of Pathologists	4	98	Consideration needs to be given the time frame. The short and long term benefits may differ.	Thank you for your comment. The timeframe at which the outcomes are captured will be discussed and agreed with the guideline committee when each review protocol is agreed.
Royal College of Pathologists	4	86	Co-location implies geographical location whilst what is more important is good communication and logistical links that is entirely different. Services can be co-located and dysfunctional or remotely located with excellent integrated working.	Thank you for your comment. It is the intention that this guideline will include the logistics of co-location beyond just the geographical location of services, this has now been made more explicit in the scope. Multidisciplinary communication and standardisation of communication have been included as key areas within the scope.
Royal College of Pathologists	4	93	This seems likely to vary on a geographical and condition basis. One size rarely fits all.	Thank you for your comment. When agreeing the protocol for this review question, the guideline committee will consider whether there are specific subgroups that require separate recommendations and whether more than one recommendation is required.

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Royal College of Pathologists	4	96	Point of care testing can be delivered well or badly. It needs to be clear who is responsible for the quality of the service.	Thank you for your comment. The focus of this guideline will be on quality and efficiency of diagnostic service delivery, therefore this will be considered.
Royal College of Pathologists	5	116	Most patients will have a suite of tests so this measure seems simplistic and meaningless. Should it mean time to diagnosis?	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed and agreed by the guideline committee when each protocol is agreed.
Royal College of Pathologists	5	106	Offering choice of bookings is likely to be an equality issue.	Thank you for highlighting this. We have noted in the equality impact assessment that there are some groups that may require specific consideration for certain questions, and we will ensure equality is a consideration throughout the guideline.
Royal College of Pathologists	5	110	Needs to include language translation and address of patients with limited capacity	Thank you for your comment. People who do not speak English as a first language and those with limited capacity have been identified in the equality impact assessment. The guideline committee will take equality issues into account when making recommendations relating to access to services and patient information and support needs.
Royal College of Pathologists	6	141	It is totally unclear how this guidance will interrelate with other guidance. Of major concern is the NHSE led current reconfiguration of genomic laboratory services being led by NHSE. See https://www.engage.england.nhs.uk/consultation/genomic-laboratories. The service specification, PQQ and ITT were due to be released week commencing 26th October with closing date	Thank you for this information. NICE is commissioned to make evidence-based guidelines. The guideline committee will make recommendations based on the available evidence for the organisation and delivery of diagnostic services, and will do so taking into account current service configuration and in light of other related NHS developments.

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			6th December. The content of this is highly relevant to this scope but as of 1/11/15, the NHSE document has not yet been released.	
Royal College of Pathologists	7	150 -191	The paper makes some very broad statements but then proceeds to provide very precise figures e.g. section 3.1 where precise workload data is provided without clarification of where the data has come from or what tests are included.	Thank you for your comment. The figures quoted were extracted from NHS diagnostic waiting times and activity data (NHS England, May 2015). The section has been amended to make this clearer.
Royal College of Pathologists	7	151	The introduction of precision medicine means that a diagnostic service may also need to recommend treatment.	Thank you for your comment. We acknowledge this may occur within some diagnostic services, however, it is not part of all services and beyond the scope of this guideline so it has not been stated here for that reason.
Royal College of Pathologists	7	166	Please also include reference to the UKGTN document confirming a variation in genetic testing rates http://ukgtn.nhs.uk/fileadmin/uploads/ukgtn/Documents/Resources/Library/Reports_Guidelines/UKGTN%20Report%20on%20molecular%20genetic%20testing%20activity%20rates%20in%20the%20UK%20201112.pdf	Thank you for this reference. We have not included this in the scope as the NHS Atlas of Variation (November 2013) gives an illustration across all diagnostic services, but we will note this reference for information.
Royal College of Pathologists	7	173	Interpretation of some genetic test results may require samples from other family members or archival tumour tissues. The time taken to obtain these may often be months so clarity is needed on the start time. In practice Genetics lab use an 'activation date' but this can mask major delays in obtaining samples from tissue banks.	Thank you for this information.
Royal College of Pathologists	8	186	The speed of result needs to be considered alongside the quality of the result and specifically a full interpretation that may require further work. This needs to be recognised so the incentive to produce more meaningful results is not eroded.	Thank you for your comment. We have amended the paragraph to emphasise the other factors connected to speed of reporting.
Royal College of	11	254	Determining who should provide & deliver services needs to be also linked to future developments and investment.	Thank you for this comment.

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Pathologists				
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so, we have liaised with the British Thoracic Society (BTS) and British Society of Gastroenterology (BSG) and wish to fully endorse their submissions. We have also liaised with: • experts in the RCP accreditation department who host the Improving Quality in Physiological Services (IQIPS) programme • the RCP Future Hospital Programme (FHP) and wish to make the following comments:	Thank you for your comments, we have responded to each below.
Royal College of Physicians	General	General	The interrelation between this guideline and the existing accreditation schemes is mentioned within the context section. Our experts believe that the scope of the guideline should also cover how they relate.	Thank you for your comment. The focus of this guideline is quality and efficiency of diagnostic service delivery. NICE is commissioned to make evidence-based guidelines. The guideline committee will make recommendations based on the available evidence for the organisation and delivery of diagnostic services, and will do so taking into account current service configuration and other related NHS developments.
Royal College of Physicians	General	General	Our experts would like to reiterate what was stated at the scoping workshop for this guideline, which is that the outcomes are very ambitious and wide ranging.	Thank you for your comment. The outcomes listed in the scope have been updated. These are only the main outcomes that are expected to be relevant for the majority of questions. Specific outcomes per review will be agreed by the guideline committee when protocols are agreed.

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Royal College of Physicians	10	243	The draft scope refers to existing accreditation schemes and line 243 refers to IQIPS. However, the term 'physiological measurement' is not correct, and our experts would like to request that this is changed to ' physiological services'.	Thank you for highlighting this, we will amend as suggested.
Royal College of Physicians	11		The RCP FHP wishes to draw attention to two concise documents with regard to the consultation questions below: *1.1 Does the use of multidisciplinary teams offering integrated reporting improve patient outcomes?* *1.2 Does co-location of services improve patient outcomes? If so, what is the most effective combination of co-located services to achieve optimum patient outcomes?* The documents are: • *Future Hospital: Caring for medical patients Executive Summary September 2013* • *What the Future Hospital Commission report means for patients September 2013* Both are available on the RCP website (https://www.rcplondon.ac.uk/projects/outputs/future-hospital-commission)	Thank you for providing this information.
Royal College of Radiologists (RCR)	general	general	We feel that draft scope is adequate for the guidance	Thank you for your comment.

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Royal College of Surgeons	2	38	Diagnostic tests are not just required at an initial referral by GPs but often are required throughout a longer term treatment. Often this may require liaison and agreement on responsibilities between specialist and local services. Often this is poorly co-ordinated	Thank you for your comment. One of the key areas that has been identified within this scope is the access to, and communication between services, which we believe will cover this issue.
Royal College of Surgeons	2	38	Diagnostic tests for emergency presentations require different organisation, especially out of hours than those for elective care, this is not reflected within the guideline scope	Thank you for your comment. This guideline will cover routine diagnostic services. Emergency presentations are not excluded. Please note that NICE is also producing service delivery guidance for acute medical emergencies in adults and young people.
Royal College of Surgeons	2	41	There are certain subgroups where liaison between specialist/ non-specialist care is required for diagnosis which are currently adversely affected e.g. children requiring specialist radiology reporting or advice and on-going management of rare illnesses, access to specialist radiology	Thank you for your comment. The guideline will cover reporting between services. The guideline committee will consider specific subgroups, if required, for this question when agreeing the protocol.
Royal College of Surgeons	4	84	Access to specialist pathology and or radiology advise when discussing diagnosis and or treatment options can be very effective within a MDT setting	Thank you for your comment and this information.
Royal College of Surgeons	4	86	• The co-location of services nearly always improves patient outcomes and this is particularly the case when considering the proximity of complex diagnostics and therapeutic services. • Co-location is not always feasible. It may be better in certain circumstances to move the patient to the test. This does require regional agreement, ideally defined through a network. • Often the most difficult aspect of services is getting access to specialist reporting e.g. paediatric radiologist to report on imaging, a specialist pathologist for uncertain/ difficult	Thank you for your comment. When refining the review protocol with the guideline committee, these issues will be explored to ensure they are captured within the review.

