

This vision does not represent government policy but provides useful insight into how upper GI cancer services might develop over the next 5 years

Annex K

Upper Gastro-Intestinal (GI¹) cancers 2015

Epidemiology

Incidence

1. The incidence of most cancers in the upper GI group is expected to rise slightly over the next five years. Junctional *oesophago-gastric* cancers are increasing in incidence particularly adenocarcinoma and although gastric cancer incidence is declining the true incidence of oesophago-gastric cancer is gradually increasing. The incidence of *pancreatic* cancer is likely to remain stable. The incidence of *intrahepatic cholangiocarcinoma* and *hepatocellular carcinoma* are rising. The incidence of *hepatic metastases* predominantly from colorectal cancer which are suitable for resection is steadily increasing.

Prevalence

2. By 2015, in part due to an ageing population, the numbers of people developing upper GI cancers will be greater than currently. The population, although older, will be fitter and more likely to be considered for a greater number of interventions than in 2010. Managing these older patients is increasingly complex with larger numbers requiring multi modality therapy strategies therefore reinforcing the need for regular service reviews for the management of this group of patients.

Aetiology

3. A number of factors need to be considered for their potential impact on incidence in the next 5 years:
 - i. lifestyle factors:
 - smoking can be a factor in *squamous cell oesophageal* cancer and is associated with around 25% of cases of *pancreatic* cancer;
 - obesity can lead to:
 - reflux problems which are associated with *oesophageal adenocarcinoma*;
 - fatty liver disease (NASH) may lead to cirrhosis and *hepatocellular carcinoma*; and
 - diabetes may predispose an individual to *pancreatic* cancer.
 - excessive alcohol consumption leading to cirrhosis which is associated with *hepatocellular carcinoma* and pancreatitis which is associated with *pancreatic cancer*
 - ii. increasing incidence of Hepatitis B & C which are causative factors in *primary hepatocellular carcinoma*;
 - iii. benign bile duct disease and malfunctioning bile ducts which can predispose to *biliary tract* cancer; and

¹ This vision covers cancers of the pancreas, oesophagus, stomach, liver (primary hepatocellular and metastatic cancer in the liver), biliary tract, duodenum and neuroendocrine cancers

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- iv. increasing incidence of colorectal cancers – of which around half will develop *liver metastases*

IOG Implementation

4. The key priority for people with upper GI cancers is that the improving outcomes guidance (IOG) is fully implemented across the country. Implementation is still inconsistent and by 2015, peer review should confirm full and consistent implementation. An increase in workforce (particularly clinical nurse specialists, allied health professionals, oncologists, histopathologists and cytopathologists) and further speciality training will be needed to support this. Commissioners should not be commissioning services from non-IOG compliant services and they need to ensure that centres are properly resourced (eg staff, equipment and ITU/specialist beds) to deal with increased patient numbers without unacceptable waiting times.

Prevention

5. Measures should be implemented to address the lifestyle aetiological factors for upper GI cancer listed in para 3, although any impact is unlikely to be minor by 2015 so action needs to be sustained.

Oesophago-gastric Cancer

6. Many GPs have now been trained to test for and treat *Helicobacter pylori* which has been associated with gastric cancer. However, the long term effects of eradication of *H.pylori* are uncertain. It is possible that reduction in prevalence of *H. pylori* gastritis may lead to an increase in Reflux oesophagitis, Barrett's oesophagus and possibly increased levels of *oesophageal adenocarcinoma*.
7. Chemo-prevention with aspirin may have a role in *oesophageal* cancer prevention in the future but by 2015 evidence will still be developing.

Hepato-cellular cancer

8. By 2015 action needs to have been taken to prevent transmission and improve treatment for those who have been infected. Screening of high risk populations also needs to have been considered – vaccination at birth implemented in the Far East has already led to a decrease in incidence of *hepatocellular carcinoma*; There is also a role for antiviral therapy in quiescent (inactive) disease for those hepatitis B&C patients undergoing chemotherapy and/or immunosuppressant therapy to reduce reactivation/exacerbation of the virus.

