The Royal College of Pathologists
Pathology: the science behind the cure

College response to the Independent Cancer Taskforce report 'Achieving World-Class Cancer Outcomes: a strategy for England 2015–2020'

The Royal College of Pathologists welcomes the opportunity to comment on the report of the Independent Cancer Taskforce and the chance to contribute to improving outcomes for cancer patients. Pathology plays a vital role in the prevention, diagnosis, treatment and follow-up of individuals with cancer and makes a key contribution to the multidisciplinary and multiprofessional teams that care for these patients from diagnosis to discharge.

We note that the significant workforce deficits in diagnostic services have been recognised, although the report focuses on radiology rather than pathology. We feel this is a significant oversight which will impact on the ability of the NHS to achieve the objectives highlighted in the report.

The College is ideally placed to contribute to the proposed National Cancer Advisory Board (8.8) to oversee national implementation of the national cancer strategy.

Histological diagnosis

Histological (microscopic) examination is the gold standard in cancer diagnosis. Although imaging is an essential and vitally important part of the diagnostic pathway, it cannot give a diagnosis at a cellular or molecular level. Oncologists will not treat patients without a tissue diagnosis of cancer, irrespective of how certain the radiologist's opinion about the diagnosis.

Histopathology, the study of diseased tissue at a microscopic level, is an art as well as a science. Tissue is appraised on a microscopic and molecular basis by a highly skilled pathologist or, increasingly, team of pathologists, with decades of training between them. Cancer is a complex and diverse group of diseases, not a single entity, and is diagnosed following identification of a range of different characteristics which, taken together, indicate the diagnosis. A pathology report is based on the expertise and experience of the pathologist and is not the product of a machine. Not all cancers demonstrate all the features of malignancy – and some tissues that have some features typical of cancer are actually benign. The more material received and the better preserved it is, the more likely it is that the pathologist will be able to make an accurate diagnosis. The presence of these benign mimics of malignancy and cancers which are 'wolves in sheep's clothing' demonstrates the need for the highest standards of training, continuous professional development and quality improvement in the clinical practice of pathology. There are no short cuts to accurate cancer diagnosis.

Challenges of early diagnosis

Cancers that are detected at an earlier stage in their development, which is the aim of the report, are often more difficult to diagnose than more advanced disease. Early cancers may show invasion in only a small area, for example, or yield insufficient material for reliable assessment. Very small lesions may be missed completely when radiologists or surgeons attempt to sample them, with normal adjacent tissue being submitted, or so little cancerous tissue may be obtained that ancillary tests, such as immunohistochemistry or molecular techniques, cannot be performed. In all of these

circumstances the procedure may have to be repeated, sometimes several times. This takes time and a multidisciplinary approach.

In all cases, the diagnosis of cancer is a multidisciplinary team effort. Pathologists are core members and work with surgeons, oncologists, radiologists, specialist nurses and others to ensure that each individual patient receives the best possible care. The diagnosis of cancer often requires correlation with imaging or clinical findings. Breast core biopsies, for example, are interpreted in the light of clinical and radiological findings. It should be recognised that diagnosing cancer earlier is not just a matter of doing the same volume and complexity of work at an earlier stage. The earlier a cancer is investigated the more difficult it is to detect clinically, radiologically and microscopically. While the use of less invasive procedures is to be welcomed, these techniques often result in very small, and sometimes traumatised, pieces of tissue being submitted, which makes interpretation difficult and necessitates additional, costly and time-consuming laboratory investigation to confirm the diagnosis.

It should be remembered that as well as being the gold standard for the diagnosis of cancer, histology is essential for the assessment of surgical specimens removed as part of the treatment of cancer. 5.3.1 states that 'surgical intervention contributes to around half of cases where cancer is cured' – it should not be forgotten that it is histological examination of the tissue removed that determines whether further treatment is required or not. Pathologists assess the size, type, spread and margins of excision of cancers, without which surgeons would not know if their operation had been adequate.

There are several references to 'cancer exclusion' in the report. While tests are becoming increasingly sophisticated and accurate they can rarely entirely exclude cancer and frequently multiple investigations over time are required including serial biopsy.

Pathologists are also central to cancer screening. Pathologists in several disciplines examine biopsies and other samples to look for possible markers of cancer or pre-cancerous changes, for example examining breast biopsies, identifying abnormalities in bowel polyps, interpreting faecal occult blood (and FIT) tests and interpreting cervical smears as part of national cancer screening programmes. The College is concerned about the proposed cuts to Public Health England's budget and the effects this might have on screening and cancer prevention, which is the ultimate aim of the cancer strategy.