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			diagnoses • Out of hours reporting is especially poor in some areas • Access to interventional radiology can be limited	
Royal College of Surgeons	4	90	• Defined access to specialist diagnostic services not available within local hospital • Multidisciplinary discussion of diagnosis and treatment of complex cases, which include radiology and pathology expertise • Urgent access to specialist imaging advice 7 days per week/ 24 hours per day • Fixed timeframe for written reports of tests	Thank you for your comment and this information. We agree this is important to consider and have included access to services and communication (including multidisciplinary communication)as key areas within the scope. The questions will be refined in more detail when the guideline committee agree the review protocol for this question.
Royal College of Surgeons	4	93	• As long as there are clear referral criteria and the ability for the secondary care to see reports/ scans etc. Otherwise it will just lead to duplication and possible delays • May have a big impact on primary care in terms of f the availability of funding to support additional services in the community • Sometimes primary care cannot access urgent investigations, so it may delay some diagnostics	Thank you for your comment and the information provided. This section lists key questions identified for further exploration. The guideline committee will work together to refine the questions and review the available published information in order to provide evidence-based recommendations.
Royal College of Surgeons	4	96	• There is no evidence that we are aware of that indicates that point of care testing in primary care improves a patient's clinical outcomes. • It may of course improve their experience.	Thank you for your comment. The specific outcomes that will be included within this review will be agreed by the guideline committee when finalising the protocol. These will not be focused on clinical outcomes, but will include patient satisfaction.
Royal College of Surgeons	4	99	• Only if access to early results then means earlier treatment- otherwise it may just cause increased anxiety	Thank you for your comment. We agree that timeliness of results depends on the population. This section lists key questions identified for further exploration. These have been updated following consultation, however, the guideline committee will work together to refine the

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				questions and review the available published information in order to provide evidence-based recommendations.
Royal College of Surgeons	4	101	• Yes- this is often not well organised with no formal agreements between services or only ad hoc services available	Thank you for your comment. We agree this is important to consider and we have identified access to services (including timeliness) as a key issue.
Royal College of Surgeons	4	104	• Especially where access is required for emergency admissions	Thank you for your comment.
Royal College of Surgeons	5	118	18 week targets are already in place and we doubt the need to add further targets. However, we would support a target which measures access to diagnostic services out of hours for emergencies.	Thank you for your comment. These outcomes are intended to inform the recommendations that will arise from this guideline and will be finalised and agreed per review protocol by the guideline committee. They are not intended to inform targets for waiting lists.
Royal College of Surgeons	5	119	This target should be for written not verbal reports	Thank you for your suggestion. This will be clarified in the review protocol when agreed by the guideline committee.
Royal College of Surgeons	5	120	This experience measure may be confounded by the anxiety of patient waiting for a diagnosis	Thank you for your comment. We agree this may be a confounding factor, but believe that is still an important outcome to capture.
Royal College of Surgeons	5	121	Maybe defined access to specialist advice would be a better outcome measure	Thank you for your comment. The outcomes listed are those that are expected to relate to the majority of review questions within the guideline. However, specific outcomes for each review question will be discussed by the guideline committee when each protocol is agreed.
Royal College of Surgeons	5	122	In areas where elective surgery is at times cancelled, especially in winter, the number of attendances to hospital or emergency admissions may be a reflection of access to planned care and	Thank you for highlighting this, we will bear it in mind when considering the evidence.

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			not of assess to diagnostic services	
Royal College of Surgeons	5	123	How would you differentiate this from the impact of the undiagnosed illness?	Thank you for your comment. The outcomes have been updated and quality of life is no longer included as a main outcome.
Royal College of Surgeons	5	106	• There is no evidence that we are aware of that indicates that patient agreed bookings for diagnostic services improves a patient's clinical outcomes. • It may of course improve their experience.	Thank you for your comment. The intention is that this review question will not consider clinical outcomes in isolation of patient experience and other non-clinical outcomes.
Royal College of Surgeons	6	147	Diagnostic tests are not just required at an initial referral by GPs but often are required throughout a longer term treatment. This should be reflected in the pathway	Thank you for your comment. The full pathway will be developed when the guideline recommendations are made and the guideline is published. The example illustration in the scope will be adapted and more detail added accordingly.
Royal Stoke University Hospital	1	23	How will the guidelines deal with referrals to specialist services across UK borders? Patients travel across UK borders when access to more specialist services are required and this will include the need for diagnostics at these specialist centres.	Thank you for your comment. 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.
Royal Stoke University Hospital	2	45	Will there be any discussion regarding access to NHS services from private referral streams?	Thank you for your comment. All NHS diagnostic services as defined in the scope will be covered including those accessed by private referral schemes.
Royal Stoke University Hospital	3	51	How will the quality delivery of diagnostic services be addressed within this guideline document? There needs to be standardisation regarding training of individuals and departments that offer diagnostic services to ensure the patient receives the best possible care and outcomes and can be assured that diagnostics were performed appropriately with no risk of adverse outcomes or misdiagnosis. This will impact on all areas of	Thank you for your comment. Quality will be assessed by the outcomes for each review question. The details of which will be refined by the guideline committee when the protocol is set.

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			healthcare, from primary to tertiary care etc.	
Royal Stoke University Hospital	4	93	Need to consider whether these services are offered by trained professionals within secondary/tertiary care or whether these are offered by community/primary care staffing which will, therefore, require an appropriate level of training and assurance of competence to perform the diagnostic tests.	Thank you for your comment. Where services are delivered will be considered within the review question. Specific details of this question will be refined by the guideline committee when compiling the protocol and undertaking the evidence review.
Royal Stoke University Hospital	4	101	Have all aspects of offering an out of hours diagnostic service been thought through to ensure appropriate clinical governance. For example, clinical cover for services when required, the additional resources, including staff, to be able to offer out of hours services?	Thank you for your comment. These questions have been updated since consultation; however, all questions will be refined by the guideline committee, including taking into consideration the factors as suggested.
Royal Stoke University Hospital	5 and 7	124 & 157	Are the correct, most up-to-date and evidence-based criteria for interpretation of diagnostic outcomes being used to ensure delivery of an accurate service. For example, in respiratory the use of percentage of predicted to determine normality have been known to be flawed for many years and yet many diagnostic services still use these, resulting in the mis-diagnosis and or under/over-diagnosis of respiratory disease.	Thank you for this information. This guideline will focus on the delivery of diagnostic services and will be unable to address specific details of how to perform diagnostic tests for named conditions which will fall under the topic specific guidance for diagnosis of that condition.
Royal Stoke University Hospital	10	243	How can accreditation of diagnostic services be assured with potential low uptake of such schemes based on resources and funding required to undertake them?	Thank you for your comment. The issues affecting uptake of accreditation is outside the scope of this guideline.
Royal Stoke University Hospital	12	256	Do current staffing structures within diagnostic services meet the likely future demands that will be placed on them? Are the current training programmes producing sufficient numbers of newly trained staff to meet future demand appropriately?	Thank you for these suggestions; however, it is beyond the remit of this guidance to provide guidance on staffing numbers required.
Stockport NHS	General	General	The guidance should always emphasise quality of the service delivered and should recommend that all POCT and all	Thank you for your comment. The focus of this guideline will be on quality and efficiency of diagnostic