Screening/ Surveillance

9. It is unlikely that there will be sufficient evidence to support national screening for upper GI cancers by 2015 but more research is needed to see if screening may be feasible in the longer term and for which groups. By 2015, it will be important to have research underway to help stratify risk in high-risk groups and to have screening pilots where appropriate. Where evidence is developed to support screening in any of these groups it should be introduced uniformly across the country in line with national guidance.

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Oesophago-gastric Cancer

10. Surveillance of people with Barrett's oesophagus could lead to an increase in diagnosis of patients with early *oesophageal* cancer. It is not yet known if surveillance of this group would be cost-effective and by 2015 this needs to have been established.

Pancreatic Cancer

11. It is not yet known if surveillance of people with a family history of *pancreatic* cancer or related genetic conditions would be cost-effective to improve outcomes. By 2015 this needs to have been established. Pancreatitis is also a risk factor for *pancreatic* cancer but endoscopic ultrasound screening of patients with pancreatitis can be difficult because the condition tends to mask small tumours. Further genetic markers may be available by 2015. More research needs to be undertaken into the link between late-onset diabetes and *pancreatic* cancer and whether this is another high risk group for potential surveillance and screening.

Bile Duct Cancer

12. There is no evidence to support the introduction of a surveillance/screening programme for people with benign bile duct diseases and malfunctioning bile ducts. By 2015 a consensus should have been reached on surveillance (both modality and interval) of these patients.

Hepatocellular Cancer

13. People with cirrhosis are more susceptible to *hepatocellular* carcinoma and *biliary tract* cancer than the general population – ultrasound screening and AFP (alpha-fetoprotein) monitoring of all Hepatitis B and cirrhotic patients for *hepatocellular* carcinoma is recommended in British Society of Gastroenterologist guidelines but is performed with variability around the country. By 2015 it is important that protocols for national surveillance are developed and implemented across the country.

Liver Metastases

14. By 2015 a national consensus needs to have been achieved on surveillance and screening for development of liver metastases and its subsequent management. NICE clinical guidelines on colorectal cancer, to be published in December 2011, may address this issue.

Raising Awareness / Improving referral

15. There is conflicting data on the role of symptoms in helping to identify patients with suspected upper GI cancers. Around third of upper GI cancers are currently referred under the 2 week wait. However, only approximately 10% of patients with pancreatic cancer are referred by this route.
16. It is estimated that only about 13% of all patients referred by GPs under the two week wait are subsequently found to have cancer. If the NICE GP referral guidance were followed patients would be referred more appropriately and larger numbers of patients referred under the 2 week wait could be found to have cancer. There is some doubt as to whether GPs make sufficient use of such guidelines for them to be useful and whether or not they can be expected

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to have sufficient knowledge to pick up potential cases of upper GI cancer early. Consultants should be able to re-assess routine referrals and upgrade them to urgent referrals to be covered by the 62 day target when necessary.

17. By 2015:

- i. the medical community needs to agree key symptoms for pancreatic cancer and potentially other upper GI cancers that can be communicated to both the public and primary care clinicians;
- ii. through the National Awareness and Early Diagnosis Initiative (NAEDI), work should continue to identify the best way to alert GPs to risk factors, signs and symptoms of upper GI cancer; and
- iii. GP referral guidelines should be updated if new evidence becomes available and it is agreed such guidelines continue to have a role to play.

Oesophago-gastric cancer

18. Existing NICE guidelines for patients with alarm symptoms and new or persistent dyspepsia over the age of 55 need to be audited with outcomes presented to PCTs and GP consortia when they are in place. The approach of symptomatic treatment in this group before investigation must be minimised by work with relevant health professionals.

Pancreatic and Biliary Tract Cancer

19. Delays in diagnosis of pancreatic and bile duct cancer must be better understood. Currently very few pancreatic cancer patients are included in the 62 day target. By 2015 we need to have completed research, surveys, audits and case control studies on the relative contributions to late diagnosis of eg delays in patient presentation, delay in GP suspicion and referral, incorrect diagnosis by gastroenterologists and other specialists and waiting times for diagnostic tests.

