Rapid review: Evidence for models of diagnostic service provision in the community

Background

This proposal seeks to address a topic suggested by Prof. Erika Denton, National Clinical Director for Diagnostics at NHS England, and identified as a priority by the Department of Health R&D Committee. The purpose of the evidence synthesis is to assess the evidence base for diagnostic services provided outside hospital settings, for example in the community or in general practice. The findings will be expected to provide actionable messages for the NHS and/or identify priorities for further research.

Diagnostic tests and their results are fundamental to clinical decision-making. In the UK NHS, general practitioners (GPs) and other primary care professionals have traditionally had a limited ability to access such tests directly. Instead a common model is for GPs to refer patients for blood, tissue or imaging tests at the local hospital, resulting in sometimes lengthy waits for appointments and availability of test results. Offering more diagnostic tests in the community could enable faster and earlier diagnosis of common conditions and avoid unnecessary referrals. Other potential benefits include greater convenience and lower costs for patients and possibly a reduction in numbers of missed appointments. The Health and Social Care Information Centre has reported that in the year to March 2014, over 4.3 million patients accounted for 6.8 million missed outpatient appointments at an estimated cost of £108 per appointment (see http://www.hscic.gov.uk/article/4801/One-in-50-outpatients-who-miss-an-appointment-fail-to-attend-three-or-more-further-appointments-within-three-months).

Diagnostic tests cover the whole range of clinical conditions and this review, while not aiming at exhaustive coverage, will include those tests and conditions most relevant to primary care and community settings. A potentially important distinction is between tests (for example, most types of imaging) that require specialist equipment and/or staff to administer and those that can be administered by any health professional or the patient him/herself in any setting or at home. We will seek to explore the evidence for both groups of tests in this review.

Greater availability of diagnostic testing in primary care is supported by both policy and technological drivers. Current NHS policy supports initiatives aimed at early diagnosis of long-term conditions with an emphasis on management in the community as far as possible. Technological drivers include:

- prices for some types of diagnostic imaging equipment (for example, ultrasound) have fallen substantially, making provision of services in primary care more feasible;

- novel diagnostic tests, often offering the facility for testing at the point of care and immediate feedback of results. These tests have extended the range of available *in vitro* diagnostic (IVD) tests.

The National Institute for Health Research (NIHR) is currently funding four Diagnostic Evidence Co-operatives (DECs) to assess the clinical validity, clinical utility, cost-effectiveness and care pathway benefits of IVDs (see http://www.nocri.nihr.ac.uk/research-expertise/diagnostic-evidence-co-operatives/).. The DEC based in Oxford has a focus on primary care and has published a number of horizon scanning reports on new tests that may be suitable for use in primary care (see Appendix A).

The primary focus of this review is on services rather than individual tests. For example, one model of service is a community diagnostic centre offering a range of tests such as X-rays, ultrasound, spirometry and electrocardiography (ECG), as described by Hollins and colleagues (see Appendix B).[1] Other models include mobile services providing a specific imaging technology such as magnetic resonance imaging (MRI) and condition-specific services for conditions such as diabetes. In assessing the evidence it will be important to take account of the specific needs of tests to be administered in primary care/community settings.

Review question(s)

The review will address the following questions (modified from those in the brief):

- What models of community diagnostic services currently exist (in the UK and internationally)?
- What is the evidence for quality, safety and clinical effectiveness of different models of diagnostic service provision outside hospital settings?
- Which tests are most commonly provided and is there any evidence for an effect on outcomes?
- Is there any evidence to support a broader range of diagnostic tests being provided in the community? This question may need further clarification but could refer to:
    - Tests that are not currently offered in community settings but which could be appropriate for such use.
    - Organisational models such as larger diagnostic centres compared with single-service models.

These questions will be used as a framework to guide the review as discussed below.

Scope (inclusion/exclusion criteria)

The focus of the project is primarily on ways of delivering services and not on diagnostic accuracy or other attributes of the tests themselves, although differences between primary care and secondary care populations may make particular tests more or less suitable for use in these populations. Suggested inclusion criteria in

terms of PICO (participants, intervention(s), comparator(s) and outcome(s) are listed below.

Participants: People with suspected acute or chronic disease in primary care/community settings. The focus is on people requiring a formal diagnosis and initial treatment/ management plan. We suggest excluding services where tests are used to help people with long-term conditions like diabetes monitor and manage their condition. This definition of participants also excludes screening of predominantly healthy general populations.

Intervention: Provision in a primary care/community setting of a diagnostic testing service accessible without referral to secondary care. In the UK context, primary care includes GPs' surgeries and urgent care/walk-in centres, while community care includes generalist or specialist care delivered outside hospital or in the patients' home. The focus is on services where all elements of the test (sampling/imaging, processing and interpretation of the result) are provided entirely within the community/primary care setting and by the service's own staff. For example, service models involving interpretation of results by clinicians in secondary care or use of external commercial laboratories will be excluded. A possible second level of intervention could be any diagnostic test evaluated specifically in such a service/setting and reporting relevant outcomes beyond diagnostic accuracy (for example, faecal calprotectin for differentiating inflammatory bowel disease from irritable bowel syndrome[2,3]).

Comparator: The main comparator is provision of diagnostic testing in a secondary care setting (with referral from primary/community care), followed by specialist referral if required. Relevant non-comparative studies will also be included.