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Trust			Pathology services provided are ISO15189 registered.	service delivery. Recommendations will be made based on the evidence that is reviewed.
Target Ovarian Cancer	4	103	The draft scope does not consider the information needs of healthcare professionals receiving and interpreting the results of diagnostic tests. For example: a GP could refer a woman for pelvic ultrasound and receive a description of the test findings, however many generalists will not be experienced in interpreting ultrasonography results and will be uncertain as to how to proceed, this could ultimately lead to delays in referral to secondary care and affect patient outcomes.	Thank you for your comment. The guideline will look at communication between services including standardisation of communication and models of reporting where we intend to address issues such as these.
The Society and College of Radiographers		General	The Society and College of Radiographers welcomes this work relating to diagnostic services, with the goal of improving access for patients, ensuring timely reporting and developing systems which should lead to improvements in patient outcomes through earlier and timely diagnosis. We support consideration to the one stop shop approach where possible, but recognise that some degree of centralisation is likely to be required for complex clinical imaging examinations requiring high value equipment and significant expertise.	Thank you for your comment
The Society and College of Radiographers		General	The Society and College of Radiographers is pleased to see that the importance of the College of Radiographers /Royal College of Radiologists UKAS accredited Imaging Services Accreditation Standard (ISAS) is acknowledged. The standards should help inform the work of the panel. The number of services accrediting to this standard is increasing. However we are disappointed that The Society and College of Radiographers has not been mentioned as a professional body who provide guidance.	Thank you for your comment. We have amended the text to state that there are other professional bodies who also provide guidance.
The		General	In relation to Clinical Imaging services we suggest that it would	Thank you for providing this information.

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Society and College of Radiographers			be useful for the panel to consider the work initiated through the NHS England Vanguard Project focused on configuration of Clinical Imaging services – East Midlands Radiology Consortium. This is not mentioned in the Scope and is a new project which commenced in September 2015.	
The Society and College of Radiographers	General	General	However, the Society and College of Radiographers is very concerned and disappointed that the advert call for panel members does not recognise the crucial role that radiography has within the diagnostics pathway. Radiographers are critical to the delivery of clinical imaging services supporting patients through their pathway of care, acquiring the clinical images and in many cases now reporting the images as key members of the Imaging MDT. A radiography service manager has a critical role to play in organising and managing efficient and effective services and we would have expected there to be a mandated position for a senior radiography/radiology service manager (despite a mandate for a laboratory manager) on the panel. Likewise in the list of specialist contributors we would have expected to see at least one radiographer listed as a potential member of the panel.	Thank you for your suggestion. We apologise for the initial oversight in not specifying a senior radiography/radiology service manager alongside a laboratory manager. Radiographers and imaging service managers were eligible to apply within the role contributing knowledge of the provision of diagnostic services (3 positions). A radiology manager has been subsequently appointed to the panel.
The Society and College of Radiographers	1	13	Whilst we recognise the challenges of minimising the panel size we do not think that the panel membership is reflective of all the services that will be covered by the guideline and think it essential that a Radiographer who is a Radiology Services Manager is included within the group.	Thank you for your comment. A radiology manager has been appointed to the committee.
The Society	1	10	It would be helpful to list which diagnostic services are included within the scope.	Thank you for your comment. We have added clarification of the definition of diagnostic services

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and College of Radiographers				included in this guideline in section 1 of the scope.
The Society and College of Radiographers	2	39	If the focus of this work covers those carrying out or receiving and interpreting the results of diagnostic services we believe that this requires a service manager with expertise in clinical imaging in order to provide intelligence to inform any recommendations for service redesign. This supports the point we made (3) above that we believe that a Radiology Services Manager is essential to the work of this panel. The work within a clinical imaging department is complex, and includes Plain film/CT/MRI/PET-CT, Mammography, Ultrasound and Nuclear medicine. The organisation of these services falls within the remit of the Radiology/Radiography service manager.	Thank you for your suggestion. As per response to comment 85, we apologise for the initial oversight in not specifying a senior radiography/radiology service manager alongside a laboratory manager. However, radiographers and imaging service managers were eligible to apply within the role contributing knowledge of the provision of diagnostic services (3 positions). A radiology manager has been subsequently appointed to the panel.
The Society and College of Radiographers	3	59 & 60	We consider that it will be difficult to make recommendations for diagnostic services; organisation and delivery if little account is taken of the capacity, demand and referral pattern and the requirement for best practice/evidence based guidance. Without this there is always the risk that inappropriate referrals could impact upon the successful implementation of this guideline and therefore the impact upon patient outcomes being aimed for is not achieved. We would suggest that Line 60 needs addressing first with best practice guidelines across diagnostic pathways being put in place first and if already available this work needs to clearly recommend their implementation and monitoring.	Thank you for your comment and suggestion. This will be discussed and agreed with the guideline committee as the protocols are agreed. The population using a service, and the capacity of the service in terms of resources, are issues that will be considered as part of evaluating the cost effectiveness of services.
The Society and	4	103	This point refers to linkages between different diagnostic services, we would suggest that there is an important point about creating systems to ensure that reporting within each	Thank you for your comment and this useful information. We will bear this in mind when this review question is considered by the guideline committee.

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College of Radiographers			diagnostic service is achieved in a timely and effective way. We are aware in clinical imaging services of large numbers of un reported images, this needs to be considered within this work, and skills mix needs to be implemented where possible to reduce delays within services. Advanced Practice Radiographers are having a significant impact in many NHS Trusts, providing a clinical imaging reporting service to support the work of the MDT, relieving the pressure upon Radiologists and providing timely reports for patients. This service redesign needs to be rolled out more widely as highlighted within http://www.cancerresearchuk.org/sites/default/files/horizon_scanning_-_final.pdf	
The Society and College of Radiographers	4	86	Co-location of services is positive where possible however there must be contingency and in clinical imaging back up equipment in case of breakdown/servicing. We presume that NICE will take account of the requirements of centralising specialist knowledge where required and the cost and impact of localisation where high value equipment is needed. It is concerning that there is already an outdated equipment base for clinical imaging services in some areas of England. Localisation may have an impact upon volume of imaging equipment required and this could impact upon overall clinical imaging costs if there is significant reconfiguration and overall value for money.	Thank you for your comment. These factors will be incorporated into the review protocol when considered by the guideline committee. These factors will also be considered when assessing the cost-effectiveness of service configurations.
The Society and College of Radiographers	6	146	Access to services - on the diagram - we believe it important that the work takes account of consideration of referrals from other registered professional groups such as HCPC Allied Health Professions	Thank you for your comment. The full pathway will be developed when the guideline recommendations are made and the guideline is published. The example illustration in the scope will be adapted and more detail added accordingly.

