Interventional Radiology: Guidance for Service Delivery

A Report from the National Imaging Board

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Interventional Radiology: Guidance for Service Delivery

A Report from the National Imaging Board

Prepared by a specially convened sub-group of the National Imaging Board (NIB) to provide advice for commissioners and providers of Interventional Radiology services and commissioned as a result of a previous publication, *Interventional radiology: improving quality and outcomes for patients. A report from the National Imaging Board*, 2009.

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Foreword

Interventional Radiology (IR) offers the NHS gains in clinical outcome, productivity, patient experience and length of stay when compared with alternative traditional procedures. Access to IR services is very variable across the country, despite the recognition that IR saves lives.

This document provides a road-map for local service development of IR. It builds on the 2009 report from the National Imaging Board which informed and stimulated discussion about how IR services can support the QIPP agenda. It describes how successful IR services have been set up, summarises the clinical evidence base and indicates a range of development options for commissioners and Trusts.

I hope it will prove a spur to action.

I should like to thank all contributors for making their time and expert knowledge available to produce this guidance for service improvement.

Sir Bruce Keogh
NHS Medical Director

Executive summary

This document has been prepared by a specially convened sub-group of the National Imaging Board (NIB) to provide advice for commissioners and providers who wish to develop their Interventional Radiology services. It was commissioned as a result of a previous publication *Interventional radiology: improving quality and outcomes for patients. A report from the National Imaging Board*, 2009.

The 2009 report illustrated how the NHS can improve quality, safety and productivity while delivering the highest quality care with comparable or better outcomes for patients, shorter hospital stays and fewer major complications.

The 2010 White Paper, *Equity and Excellence: Liberating the NHS* aims to put patients at the centre of decisions made about their care and to ensure that care is effective, safe and meets patient expectations. The white paper also expects to give patients choice over some treatment options. Already clinicians are working to facilitate patient choice by giving patients the information they need to make effective decisions.

Currently the provision of Interventional Radiology (IR) services varies throughout the NHS in England; the NIB in its previous report pointed to the implications for quality of care and the choice available to patients. There are units currently providing good quality IR care delivered by skilled multidisciplinary teams and this document is in no way meant to destabilise areas of good practice.

The document provides a summary of the evidence base for how comprehensive IR services can contribute to improved outcomes, safety and experience for patients who present with relevant emergency and planned care conditions. In the appendices we have provided a synopsis of the main literature in this field and a list of key references for further reading.

An effective, well resourced IR service can contribute to significant efficiencies (financial and non-financial) in care pathways in both planned and emergency care.

This document describes a framework for IR and will support providers and commissioners to plan appropriate provision of IR services for their patients. Such services should be available at all times and delivered using appropriate equipment by well trained doctors, radiographers and nurses.

This document does not consider IR services for children in detail although it acknowledges that access to paediatric IR services is also variable. A 2010 report from the National Imaging Board on *Delivering quality imaging services for children* discusses this in more detail. Many of the radiologists providing IR services to children are not currently trained specifically in children's IR. In June 2010 the Royal College of Radiologists and the Royal College of

Paediatrics and Child Health published a joint report *Improving paediatric interventional radiology services* which examines the problems in, and suggests solutions to, improving service delivery and access to paediatric IR services.

Although this document refers only to services in England, the Managed Diagnostic Imaging Clinical Network in Scotland and NHS Scotland have also produced a report (in final draft 2010) *Standards for Haemorrhage Control Services in Scotland*. Their report recognises that IR services have an important and developing role to play. It sets out the aim to provide equity of access to emergency haemorrhage control services provided by their IR teams.

The current constraints to delivering a comprehensive service are explored here and include:

- a lack of awareness amongst commissioners and providers of the true role for IR
- a lack of an appropriately trained workforce including dedicated training and consultant posts in IR with clear career pathways. This also applies to nurses and radiographers
- a lack of clarity on funding such a service within Payment by Results
- a lack of availability of appropriate diagnostic equipment e.g. modern CT and MRI
- a lack of access to out-patient clinics, admission rights, and support staff.

This document provides examples of how a comprehensive IR service can be achieved in a variety of settings. IR is not a service where ‘one size fits all’ so this document explores different models of service.

What is Interventional Radiology?

IR is a minimally invasive alternative to open surgery or medical interventions that uses radiological image guidance (fluoroscopy, ultrasound, computed tomography [CT] or magnetic resonance imaging [MRI]) to effect treatment. IR has developed over the last 45 years within a diagnostic discipline so the role of IR as a therapeutic specialty is often ignored and misunderstood. IR is as different to diagnostic radiology as surgery is to medicine, but just as a surgeon needs the diagnostic skills of a physician the interventional radiologist requires the same skills as the diagnostic radiologist. The basic skills of an interventional radiologist are in image interpretation and, therefore, core diagnostic radiology is at the heart of IR training.

There is hardly any area of hospital medicine where IR has not had some impact on patient management. Although interventional radiologists have many techniques at their disposal it should be recognised that not every interventional radiologist has all these skills: some continue to specialise in the area of their diagnostic radiology specialty and provide expertise in some areas of intervention (e.g. vascular vs. non-vascular techniques).

For the purposes of this document IR is defined by the subject areas referred to in the review of the literature only and cardiac interventions, neurological interventions and specialist paediatric services are not considered.

If it were practical an IR service would provide a local service which was safe and timely with well documented high quality clinical outcomes. However it is acknowledged that there will be capacity and capability issues which may make it unrealistic for some smaller hospitals to achieve this in isolation. In addition, for certain procedures such as transjugular intrahepatic portosystemic shunts (TIPS), patients should travel to a few dedicated centres undertaking enough cases to ensure the appropriate levels of expertise are sustained.

Why do we need good IR services? The Key Messages

IR provides a cornerstone to many clinical pathways across a very broad spectrum of specialty areas.

Described below are the most common clinical scenarios requiring IR. This is not an exclusive list. Appendix A provides more detail on the broad scope of IR practice. The paragraphs below give just the key messages.

Gastrointestinal (GI) Bleeding

Acute Upper GI bleeding

Evidence suggests that 65 patients per annum are admitted per 100,000 population with acute upper GI bleeding. Of this number 15% will require IR because of conditions such as haemorrhage from peptic ulceration. This equates to approximately 100 patients per annum for a population of 1 million but does not include additional cases such as post operative bleeds or other conditions such as acute pancreatitis and portal hypertension that can cause massive upper GI bleeding and can be managed by IR techniques.

Acute Lower GI Bleeding

A further 20.5 patients per annum are admitted per 100,000 population with acute lower GI bleeding. For a population of 1 million approximately 20 will need IR with the other 90% being treated with conservative measures. However the evidence suggests that this may be an under estimate for some regions: for example the figure for the West of Scotland is 170 GI haemorrhage incidents per 100000 population.