20. Where there is a suspected *pancreatic, biliary tract* or *primary hepatocellular* cancer it is important that patients are referred to specialist centres immediately after rapid local assessment. Jaundiced patients must be discussed with the centre with a view to urgent transfer before any interventions are undertaken. This will result in a greater caseload in centres and they need to be resourced to cope with this.

Diagnostics/Staging

21. This is a disparate group of cancers with different diagnostic needs. It is clear that with a general increase in incidence and prevalence over the next five years expected diagnostic capacity will need to be increased and out of hours and weekend access to imaging (MRI/CT) etc will need to be considered to avoid diagnostics and staging becoming bottlenecks in the system. Staffing will be the rate-limiting step in expanding diagnostic services.

22. By 2015 it will be important to have sufficient numbers of staff and proper training to enable site-specialisation in diagnostics. It will be particularly important that any diagnostic imaging is read by specialists in the tumour site

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in question rather than generalists and this should be reflected in clear quality parameters set as part of all contracts, irrespective of who the provider is.

23. There is already evidence to support the use of PET-CT in staging to prevent unnecessary treatments, for example, for all patients where radical surgical and non-surgical treatment is proposed. By 2015 adequate capacity for PET-CT needs to be available to match staging pathways and prevent increased delays and breaches of cancer waiting times.
24. For the benefit of patients, it will be important to streamline diagnostics where possible in one stop clinics where most tests are performed on the same day – this is unlikely to increase workload but will require some streamlining of services. By 2015 diagnostic services should have been redesigned to ensure that, where possible, patients are able to have the majority of diagnostic tests they may need on the same day.
25. In addition to the concept of one stop clinics it would be a major benefit for patients if multi disciplinary ‘triage’ reviews were trialled to direct patients straight to the most appropriate medical clinics. Given that surgical availability and expertise can be major rate limiting steps it would be interesting to explore new models more aligned to lung cancer and in cardiology with benign disease. The key to this will be piloting bringing ownership of the staging process to the front of the pathway and having triage diagnostic teams. This has been shown to work in lung cancer.
26. Access to high quality pathology services with facilities for sophisticated diagnostic investigation of specimens where this is appropriate will be vital. This will need to include high quality (nationally accredited) immunohistochemistry and molecular biology, not only to make diagnoses but also to assess markers that will predict targeted neoadjuvant therapies. Some of these sophisticated techniques have relevance today, but will grow in importance over the next 5-10 years.
27. It will be important to have sufficient histopathologists and cytopathologists to manage this. By 2015 it will be necessary to have increased workforce and changed service configuration to ensure that a report from a biopsy of a suspicious lesion is available within 48 hours of the biopsy being taken.
28. Pathology also has an important role to play in the diagnosis and evaluation of resection specimens (as opposed to the initial diagnosis of cancer) and in the functioning of MDTs. This is not only important for the management of the individual patient (by giving pathological tumour staging) but can play an important role in audit and quality assurance of radiology and surgery. Detailed pathology at this stage is time consuming but important and should be done according to the Guidelines and Datasets published by the Royal College of Pathologists.
29. Specific diagnostics:
 - i. over the next five years more *endoscopy* and *ultrasound* will be carried out in primary care and/or community settings and

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- increasingly by nurses and GPs. It is essential that all staff undertaking or interpreting endoscopy and ultrasound have had adequate training, work to agreed quality standards and have their work regularly audited against those standards;
- ii. the level of *endoscopic ultrasound* (EUS) provision and training in the UK is behind the levels in the continent and needs to increase over the next five years. Its role is likely to increase with more interventional procedures for diagnosis and staging;
 - iii. *endoscopic ultrasound* (EUS) will increasingly be required to do needle biopsies for selected gastro-oesophageal and pancreatic patients to complete staging and help with management decisions. This requires more capacity but needs cytologists to be available at the procedure to get maximum yield and diagnostic gains;
 - iv. *endoscopic ultrasound* (EUS) and/or CT-PET are likely to be required for image fusion and planning of complex radical radiotherapy;
 - v. MRI should increasingly be used as complimentary modality to others to distinguish operable lesions and in oesophageal cancer it is likely to be used to help identify those patients for whom pre-operative Chemoradiotherapy may be appropriate; and
 - vi. The increase in laparoscopic diagnostic and staging procedures will continue and will necessitate an increase in appropriately trained surgeons.