Outcomes: Primary outcomes are any measure of effect on patient management/outcomes, patient experience or costs/resource use. Resource use includes differences in staffing and staff costs as well as training. Diagnostic accuracy may also be a relevant outcome but not the main focus.

Study design: Relevant study designs include systematic literature reviews and primary studies of any design that describe or evaluate a relevant service. Relevant designs could include retrospective or prospective service evaluations and audits as well as experimental and observational studies and economic evaluations. Qualitative studies of patient or staff experience and studies that report on barriers and facilitators of service development or implementation will also be included. Non-peer-reviewed evidence will be tabulated but not analysed.

Methods

We propose to undertake the review in two stages. We will carry out an initial mapping exercise to assess the quantity and nature of the available research evidence. We will use the results of this exercise to identify areas to focus on in more detail.

Mapping exercise

Databases to be searched will include MEDLINE, EMBASE, the Cochrane Library (includes the Cochrane Database of Systematic Reviews and DARE), Web of Science (Science Citation Index and Social Science Citation Index) and CINAHL. Searches for the mapping exercise will cover the period 2000 to 2014 and filters will be used to limit the searches by study design. Search results will be sifted by one reviewer to identify relevant literature reviews (systematic and narrative/non-systematic) and comparative studies that appear to meet the inclusion criteria above. Brief details of relevant literature will be summarised and tabulated in the form of a matrix showing the conditions and technologies for which the best evidence appears to be available. The findings will be discussed with the HS&DR programme and other relevant stakeholders (e.g. NHS commissioners and clinical experts) and used to guide further evidence synthesis.

Update to protocol, February 2015

Based on the results of the mapping exercise, it was decided to perform three focused rapid reviews covering:

- Logistics of diagnostic modalities in primary care: This review reflects the finding from the mapping exercise of a variety of different diagnostic technologies with different implications arising from being located in primary care. It was agreed that it would be helpful to characterise key technologies (e.g. radiology, audiology, point-of-care testing) against a common set of logistic and service delivery considerations. This review will be undertaken as a framework map and synthesis.

- Diagnostic ultrasound services: A more detailed focused review of ultrasound services will also be performed. The mapping exercise revealed some evidence on these services and ultrasound is used in diagnosing a wide range of conditions. This review is likely to focus on issues around equipment (small portable scanners, including hand-held devices, are available) and training.

- Primary care-led diagnostic pathway: This review is expected to cover the differential diagnosis of breathlessness (to be confirmed) and examine issues related to decision-making and availability of multiple tests in primary care/community settings.

Protocols will be developed for each of these rapid reviews before starting further searching. They will be reported separately but overall implications for service delivery and organisation will be considered in the discussion section of the final report.

Evidence synthesis

We will perform a number of rapid reviews focused on areas where there is comparative evidence of the performance of different models of service, particularly comparing community-based services with hospital-based services accessed by referral. We anticipate that this stage of the project will take 4 to 6 months depending on the number of conditions/technologies included.

The searches performed for the mapping exercise will be extended to identify any additional studies (e.g., qualitative or descriptive papers) meeting the inclusion criteria. Searches will not be limited by language. However, resource constraints mean that only English-language publications will be included in the review. Any potentially relevant publications in other languages, and any implications of omitting them from the review, will be noted. In addition, we will undertake the following to identify key evidence for the review:

- Liaison with topic experts
- Citation searching on included papers and any other key papers identified by topic experts
- Scanning lists of studies included in systematic reviews included in the mapping exercise
- Browsing of selected web sites
- Searches of older literature (pre-2000) if considered necessary based on expert advice.

Selection of studies for inclusion (scanning of titles/abstracts and full text publications) will generally be carried out by one reviewer. In cases of doubt, a second reviewer will independently examine the full text. Any disagreements will be resolved by discussion and consensus, with reference to a third reviewer if necessary.

Included experimental or observational studies will be assessed for quality using relevant tools (e.g. Cochrane risk of bias tool for clinical trials, Newcastle–Ottawa scale for observational studies.) Data will be extracted using forms set up in advance and piloted on a small number of studies. Data extraction and quality assessment will be checked by a second reviewer. Any discrepancies will be resolved by discussion and consensus, with reference to a third reviewer if necessary.

Given the nature of the topic and the likely evidence base, quantitative synthesis by meta-analysis is unlikely to be possible. We expect to perform a narrative synthesis by type of service model and/or condition/patient pathway. The synthesis will provide an analysis of the quality of evidence and the strength of conclusions which can be drawn from current studies. For studies where the provision of the community service was supported or facilitated by study staff, we will assess the feasibility of providing the service in routine practice (including any required training).

In addition to reviewing the evidence around individual technologies, we will seek to assess potential implications for the overall health system of providing more diagnostic services in community settings. For simplicity we propose to highlight

relevant issues in the introduction section of the report and provide a separate summary of related evidence. An alternative would be to structure the synthesis as a 'whole system' report and look at the implications of each technology in possible conjunction throughout. However, this would probably require more time and resources for the synthesis without necessarily providing benefits in terms of relevance and usefulness for NHS decision-makers.

