Evaluating pathology services across the UK

Aim of project
The aims of this piece of work are to:

- improve our knowledge of the quality of pathology services in the NHS in England and current capacity, demand and variation;
- ascertain whether barriers exist to delivering world-class pathology services and research;
- ascertain whether barriers exist to delivering molecular diagnostic tests;
- ascertain by how much demand for pathology services is likely to grow over the next five years and beyond;
- identify levels of resource (including equipment and facilities) necessary to meet growing demand;
- identify any new, evidence-based technologies and how best to ensure their introduction into the service;
- identify numbers of staff needed by 2020, how to optimise skills mix and what action is required to achieve this;
- crucially, identify potential solutions and make recommendations for how to achieve them;
- highlight in particular where any of the above impact particularly upon cancer.

We wish for this work to be replicated for Scotland, Wales and Northern Ireland and would like applicants to include UK-wide consideration as part of their proposal.

This will help Cancer Research UK (CR-UK) to develop evidence-based policy calls around pathology which will ensure people requiring pathology services (to support diagnosis, treatment and research) receive results in a timely, quality-assured and safe manner, contributing to improved outcomes. It is intended that this piece of work will look at the pathology service as a whole, because it is impossible to separate cancer from the rest of the service and improving the service as a whole would undoubtedly bring benefits for cancer patients. However, where possible the focus of any recommendations should be on improving the service for cancer patients. The different types of pathology work are detailed in the appendix to this document.

Rationale
The recent cancer strategy for England, Achieving World Class Cancer Outcomes, set out an ambition that 95% of people being tested for cancer should receive a definitive diagnosis within four weeks and the Government has committed to making this a reality. Pathology will be crucial to realising this ambition. However, it is not necessarily a visible element of diagnostic services especially as patients do not interact directly with the service, and so it can be overlooked. Nevertheless, it is important that its role is considered alongside more visible elements of the patient pathway when considering early diagnosis and potential delays in meeting the four week ambition. The outputs of this research are intended to be used alongside Cancer Research UK’s other reports on imaging and endoscopy, Horizon Scanning and Scoping the Future, to give a comprehensive picture of diagnostic services, and alongside Cancer Research UK’s recent report Molecular diagnostic provision in England to ensure personalised treatment aspects are considered.

The Carter review represented a major review of Pathology services in England and was carried out in 2006. More recent work has been carried out by NHS England and the Royal College of Pathologists. A number of issues with pathology services have been highlighted:

Unacceptable variation in testing, methods and provision – A pathology quality assurance review undertaken in Jan 2014 by NHS England noted that there is wide variance in error reporting within pathology providers. The review also found different approaches to testing and variation in provision, methods, turnaround times and communication of results across the country.
Poor uptake of digital technology – A 2011 workplace study of histopathologists found that manual working practices are time consuming, but digital microscopy uptake (which could improve this) was slow. NHS England also recently launched its Digital First report, highlighting new digital innovations in pathology to encourage uptake and share good practice.

Standardisation of data – The Digital First report also found that the catalogue of pathology reports, the Pathology Bounded Code List (PBCL) system is limited. NHS England’s National Pathology Programme is working on a National Laboratory Medicine Catalogue, to deliver consistent and comparable information on pathology services and better data sharing.

Pathology lab errors – A systematic review of delays to cancer diagnoses found that of 508 patient safety incidents, 41% related to pathology. This broke down further to 47% pre-laboratory (incorrect labelling, poor preservation of specimens and transport issues) 44% in-laboratory (reporting delays, reporting errors and processing errors) and 9% post-laboratory.

Unnecessary testing – The Carter review estimated that 25% of all pathology tests were unnecessary.

Pathologist working capacity – Given the cross-cutting role of the pathologist in cancer diagnoses, research by National Cancer Action Team (NCAT) from 2009 found that pathologists are often members of five or more site-specific Multi-Disciplinary Teams (MDTs). Being a member of so many teams can prevent attendance at all relevant MDT meetings for histopathologists due to ‘considerable’ preparation time required at each.