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Society and College of Radiographers	6	146	Service delivery: new service models with Radiographer reporting should be considered within this section in relation to some procedures within clinical imaging. Where implemented in line with Royal College of Radiologists and College of Radiographers guidance there is significant improvement in the reporting times for clinical imaging. We can provide further information to support this.	Thank you for your comment. The full pathway will be developed when the guideline recommendations are made and the guideline is published. The example illustration in the scope will be adapted and more detail added accordingly.
The Society and College of Radiographers	7	159	The increasing complexity of clinical imaging examinations must also be taken into account as this impacts on patient throughput	Thank you for this useful information.
The Society and College of Radiographers	7	161	The recently published NHS Diagnostic Imaging Dataset (DID) provides accurate information on Clinical Imaging services https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostic-imaging-dataset/diagnostic-imaging-dataset-2015-16-data/	Thank you for this useful information.
The Society and College of Radiographers	7	173	Waiting *and reporting* times are key issues for diagnostic services	Thank you for your comment. We have amended this section as suggested.
The Society and College of	10	235	Within clinical imaging services there are specific legal requirements when using ionising radiation, **IR(ME)R 2000 and IR(ME) Amendment Regulations 2006 & 2011 , and The Ionising Radiations Regulations 1999 (IRR'99): these must**	Thank you for this information. We have added these details to the legislation section.

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Radiographers			**be accounted for and included within this section in relation to clinical imaging.**	
The Society and College of Radiographers	10	236	Professional bodies such as the SCoR, IPEM and BCVS also produce best practice guidance and this needs to be recognised within the document.	Thank you for this information. We have amended this section to reflect that best practice guidance is produced by a range of different professional bodies.

Registered stakeholders who were invited to comment but did not:

5 Boroughs Partnership NHS Foundation Trust
Academy for Healthcare Science
ALD Life
Arthritis Research UK
Ashford and St Peter's Hospitals NHS Trust
Association for Clinical Biochemistry and Laboratory Medicine
Association of Anaesthetists of Great Britain and Ireland
Belfast Health and Social Care Trust
Boehringer Ingelheim Ltd
Brahms UK Limited-Thermo Fisher Scientific
British Association for Music Therapy
British Geriatrics Society
British Medical Association
British Medical Journal

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British Nuclear Cardiology Society
British Nuclear Medicine Society
British Psychological Society
British Red Cross
British Society of Interventional Radiology
Care Quality Commission
Children's Heartbeat Trust
CMV Action UK
Cochlear Implanted Children's Support Group
College of Paramedics
Crohn's and Colitis UK
Department of Health
Department of Health, Social Services and Public Safety - Northern Ireland
East Midlands Strategic Clinical Network
East of England Strategic Clinical Network
Ferring Pharmaceuticals
FTWW
Health and Care Professions Council
Health and Social Care Information Centre
Healthcare Improvement Scotland
Healthcare Quality Improvement Partnership
Healthy Step
Heartlands Hospital
Hypermobility Syndromes Association
Institute of Physics and Engineering in Medicine
Kidney Cancer Support Network
King's College London
Mastercall Healthcare
MDS UK Patient Support Group
Medicines and Healthcare Products Regulatory Agency
Medway Community Healthcare

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Menarini Diagnostics UK
Merck Serono
Ministry of Defence
MRSA Action UK
National Autistic Society
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Community Hearing Association
National Deaf Children's Society
National Institute for Health Research
NHS Choices
NHS Eastern Cheshire CCG
NHS Health at Work
NHS Oxfordshire CCG
NHS Sheffield CCG
NHS Somerset CCG
NHSCC
Northern Health and Social Care Trust
Nursing and Midwifery Council
Oxford University Hospitals NHS Trust
Parkinson's UK
Piramal Imaging
Prostate Cancer UK
Public Health England
Roche Diagnostics
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Nursing

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Royal College of Obstetricians and Gynaecologists
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Speech and Language Therapists
Royal Cornwall Hospitals NHS Trust
Royal Pharmaceutical Society
Scottish Directors of Public Health
Scottish Intercollegiate Guidelines Network
Social Care Institute for Excellence
Society for Endocrinology
South Eastern Health and Social Care Trust
Southern Health & Social Care Trust
Superdrug Stores plc
Teenagers and Young Adults with Cancer
The Brain Tumour Charity
The British In Vitro Diagnostics Association
Thermo Fisher Scientific
Tillotts Pharma UK Ltd
Tuberous Sclerosis Association
Welsh Association Gastroenterology and Endoscopy
Welsh Government
Welsh Scientific Advisory Committee
Western Health and Social Care Trust
Wolfson Institute of Preventive Medicine

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[i] Right Care (2013) Atlas of Variation, Map 23 (page 102) and Map 24 (page 104)

[ii] RNID, 1988. Hearing aids a case for change. p. 5: RNID, 1999. Waiting to Hear. London p. 21; Department of Health, 2007. Evidence Submission to Health Select Committee. pp.74-75 in Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Department of Health, 2007. Improving Access to Audiology Services in England. Leeds: Department of Health; Department of Health, 2009. Hearing Services for Older People. London: Department of Health; NHS Improvement, 2010. Audiology Improvement Programme: Pushing the boundaries: Evidence to support the delivery of good practice in audiology. Leicester: NHS Improvement. p.5; Action on Hearing Loss, 2011. Hearing Matters. P.68;

[iii] NHS England and Department of Health, 2015, Action Plan on Hearing Loss http://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf

[iv] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients and reference cost data provided above.

[v] SEE follow sources for a guide to systemic system shortcomings and resistance to change even when independent evidence shows community-based services have advantages over the hospital model of care. SEE: Johnson, J. et al., (1984). "A survey of National Health Service hearing aid services. An RNID Scientific and Technical Department Report". RNID, London; RNID, Age Concern and British Association of the Hard of Hearing (1986) Breaking the Sound Barrier; RNID (1988) "Hearing aids the case for change". London; RNID (1999) "Waiting to hear? A report on waiting times for hearing tests" RNID, London; Audit Commission, (2000). "Fully equipped: the provision of equipment to older or disabled people by the NHS and social services in England and Wales" Audit Commission, London; Jayarajan, V. and Rangan, S. 2000. Evaluation of hearing-aid provision in adults. Journal of Audiological Medicine, 9(1), pp. 25-34; RNID (2001) "Audiology in crisis, still waiting to hear". RNID, London; Davis A, 2003. Private Sector Dispenser Pilot Evaluation November 2003 Executive Summary; Davis, A.2005. Effective ways for implementing research in a clinical environment: benefits, barriers and future challenges. P. Littlejohns 2005. Delivering Quality in the NHS 2005. Oxon: Radcliffe Publishing Ltd; Department of Health, 2007. Good Practice in Transforming Adult Hearing Services for Patients with Hearing Difficulty. Leeds: Department of Health; Department of Health, 2007. Improving Access to Audiology Services in England. Leeds: Department of Health; Department of Health, 2007. Evidence Submission to Health Select Committee. pp.74-75 in Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Ross, L. 2008. Modernizing times: UK hearing-impaired consumers at the policy crossroads. International Journal of Consumer Studies, 32 (2), pp. 122-127; NHS Improvement, 2011. NHS Improvement: The best of clinical pathway redesign. Practical examples delivering benefits to patients. Leicester: NHS Improvement; Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716; Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716; Lowe, C (2015) "Under Pressure: NHS Audiology Across the UK." London, Action on Hearing Loss; Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients.

Then see opposition in context by referring to:

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Evidence Submission to Health Select Committee (various), in Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Ross, L. 2008. Modernizing times: UK hearing-impaired consumers at the policy crossroads. International Journal of Consumer Studies, 32 (2), pp. 122-127; and AQP engagement blogs hosted by the Department of Health (AQP team) prior to 2012 implementation

[vi] E.g. In 1997, in a Department of Health sponsored study, heads of NHS audiology departments were surveyed about the benefits associated with delivering care closer to home. The response rate in England was 87%[vi]. The table below shows that, according to experts, care closer to home had considerable advantages for patients (Table 1); including improved access and the potential to improve hearing aid compliance. It also shows there was strong agreement on the benefits of care closer to home. Despite this, and the fact there was no evidence of hospitals attempting to deliver more diagnostic services for adult hearing loss outside of hospital, there has been opposition to community hearing care providers delivering this non-medical service outside of hospital in the last seven years.