Searching

Potentially relevant MeSH terms include: diagnostic services; clinical laboratory services; genetic testing; mobile health units. Combining terms like these with terms for specific tests or types of test (e.g. 'ultrasound', 'spirometry') could result in large numbers of results but a low yield of relevant studies. Therefore, given that this is a rapid review, we will aim to concentrate on identifying the key evidence of most relevance to the review question. This could involve approaches based on data mining (e.g. the 'progressive fractions' method); reference checking and citation searching of relevant studies; and use of literature reviews as sources of references.

Timeline

Activity	**Start**	**Finish**
Prepare draft protocol	22 September	15 October
Review of protocol by HS&DR programme	16 October	31 October
Protocol sign-off (phone conference to be arranged)	1 November	14 November
Literature searching and mapping exercise	15 November	15 January
Define and agree scope for focused rapid reviews	16 January	30 January
Additional literature searches, follow-up of references; citation searching etc.	31 January	27 February
Further evidence synthesis for selected models/technologies	2 March	31 March to 30 April*
Analysis and report writing	1 April to 1 May	28 May to 30 July
Delivery of draft report	29 May to 31 July	29 May to 31 July

*Range of dates reflects uncertainty over the number of conditions/technologies to be reviewed

References

1. Hollins L, Elliott-Rotgans D, Eaton M. A viable plan for virtual reporting. *Health Service Journal* 2011 September 15;121(6274):22–4.
2. Pavlidis P, Chedgy FJ, Tibble JA. Diagnostic accuracy and clinical application of faecal calprotectin in adult patients presenting with gastrointestinal

symptoms in primary care. *Scand J Gastroenterol*. 2013 Sep;48(9):1048-54.
3. Waugh N, Cummins E, Royle P, Kandala NB, Shyangdan D, Arasaradnam R, Clar C, Johnston R. Faecal calprotectin testing for differentiating amongst inflammatory and non-inflammatory bowel diseases: systematic review and economic evaluation. *Health Technol Assess*. 2013 Nov;17(55):xv-xix, 1-211.

Appendix A: Tests covered by Oxford DEC horizon scanning reports

Type of test	Condition	Comments
Non-contact thermometer	High temperature/fever in children	Research needs discussed
POC cardiac markers	Suspected heart attack	Primarily ED based. Clinical implications discussed
POC calprotectin	IBS/IBD	Primary care relevant; clinical implications and research needs discussed
POC faecal occult blood	Bowel cancer	Primary care relevant; clinical implications and research needs discussed. Overlap with screening programme.
Portable ultrasound	Various	Primary care relevant but major evidence/research gaps identified
Urinalysis self-testing in pregnancy	Proteinuria (sign of pre-eclampsia)	Primary care relevant but focus on self-testing
POC creatinine testing	Kidney disease	Primary care relevant; overlap with screening and monitoring
POC testing for heart-type fatty acid binding protein	Suspected heart attack	Primarily ED based? Clinical implications and research needs discussed

ED, emergency department; IBS/IBD, irritable bowel syndrome/inflammatory bowel disease; POC, point-of-care

Appendix B: Services potentially available via a 'community diagnostic centre'

Type of test/service	Condition	Comments
X-ray	Various	All mentioned in HSJ article[1]
Ultrasound	Various	
Spirometry	COPD	
Ambulatory ECG	Various	
Ambulatory blood pressure	Various	
Resting ECG	Various	

COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram

Logistics of Diagnostic Modalities in Primary Care: a Framework Map and Synthesis – Review Protocol

Background

Recent years have witnessed increasing momentum towards improved access to diagnostic services for general practitioners and community-based allied health professionals [1, 2]. Political drivers towards improved primary care access to diagnostic services are identifiable from such Department of Health documents as *Care Closer to Home* [3] and *NHS Next Stage Review: Leading Local Change* [4], chaired by Lord Darzi. These documents outline a need to achieve change through "disruptive innovation", *i.e.* change involving radical service redesign and an emphasis on empowering the frontline by devolving key aspects of care pathways from secondary to primary care [1].

Concerns around service redesign include material dimensions (including the test platform, equipment, reagents and supplies) and the health professionals, their roles, their relations and the socio-cultural context in which testing occurs. In addition little operational research has been undertaken into health system requirements and the impact of technologies on diagnostic accuracy, retesting and diagnostic delays. Factors associated with reconfiguration within the health system relate to skills, training, cost, equipment, premises, and referral linkages between primary and secondary care.

Empowerment of general practitioners and community-based allied health teams requires identification of perceived barriers and facilitators to redesign of diagnostic services. A recent systematic review of qualitative studies revealed that primary care clinicians believed point-of-care testing improved diagnostic certainty, targeting of treatment, self-management of chronic conditions, and clinician-patient communication and relationships [5]. At the same time clinicians expressed concerns about test accuracy, over-reliance on tests, undermining of clinical skills, cost, and limited usefulness.

This Framework Map and Synthesis is being undertaken as part of a larger review project looking at provision of diagnostic services in community settings. Initial literature mapping revealed a variety of diagnostic modalities with different implications for being located within Primary Care. In addition to examining one modality in detail, diagnostic ultrasound (See accompanying Review Protocol) it was agreed that it would be helpful to characterise modalities against a common set of logistic and service delivery considerations. These considerations would not only be populated by data relating to existing modalities but the resultant framework could become a basis for evidence gathering for potential and future technologies.

Review question

What are the logistic and service delivery considerations associated with the introduction and ongoing provision of diagnostic services in community or primary care settings? These should include implications for NHS organisations (e.g. related to provision of staff, premises, training and equipment, costs and cost-effectiveness) and patients (e.g. related to changes in management/pathways, acceptability to patients, accuracy of diagnosis, differential performance of tests and longer-term clinical outcomes).