Background

Pathology describes clinically-led diagnostic and post-mortem services. 70-80 per cent of all health care decisions affecting diagnosis and treatment involve a pathology investigation. This is likely to be higher for cancer diagnoses. As a clinical service it employs 25,000 staff and costs the NHS in England in the order of £2.5 billion a year, representing nearly 4 per cent of total NHS expenditure (information from 2006).

The only definitive way to establish a cancer diagnosis is through examining cell samples under the microscope, though for a variety of reasons this may not be possible for all patients. Cancer Peer Review standards for site specific cancers require MDTs to include a pathologist as a core member. The role of the lead pathologist in an MDT is to report on specimens (most commonly cell samples from biopsies) from patients under the team’s care. In cases where the work of an MDT involves more than one specialist pathology area, the lead pathologist should determine the need for MDT attendance by another specialist pathologist. According to Royal College of Pathologists 2014 guidance, most teams have a level of pathology cover approaching 100% in meeting attendance.

The Royal College of Pathologists has developed specific guidance for pathologists’ reporting of a number of cancers (breast, bone, endocrine, eye, gastrointestinal tract, head and neck, lung, paediatrics, skin, urinary tract and testis). In certain types of cancer ‘double-reporting’ (where a diagnosis of malignancy is given a review) is required by specialist pathologists in cancer centres. These cancer types include melanomas, sarcomas, certain kinds of bowel cancer and rare tumours. The diagnostic pathology role has also been described as an ‘essential component’ of cancer screening programmes.

Key questions to cover

- What will be the estimated total demand on pathology services in the coming years (up to next five years)?
- How will potential new screening programmes (lung and ovarian) and changes to current programmes (Faecal Immunochemical Testing for bowel and Human Papilloma Virus primary testing for cervical) affect demand?
• How developments in symptomatic testing and surveillance may affect demand, including a lower referral threshold?

• How the proposed uplift in molecular diagnostic testing will affect demand?

• What staffing and capacity levels are required to meet this demand?

• How far away is England from meeting this threshold?

• What are the barriers to achieving this and how can they be addressed? (staffing in all relevant disciplines, training, equipment, facilities, financial investment, or others?)

• Are there areas of the country experiencing particular delays in pathology reporting times? How does this vary for different types of pathology analysis?

• What examples are there of good practice pathology services that have coped with demand and how can other areas learn from these? (including an international perspective as/where appropriate)

• Is the service well equipped to support the delivery of high quality research? If not, how could this be optimised?

Suggested Methodology

• Review of existing literature on this topic

• Interviews/surveys with key English stakeholders to identify challenges and good practice from a range of different types of service to achieve a spread of insights

• Examine publicly available statistical data, including data on workforce

• Modelling current demand/capacity and projected growth in service for next five years

• Appreciative inquiry (method that aims to identify a way of building organisations around what works, rather than trying to fix what doesn’t – the opposite approach to problem solving)

Product

The product(s) of the research is likely to include:

• An executive summary of key findings, recommendations and how the work adds to the evidence and policy in this area

• The methodology and approach to the work

• A solutions-focused full account of all of the research findings (tested with experts before publication)

• Recommendations for ways to address issues in pathology services in England, both short and long-term

• Illustrations of good practice from services which are meeting demand and quality standards

• ‘Heat maps’ of pathology bottlenecks and capacity across England

Budget

We would ask for submissions to include a range of costed options to choose between.

Cancer Research UK will award the project grant to one contracting organisation only; however it may be possible for applicants to sub-contract aspects of the project subject to the approval of Cancer Research UK. This should be discussed at application stage.

Governance

CR-UK will expect regular meetings with the research team. Following the submission of the final report, there will be an iterative process of developing suitable policy recommendations between CR-UK and the research team.

Timescale

Expressions of interest should be submitted by 30th October 2015
A full application giving detailed methodology and budget breakdown should be submitted by **13th November 2015**
The intention is that a decision will be made by **27th November 2015**
An interim report with emerging findings is requested by **29th February 2016**
The full report should be submitted to Cancer Research UK by **13th May 2016**

**Submission**
Please send the following to Policy Manager Sara Bainbridge ([sara.bainbridge@cancer.org.uk](mailto:sara.bainbridge@cancer.org.uk); 0203 469 6142):

- Proposed approach to project and methodology
- Budget breakdown (including a range of costed options)
- CVs of staff who will work on the project and a short summary of experience carrying out this type of work (including an clinical/expert adviser to the project)
- Information about relevant governance arrangements within your institution.