Benefit	Major benefit	Minor benefit	Not a benefit	Reverse applies
Improved convenience/access for patients	95%	4%	1%	–
Encourages hearing aid use and maintenance	57%	24%	19%	1%
Provides better continuity of care	57%	23%	14%	7%
Reduces number of domiciliary visits	39%	33%	25%	3%
Fewer non-attendees at outreach sites	37%	33%	24%	7%
Secures work for department	36%	28%	36%	1%
Reduced waiting times for patients at outreach sites	35%	35%	22%	9%
Improves willingness of GPs to refer[a]	37%	41%	21%	–
Increased job satisfaction for audiologists	27%	40%	24%	9%
Improved communication with GPs[a]	37%	40%	23%	–
Educational for GPs[a]	21%	39%	40%	–
Educational for audiologist	8%	34%	50%	7%

[a] *Percentages based on sample restricted to centres holding clinics at GP sites, n = 75*

Table 1: Head of audiologists' view on the advantage of outreach work in 1997 (i.e. care closer to home (source: Reeves et al., 2000)

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[vii] Davis, A. and Smith, P., 2013. Adult Hearing Screening: Health Policy Issues – What Happens Next? American Journal of Audiology, 22(1), pp. 167-170. Note: Davis and Smith update estimates from previous research but do not provide their methodology. Their earlier research took place before digital hearing aids were introduced into the NHS. Since then more people have been fitted and therefore Davis and Smith's estimate of 3.8 million might slightly over estimate unmet need.

[viii] NB. Monitor notes "the introduction of choice has also made services more transparent" and that "the introduction of choice has strengthened the opportunity for [CCGs] to achieve better value for money. In areas with choice, commissioners have often put in place more robust or higher service specifications that raise expectations of providers. In some cases, commissioners have also established locally determined prices that are 20−25% lower than the national non-mandated tariff" (Monitor, 2015).
This is because:
The original structure of the non-mandated tariff for adult hearing services was noted in the Department of Health's "Payment by Results Guidance 2009-10" – (available here)

- the tariff included one follow-up and commissioners then paid for each additional aftercare
- it did not include any service specification or standards

This can be compared to the specification and prices in the Department of Health's Best Practice Guidance (BPG) published on 20th December 2012 (available here). BPG includes:

- clear standards – expectations, targets, accountability (available here)
- clearly defined prices (available here)

BPG shows that prices were reduced by 10% compared to the non-mandated tariff (page 40 - available here)

In addition to this 10% reduction there were other savings. For example all aftercare visits were included in the package of care. It is estimated that CCGs would save between 20% and 25% by using the BPG compared to the non-mandated tariff system. In some areas CCGs have also not adjusted local prices for MFF and therefore made savings in excess of 25% per patient (i.e. in some cases 10x the efficiency savings required in the Five Year Forward View). The new service specifications also set KPIs which mean providers are assessed on outcomes rather than activity – reducing the incentives to diagnose hearing loss but then fit and forget in order to meet referral to treatment targets. We believe such a model creates positive incentives to diagnose and then manage patients in the long-term and that because of this, other things being equal, the BPG is likely to be more cost-effective (in that it would dominate the non-mandated tariff model in any cost-effective analysis because by any definition the NHS is getting more for less). Patients are also not travelling as far to access care in areas where community diagnostics are accessible and therefore the societal cost of out of hospital audiology is also likely to be favourable in any cost-effectiveness model that captures service user costs.

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[ix] Swan, I.R.C. and Browning, G.G. 1994. A prospective evaluation of direct referral to audiology departments for hearing aids. The Journal of Laryngology and Otology, 108(2), pp. 120-124; Reeves, D.J. et al., 2000, Community provision of hearing aids and related audiology services, Health technology assessment (Winchester, England), vol. 4, no. 4; Abdelkader, M. et al. 2003. Prospective evaluation of the value of direct referral hearing aid clinic in management of young patients with bilateral hearing loss. Clinical Otolaryngology & Allied Sciences, 29(3), pp. 206-209; Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Eley, K. A. and FitzGerald, J. E. 2010. Quality improvement in action: Direct general practitioner referrals to audiology for the provision of hearing aids: a single centre review. Quality in Primary Care, 18(3), pp. 201-206; Zapala, D. A. et al 2010. Safety of Audiology Direct Access for Medicare Patients Complaining in Impaired Hearing. Journal of the American Academy of Audiology, 21(6), pp. 365-379.

[x] SEE: Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients and reference cost data provided above. In comparison 88,000 hearing assessments were done in primary care settings in the same year (NCHA dataset). See footnotes above for evidence of barriers to shifting services outside of hospital.

[xi] Right Care (2013) Atlas of Variation, Map 23 (page 102) and Map 24 (page 104)

[xii] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients

[xiii] We take Monitor's data on page 44 (click here) on completed Direct Access Audiology pathways for each year. We assume that all these patients had a hearing test when referred. We take reference cost activity data for 2012/13 (provided below). We compare the number of reported assessments to Monitor's reported figures and calculate an average of 71% (range 69-76%). To check our 71% estimate we compare this to the known causes of hearing loss in a population and our calculations for England which suggest 73% of all hearing loss can be managed by audiologists and for people aged 55 and over at least 89% of patients do not need ENT referral. And compare this to the 90% estimate in the peer-reviewed literature (Zapala, D. A. et al 2010. Safety of Audiology Direct Access for Medicare Patients Complaining in Impaired Hearing. Journal of the American Academy of Audiology, 21(6), pp. 365-379.) As age-related hearing loss will be the main driver of activity in coming years, and is already provided safely in primary care settings, we estimate 71%-90% of all activity could be done in the community.

[xiv] We provide reference cost activity for NICE to review. It is clear that most audiology activity is driven by hearing aid repairs (graph below). Other sections in our submission explain the prevalence of hearing loss and differential diagnosis.

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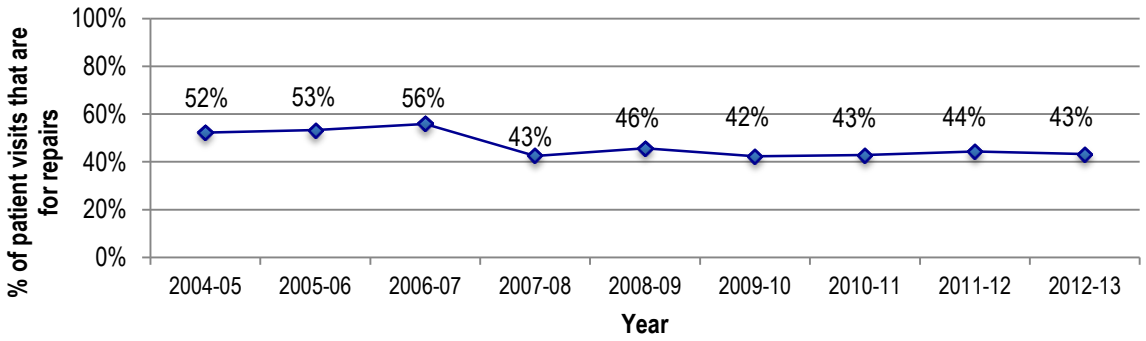

Graph: Percentage of adult patient visits that are devoted repairs in each year per audiology service provider (Calculated by dividing total reported activity by the number of submissions (Source: reference cost data 2004-2012).