Inclusion/exclusion criteria

Population: people requiring diagnostic services for any condition (excluded: universal screening and monitoring, including pregnancy). Studies that describe screening for selective populations (e.g. by age, gender, ethnic group) or for individuals indicated to be at

risk will be included provided factors that are identified are either common or concentrated within the UK population.

Intervention: diagnostic services provided in a primary care or community setting by primary care/community staff using any type of equipment. Open access services provided to GPs by a hospital using its premises, equipment and staff will be treated as a comparator intervention.

Comparator: hospital-based diagnostic services (open access or traditional). 'Outreach' services using hospital-based staff to deliver services in community settings would also be relevant comparators

Outcomes and study designs: the main focus is research studies conducted in any developed world setting that evaluate community diagnostic services against a comparator. Audits, service evaluations, descriptive studies, economic evaluations and qualitative research studies will be included if they have been conducted in a UK setting. Systematic reviews with no geographic limits or where geographic limits include UK settings will also be eligible for inclusion. In addition, we will include relevant expert opinion or reports from professional bodies that identify and/or discuss practical issues related to the provision of community diagnostic services. (4)

We will use our innovative STEPUP framework as the basis for comparison and analysis.

SKILLS: Skill mix; Extended roles; Inappropriate Test Ordering
TRAINING: Training Needs; Training Costs; Duration
EQUIPMENT: Equipment for modality and for analysis; consumable costs
PREMISES: Cost of Premises
USER PERSPECTIVE: Waiting Times; Acceptability; Repeat Procedures.
PRIMARY-SECONDARY INTERFACE: Referrals, Changes to Diagnosis or Management Pathways; Differential rates of Diagnosis in Primary versus Secondary Care

Given that the focus of the review is on models of service, studies that only report on the diagnostic accuracy of modalities will not be included.

Methods

Searching

We will undertake a two stage search strategy:

(i) Stage One - Identification and location within STEPUP framework of sub-factors of relevance to each modality

This requires rapid mapping from systematic reviews, opinion pieces, "barriers" literature, feasibility studies, policy documents etcetera to generate a comprehensive framework across modalities. The aim is to be expansive in identifying as many factors as possible across all modalities, rather than exhaustive.

Search methods:

a. Database searches: 2005 to present using review filters.
b. Citation searching
c. Internet searching: Specified websites (including Oxford Diagnostic Evidence Co-Operative) plus limited searching of Google Scholar

d. Contact with experts

(ii) Stage Two - Population of extended STEPUP framework with empirical evidence

This will require systematic identification of comparative studies [UK/international], qualitative studies [UK/international], audits and service evaluations [UK only], economic evaluations and cost studies [UK only]. The aim will be to identify the most rigorous, useful and informative studies within a finite search period.

Search methods:

a. Database searches: 2005 to present. (i.e. only factors of current relevance to technologies/ UK Primary Care settings) using a combination of study filters and "hedges" linked to each domain on the STEPUP framework.
b. Internet searching: Specified websites (including Oxford Diagnostic Evidence Co-Operative) plus limited searching of Google/Google Scholar
c. Citation searching

Study selection

Stage One: Development of Framework

Search results will be imported into an Excel Spreadsheet to allow ease of coding. Items for inclusion will identify one or more perceived or actual factors facilitating or inhibiting the introduction of diagnostic technologies into a primary or community care. A cumulative list of sub-factors will be developed and then examined for redundancies or interrelationships. Subfactors will be organised within the STEPUP Framework. Where specific empirical research is cited in support of a particular facilitator or inhibitor the reference will be documented and carried over for detailed examination in Stage Two.

Stage Two: Population of Framework

Search results will be stored in a reference management database, where decisions on inclusion/exclusion will be recorded. Selection of studies for inclusion (scanning of titles/abstracts and full text publications) will carried out by one reviewer. In cases of doubt, a second reviewer will independently examine the full text.

Data extraction and quality assessment

Stage One: Development of Framework [Any reference type]

All data will be handled through the Excel spreadsheet which will include reference identifiers, bibliographic details and identified factors. Links between references and identified factors will be explicit to aid transparency.

Stage Two: Population of Framework [Empirical Studies and UK Audit/Evaluations only]

Data will be extracted by a single reviewer to a template of study characteristics plus a three-four line summary of main study findings using forms/tables set up in advance and piloted on a small number of studies.

As the intention is to highlight issues, against the best available evidence currently available to address them, there will not be a formal assessment of quality for each included study. A brief indication of study quality based on study design and any highlighted study limitations will be used to annotate each included study.

Synthesis of evidence

We will use the data as identified above to develop and populate the following framework:

SKILLS & EXPERTISE: Skill mix; Extended roles; Inappropriate Test Ordering
TRAINING: Training Needs; Training Costs; Duration
EQUIPMENT: Equipment for modality and for analysis; consumable costs
PREMISES: Cost of Premises
USER PERSPECTIVE: Waiting Times; Acceptability; Repeat Procedures.
PRIMARY-SECONDARY INTERFACE: Referrals, Changes to Diagnosis or Management Pathways

We expect to accompany this framework synthesis with a narrative synthesis that characterises the type and nature of the evidence for each factor. Evidence will be grouped by modality and by factor allowing comparison across and within modalities. The synthesis will include a brief notation that will indicate both the quality of evidence and the strength of findings in support of each factor. A major output of the process will be a map that indicates evidence gaps by which to inform future research.