Raising awareness of disease prevention

The Royal College of Pathologists runs a highly successful public engagement campaign, the highlight of which is National Pathology Week, which takes place in the first week of November every year. Over 2000 events have taken place in schools, hospitals and communities around the country, raising awareness of the role of pathology and increasing understanding of how lifestyle choices contribute to future health. Previous events have focussed on the effects on health of alcohol, diabetes, obesity, healthy diets, exercise, screening and vaccination. There have even been events highlighting the healthiest new year's resolutions and talks debunking many of the myths around health and disease. National Pathology Week 2015, which will take place on 2–8 November, has the theme 'Pathology: the key to your health', focussing on the role of molecular diagnostics in disease prevention, diagnosis and treatment. Hundreds of events are planned around the country. The UK programme has been so successful that the initiative has been rolled out worldwide and the second International Pathology Day will take place on 18 November, highlighting the role that pathology plays in global health.

Diagnostic capacity

We particularly welcome the Report's recognition of the fact that definitive diagnosis of cancer is almost always made by histological examination of tissue by a pathologist (5.2.2). Unfortunately this acknowledgement is not supported throughout the rest of the document, in which diagnostic

services appears to primarily be concerned with radiology. Pathology faces the same challenges as diagnostic imaging in relation to training, capacity and equipment.

Any increase in cancer imaging investigations will result in a proportionate increase in pathology diagnostic tests. If pathology services are to meet the needs of cancer patients there will need to be significant investment in skilled personnel and equipment. Training pathologists and scientists takes many years and requires immediate investment in training places to see an increase in skilled staff in 5-10 years' time. The difficulty more rapid expansion will cause should not be under-estimated as there is a shortage of trained specialists in the UK. Many colleagues have been recruited from the EU but there is still a shortfall, even at current workload levels. The College has always supported international recruitment and has suffered, as have many medical specialties, by increasingly stringent immigration laws, which have limited the number of overseas doctors able to work in the UK. The proposed increase in cancer-related workload will widen this gap. The diagnostic pathway requires appropriate investment for both radiology and pathology to give timely support to clinical care.

Recommendation 16 acknowledges that diagnostic capacity may be an issue for GPs implementing the recent NICE guidelines on early referral. Mid-2016 seems optimistic for expecting the significant increase in diagnostic capacity that will be required, given the long lead time for specialist training. Section 5.2.5 recognises that 'the ability to undertake a transformational shift in the level of investigative testing is limited.'

Existing funding models do not allow Trusts to see their diagnostic services as enablers of high quality care rather than 'overheads'. We welcome the report's recommendation that hospitals should take 'a different approach to providing increased capacity' (5.2.5) and that a national diagnostic capacity implementation fund should be established. It is essential that this fund invests in pathology services as well as imaging.

The Report highlights the importance of GPs having access to specialist advice (Recommendation 17). Many pathologists provide extensive advice to GPs and secondary care colleagues, despite it not being recognised in their job plans. We have long argued that this is one of the prime roles of consultants and senior scientists, particularly as there is less and less pathology included in medical school curricula. This has resulted in many junior doctors qualifying without the knowledge required to request and interpret pathology tests, a gap that pathologists have to fill themselves. While ideally placed to do so, this important work should be recognised and included in pathologists' job plans. With the move towards patients having access to their own pathology test results, making pathologists available to answer questions will become even more important.

The College has worked for many years to support the development of clinical and biomedical scientists in providing much of the pathology services in the UK. Many clinical scientists run laboratories and biomedical scientists (BMS) are taking on extended roles, undertaking work traditionally done by pathologists. There is a BMS reporting pilot, for example, which enables a BMS to train to dissect and report certain cancer specimens. We would anticipate that this role would continue to expand over the coming years but currently the trainees are at an early stage and in small numbers – this is not the solution to the capacity gap in the short term.

A significant proportion of pathologists are in their 50s and likely to retire in the next five years. Significantly increased workplace stress and contractual changes have increased the number of consultants retiring early. This will add to the challenges of increasing capacity in pathology services, Molecular Diagnostics and Research.

Pathologists are at the forefront of innovation and research in many disease areas but particularly in cancer. 5.8.1 recognises the importance of research in 'developing our understanding and preventing, managing and curing cancer' but fails to recognise the vital role research plays in cancer diagnosis.

The number of academic pathologists has fallen dramatically over the last decade, despite the College's attempts to reverse the trend. Research opportunities are being developed to encourage trainees at all stages to undertake research. As well as carrying out their own research, pathologists contribute to the work of others, including national trials. The report correctly identifies that 'participation in clinical trials has increased dramatically since 2001' (5.8.1).