The literature states that:

- transcatheter embolisation has a positive impact on patient survival in the treatment of upper gastro-intestinal bleeding
- transcatheter embolisation is the treatment of choice for lower GI Bleeding
- transjugular intrahepatic portosystemic shunt (TIPS) is the treatment of choice for portal hypertension causing massive lower GI variceal haemorrhage.

The Kidney and Acute Kidney Injury

The reported UK incidence of acute kidney injury (AKI), formerly referred to as acute renal failure increases from 172 per million population per year in 1993 to 486-630 per million per year between 2001-2005. AKI is common in hospitalised patients. It is estimated that between 5 and 20% of all critically ill patients have an episode of AKI. Data from the Intensive Care

National Audit Research Centre (ICNARC) suggests that AKI accounts for nearly 10 per cent of all ICU bed days.

The literature states that:

- percutaneous nephrostomy (PCN) is a well established technique which should be available in all hospitals where patients may present acutely with renal obstruction
- most patients can be treated in 'normal hours' but some emergency presentations require access to a 24/7 PCN service.
- the operator should be adequately trained and have sufficient activity to maintain competence
- PCN is not the only means of treating renal obstruction. There should be close cooperation between radiologists and urologists in all cases.

Trauma

Major trauma is the leading cause of death in patients under 45 years old, the most common cause being road traffic accidents. The National Audit Office (NAO) estimate that there are at least 20,000 cases of major trauma each year in England resulting in 5,400 deaths and many cases of permanent disability requiring long term care. There are approximately an additional 28,000 cases who do not meet the precise definition of 'major trauma' who would be cared for in the same way. They estimate that the cost to the NHS is between £0.3 and £0.4 billion per annum in immediate care and that the annual cost of lost economic output following major trauma is between £3.3 and £3.7 billion. Specific examples of where IR has a major impact in trauma care include dealing with acute haemorrhage due to splenic trauma and major pelvic fractures.

The literature states that:

- in the severely injured patient rapid diagnosis and treatment is critical to avoid death or significant morbidity. The main priority is to diagnose ongoing haemorrhage and instigate prompt and appropriate treatment
- the need for timely high quality CT located in or near the emergency department is key to the survival of trauma patients
- this should be combined with a 24/7 IR service which, once the site of haemorrhage is identified, can provide diagnostic angiography and definitive haemostasis by embolisation or stent grafting
- the *Regional Networks for Major Trauma NHS Clinical Advisory Groups Repo*rt, September 2010, calls for an interventional radiologist to be in attendance within 60 minutes of patient admission in order to control major haemorrhage.

Abdominal Aortic Aneurysms (AAAs)

Abdominal Aortic Aneurysms (AAA) are most common amongst men aged 65 and older. An AAA is said to be present if the aorta is 3cm or wider in diameter. If an AAA is 5.5cm or larger,

treatment – normally surgery – is usually recommended due to the risk of rupture. In 2000 in England and Wales, AAA ruptures accounted for 6,800 deaths and 2.1% of deaths in men aged 65 and older.

In the Multicentre Aneurysm Screening Study (MASS), aneurysms were present in 4.9% of men aged 65-74 years. AAAs 5.5cm or greater were present in 0.6% men aged 65-74. In a population of 100,000, around 4% (i.e. 4,000 men) are aged 65-74. Therefore approximately 24 men in a population of 100,000 are likely to have an aneurysm of 5.5cm or greater. AAAs are around six times less common in women but there are more women than men aged over 65. Approximately six women in a population of 100,000 are also likely to have an aneurysm of 5.5cm or greater.

This equates to a total of 30 untreated aneurysms among 65 to 74-year-olds in a population of 100,000. In recent years endovascular aneurysm repair (EVAR), which involves IR and vascular surgery to insert a stent graft rather than major open surgery, has become the first choice treatment option for a significant proportion of patients with AAA. As most IR units serve a population 10 times that size and around half the AAAs are suitable for EVAR most units should be doing approximately 150 procedures per year.

The literature states that:

- the low 30-day mortality rate, lower hospital stay, reduced use of in-patient resource and public desire for less invasive techniques will support the continued use of EVAR in patients who are anatomically suitable for aneurysm repair
- the continued development of devices, less intervention in certain clinically insignificant post-intervention findings combined with rationalisation of follow-up protocols will drive down the cost of stent-grafts
- the number of interventions is likely to increase with the ongoing implementation of the NHS AAA Screening Programme, more widespread use of EVAR to manage ruptured AAA, and with technological improvements to increase the number of patients anatomically suitable for EVAR.

Peripheral Vascular Disease

Atherosclerosis sufficiently severe to reduce the blood pressure at the ankle is present in 7-15% of middle aged and elderly patients of Britain. In patients aged 50 and over around 5% complain of intermittent claudication (see appendices page 26-7), rising to 14% of men over 65 yrs. Critical limb ischaemia (CLI) is present in 400 cases per million population i.e. 1 in 2500 of the population annually. With an increasing rate of diabetes and an ageing population the incidence and prevalence of both claudication and CLI is increasing. One third of diabetic patients over 40 have lower limb arterial disease and 15% go on to develop ulceration of the foot. Over a 10 year period the number of major amputation in patients with type 2 diabetes has nearly doubled.

The literature states that:

- the use of IR techniques results in both an improvement in quality of life and good limb salvage results
- IR techniques offer improved patient experience, have low in hospital stay and are cost effective.

The Liver

Liver disease mortality in the UK is increasing at a time when liver death rates are dropping practically everywhere else in Europe. Over the last 30 years liver disease mortality in young and middle-aged people in the UK has increased at least six-fold and liver admissions and liver deaths are both rising at between 8-10% per year. Liver cancer is within the top twenty most common cancers in the UK with 3,407 new cases diagnosed in 2007 and 3,390 deaths in the UK in 2008. Approximately 220 cases per year are recorded in people under 50.

The Liver – Hepatic Malignancy

The literature states that:

- radiofrequency ablation (RFA) is an extremely successful method of providing focal tumour ablation and in skilled hands has a low rate of complications
- patients with treatable extrahepatic disease or those with tumours that have been downsized by chemotherapy (but are not resectable) may be considered for ablative therapy
- transarterial chemoembolisation (TACE) and Y90 radioembolisation treatments are important treatments for primary and metastatic hepatic tumours
- RFA and TACE can downstage primary liver tumours to the point where the patient can then be considered for transplant.