Deliverables:

Stage One: Development of Framework

1. Fully Developed Conceptual Framework indicating both generic and modality-specific considerations relating to introduction and delivery of diagnostic services in a primary or community care setting

Stage Two: Population of Framework

2. Map of available empirical and UK evidence relating to logistics of delivering diagnostic services in a primary or community care setting indicating level of uncertainties and priorities for future research.

Timeline

Activity	***Start***	***Finish***
Protocol development	20 January	6 February*
Protocol sign-off (HS&DR team & Prof. Denton)	8 February	13 February
Literature searching – Phase 1 – Iterative Development of Framework	16 February	13 March
Literature searching – Phase 2 – Population of Framework	13 March	31st March
Presentation of draft framework to HS&DR Team	Late March – Early April	
Study selection and mapping	1st April	31st May
Analysis and report writing	1 June	30 July
Delivery of draft developed and populated framework		31 July

*Including internal peer review by team

References

[1] Birchall, D. (2010). Primary care access to diagnostics: a paradigm shift. *Primary care*, *83* (986).

[2] O'Riordan, M., Collins, C., & Doran, G. (2013). *Access to diagnostics: A key enabler for a primary care led health service*.

[3] Department of Health. *Care Closer to Home*. London: Department of Health; 2008.

[4] Department of Health. *Our NHS Our Future: NHS Next Stage Review – Leading Local Change.* London: Department of Health; 2008.

[5] Jones, C. H., Howick, J., Roberts, N. W., Price, C. P., Heneghan, C., Plüddemann, A., & Thompson, M. (2013). Primary care clinicians' attitudes towards point-of-care blood testing: a systematic review of qualitative studies. *BMC family practice*, *14*(1), 1-9.

Appendix – Search Strategies

Stage One

Setting	Primary Care or General Practice or Community Care
Intervention	Diagnostic Techniques and Procedures; Diagnostic Services; Diagnostic Tests or One of the following modalities: Audiology; Point of Care Testing; Cardiac Services; ECG; Echocardiography; Diabetic Services; Endoscopy; Genetic Testing Laboratory Tests; Magnetic Resonance Imaging; Radiology/X-Ray Respiratory Tests; Ultrasound. "direct access imaging" "direct access mri" "rapid access cardiology"
Factors/Considerations	Barrier$ or Facilitator$ or Logistic$ or Cost$ OR Feasib$ OR /organization & administration OR /economics

Stage Two

Domain	Concepts	Search Terms
SETTING	Primary Care or General Practice or Community Care	Family Practice
	UK	Great Britain
MODALITIES	Audiology	exp Diagnostic Techniques, Otological
	Cardiac Services	exp Diagnostic Techniques, Cardiovascular
	ECG	
	Echocardiography	exp Echocardiography
	Diabetic Services	
	Endoscopy	exp Endoscopy
	Genetic Testing	exp Genetic Testing
	Laboratory Tests	
	Magnetic Resonance Imaging	exp Magnetic Resonance Imaging

	Point of Care Testing (haemoglobin A1c (HbA1c) and urine albumin: creatinine ratio (ACR) on patients with diabetes, total cholesterol, triglyceride and high density lipoprotein (HDL) cholesterol on patients with hyperlipidaemia, and international normalised ratio (INR) on patients on anticoagulant therapy).	Point-of-Care Systems
	Radiology/X-Ray	exp Radiography
	Respiratory Tests	exp Diagnostic Techniques, Respiratory System
	Ultrasound	exp Ultrasonography /ultrasonography
FACTORS/ CONSIDERATIONS	**S**KILLS & EXPERTISE: Skill mix; Extended roles; Inappropriate Test Ordering	Physician's Practice Patterns /manpower
	TRAINING: Training Needs; Training Costs; Duration	/education
	EQUIPMENT: Equipment for modality and for analysis; consumable costs	Diagnostic Equipment Equipment Safety Equipment Design Equipment Failure Equipment Failure Analysis Maintenance /economics /utilization
	PREMISES: Cost of Premises; Health & Safety	/economics
	USER PERSPECTIVE: Waiting Times; Acceptability; Repeat Procedures.	Waiting Lists Patient Acceptance of Health Care
	PRIMARY-SECONDARY INTERFACE: Referrals, Changes to Diagnosis or Management Pathways	/utilization

Rapid review protocol: Diagnostic ultrasound services in community settings

Background

This focused review is being undertaken as part of a larger review project looking at provision of diagnostic services in community settings. Initial literature mapping revealed a very limited number of published studies comparing different models of service. One of the few comparative studies found compared a primary care-based mobile diagnostic ultrasound service with a hospital-based open access service.(1) There are other potentially relevant papers not found by the mapping search, which was not focused on specific technologies.(2, 3) Diagnostic ultrasound was chosen as a topic for further review based on existence of some evidence and expert advice about the need for evidence synthesis to identify critical evidence gaps and to guide policy and practice. Nationally, health policy is supporting development of more community-orientated service models with the overall aim of making a range of services more accessible and more effective/efficient though more local provision. This has also been facilitated by changes in service organisation and commissioning arrangements introduced following implementation of the Health and Social Care Act 2012 which allow CCGs to commission a wide range of different models of service from a wider range of service providers. New care models envisaged in the *NHS five year forward view*, particularly the multispecialty community provider model, envisage a major expansion of diagnostic testing in community settings.(4)

Diagnostic ultrasound is used in a wide range of medical specialties, including cardiology (echocardiography), emergency medicine, gastroenterology, urology and musculoskeletal medicine. Its advantages over other forms of imaging include a lack of exposure to potentially harmful ionising radiation. Of particular relevance to primary care/community services, the equipment is relatively inexpensive and small portable scanners (including hand-held devices) are available.(5) The quality of ultrasound images is dependent on the skill and experience of the operator, which suggests that staffing/training issues could be a barrier to expanding diagnostic ultrasound in community settings.