Treatment

30. By 2015 it is likely that there will be a further expansion in potentially available targeted therapies particularly more “mabs” (eg. Cetuximab) and neoadjuvant chemotherapy, but these will have significant cost implications. There is also the potential that there may be a wider “choice” of chemotherapy treatments/ trials for patients with more advanced cancer. These treatments will largely be additive rather than substitutive and thus additional costs to the NHS will be incurred per patient. There is also likely to be more need for radiotherapy and therefore an increase in radiotherapy capacity will be needed in line with the National Radiotherapy Advisory Group’s recommendations.
31. There will also be more need for complex radiotherapy techniques such as Intensity Modulated Radiation Therapy (IMRT) for upper oesophageal lesions and Image-Guided Radiation Therapy (IGRT) or IMRT for gastro-oesophageal junction and pancreatic lesions. This will improve quality and outcomes with reduced toxicity.
32. It seems likely that there will be increased demand for a new strategy of pre-operative Chemoradiotherapy for pancreatic cancer due to the higher rate of positive resection margins with surgery alone.
33. Further improvement is required to access fast assessment and insertion of stents; it is still a problem that needs to be tackled due to inadequate nurse specialists, radiology, endoscopy and bed availability.

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34. There needs to be greater clarity about different types of NICE guidance for patients, particularly:
 - i. interventional procedures guidance which advises if a treatment is safe but not whether the NHS should use it despite some of the marketing of companies that produce such treatments; and
 - ii. technology appraisals which advise whether a treatment is clinically or cost effective.

35. By 2015:
 - i. there should be equity of availability of new interventions for all patients;
 - ii. it should be clear to the public which treatments the NHS should use; and
 - iii. value-based pricing should give patients, the public and the NHS more clarity about the true value of treatments for upper GI cancers

36. Upper GI cancers often require complex surgery as part of their treatment and it is vital that the centralisation set out in the IOG is fully completed as soon as possible. It is estimated that around 30% of *gastric* resections are still not being centralised. In addition a relatively low proportion of patients with *pancreatic* cancer are referred centrally. The implication is that clinicians in outlying hospitals are making decisions about whether a patient is suitable for surgery rather than that decision being made centrally. It is important that commissioners do not commission services from non-IOG compliant services.

37. The service requirements of such surgical services are addressed in the recent position paper of the Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland which has been endorsed by the English Department of Health.²

38. It is not yet clear whether more surgeons will be needed over the next five years but it is important that this surgical discipline is developed and that by 2015 training fellowships have been funded. It is likely that there will be increased use of laparoscopic surgery over the next five years and it will be important that this does not creep in without mentorship or quality control. By 2015 it will be important to have a sufficient number of surgeons training in laparoscopic upper GI surgery.

39. It is important to note that staff carrying out complex benign work are often the same as those carrying out cancer work. This needs to be taken into account in service planning, for example, to ensure that there is sufficient capacity to manage both emergency surgery for pancreatitis and planned surgery for chronic pancreatitis and other benign diseases as well as *pancreatic* cancer surgery. Centralisation of emergency surgery for acute pancreatitis will require a substantial commitment of critical care resources for these patients who often have prolonged ITU stay. It will also be important to

² Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland: Guidance on minimum surgeon volumes (October 2010)
http://www.augis.org/pdf/reports/AUGIS_recommendations_on_Minimum_Volumes.pdf

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increase the number of operating lists for both *pancreatic* and *hepatobiliary* cancers.