**Further information**
Should you have any questions about this project, please contact Sara Bainbridge using the contact details above.

**Appendix: Pathology Specialties**

**Pathology specialties**
Pathology comprises five main disciplines: chemical pathology (also, and increasingly, known as clinical biochemistry); haematology, histopathology, immunology and medical microbiology.

Within these disciplines there are 19 pathology specialties. They are:

- **Clinical biochemistry**: Also called biochemistry, the pathology specialty that is concerned with the analysis of body fluids such as blood and urine. Clinical biochemists can diagnose, treat and monitor diseases by interpreting the level of different chemicals in samples.
- **Clinical cytogenetics**: The pathology specialty that involves the microscopic analysis of chromosomal (DNA) abnormalities that may result in disease.
- **Clinical embryology**: The specialty that involves the handling of gametes (sperm and eggs) and embryos to treat male and female infertility.
- **Cytopathology**: Cytopathology is the study of abnormal cells in body fluids, smears and tissue samples, for example, cervical smears for the detection of changes in the cervix that could lead to cancer.
- **Dermatopathology**: The branch of pathology that studies disease of the skin. For example, rashes, lumps and skin cancer.
- **Forensic pathology**: This is the branch of pathology in which doctors examine people who have died, usually when there is concern that the cause of death was unnatural (for example, not due to an illness). Forensic pathologists often give evidence in court, for example in murder trials. Although this is a branch of pathology that many people have heard of, it is one of the smallest specialties.
- **Haematology**: The pathology discipline involved in the care and treatment of patients with blood disorders such as anaemia or leukaemia.
- **Histocompatibility and immunogenetics**: The study of organ transplantation and tissue matching. These pathologists make sure that transplanted organs are suitable for the recipient to try and avoid the organ being rejected.
- **Histopathology**: The branch of pathology that involves looking at tissue under the microscope to diagnose disease. If you have a mole or a breast lump removed, the histopathologist will examine it to work out what it is.
• **Immunology**: The science of disorder of the immune system. Doctors who specialise in the diagnosis and treatment of disorders of the immune system are called Clinical Immunologists. They often also run the specialist laboratories that provide testing for immunological disorders as well as looking after people with autoimmunity, immune deficiency and allergies.

• **Medical microbiology**: The branch of pathology which deals with the investigation, treatment and monitoring of infections in humans.

• **Metabolic medicine**: A group of overlapping areas of clinical practice with a common dependence on the detailed understanding of basic biochemistry and medicine. These areas fall within the territory of both physicians and chemical pathologists. They include clinical nutrition, lipid abnormalities, diabetes, metabolic bone disease, porphyria and adult inherited metabolic disorders.

• **Molecular genetics**: The study of heredity and variation. Genetics also includes the study of the changes underlying genetic diseases, for example, cystic fibrosis.

• **Neuropathology**: The branch of cellular pathology that is concerned with the diagnosis of diseases of the brain, spinal cord, skeletal muscle and nerves by the examination of biopsy specimens and through post mortem examinations. Neuropathologists diagnose conditions such as brain tumours, muscular dystrophy and dementia.

• **Paediatric and perinatal pathology**: The branch of pathology concerned with diseases and disorders of babies and children, including foetuses. Paediatric pathologists look at samples under the microscope and also perform post mortem examinations following the death of a foetus or child.

• **Toxicology**: The branch of pathology concerned with the study of drugs and poisons and their effects on the body.

• **Transfusion medicine**: The branch of pathology concerned with the study of drugs and poisons and their effects on the body.

• **Veterinary pathology**: Veterinary pathology is the branch of pathology concerned with investigation of disease in animals. Veterinary pathologists further specialise in a diverse range of species groups.

• **Virology**: The term applied to the study of viruses and the diseases caused by them. The term ‘Medical Virology’ is applied to human diseases caused by viruses. Specialists in medical virology help in the investigation and treatment of patients suspected of having a viral infection.

Not all of these are relevant to cancer but this illustrates the breadth of the specialty and the role it plays in healthcare provision.