Community diagnostic ultrasound in the form of open access services provided to GPs using hospital-based staff and equipment has been available for many years, for example echocardiography services for diagnosis of cardiac conditions.(6) The focus of this rapid review is on services provided in primary care/community settings using the organisation's own staff and/or equipment.

Review question

What is known about the implications of different ways of providing diagnostic ultrasound services in community or primary care settings? This includes implications for both NHS organisations (e.g. related to provision of staff, premises, training and equipment, costs and cost-effectiveness) and patients (e.g. related to changes in management/pathways, acceptability to patients, accuracy of diagnosis and longer-term clinical outcomes).

Inclusion/exclusion criteria

Population: people requiring diagnostic ultrasound for any condition (excluded: population screening and monitoring, including pregnancy). Studies described as screening may be included if the people being screened are identified by having a specific risk factor for a medical condition (rather than a screening programme offered to all individuals on the basis of age and/or gender) and the identified factors are either common or concentrated (e.g. common within a particular minority ethnic group) within the UK population.

Intervention: ultrasound provided in a primary care or community setting by primary care/community staff using any type of equipment (including portable ultrasound devices). Open access services provided to GPs by a hospital using its premises, equipment and staff will be treated as a comparator intervention.

Comparator: hospital-based diagnostic ultrasound services (open access or traditional). 'Outreach' services using hospital-based staff to deliver services in community settings would also be relevant comparators

Outcomes and study designs: the main focus is research studies in developed countries that evaluate community diagnostic ultrasound services and have a comparator; given that we expect comparative studies to be scarce we will also include evaluative studies without a comparator group (e.g. audits and service evaluations (UK only)) and descriptive studies that provide usable information about service delivery in UK settings. Systematic reviews, UK-relevant economic evaluations/cost studies and qualitative research studies will also be eligible for inclusion.

In addition, we will include relevant expert opinion pieces or reports from professional bodies that identify and/or discuss practical issues related to the provision of community diagnostic ultrasound services (e.g. staffing, training, equipment and premises) in UK settings.(7)

Outcomes of interest include patient outcomes (e.g. waiting times; acceptability; changes to diagnosis or management; and any clinical outcomes) and service/process outcomes (e.g. costs/resource use; cost-effectiveness; needs for training, premises and equipment). Resource use outcomes include any implications for test ordering by GPs(8).

Given that the focus of the review is on models of service, studies that focus on the diagnostic accuracy of ultrasound in community settings for particular conditions(9) will not be included unless they are relevant to the primary–secondary care interface, as defined in the accompanying protocol (e.g., they contain information on referrals or changes to diagnosis or management pathways).

Methods

Searching

The following databases will be searched:
- MEDLINE via Ovid SP
- Embase via Ovid SP
- Cochrane Library
- Cumulative Index of Nursing and Allied Health Literature (CINAHL)
- Web of Science

From the initial mapping exercise it has become evident that ultrasound in a primary care setting goes back to the mid-1990s.(10) The proposed search strategy in Appendix 1 therefore includes a date restriction of 1995 to current.

No methodological filters have been applied to the strategy since we are interested in all types of evidence and the evidence base is in any case relatively small.

Given the limited nature of the evidence base, citation searches of key titles will be performed as a supplementary exercise.

In addition to the database/citation searches, searches for grey literature will be undertaken. Along with some general searching via a search engine such as Google, the following websites will be searched:

- Oxford Diagnostic Evidence Co-Operative
- Websites of service providers

The grey literature element of the searches is likely to be informed by our contact with clinical experts, who may be able to suggest particular resources/websites of interest.

Study selection

Search results will be stored in a reference management database, where decisions on inclusion/exclusion will be recorded. Selection of studies for inclusion (scanning of titles/abstracts and full text publications) will generally be carried out by one reviewer. In cases of doubt, a second reviewer will independently examine the full text. Any disagreements will be resolved by discussion and consensus, with reference to a third reviewer if necessary.

Data extraction and quality assessment

Any included experimental or observational studies will be assessed for quality using relevant tools (e.g. Cochrane risk of bias tool for clinical trials, Newcastle–Ottawa scale for observational studies). Data will be extracted using forms/tables set up in advance and piloted on a small number of studies. Data extraction and quality assessment will be checked by a second reviewer. Any discrepancies will be resolved by discussion and consensus, with reference to a third reviewer if necessary.