The Liver- Infection

The literature states that:

- percutaneous drainage of hepatic abscess is the therapeutic procedure of choice and is successfully curative in >90% of cases. Percutaneous abscess drainage is an IR procedure but is often performed by general radiologists both during the normal working day and out of hours.

Uterine Disease – Fibroids

Fibroids are the most common gynaecological problem experienced by UK women and are present in 74% of premenopausal women (all races average). They cause clinical symptoms in 30%. For a population of 100,000 women on average 20,000 will have symptoms. Most are managed medically but in 2004/5 38,000 hysterectomies were carried out in the UK. This compares with 57,000 in 1998/9. This decline in hysterectomies continues as practice changes and alternative treatments like uterine artery embolisation (UAE) are used.

The literature states that:

- hysterectomy results in longer hospital stays, longer return to normal activities and higher hospital costs than UAE but is the preferred treatment if amenorrhoea is the preferred outcome
- UAE is efficacious and relieves and stabilises the symptoms of menorrhagia and pain in >90% of patients and pressure symptoms in 60-80%. It carries a high success rate and low complication rate that are sustained in the long term
- whilst there is limited patient satisfaction data available, what is available generally favours UAE as the treatment of choice
- UAE is a less expensive option when compared with hysterectomy even when the costs of repeat procedures and associated complications are factored in.

Uterine Disease – Postpartum Haemorrhage (PPH)

Major PPH occurs in 1 in 2000 live births. Waterstone et al report that there are 14,724 reported cases per annum of severe PPH in the UK, although not all are reported and NHS statistics are inaccurate and HES data shows that 1948 emergency hysterectomies for PPH were performed between1998-2000 in England alone with 30 deaths.

The literature states that:

- arterial embolisation in the setting of PPH is safe, non-invasive, and reproducible with low rates of complication and allows patients subsequent normal pregnancy
- if pharmacological measures fail to control haemorrhage, intrauterine balloon tamponade is an appropriate first-line “surgical” intervention for most women where uterine atony is the only or main cause of haemorrhage. If this fails to stop the bleeding, one of the recommended conservative interventions is selective arterial embolisation
- hospitals with obstetric services should provide an emergency IR service to save the lives of patients with catastrophic PPH.

Cancer Management

In cancer management interventional radiologists use a variety of techniques, many of which are rapidly evolving, to reduce the size of primary and secondary cancers and IR also plays an essential role for temporary venous access for drug treatment and intravenous feeding e.g. Hickman lines. Palliative cancer care by IR includes the placement of oesophageal and colonic stents.

Cancers in many organ systems are detected at a smaller size than ever before. Smaller tumours are amenable to image-guided ablation (IGA) techniques in the liver, lung and kidney, for example, increasingly avoiding the need for more invasive and costly traditional surgical techniques. There is a rapidly accruing literature confirming the oncologic effectiveness of radiologically-guided thermal ablation techniques such as radiofrequency, microwave and cryoablation.

RFA works by inserting a probe into a tumour and then applying heat to ablate the cancer cells. The interventional radiologist uses image guidance (ultrasound, CT scanning or MRI) to guide the placement of a long, thin insulated needle into the tumour. The distal end of the needle is not insulated and emits radio waves. Electrodes are attached to a generator and the electrical energy is converted to heat that kills cells through coagulation necrosis. This can be performed as an outpatient with conscious sedation and local anaesthesia. RFA may be repeated for new or recurrent disease.

The literature shows that ablative therapy has a lower complication rate than surgery due to its minimally invasive nature and appears to be as effective as surgery in appropriately selected cases. Results indicate a major role for IGA techniques in the management of sub-3cm primary lung tumours and metastases, primary hepatocellular carcinoma, small renal tumours and metastases in the liver.

Gastrointestinal Malignancy and Stenting

Colonic cancer is the third leading cause of cancer related death in the Western world. Oesophageal cancer is eighth and the incidence is rapidly increasing. Oesophageal and gastric cancer often present late and are then only suitable for palliative care. Stenting of the obstructed gastrointestinal tract is now a well established palliative technique bringing rapid symptomatic relief and facilitating further management with chemotherapy and radiotherapy. Stenting is often undertaken by interventional radiologists although other groups may also do this work e.g. endoscopists.

The literature states:

- gastrointestinal stenting is an important palliative tool for advanced cancers of the gut
- colonic stenting may also be used as a “bridge to surgery” avoiding formation of a stoma and staged operations
- technical and clinical success rates are approximately 80-90% with acceptable morbidity and mortality.

Renal Vascular Access

Vascular access is essential for haemodialysis and the 2006 national report *Organisation and delivery of the vascular access service for maintenance haemodialysis patients* has acknowledged its suboptimal provision in the U.K. Approximately 100 new patients per million population start renal replacement treatment in the U.K. each year and the number is rising rapidly with the increase in diabetes. IR provides considerable support for these patients including imaging and intervention to maintain the function of a fistula, rescuing thrombosed fistulae and placing external central lines for dialysis access if a fistula is lost. This work is recurrent as virtually all access routes fail with time and require repeated revision. The 2006 report described above estimates 2 sessions of consultant IR time per week per 100 haemodialysis patients.

Venous Thrombo Embolic Disease

Interventional radiologists may place filters into the inferior vena cava to prevent thrombus travelling from the lower limbs to the thorax and potentially fatal consequences. Where a pulmonary embolus has occurred IR can be used to effect thrombolysis treatment.

Specification for an IR Service

The delivery of IR services cannot be met by a 'one size fits all' solution. The creation of an imaging network model similar to existing cancer, trauma and stoke networks is possible for IR.

Local services will develop according to the skills of the local workforce and service need. This service specification has been designed to be implemented flexibly to reflect decisions by commissioners and service providers. If there is not a local solution, service providers will want to work together to provide a network of services to deliver comprehensive cover across the range of all IR techniques but principally for the treatment of:

- haemorrhage from trauma, obstetric emergencies, ruptured aortic aneurysms and gastrointestinal bleeding
- fibroids
- renal obstruction
- abscess requiring image guided drainage.
- critical limb ischaemia.
- renal dialysis vascular access
- many cancers for example by liver metastasis therapies and oesophageal and rectal stents.

All acute hospitals will want to develop a formal documented process for access to IR services 24 hours a day, every day. The experience of IR clinicians shows that the following issues need to be addressed to ensure this approach is successful in delivering high quality IR services.

Organisational Commitment

- Board level commitment from both commissioning and provider organisations will be important.
- The presence of a governance structure and clinical leadership which assures quality of service and allows for continuous measurement and improvement.
- A commitment to the development of an IR network that will ensure equality of access for patients to high quality IR.
- Presence of a clinical structure which facilitates the development of IR with the co-dependent specialties e.g. vascular surgery, obstetrics and gynaecology etc.
- Provision of multi-professional education and training to provide the IR workforce of the future.
- Patient and public involvement in developing services to meet patient need.
- Business planning models that recognise the importance of IR and provide revenue streams for service development.