The pathology input into many clinical trials is not funded. While the resource commitment for each individual trial may not be onerous, a single department may support over 20 different trials, which add up to a significant amount of administrative work. Selecting material, retrieving blocks, packaging and posting all take time out of the already busy day. Despite an interest in research some departments have to turn down the opportunity to participate in unfunded trials. An increase in the proportion of cancer patients participating in research is to be welcomed, but the resources for administration must be provided.

Molecular techniques will revolutionise the way in which cancer is diagnosed and treated. The Report notes that 24,000 molecular diagnostic tests were undertaken in 2014 (5.4.2) but that many patients are likely to have missed out on having the tests done because of variability of availability. The College is aware of significant regional variation in the use of many pathology tests, including those used in the early diagnosis of cancer, such as CA125 and PSA. The Diagnostic Atlas of Variation demonstrated a marked difference in test requesting. The Royal College of Pathologists and Royal College of General Practitioners are already working together to reduce this variation.

The 100,000 Genomes Project will mean that England leads the way in research into and application of new techniques. A move towards stratified/personalised medicine will improve outcomes for patients and minimise wasteful treatments. The Report notes that there is no national tariff or approach to commissioning for molecular testing (5.4.2). It is hoped that the 11 Genomic Medicine Centres leading the delivery of the 100,000 Genomes Project will act as hubs for the development of coordinated regional centres for genomic services and training.

We welcome the recommendation (37) that NHS England should undertake a review of molecular diagnostics capacity and commission access to tests. We are already working with Health Education England to plan future workforce provision for molecular diagnostic services and have developed curricula for clinical scientists in molecular pathology. A College working group has been set up to look at how molecular pathology training is developed. Changes to the histopathology training curriculum have already been submitted to the GMC, incorporating further molecular pathology training for all trainees.

The College has introduced an undergraduate category of membership and co-hosts an annual pathology summer school for medical students, which focuses on research and innovation, particularly molecular pathology. It is hoped that by enthusing students at an early stage in their training, many will consider careers in pathology, particularly in these areas.

Access to innovative drugs

New cancer drugs are being developed all the time and provide new hope for patients with certain cancers. The majority of new cancer drugs target cancers according to the tumour's genetic make up or immunoprofile. Pathology tests are required to identify which patients are likely to respond to each drug. Although it pales into insignificance compared to the cost of the drugs themselves, there is a cost to testing for susceptibility to the drug, which falls on pathology departments, usually without additional funding. The sustainable solution for access to new cancer drugs must include funding for the initial pathology test.

Chemo-prevention

The Report rightly highlights the increasing importance of using drugs to prevent cancer (Recommendations 6 and 7). Individuals with HNPCC, for example, should be treated with aspirin to reduce the risk of developing colorectal cancer. Diagnosis of HNPCC requires a pathology test

(MMR), which is not currently available or funded everywhere. The Royal College of Pathologists has recommended the use of this test in colorectal cancer patients under the age of 50 and has approached NICE to propose that reflex MMR testing should be submitted to the Medical Technologies Advisory Committee for consideration. Similarly, testing for BRCA1/BRCA2 in some patients with ovarian and breast cancer must be funded.

Patient access to results

The College has been working closely with the Department of Health, Lab Tests Online, patient groups and informatics providers for many years to improve patients' access to their pathology test results. The National Laboratory Medicine Catalogue (NLMC) would standardise the format, units and reference ranges for pathology tests, allowing patients to compare a test result obtained from one provider with that obtained from another. It would also reduce the currently high number of unnecessarily duplicated tests. Many GP practices already give their patients access to test results online, as do services for people with chronic conditions such as diabetes or kidney disease. There are concerns about patients having access to potentially life-changing results online, particularly diagnoses of malignancy. The College supports the recommendation (6.5) that a cancer diagnosis should be given in person with immediate support available from a cancer specialist nurse, and the further work required to ensure that a system is in place to release appropriate results promptly.

National Laboratory Medicine Catalogue

The NLMC, which is partially completed, will allow doctors and patients to compare test results from different providers. It will reduce the need to repeat tests, if adopted nationally will help address the problem of test results not being available when they are required and support patients having access to their own test results. Work on the NLMC has currently paused while those resourcing and working on it take stock – its rapid introduction supports many of the recommendations of the report.

Conclusions

In summary the College fully supports the ambition to make cancer outcomes in the UK among the best in the world and will continue to lead the way in setting and raising standards for cancer diagnosis. The recognition that investment in diagnostics training, equipment and organisation is essential to meet the needs of patients is welcomed, with a reminder that pathology is an essential part of diagnostic services, without which the vast majority of the Report's recommendations cannot be achieved.

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