Synthesis of evidence

Given the nature of the topic and the likely evidence base, quantitative synthesis by meta-analysis is unlikely to be possible. We expect to perform a narrative synthesis using patient-related and service-related issues (as defined above) as a framework for the synthesis. Evidence will be grouped by type of service model and if appropriate by indications/patient groups covered. The synthesis will provide an analysis of the quality of evidence and the strength of conclusions which can be drawn from current studies. We will also seek to identify evidence gaps to inform future research.

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Timeline

Activity	Start	Finish
Protocol development	20 January	6 February*
Protocol sign-off (HS&DR team & Prof. Denton)	8 February	13 February
Literature searching	16 February	6 March
Study selection and data extraction	9 March	3 April
Analysis and report writing	6 April	30 July
Delivery of draft report		31 July

*Including internal peer review by team

References

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Appendix 1: Proposed MEDLINE search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Please note: The proposed search strategy is for MEDLINE only, and will be adapted according to each of the other databases.

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1 primary care.tw. (73448)

2 general practi$.tw. (63001)

3 primary health care.tw. (15131)

4 Community Mental Health Services/ (16715)

5 Family Practice/ (59984)

6 Home Care Services/ (27904)

7 Physicians, Family/ (14697)

8 Community Health Services/ (27031)

9 Community Health Nursing/ (18468)

10 Community Pharmacy Services/ (2926)

11 Community Health Workers/ (3300)

12 Preventive Health Services/ (10983)

13 or/1-12 (266825) – Primary Care terms

14 *Diagnostic Services/ (1050)

15 *Clinical Laboratory Services/ (94)

16 *Genetic Testing/ (12574)

17 *Mobile Health Units/ (1937)

18 diagnostic service$.ti,ab. (1039)

19 clinical laboratory service$.ti,ab. (121)

20 genetic test$.ti,ab. (12840)

21 mobile health$ unit$.ti,ab. (52)

22 mobile health$ clinic$.ti,ab. (21)

23 (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab. (1720)

24 diagnos$.ti,ab. (1712643)

25 test$.ti,ab. (2238299)

26 24 or 25 (3648877)

27 26 and primary care.tw. (24260)

28 or/14-23,27 (51312) – diagnostics terms

29 13 and 28 (24994) – PC and diagnostics terms combined

30 Ultrasonography/ (63040)

31 ultrasonic diagnos$.ti,ab. (1831)

32 (ultrasound adj3 imaging$).ti,ab. (10335)

33 (ultrasonic adj3 imaging$).ti,ab. (1257)

34 sonograph$.ti,ab. (44056)

35 ultrasound scan$.ti,ab. (7156)

36 Echocardiography/ (67752)

37 (echocardiography or echocardiogram).ti,ab. (85342)

38 (echo adj2 cardi$).ti,ab. (555)

39 or/30-38 (227956) – terms around ultrasonography/echocardiography

40 29 and 39 (315) – all elements combined in the final line

41 limit 40 to yr="1995 -Current" (289) – date limit

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Final Protocol:

Rapid review of primary care / community led diagnostic pathways for the assessment of breathlessness.

Background

Breathlessness (shortness of breath, SOB, dyspnoea) is a common symptom associated with a range of acute and chronic conditions including Chronic Obstructive Pulmonary Disease (COPD), asthma, lung cancer, heart failure, atrial fibrillation, anxiety and obesity. Outcomes for these conditions can be improved with an early diagnosis (NHS Improving Quality 2014). Within the NHS, diagnostics have traditionally been offered in hospital settings. However, rising demand year on year is contributing to overloading within the secondary care system that impacts on patient pathways, despite relatively recent recommendations to increase the hours of access (NICAG 2012). Providing diagnostics within the community or in primary care has the potential to ease flow through the health system as well as increase access to an early diagnosis. However, obtaining a differential diagnosis for a condition such as COPD requires training in the delivery of investigations and increased utilisation of resources and equipment (NICE 2010). Therefore a primary care led diagnostic service would need to account for implementation costs and benefits accordingly.

International guidelines exist for primary care diagnosis of lung conditions (Levy et al. 2006); however not all breathlessness is associated with a lung condition and not all lung conditions initially present with breathlessness. A number of national and international models of care and pathways currently exist for primary care and/ or community diagnosis for symptoms of breathlessness, including rapid access breathlessness clinics and diagnostic pathways. For example, one aim of providing a rapid access clinic is to allow multi-morbidities to be accounted for in a setting dedicated to breathlessness diagnostics. Another approach is the federated model which links a network of GP practices to form a collaborative effort in providing diagnostic and follow up services (NHS Improving Quality 2014).

However there is no published consensus about the clinical or cost-effectiveness or the acceptability for service users of any particular service model.

Aim: To assess the evidence base for diagnostic services provided outside hospital settings (e.g. community or general practice) for undiagnosed individuals presenting with symptoms of breathlessness.

Research Questions:

- What service models and pathways for breathlessness diagnostics delivered in primary care or community settings currently exist in the UK and internationally?
- What evidence is there for the quality, safety, feasibility, acceptability, clinical and cost effectiveness of such models and pathways?
- What are the barriers and facilitators to developing and implementing such service models and pathways?

Inclusion / exclusion criteria:

Participants: People with symptoms of breathlessness who have a suspected condition such as COPD or heart failure (NOT people who have a diagnosis and are being monitored / managed in a primary care setting; NOT screening an “at risk” population for a particular condition).
Intervention: Service models and pathways that are designed to be initiated in primary care or the community in order to make a differential diagnosis from a presenting symptom of breathlessness.