24/7 Service delivery

- Where vascular and non-vascular intervention is to be delivered 24 hours a day every day formal consultant led rotas need to be structured to reflect this. These should allow for the

provision of immediacy of care for emergencies within the unit or transfer of the patient or key staff within a structured network.

- 24 hour care that allows IR access to co-dependent specialties particularly for network transfers including amongst others critical care/anaesthesia, vascular and upper GI surgery, gastroenterology, renal services and obstetrics.
- Consultant job plans should allow the relevant balance of non IR activities for both part time and full time IR specialists to ensure staff develop the necessary spectrum of expertise and maintain competency in other aspects of imaging if required.
- On call rotas should ensure that emergency provision should not delay elective IR care for other patients e.g. vascular access, cancer care and elective vascular intervention.
- Advice to the service from NHS clinical advisors already stipulates that protocols should meet the criteria for delivery of IR in trauma within 30 minutes from referral which should be no more than 60 minutes in total from admission, with safe transfer, monitoring and resuscitation facilities.
- Provision of IR infrastructure e.g. fixed angiographic equipment, appropriately located CT and immediate availability of consumable equipment and devices.
- Acknowledgement that the service is delivered by a multidisciplinary team including a radiologist, trained radiographers and nurses with appropriate rotas for all these staff groups.
- Deaneries are responsible for IR training posts and should consider training requirements to provide IR National Training Numbers (NTNs) whilst remaining mindful of the ever increasing demand for diagnostic imaging services.

9-5 Service delivery within a network

- All Trusts delivering IR could be part of a network with network agreed levels of service delivery. This should provide for local delivery of some aspects of IR during the normal working day and IR expertise out of hours across the network.
- Consultant job plans and rotas for individual units and across a network should ensure service delivery for elective and emergency care to minimise delays in intervention which will adversely impact on patient outcomes and length of stay.
- An infrastructure for IR includes nursing and radiographic training and support.
- All elective and emergency intervention that can be conducted by a trained interventional radiologist and has the clinical support of co-dependent specialties should be delivered locally as agreed by the network.
- Interventional teams from across the network would participate in network and national data collection as required.

Network development

- Commissioners should take overall responsibility for ensuring the provision of a high quality IR service for its catchment population.
- A network should be based on a geographical framework based on current referral practice and partnerships.

- All relevant providers could be part of a network but will need an agreed level of service delivery.
- A network could include more than one provider delivering 24/7 IR.
- There needs to be defined governance systems and recognised leadership with clear understanding of the structure, roles and responsibilities of all involved.
- Protocols in all acute Trusts should ensure that patients can access IR services either locally or via a network and that current areas of good practice delivered by skilled radiologists should not be destabilised.
- The network structure should include the continuing professional development (CPD) of all IR staff across the network and provide opportunities for acquiring IR skills and improved service delivery.
- Evidence based network guidelines and protocols for management need to be agreed, regularly updated and communicated throughout the network.
- Effective and safe patient transfer according to agreed protocols of communication within clinical teams need to be in place, regularly updated and communicated throughout the network with full engagement of the ambulance services in network transfer and triage.
- The network should explore outreach solutions for IR services. The decision to transfer a patient or deliver care on site should be made on a case-by-case basis between the on call interventional radiologist and the clinical teams both at the receiving and referring hospitals.
- The network should regularly review patient outcomes and ensure that there are processes in place for identification of network related critical incidents and action plans designed to improve performance.

Providing an out-of-hours interventional radiology service

The evidence contained in the appendices suggests that the quality of IR services at night and over weekends must be the same as that expected during the normal working day. Where out of hours services are being implemented co-ordinated weekend services should be planned for sufficiently large populations to ensure that IR skills are maintained and job plans are acceptable.

As discussed elsewhere in this document there are a number of common factors across the country that may hinder the ability to provide an IR service. Local factors may also be important, particularly for emergency IR work. For example, vascular interventional radiologists will not generally work in a hospital which does not have a vascular surgical unit. This same hospital may have busy gastroenterology and general surgical units and therefore have a requirement for IR for embolisation in internal bleeding, a procedure usually performed by vascular interventional radiologists.

Even for centres which take acute admissions across many medical specialties the provision of out-of-hours IR across the UK is patchy. Commonly cited difficulties in setting up an on call IR service include:

- insufficient numbers of interventional radiologists to allow an acceptable on call rota
- lack of enthusiasm from existing interventional radiologists to commit to a formal on call service because of low numbers
- reluctance of general radiologists for their interventional colleagues to leave the general on call rota. (A significant proportion of IR in the UK is performed by radiologists who also undertake general non-interventional radiology and who are on general radiology on call rotas.)
- insufficient numbers of specialist radiology nurses to support an out-of-hours service
- insufficient numbers of radiographers trained to work in the interventional suite
- no funding stream for the service
- lack of support from managers or other clinical colleagues because of lack of understanding of the importance of emergency IR
- the perception that out-of-hours IR is rarely required and therefore that an ad hoc or ‘goodwill’ service is acceptable.

Despite these challenges there are centres in the UK that have successfully set up sustainable out-of-hours IR services. Enthusiastic interventional radiologists usually drive this process but the support of their clinical and managerial colleagues is crucial. This seems to be easier in large units with larger staff numbers and these tend to be tertiary referral centres which provide a large range of clinical services. However some smaller acute hospitals have managed to provide effective services too.

Geographical factors are important and the following are examples of existing, sustainable out-of-hours IR services in the UK.

- District General Hospital (DGH) with its own IR on call service. Most DGHs do not have a sufficiently large pool of interventional radiologists to provide a sustainable service and do not have the volume of in-hours work to justify expansion of staffing numbers. Where such a service has been provided for example with only three interventional radiologists this has been a temporary solution whilst planning to set up a local network. Very onerous on call rotas are not sustainable, dangerous, and risk breaching the European Working Time Directive.
- federated or networked DGHs. For example where there are two neighbouring DGHs in a rural region which are some miles apart but significant distances from tertiary centres. They can develop a linked on call service with, for example, six interventional radiologists. Each DGH has its own interventional radiographer and nursing cover but the radiologist covers both sites out-of-hours. In the majority of cases the radiologist will travel to the patient rather than transferring the patient.
- large conurbation with several acute hospitals providing IR in-hours. Out-of-hours the on call interventional radiologist may travel to the patient requiring emergency treatment, the patient may travel to the radiologist's main base or there may a combination depending on the clinical state of the patient. In some centres the IR nurse may also cover several sites on call or each site may provide its own nursing staff. It is most usual for the radiographer to stay at the host site as familiarity with the equipment is essential.
- large tertiary referral centre with between approximately five and eight interventional radiologists providing vascular intervention (including embolisation for bleeding etc). There are several such centres in the UK and they will often have separate formal on call rotas of specialist radiologists covering other non-vascular IR such as nephrostomy insertion. Such large centres may receive patients out-of-hours from neighbouring acute hospitals that can provide IR in-hours but do not have an out-of-hours service. There will often not be a formal referral or funding infrastructure for this.