[xv] AGE: Davis, A. et al., 2007. Acceptability, benefit and costs of early screening for hearing disability: a study of potential screening tests and models. Health technology assessment, 11(42); NCHA (2014) data on 88,203 hearing assessments. DISTANCE: Annex 2 of Monitor's 2015 report: NHS adult hearing services in England: exploring how choice is working for patients for modelling of distance travelled before and after introduction of community provision (here)

[xvi] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients

[xvii] Department of Health:

Department of Health, 2007. Evidence Submission to Health Select Committee. pp.74-75 in Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Department of Health, 2007. Improving Access to Audiology Services in England. Leeds: Department of Health; Department of Health, 2009. Hearing Services for Older People. London: Department of Health; Department of Health, 2012. Any Qualified Provider Adult Hearing Services Implementation Packs. London: Department of Health.

NHS England, NHS Improvement et al:

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NHS Improvement, 2010. Audiology Improvement Programme: Pushing the boundaries: Evidence to support the delivery of good practice in audiology. Leicester: NHS Improvement. p.5
NHS England and Department of Health, 2015, Action Plan on Hearing Loss http://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf

Patient Groups:

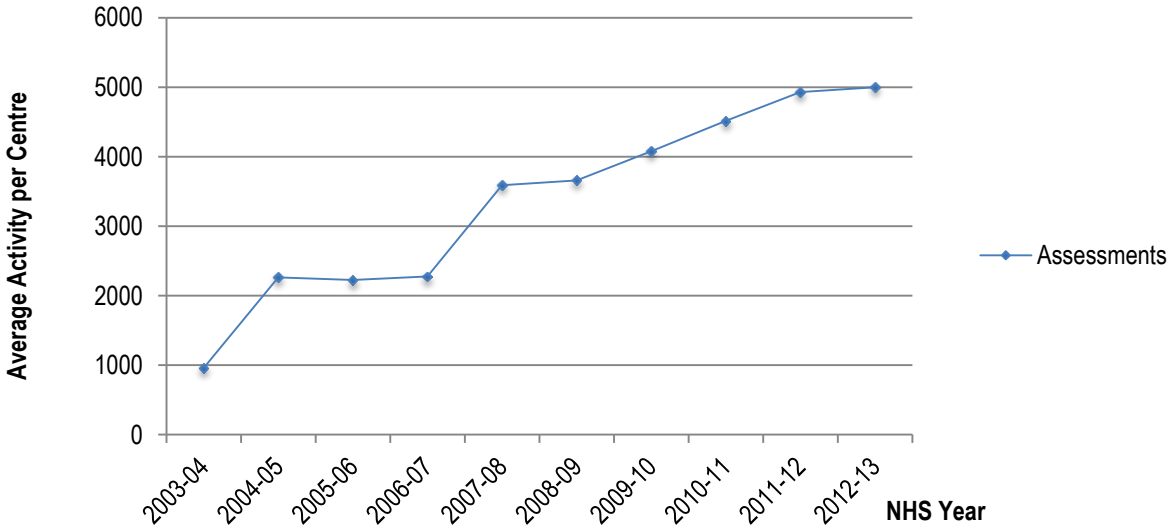
RNID, 1988. Hearing aids a case for change. p. 5: RNID, 1999. Waiting to Hear. London p. 21; Action on Hearing Loss, 2011. Hearing Matters. P.68

[xviii] Right Care (2013) Atlas of Variation, Map 23 (page 102) and Map 24 (page 104)

[xix] Right Care (2013) Atlas of Variation, Map 23 (page 102)

[xx] This includes reported activity for hearing assessments, fits, follow-ups and repairs rising from 1,098,196 (2002/2003) to 2,657,610 (2012/2013): Audiology Service Activity 2004-2013 (source: Department of Health).

The graph below shows estimated growth at department level



Graph: Average number of patient visits for a hearing assessment per audiology service provider (Calculated by dividing total reported activity by the number of submissions (Source: Reference cost data 2003-2012).

[xxi] Davis, A. and Smith, P., 2013. Adult Hearing Screening: Health Policy Issues – What Happens Next? American Journal of Audiology, 22(1), pp. 167-170. Note: Davis and Smith update estimates from previous research but do not provide their methodology. Their earlier research took place before digital hearing aids were introduced into the NHS. Since then more people have been fitted and therefore Davis and Smith's estimate of 3.8 million might slightly over estimate unmet need.
[xxii] NHS Improvement, Diagnostics (2013) Page 8, NHS Improvement – Diagnostics. Top tips to overcome the challenge of commissioning diagnostics services. Page 8

[xxiii] We take Monitor's data on page 44 (click here) on completed Direct Access Audiology pathways for each year. We assume that all these patients had a hearing test when referred. We take reference cost activity data for the same period. We compare the number of reported assessments to Monitor's reported figures and calculate an average of 71% (range 69-76%). To check our 71% estimate we compare this to the known causes of hearing loss in a population and our calculations for England which suggest 73% of all hearing loss can be managed by audiologists, and for people aged 55 and over at least 89% of patients do not need ENT referral. To validate this we compare this to the 90% estimate in the peer-reviewed literature (Zapala,

D. A. et al 2010. Safety of Audiology Direct Access for Medicare Patients Complaining in Impaired Hearing. Journal of the American Academy of Audiology, 21(6), pp. 365-379.) As age-related hearing loss will be the main driver of activity in coming years, and is already provided safely in primary care settings, we estimate 71%-90% of all activity could be done in the community. We apply this to total activity linked to adults and estimate that 1.8-2.3 million patient contacts could be delivered outside of hospital.

[xxiv] Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716

[xxv] NDCS, 2014, Listen Up, available here http://www.ndcs.org.uk/document.rm?id=9393

[xxvi] Zapala, D. A. et al 2010. Safety of Audiology Direct Access for Medicare Patients Complaining in Impaired Hearing. Journal of the American Academy of Audiology, 21(6), pp. 365-379.

[xxvii] Chisolm, T. et al. 2007. A Systematic Review of Health-Related Quality of Life and Hearing Aids: Final Report of the American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults. Journal of the American Audiology, 18(2), pp. 151-183; Barker, F. et al, 2014. Interventions to improve hearing aid use in adult auditory rehabilitation (Protocol). Cochrane Database of Systematic Reviews: Reviews 2014; Issue 7 and most recently see NHS England and Department of Health, 2015, Action Plan on Hearing Loss http://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf page 12-13

[xxviii] Department of Health; Department of Health, 2012. Any Qualified Provider Adult Hearing Services Implementation Packs. London: Department of Health (2012) p.10

[xxix] Swan, I.R.C. and Browning, G.G. 1994. A prospective evaluation of direct referral to audiology departments for hearing aids. The Journal of Laryngology and Otology, 108(2), pp. 120-124; Reeves, D.J. et al., 2000, Community provision of hearing aids and related audiology services, Health technology assessment (Winchester, England), vol. 4, no. 4; Abdelkader, M. et al. 2003. Prospective evaluation of the value of direct referral hearing aid clinic in management of young patients with bilateral hearing loss. Clinical Otolaryngology & Allied Sciences, 29(3), pp. 206-209; Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Eley, K. A. and FitzGerald, J. E. 2010. Quality improvement in action: Direct general practitioner referrals to audiology for the provision of hearing aids: a single centre review. Quality in Primary Care, 18(3), pp. 201-206; Also see identical referral criteria for community and hospital audiology: Department of Health; Department of Health, 2012. Any Qualified Provider Adult Hearing Services Implementation Packs. London: Department of Health Health (2012)