40. Treatment of *neuroendocrine* tumours is only carried out in a few centres and access to radio-targeted therapy is limited to three centres in England (Royal Free, Royal Marsden and Liverpool). By 2015 the evidence base for this treatment needs to have improved with well conducted trials. This may enable treatment to roll out to other specialist neuroendocrine centres across the country – such centres would need to be designated as such and are likely to be co-located with Liver / HPB centres.
41. It will be important that whatever treatment a patient needs is provided quickly. By 2015:
 - i. the NHS should be delivering all cancer treatments to the 31 day target from the decision to treat including treatment for recurrence. All tertiary /specialist referrals should be sent to the specialist team by day 31 from initial referral;
 - ii. provision needs to be made for “emergency” or “urgent” surgery for patients with suspected *pancreatic / biliary cancer* who present with jaundice so that specialist surgeons have the option to operate without prior stenting. Referral protocols from Unit to Centre must be in place to minimise waiting times. Stenting should not be considered as a possible first treatment; and
 - iii. improving waiting times will not be easy to implement and will require adequate resourcing.
42. Finally there should be an improved IT interface to ensure the smooth running of services. Full clinician, managerial and IT consultation will be needed to ensure the technology is fit-for-purpose.

Supportive & Palliative Care

43. Unfortunately, by 2015, many patients with upper GI cancers (especially *pancreatic* cancer) will still be diagnosed with inoperable disease due to factors such as diagnosis at a late stage and frailty. Palliative treatment involving both radiotherapy, chemotherapy and pain/symptom management will continue to play a major role in managing this group of patients.
44. By 2015:
 - i. supportive & palliative care should be available from diagnosis as patients with upper GI cancers can experience a range of physical symptoms – as well as psychosocial problems - the role of allied health professionals and palliative care physicians will all be essential to continued care;
 - ii. the integral role of clinical nurse specialists in multi-disciplinary teams and in improving patient experience should be recognised by managers and commissioners;
 - iii. regular patient surveys including quality of life assessments should take place and findings should be acted on – the IOG already sets out the importance of patient experience surveys but recent peer review has indicated that implementation is variable. Given that

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- patients may feel inhibited giving accurate feedback to staff, patient experience surveys are a good tool and need to be embedded into services and inform how they are commissioned;
- iv. links to patient support groups should be well established - for less common cancers there may be few (if any) local support groups but phone access to national support groups should be available as a minimum; and
- v. the hidden consequences for patients of centralising services in terms of travel times and costs etc need to be considered and addressed.

Follow up

45. Existing follow-up protocols are not evidence based and are not always patient-centred. For example, appointments may be six monthly but it is possible that a patient could have concerns between appointments and if they delay raising them until the appointment it is possible that a re-occurrence or a severe side-effect could be picked up too late. It is also known that some patients feel worried if they are “signed-off” and do not have further opportunities to see a specialist. All patients should have access to appropriate support from healthcare professionals as and when they need it.
46. By 2015 there should be clarity about follow-up for patients with upper GI cancers including the need for open access to specialist advice when needed and the role of shared care protocols.

Underpinning programmes

Information

47. By 2015 the National Oesophago-Gastric Cancer audit should have been extended to cover the full range of upper GI cancers and it should be mandatory for MDTs managing all these cancer patients to participate in this audit. This should include collecting data on co-morbidity, staging and performance status. Collection of data across the whole patient pathway from first symptom, through GP referral, diagnostic techniques, treatments and palliative care is desirable. Risk-adjusted performance and outcome data should be published at regular intervals to support service improvement and informed patient choice.

Research

48. More work is required on epidemiology, early warning signs, symptoms and markers, risk factors, predictors of response to treatment (to tailor treatments and prevent wastage in unresponsive patients), improved palliative care and nutrition, prevention of complications and novel treatments. There need to be national case control studies. By 2015 there needs to be more clinical and translational research related to upper GI cancers, increased recruitment to the existing (and future) portfolio of trials and equal opportunities to access relevant trials for all patients. This will be vital if survival rates are to improve.