Payment by Results (PbR) and Activity Data

Healthcare Resource Groups (HRGs) provide a means of categorising the treatment of patients in order to monitor and evaluate the use of resources. A new Interventional Radiology HRG4 chapter has been developed to enable accurate counting and costing of IR activity. In 2010-11 hospitals will be asked to provide reference costs for these new HRGs. There are currently therefore no separate tariffs in PbR for the majority of IR activity, although the cost is included in other HRGs.

IR PbR best practice tariffs (BPTs) have however been developed to incentivise two specific IR procedures:

1. Endovascular Aortic Repair
2. Uterine Fibroid Embolisation.

The aim of these BPTs is to encourage these procedures, where clinically appropriate, by making them more visible in the payment system; but without incentivising their provision over their open surgery alternatives.

The tariff price will reflect the estimated cost of providing these procedures, and therefore aim to incentivise their provision through adequately reimbursing the costs of provision, without incentivising their provision over the open surgery alternatives where this is not clinically appropriate. From April 2011, for adult renal dialysis there will also be a tariff incentive for the best practice characteristic of definitive vascular access for haemodialysis. This will incentivise provision and maintenance of effective venous access which requires skilled IR clinicians.

Further updates on PbR in 2011-12 can be found at:
www.dh.gov.uk/en/Managingyourorganisation/NHSFinancialReforms/index.htm

The PbR guidance for 2010-11 can be found at:
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112284

Activity

In the production of this document, we reviewed the activity data from a number of imaging departments with IR services. These included both a geographical spread and representative services from tertiary centres to typical acute Trusts.

It was envisaged that this would help to offer some indicative workload figures. This proved to be problematic and was abandoned as there was inconsistency in the coding and no definitive list of which examinations count as IR. IR coding is among the most complex and presents a unique set of challenges. IR procedures are embedded in the HRGs of other services and it is challenging to separate them. The RCR has worked with the Information Centre and other UK bodies to create new IR HRGs codes which are now in use, with reference costs being collected against them for use in 2010/11.

Radiology departments store their information on Radiology Information Systems (RIS). A RIS is a commercially available product that varies from manufacturer to manufacturer but the core functions are to process requests, schedule exams and generate reports, as well as capture information on procedures performed and interpreted in the radiology department. Information is usually entered on to RIS before the patient examination is undertaken most often by non-clinical staff in order to generate a record. It is not uncommon for there to be a change in the exact procedure carried out from that initially booked onto the system. This is dictated by clinical issues at the time of procedure. In addition, some patients will have more than one diagnostic and/or interventional procedure performed on one occasion. However many older RIS systems do not allow multi-exams to be reported as one composite study from PACS, therefore a number of ‘compromise’ codes have developed to cover this situation. Hence accounting for IR activity via RIS is inherently inaccurate.

Conclusion

This document illustrates why patients should have access to IR services whether in an acute hospital or provided as part of a network. The geographical variation of IR service provision needs to be tackled if this is to be achieved.

The example below exemplifies the reasons for the changes required. The table describes two real cases admitted on the same day, with the same problem (ruptured aneurysm), but very different outcomes – patient 2 died the day after patient 1 was discharged.

Table1

PATIENT 1 • 24th March 2009 @1325 • 78 years old patient admitted via A+E • Ruptured AAA diagnosed on CT. • Shocked • 1350 in cath lab surgeon has exposed right femoral artery • 1405 interventional radiologist has inserted a stent graft and occluder • 1450 surgeon has completed crossover graft. • Patient goes to HDU for one night • 25th March goes to vascular ward • 31st March discharged home	FINANCIAL COSTS • A&E resuscitation • CT scan • Staff • IR suite • consumables = £4350,* • one night HDU cost =£500* • 6 days ward costs
PATIENT 2 • Same day @ 1425 • 78 year old patient admitted via A+E • Ruptured AAA diagnosed on CT • Shocked • 1430 decision made to perform open repair in theatre • 1445 arrives in emergency theatre • 1900 open repair finished and patient arrives in theatre recovery • 2000 patient arrives ITU • Patient stays on ITU for 8 days • 27th March patient requires dialysis • 1st April patient dies of multiorgan failure	FINANCIAL COSTS • A&E resuscitation • CT scan • Staff • Emergency theatre • 8 days ITU at £1800 per day= £14, 400*

*costing based on the same set of data

Comparison of patient outcome, length of stay and cost are examined in more detail in Appendix A under Abdominal Aortic Aneurysm.

Appendix A - Review of the literature

There is an extensive literature demonstrating that appropriate, timely radiology intervention enhances patient safety, patient experience and patient outcomes with proven efficiencies to the service.

The messages from the literature are clear and real cases in which patients benefit from IR are seen on a daily basis.

Aortic Disease

Abdominal Aortic Aneurysms (AAAs)

Population studies indicate that AAAs are common, occurring in about 4% of men older than 65 years. Most are asymptomatic until they present with acute rupture, after which 75% will die before reaching hospital. 40-50% of those admitted to hospital for emergency aneurysm repair will also die. This peri-operative mortality rate has not changed over the last 2 decades.

Population screening began in the UK in 2009 with the intention of reducing death from AAA rupture by increasing the numbers treated electively.

Unruptured AAAs are treated when the diameter exceeds 5.5cm. Two techniques are available; conventional open surgical repair (OSR) and endovascular aneurysm repair (EVAR). EVAR is a minimally invasive procedure undertaken without an abdominal incision requiring image guidance and is commonly done by Interventional Radiologists in collaboration with a Vascular Surgeon. The procedure requires the implantation of a stent-graft into the aneurysm; only approximately 50% of aneurysms have the correct morphology (shape) to allow this to be a treatment option.

Key data

The National Institute for Clinical Effectiveness (NICE) has confirmed in their documents *Stent-graft placement in abdominal aortic aneurysm – guidance* and *Endovascular stent-grafts for the treatment of abdominal aortic aneurysms* that the current data supports the use of EVAR.

Furthermore, in 2005 the National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD) report *Abdominal Aortic Aneurysms: A service in need of surgery?* has recommended that all patients who are suitable for EVAR should have this therapy made available to them.