This could include specific diagnostic technologies such as spirometry though the effectiveness of such technologies will not be assessed.
Comparator: Service delivery models or pathways developed to assist diagnosis from breathlessness symptoms and delivered in secondary care settings. This is expected to include a comparison of clinical effectiveness, cost effectiveness, quality, safety, feasibility and acceptability of the intervention between settings.
Outcomes: Any measure of effect on patient management, outcomes, patient experiences or costs / resource use including training.
Setting: Diagnostics delivered in a primary care or community setting.
Study Design: Systematic literature reviews and primary studies of any design that describe or evaluate a pathway of care for breathlessness. These could include retrospective / prospective studies and audits as well as experimental, observational and economic evaluations. Qualitative studies will be included that report service user or staff views about the barriers and facilitators to service development and use of the pathways (received care or decision making). The availability of multiple tests within the community setting will be assessed.

Search Strategy:
Databases: Databases including MEDLINE, Embase, the Cochrane Library, CINAHL and Web of Science will be searched for the years 2000-2015. A MEDLINE search strategy is presented in Appendix 1.

Potentially relevant MeSH terms include: diagnostic services; clinical laboratory services; mobile health units. Combining terms like these with terms for specific tests or types of test (e.g. 'spirometry') could result in large numbers of results but a low yield of relevant studies. Therefore, given that this is a rapid review, we will aim to concentrate on identifying the key evidence of most relevance to the review question. This could involve approaches based on data mining (e.g. the 'progressive fractions' method); reference checking and citation searching of relevant studies; and use of literature reviews as sources of references.

Searches will not be limited by language although resources may limit the analysis of non-English language literature.

It is known that a number of local interventions exist in the UK, therefore grey literature will be searched for UK examples of a primary care / community led diagnostic pathway for breathlessness.

Other searching methods:

- Liaison with topic experts.
- Citation searching on included papers and any other key paper identified by topic experts.
- Scanning lists of references in included studies.

Study selection / data extraction:
Selection of studies for inclusion (scanning of titles/abstracts and full text publications) will generally be carried out by one reviewer. In cases of doubt, a second reviewer will independently examine the full text. Any disagreements will be resolved by discussion and consensus, with reference to a third reviewer if necessary.

Data will be extracted using forms set up in advance and piloted on a small number of studies. Data extraction will be checked by a second reviewer. Any discrepancies will be resolved by discussion and consensus, with reference to a third reviewer if necessary. Quality, including risk of bias, will be assessed using appropriately tailored tools for the types of evidence identified, but not used as an exclusion criterion.

Analysis:
Given the nature of the topic and the likely evidence base, quantitative synthesis by meta-analysis is unlikely to be possible. We expect to perform a narrative synthesis by type of service model and/or patient pathway. The synthesis will provide an analysis of the quality of evidence and the strength of conclusions which can be drawn from current studies. For studies where the provision of the community service was supported or facilitated by study staff, we will assess the feasibility of providing the service in routine practice (including any required training).

Timeline:

Activity	Start	Finish
Prepare draft protocol	6 April	30 April
Review of protocol by HS&DR programme	1 May	15 May
Protocol sign-off (phone conference to be arranged)	16 May	20 May
Literature searching	21 May	15 June
Additional literature searches, follow-up of references; citation searching etc.	15 June	31 June
Analysis and report writing	10 July	September
Delivery of draft report		September

References:

Levy MK, Fletcher M, Price DB, Hausen T, Halbert RJ, Yawn BP. International Primary Care Respiratory Group (IPCRG) Guidelines: Diagnosis of respiratory diseases in primary care. Primary Care Respiratory Journal 2006: 15: 20-34

National Imaging Clinical Advisory Group (NICAG). Implementing 7 Day Working in Imaging Departments. 2012; UK: Department of Health

National Institute for Health and Care Excellence (NICE) Guidelines [CG101]: Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in adults in primary and secondary care. 2010: https://www.nice.org.uk/guidance/cg101

NHS Improving Quality: Summary of scoping research on models of care to support earlier diagnosis of diseases related to breathlessness as a symptom. 2014: UK. www.nhsiq.nhs.uk

Appendix 1

MEDLINE search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
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1 exp Dyspnea/ (16221)
2 dyspn?ea.ti,ab. (33297)
3 breathless$.ti,ab. (3617)
4 (short$ adj2 breath).ti,ab. (5425)
5 (breath$ adj2 difficult$).ti,ab. (1543)

6 orthopnea.ti,ab. (425)
7 or/1-6 (49548)
8 pathway$.ti,ab. (741836)
9 ((care adj2 model$) or (clinical adj2 model$) or federated model$ or organisational model$).ti,ab. (18119)
10 Algorithms/ (185228)
11 algorithm$.ti,ab. (149426)
12 or/8-11 (1014328)
13 Diagnostic Services/ (1781)
14 diagnos$.ti,ab. (1767864)
15 Mobile Health Units/ (3044)
16 mobile health unit$.ti,ab. (52)
17 mobile health clinic$.ti,ab. (23)
18 (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab. (1828)
19 rapid access clinic$.ti,ab. (38)
20 one stop shop$.ti,ab. (364)
21 community respiratory team$.ti,ab. (2)
22 or/13-21 (1773272)
23 7 and 12 and 22 (304)
24 limit 23 to yr="2000 -Current" (268)

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