[xxx] (Provided by Sandhu, H): The vast majority of hearing assessments will result in a diagnosis of age-related hearing loss. Life or hearing threating pathology is very (relatively) rare. We believe the community-based model of care, other things being equal, would be at least £30 million per annum less costly than the hospital c. £250million per annum reported cost. Given this significant cost reduction, the cost per case of detecting rare diseases is unlikely to be justifiable on the NHS (see stage two). But more importantly, there is no evidence to support that hospital and community audiologists are better or worse than each other in detecting conditions that require onward referral to ENT. In fact, most diagnostic tests for conditions/symptoms requiring onward referral are not complicated and can be performed by both groups (ref: Swan, I.R.C. and Browning, G.G. 1994. A prospective evaluation of direct referral to audiology departments for hearing aids. The Journal of Laryngology and Otology, 108(2), pp. 120-124; Reeves, D.J. et al., 2000, Community provision of hearing aids and related audiology services,

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Health technology assessment (Winchester, England), vol. 4, no. 4; Abdelkader, M. et al. 2003. Prospective evaluation of the value of direct referral hearing aid clinic in management of young patients with bilateral hearing loss. Clinical Otolaryngology & Allied Sciences, 29(3), pp. 206-209; Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Eley, K. A. and FitzGerald, J. E. 2010. Quality improvement in action: Direct general practitioner referrals to audiology for the provision of hearing aids: a single centre review. Quality in Primary Care, 18(3), pp. 201-206). This means the marginal cost per additional case of pathology detected is likely to be a) difficult to prove, and b) in any case not offer a cost-effective alternative to community-based care.

Stage One Calculations: Updated estimate of the number of people with a hearing loss in England based on ONS (2013) on mid-2011 population estimates.

Age Group	Population (A)	Prevalence % (95% confidence intervals) (B)	Number of People with a Hearing Loss (A * B)
0-16	10,673,755	0.33[1]	35,000
17-30	10,032,199	1.8 (0.7-2.9)	180,580
31-40	7,088,145	2.8 (1.2-4.4)	198,468
41-50	7,722,768	8.2 (6.1-10.3)	633,267
51-60	6,284,198	18.9 (16.1-21.7)	1,187,713
61-70	5,536,021	36.8 (32.4-41.2)	2,037,256
71-80	3,606,835	60.2 (53.0-67.5)	2,171,315
>80	2,163,248	93.4 (91.7-95.0)	2,020,474

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Total number of children with a hearing loss in England (**Source: White et al., 2013**)	35,000
Total number of adults (aged 17 and over) in England with a hearing of impairment of ≥ 25 decibels in the better ear (**Source: Davis, 1989; Davis, 1995, p.822**)	8,499,073
Total number of people with a hearing loss in England	**8,534,073**

[1]Based on 35,000 children in England having a hearing loss (White et al., 2013) and the population of people aged ≤16 being 10,673,755 (ONS, 2013)

Stage Two Calculations: Estimated number of people with a hearing loss in England that can be managed effectively by an audiologist without referral to ENT.

Description	Population (Prevalence %)		Reference(s)
Number of people aged ≥55 in England[1]	14,895,459 (NA)	A	(ONS, 2013)
Estimated number of people aged ≥55 with at least a mild hearing loss (≥25dB) in the better ear. People aged ≥55[1] are eligible for accessing NHS audiology without ENT review.	6,907,432 (46%) (Therefore 82% of the population with a hearing loss are age ≥55)	B	[ONS (2013) population estimates for each age group in England] multiplied by [prevalence in each age group (Davis, 1989; Davis, 1995, p.822]. Overall prevalence of mild loss (B/A*100)
Chronic otitis media (44,989 cases per 1 million) [2] needs referral to ENT	670,132 (4.5%)	C	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]

Meniere's disease (1500 cases per 1 million) [2] needs referral to ENT	22,343 (0.15%)	D	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Otosclerosis (560 cases per 1 million) [2] needs referral to ENT	8,341 (0.06%)	E	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Sudden idiopathic sensorineural loss (200 cases per 1 million) [2] needs referral to ENT	2,979 (0.02%)	F	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Cholesteatoma (92 cases per 1 million) [2] needs referral to ENT	1,370 (0.01%)	G	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Hearing loss in multiple sclerosis (86 cases per 1 million) [2] needs referral to ENT	1,281 (0.01)	H	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Labyrinthitis (35 cases per 1 million) [2] needs referral to ENT	521 (0.004%)	I	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Vestibular schwannoma or other retrocochlear mass (15 cases per 1 million) [2] needs referral to ENT	223 (0.002%)	J	[Prevalence of condition (Zapala et al., 2010)] multiplied by [A]
Estimated total number of cases of hearing loss in people aged ≥55[1] requiring medical review [Σ: C:J]	707,192	K	
Conservative estimate of the number of people aged ≥55[1] with at least a mild hearing loss (≥25dB) that do **not** need medical opinion [B-K]	6,200,240	M	

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Estimated (%) of people with a hearing loss aged ≥55[1] that can be managed by a community-based audiologist [M/L] – i.e. is mainly a ARHL[3]	89.8%[3] (or 73% of all people with hearing loss if including people <55)[4]

[1] In 2012 the Department of Health published guidance on referral criteria for ARHL and set the age for General Practitioners referring patients for ARHL at 55. Therefore this table is based on people aged ≥ 55 (Department of Health, 2012, p.51). [2] Zapala et al., (2010) provide the highest estimates of conditions that would require medical review, whilst their study is based in the United States, their estimates are from the literature and therefore more generalisable. Estimates could be updated with local epidemiological data but this was outside the scope of this study and there was no reason to assume these conditions would be higher in England than other Western Countries. [3]This is consistent with Zapala et al., (2010) who note very conservative estimates suggest that 89% of people aged ≥65 with a hearing loss would not need a medical review. Zapala et al. also provide prevalence estimates of 15% for noise-induced loss. After consulting expert opinion (Anon), both noise and ARHL are forms of sensorineural losses and ARHL is a function of (age, noise exposure and other unknown factors). Therefore noise induced hearing loss is difficult to differentiate from ARHL in older people and in any case does not need medical review. Therefore 15% noise-induced hearing loss was not used separately. [4] Based on (6,200,240/8,534,073 from section one).

[xxxi] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients p.31-34

[xxxii] See: Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients. Monitor's report makes clear that introducing choice can help drive better value for money. Monitor also provides commissioners with guidance on how to make choice work better for patients and explains that where there is unmet need, total costs might rise, but that in its view the benefits are likely to outweigh the costs.

[xxxiii] This includes reported activity for hearing assessments, fits, follow-ups and repairs rising from 1,098,196 (2002/2003) to 2,657,610 (2012/2013): Audiology Service Activity 2004-2013 (source: Department of Health)

[xxxiv] NDCS, 2014, Listen Up, available here http://www.ndcs.org.uk/document.rm?id=9393

[xxxv] These can be reviewed in: Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients, p.32. If NICE would like the original DoH document we would be happy to forward this.