Elective treatment of AAA

Two randomised studies in the UK, the EVAR1 and EVAR2 trials, have investigated the outcomes of AAAs treated by EVAR. The EVAR1 trial compared the outcome of EVAR against

OSR in patients who were suitable for OSR and had suitable morphology for the stent-graft. EVAR 2 looked at EVAR outcomes in a more fragile group of patients who had aneurysms suitable for EVAR but who were not suitable for OSR. This was typically because they had either severe co-morbidity or conditions that make open surgery difficult e.g. previous abdominal surgery.

Within the EVAR1 trial there was a near three-fold reduction in 30 day mortality with the use of EVAR when compared to conventional open surgery. A recent publication shows that in the long-term EVAR has the same benefit with respect to aneurysm-related mortality as OSR. The benefit of EVAR has been confirmed outside the major trials, and the Medicare report on 45,660 patients demonstrated not only the value of the procedure but showed increasing advantage with advancing age. This same study indicated that patients presenting with an AAA were 4 times more likely to die, 7 times more likely to undergo a tracheostomy and 12 times more likely to have lysis of adhesions (the process of cutting scar tissue within the body to restore normal function or appearance) due to bowel obstruction with OSR when compared to EVAR. Almost all data confirm the expectation that EVAR has shorter in-hospital stay, less use of intensive care and reduced blood requirements for the index procedure compared to OSR. The EVAR 2 trial indicated that for patients unsuitable for OSR there was no overall benefit in those treated with EVAR compared to no intervention. Some of this unexpected result may be explained by the delay in treatment resulting in a high death rate prior to EVAR, and by a high procedural death rate not seen in some of the registries. For this reason EVAR continues to be offered to some patients perceived as high risk for OSR.

Emergency treatment of ruptured AAA

The high operative mortality rate for ruptured AAA has stimulated interest in the use of EVAR for this high-risk group. A 2008 systematic review and meta-analysis showed a pooled mortality after EVAR of 21%. Without randomised data it is unclear as to whether this is due to real benefit over OSR, publication bias, or case selection. However a recent publication showed that, following the introduction of EVAR into an urban hospital to manage ruptured AAA, there was a decline in the death rate.

NCEPOD has recognised that a failure to provide 24 hour radiology imaging and IR for these patients puts lives at risk.

Length of Stay (LoS) and Cost

LoS is one major area of benefit in employing IR. The largest data source from the USA indicates a length of stay for routine EVAR of 3.4 +/- 4.7 days compared to 9.3+/- 8.1 days for open repair.

In the UK the saving in LoS is very similar. The largest data set for EVAR is the EUROSTAR registry and the National Vascular Database. These show a LoS for EVAR of 6 days compared

to 13 days for open repair. To acquire contemporary data the HES dataset has been interrogated. This shows a LoS for elective AAA repair in the UK to be 6 days for EVAR compared to 11 days for open repair.

The clinical advantage of EVAR comes at a price. The costs of EVAR are higher than OSR and this is due to the costs of the device, the requirement for continued surveillance, and a continued need for secondary interventions to maintain the stent-graft. It should be noted however that in high risk patients the Ontario London Health Science Centre found EVAR to be a cost effective strategy.

Peripheral Vascular Disease

The management of atherosclerotic peripheral artery disease is a major part of the activity of any vascular unit. Revascularisation of poorly perfused legs is often required using either IR (endovascular) or open surgical techniques. Data from both the USA and UK demonstrate a swing towards the use of endovascular intervention rather than open surgery because it is minimally invasive, requiring less in-patient resource, with fewer major complications, and good clinical outcomes. As such endovascular techniques, particularly angioplasty and stenting, are now seen as the first option in patients with chronic lower limb arterial disease. Data from Hospital Episode Statistics (HES), the Department of Health data warehouse, shows that angioplasty is now performed three times more frequently than open lower limb surgical bypass.

Claudication

Peripheral artery disease (PAD) is common, being present in 7-15% of the middle-aged to elderly population. Claudication describes exercise induced muscle pain due to reduced perfusion of the muscles. This disabling symptom is present in approximately 5% of subjects aged 55 -74 years. PAD becomes markedly more common with age, and with the increasing life expectancy of the population and increasing prevalence of diabetes, the burden of claudication will increase. In addition, these patients have a high risk of stroke and cardiac related death and morbidity.

Key clinical data

Claudication has a relative benign prognosis in terms of limb loss. Unfortunately drugs have little effect upon walking distance and bypass surgery is associated with significant morbidity. The only randomised trial of angioplasty against open surgery demonstrated that endovascular intervention has the same patency and clinical effect as open surgery, but fewer procedural complications.

Exercise therapy and endovascular intervention are now the principal interventions for claudication. Iliac angioplasty and stenting is safe with very little morbidity or mortality associated with the intervention. Whilst exercise therapy is safe, patients are willing to accept

risk of treatment and intervention is more effective and durable in the long term. In addition, the recently published MIMIC trial demonstrated that both iliac and infra-inguinal angioplasty combined with exercise therapy was significantly better than exercise therapy alone.

Claudication significantly affects a patient's quality of life, both physically and socially, and angioplasty and stenting results in a significant durable improvement.

Key cost data

The endovascular management of claudication has been found to be cost-effective. A recent Swedish study concludes that 'the incremental QALYs (quality-adjusted life years) gained by treatment are achieved at a reasonable cost and revascularisation appears to be cost effective'. Unlike surgery, the majority of endovascular interventions for claudication can be undertaken as a day case.

Critical Limb Ischaemia

When the distribution of atherosclerosis becomes severe, limb perfusion falls to such a level that the patient experiences pain at rest, develops ulceration or gangrene, with the leg at risk of amputation. This clinical situation is referred to as critical limb ischaemia (CLI).

Key data

When arterial revascularisation is required for iliac disease the Trans-Atlantic Inter-Society Consensus (TASC) guidelines recommend angioplasty and stent placement for simple (type A & B) lesions. In practice the majority of large units treat all iliac disease where possible by endovascular techniques. There are no randomised trials in CLI comparing endovascular versus open surgical techniques for iliac disease.

For the majority of patients with infrainguinal disease both endovascular techniques and surgical grafts may be used. Subintimal angioplasty has revolutionised the opening of long occlusions. Subintimal angioplasty differs from intraluminal angioplasty. It is performed in the wall of the artery to create a new non-diseased channel underneath the diseased lumen area, whereas traditional angioplasty opens the narrowed lumen. Where this technique is available most patients are now treated using endovascular techniques first rather than open surgery.

In patients where the pattern of disease was thought to be suitable for both angioplasty and open surgery as the first therapy the BASIL trial found that long-term freedom from death and amputation was the same for both strategies. However, there was a longer hospital length of stay (10 days) and more frequent need for Intensive Therapy Unit and High Dependency Unit facilities following surgery. Not surprisingly therefore after one year the hospital costs for surgery are one third higher than an endovascular first strategy. The generalisability of this trial has been questioned because only 15% of patients with CLI due to infrainguinal disease were randomised within the trial.

Surgical grafts have good patency and limb salvage rates but are recognised to be associated with 18% major morbidity, including at least 3% death and a wound infection rate of 25%. Endovascular techniques are therefore attractive in fragile patients. A recent meta-analysis of infrapopliteal angioplasty in CLI was compared with a similar meta-analysis of bypass grafts in CLI. The conclusion was that given the similar limb salvage rates then angioplasty of tibial vessels is a good option for treating this difficult group of patients.

The Severely Injured Patient

Trauma is a major cause of death across all age groups with over 16,000 deaths in England and Wales each year. The ratio of patients surviving to dying has not changed in 30 years for severely injured patients and in the UK is approximately 40%. Indeed as social awareness and policing has reduced road traffic accidents, the number of patients dying in them has risen as a proportion. The mortality rate in the UK is 15% higher than in other developed countries. Because trauma tends to kill the young more years of life are lost by trauma than by cardiovascular disease and cancer together. Thousands of trauma victims remain temporarily or permanently disabled. The primary determinant of survival and better quality of life for such trauma patients is the time from being injured to receiving definitive treatment by either surgery or intervention in a centre with the appropriate specialist staff and equipment. Increased specialisation within radiology and surgery means that the specialist skills and equipment required for trauma patients are not, unfortunately, likely to be available at every hospital. This necessitates re-evaluation of the organisation and delivery of trauma care across the country.

Death from trauma has a trimodal distribution. Many patients die immediately at the scene of the accident. A second early mortality peak occurs within the first 24 hours. Death in both of these groups results from predictable mechanisms - usually injury to the central nervous system and large vessels. Trauma victims who reach hospital alive are at risk of dying from internal haemorrhage during the first hours after admission. The third mortality peak that occurs days or weeks after the event is often the result of poor haemorrhage control and management within the first 24 hours.

The primary objective of early imaging in severely injured patients is the assessment of ongoing internal haemorrhage and of any other immediately life threatening condition. The second objective is to recognise at once all injuries present and to rank them according to their clinical significance. It is essential to the patient's survival that ongoing bleeding from internal injury is ruled out before valuable time is spent imaging non life threatening injuries.

Key data

The 8th edition of the *Advanced Trauma Life Support Guideline*s (ATLS) recommends Embolisation as a primary treatment for haemorrhage as do European guidelines. The conclusions of the National Confidential Enquiry into Perioperative Outcome and Death report on Trauma (NCEPOD) support this recommendation.

A recent study published in 2007 looked at 185 trauma patients managed conventionally as per ATLS protocols and 185 managed by ABC and early multidetector computerised tomography (MDCT). Accurate diagnosis was significantly faster and emergency room occupancy shorter in the group undergoing early MDCT. As a result ITU stays and ventilation days were shorter and rates of organ failure significantly fewer. The conclusion of the study was that in patients with blunt major trauma early MDCT leads to more accurate and faster diagnosis, and reduction of early clinical time intervals. The report also observed a reduction in ventilation, ICU, and hospital days, and in organ failure rates. In one large study the integration of whole-body CT into early trauma care significantly increased the probability of survival in patients with polytrauma. Whole-body CT is recommended as a standard diagnostic method during the early resuscitation phase for patients with polytrauma.

The demonstration of haemorrhage or a site of potential haemorrhage on CT should lead to angiography and then to intervention. The dogma that patients cannot be transferred to angiography is no longer tenable. Surgeons, anaesthetists and radiologists are increasingly aware that intractable bleeding associated with solid organ or pelvic fractures and damage to other arterial structures is best treated by emergency arterial embolisation or stent grafting.

The Kidney

Percutaneous nephrostomy

Percutaneous nephrostomy (PCN) is a procedure in which access to the collecting system of a native or transplanted kidney is obtained through the skin, providing external drainage and/or a portal for additional minimally invasive procedures such as antegrade ureteric stent insertion.

Key clinical data

Percutaneous nephrostomy is most commonly indicated for the treatment of acute kidney injury ((AKI), formerly referred to as ‘acute renal failure’) secondary to ureteric obstruction, but there are a variety of other acute and non-urgent indications such as drainage of an infected obstructed kidney, access for stone removal or antegrade ureteric stent placement.

Some of these indications do not require a PCN service to be available 24 hours a day. However, infection of the urine in an obstructed kidney (pyonephrosis) usually needs to be treated as an emergency and AKI may also need emergency or urgent PCN. A recent report from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) reaches the conclusion that; ‘access to renal ultrasound and the ability to insert a nephrostomy are vital services and ideally should be available 24 hours a day, 7 days per week’.

A retrospective analysis of 401 patients treated with 569 PCNs over a 5-year period concluded that PCN is a relatively non-invasive procedure associated with high technical success and low morbidity. However, serious complications can occur. An audit of performance of a PCN service found that sepsis was the most serious complication contributing to death or a

significant increase in the level of care required. Risk is greatest after failed instrumentation and particularly if there is a further delay before renal drainage is established.

Key cost data

There are published studies comparing outcomes for PCN and internal ureteric stenting in various clinical settings but no relevant up-to-date comparative costing was identified in the literature reviewed.

Renal Cancer

Renal cancer is a relatively common cancer which is eminently suitable for effective treatment by IR using radiofrequency ablation (up to ~35mm) and by cryoablation (up to 6cm in diameter). This technique may replace the need for invasive partial nephrectomy.

Gastrointestinal Bleeding

Acute GI bleeding is a medical emergency that if not managed acutely and correctly can have a high mortality, reported as high as 42%. Mortality from lower GI bleeding has previously been recorded to be as high as 25%.

Key data

Angiography can be used to localise the site of bleeding. This can be treated by selective transcatheter embolisation. This technique is used in controlling upper GI haemorrhage, usually following unsuccessful endoscopic management; it can achieve high rates of technical success (98%), no rebleeding within 30 days (68-76%), and low complication rates (4-5%). Embolisation has also proved successful for a wide variety of causes of non-variceal upper GI haemorrhage such as pancreatitis and post-surgical bleeding.

A retrospective review of 163 patients with acute upper gastrointestinal haemorrhage and transcatheter embolisation reviewed factors associated with clinical success and concluded such treatment had a positive impact on survival independent of clinical condition.