[xxxvi] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients, p. 32-33

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[xxxvii] Johnson, J. et al., (1984). "A survey of National Health Service hearing aid services. An RNID Scientific and Technical Department Report". RNID, London; RNID, Age Concern and British Association of the Hard of Hearing (1986) Breaking the Sound Barrier; RNID (1988) "Hearing aids the case for change". London; RNID (1999) "Waiting to hear? A report on waiting times for hearing tests" RNID, London; Audit Commission, (2000). "Fully equipped: the provision of equipment to older or disabled people by the NHS and social services in England and Wales" Audit Commission, London; Jayarajan, V. and Rangan, S. 2000. Evaluation of hearing-aid provision in adults. Journal of Audiological Medicine, 9(1), pp. 25-34; RNID (2001) "Audiology in crisis, still waiting to hear". RNID, London; Health Committee (2007) "Audiology Services, Fifth report of session 2006-07" London, HC; Matthews, L. (2011) "Seen but not heard: People with hearing loss are not receiving the support they need". London, RNID; Action on Hearing Loss (2011) "Hearing Matters", London. [3]Davis, A. (2005). "Effective ways for implementing research in a clinical environment: benefits, barriers and future challenges" in P. Littlejohns 2005. "Delivering Quality in the NHS" 12955 33 2005. Oxon: Radcliffe Publishing Ltd.

[xxxviii]Department of Health (2010) Impact Assessment Any Qualified Provider (here)

[xxxix] SEE: Johnson, J. et al., (1984). "A survey of National Health Service hearing aid services. An RNID Scientific and Technical Department Report". RNID, London; RNID, Age Concern and British Association of the Hard of Hearing (1986) Breaking the Sound Barrier; RNID (1988) "Hearing aids the case for change". London; RNID (1999) "Waiting to hear? A report on waiting times for hearing tests" RNID, London; Audit Commission, (2000). "Fully equipped: the provision of equipment to older or disabled people by the NHS and social services in England and Wales" Audit Commission, London; Jayarajan, V. and Rangan, S. 2000. Evaluation of hearing-aid provision in adults. Journal of Audiological Medicine, 9(1), pp. 25-34; RNID (2001) "Audiology in crisis, still waiting to hear". RNID, London; Department of Health, 2007. Improving Access to Audiology Services in England. Leeds: Department of Health; Department of Health, 2007. Evidence Submission to Health Select Committee. pp.74-75 in Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Ross, L. 2008. Modernizing times: UK hearing-impaired consumers at the policy crossroads. International Journal of Consumer Studies, 32 (2), pp. 122-127; NHS Improvement, 2011. NHS Improvement: The best of clinical pathway redesign. Practical examples delivering benefits to patients. Leicester: NHS Improvement; Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716; Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716; Lowe, C (2015) "Under Pressure: NHS Audiology Across the UK." London, Action on Hearing Loss.

[xl] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients, p.21

[xli] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients, p.5

[xlii] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients, p.21

[xliii] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients

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[xliv] NHS England and Department of Health, 2015. Action Plan on Hearing Loss, p. 11

[xlv] RNID, 1999. Waiting to Hear. London p. 21;

[xlvi] Action on Hearing Loss, 2011. Hearing Matters. P.68

[xlvii] Reeves, D.J. et al., 2000, Community provision of hearing aids and related audiology services, Health technology assessment (Winchester, England), vol. 4, no. 4

[xlviii] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients, p. 4

[xlix] NHS England and Department of Health, 2015. Action Plan on Hearing Loss, p. 11

[l] SEE: Johnson, J. et al., (1984). "A survey of National Health Service hearing aid services. An RNID Scientific and Technical Department Report". RNID, London; RNID, Age Concern and British Association of the Hard of Hearing (1986) Breaking the Sound Barrier; RNID (1988) "Hearing aids the case for change". London; RNID (1999) "Waiting to hear? A report on waiting times for hearing tests" RNID, London; Audit Commission, (2000). "Fully equipped: the provision of equipment to older or disabled people by the NHS and social services in England and Wales" Audit Commission, London; Jayarajan, V. and Rangan, S. 2000. Evaluation of hearing-aid provision in adults. Journal of Audiological Medicine, 9(1), pp. 25-34; RNID (2001) "Audiology in crisis, still waiting to hear". RNID, London; Department of Health, 2007. Improving Access to Audiology Services in England. Leeds: Department of Health; Department of Health, 2007. Evidence Submission to Health Select Committee. pp.74-75 in Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Health Committee, House of Commons, 2007. Audiology Services. (HC 392, Fifth Report of Session 2006-7) – Report, together with formal minutes, oral and written evidence. London: The Stationary Office Limited; Ross, L. 2008. Modernizing times: UK hearing-impaired consumers at the policy crossroads. International Journal of Consumer Studies, 32 (2), pp. 122-127; NHS Improvement, 2011. NHS Improvement: The best of clinical pathway redesign. Practical examples delivering benefits to patients. Leicester: NHS Improvement; Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716; Hind et al. 2011. Prevalence of clinical referrals having hearing thresholds within normal limits. International Journal of Audiology 2011; 50: 708–716; Lowe, C (2015) "Under Pressure: NHS Audiology Across the UK." London, Action on Hearing Loss; Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients

[li] The main reason for visiting an hospital audiology department is for a hearing aid repair.

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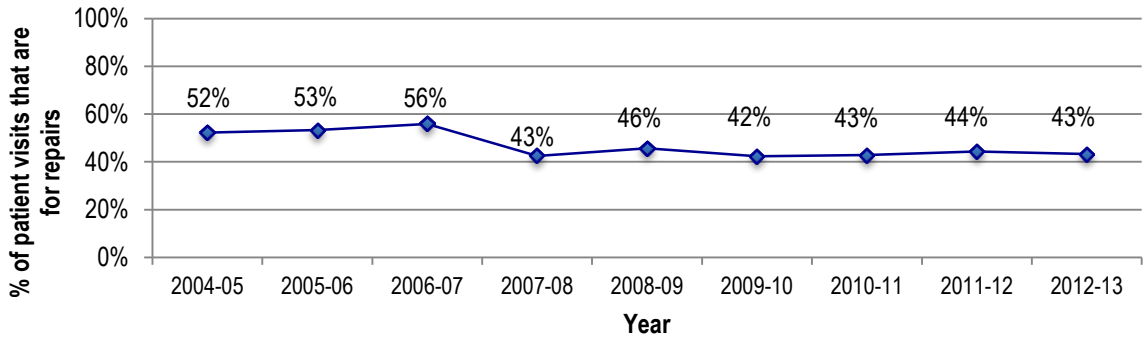

Graph: Percentage of adult patient visits that are devoted repairs in each year per audiology service provider (Calculated by dividing total reported activity by the number of submissions (Source: reference cost data 2004-2012).

[lii] Head of audiologists' view on the advantage of outreach work in 1997 (i.e. care closer to home (source: Reeves et al., 2000)

[liii] See infographic and notes at: http://www.the-ncha.com/data/

[liv] Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients

[lv] NHS England and Department of Health (2015) Action Plan on Hearing Loss, p.19-20.
http://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf

[lvi] Chisolm, T. et al. 2007. A Systematic Review of Health-Related Quality of Life and Hearing Aids: Final Report of the American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults. Journal of the American Audiology, 18(2), pp. 151-183; Davis, A. et al., 2007. Acceptability, benefit and costs of early screening for hearing disability: a study of potential screening tests and models. Health technology assessment, 11(42) pp. 75-78; Acar, B. et al. 2011. Effects of hearing aids on cognitive functions and depressive signs in elderly people. Archives of Gerontology and Geriatrics, 52(3), pp. 250-252.

[lvii] NHS England and Age UK, 2015, A Practical Guide to Health Ageing

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[lviii] NICE, 2013. Mental wellbeing of older people in care homes. NICE Quality Standard 50. pp. 28-31. https://www.nice.org.uk/guidance/qs50/resources/guidance-mental-wellbeing-of-older-people-in-care-homes-pdf Accessed 1 February 2015

[lix] See: Monitor, 2015. NHS adult hearing services in England: exploring how choice is working for patients

END