Acute variceal bleeding, which is most commonly seen in patients with alcoholic liver disease, but is also caused by other conditions, will often continue despite the combination of endoscopic therapy and drug therapy. Expert opinion recommends managing such patients in two stages: initial emergency therapy to arrest the blood loss, and second line therapy to address the underlying cause. Balloon tamponade is a temporary measure that can control massive variceal bleeding which does not respond to endoscopic therapy. Definitive transjugular intrahepatic portosystemic shunting (TIPS) is performed to stop the bleeding which is refractory to all other attempts at treatment. A recent randomized controlled trial published in the NEJM found that primary TIPS and best medical management versus best medical management (which included endoscopic interventions) resulted in successful control of bleeding, decreased rate of rebleeding and improved mortality without increased complications such as encephalopathy.

Though historically colonoscopy and surgery have been the treatments of choice for lower GI haemorrhage these treatments are now only used where IR is not available. Commonly, accepted management since the late 1990's has been embolisation, often following CT evaluation. This is because multiple studies have identified that superselective embolisation in the treatment of lower GI haemorrhage is associated with high technical success in 89-100% of cases and clinical success rates of 80-91% of cases with much lower complication rates than surgery.

The Liver

Liver disease mortality in the UK is increasing at a time when liver death rates are dropping practically everywhere else in Europe. Over the last 30 years liver disease mortality in young and middle-aged people in the UK has increased at least six-fold and liver admissions and liver deaths are both rising at between 8-10% per year.

High quality, timely IR should form part of the planning and operation of liver transplantation services.

Hepatic Malignancy

Key clinical data

Hepatocellular carcinoma (HCC) causes approximately 1,500 deaths per year in the UK and there is strong evidence from the USA that the incidence of HCC is rising.

At present the only proven potentially curative therapy for HCC remains surgery, either resection or liver transplantation. However there are IR techniques that can affect survival in highly selected patients with good liver reserve. These techniques can also downstage the disease which can then turn the previously inoperable patient into a candidate for resection or transplantation. These include percutaneous ethanol injection (PEI) and chemoembolisation that can both produce tumour necrosis. Transarterial chemoembolisation (TACE) utilises selective catheterisation of the hepatic artery to deliver regional chemotherapy and embolise tumour-feeding arteries.

Injection of 90% ethanol under ultrasound guidance is technically straightforward, inexpensive, safe and depending upon the underlying cirrhosis can result in 5-year survival of up to 50%. Complete tumour necrosis is seen in 70% of tumours less than 3cm in diameter but this falls with increasing size, maybe due to the inability of the injected volume to disperse throughout larger tumours.

Radiofrequency Ablation (RFA) is used in many areas of the body. It works by heating a probe inserted into the tumour. The interventional radiologist uses ultrasound, CT scanning or MRI to guide the percutaneous placement of a long, thin insulated needle into the tumour. The distal

end of the needle is not insulated and emits radio waves. Electrodes are attached to a generator and the electrical energy is converted to heat that kills cells through coagulation necrosis.

RFA is recommended for HCC by NICE provided the selection of the patient is carried out by a multidisciplinary team. RFA for the treatment of HCC is usually performed percutaneously (as apposed to laparoscopically) under image guidance as a day case procedure under conscious sedation. It has less morbidity and mortality than surgery. RFA may be repeated for new or recurrent disease and has a lower complication rate due to its minimally invasive nature. Patients with treatable extrahepatic disease or those with tumours that have been downsized by chemotherapy (but are not resectable) may be considered for ablative therapy.

RCTs have been conducted that compare RFA with PEI. A study in patients with tumours up to 4cm demonstrated that RFA was superior in terms of tumour necrosis and survival, with 3-year survival of 74% versus 51%. Further studies have demonstrated similar advantages for RFA in treating small tumours. In general RFA was associated with fewer sessions to achieve complete tumour necrosis, with no significant differences in morbidity and a likely improvement in survival.

Key cost data

The Ontario Health Technology Assessment carried out in 2004 reported that level 2 evidence suggests that RFA is:

- as safe and perhaps more effective than PEI in treating HCC
- RFA and PEI are more effective and more cost effective than transcatheter arterial embolisation
- RFA is more expensive but more cost effective than PEI
- complications are few but experienced interventional radiologists should carry out the procedure
- RFA may benefit some patients with liver metastases or other primary cancers although published evidence of effectiveness has not yet been established.

Metastatic cancer in the liver

A significantly improved outlook is possible for patients with metastatic colon cancer yielding 5 year survivals up to 33% for inoperable patients using image guided ablation techniques. Such cytoreductive techniques therefore have the potential to work alongside modern chemotherapy to improve outlook or, in the case of small volume metastatic disease, to replace resection.

Trauma, bleeding and Infection

Key clinical data

For trauma to the liver, and in haemodynamically unstable patients with liver injuries embolisation is an adjunctive therapy for patients with ongoing haemorrhage. In Norway a review of outcomes for 114 patients with liver injury before, and after, the introduction of embolisation in trauma services showed a survival rate that was stable at 89-90% (in the UK survival rate for comparable patients is 78%). There was also a reduction in laparotomy rates from 58% to 34% and complication rates were lowered by 40%. Mohr et al also examined the medical records of 37 consecutive patients admitted from 1995 to 2002 who underwent hepatic angiography with the intent to embolise. They found that patients who underwent early angiographic embolisation (AE) received significantly fewer blood transfusions and only 26% of patients required liver-related surgery after AE.

Zheng et al conducted a meta-analysis of the effects of transjugular intrahepatic portosystemic shunt (TIPS) for the reduction of variceal bleeding (VRB). Most of the RCTs reviewed were judged to be of high quality and they concluded that TIPS is currently the first choice to prevent rebleeding. Active surveillance with ultrasound is required to ensure early detection and treatment of TIPS dysfunction but this has improved significantly since the introduction of covered stent-grafts. There is a risk of post procedure encephalopathy associated with TIPS so alternative interventions for variceal bleeding should be investigated to minimise risk.

Kurmis reported results in a small series, over 9 years from a single centre compared to those published in the literature. They carried out retrospective case note review of 20 consecutive TIPSS procedures from Jan 1997 to Dec 2005. There were no peri-procedure deaths; however, 90 day mortality was 20%. TIPSS dysfunction rate was 35% at 1 year. TIPSS procedure outcomes are similar to those reported in the literature from large centres. TIPSS patency rates may be improved with regular monitoring and early intervention when stenosis occurs.

Uterine Disease

Uterine Fibroids

Symptomatic fibroids are a common gynaecological condition. There is no long term effective medical treatment. In the UK, women have a one in five chance of having a hysterectomy by the age of 55 with around one third due to fibroids.

Hysterectomy has been recommended as the gold standard by which other treatments are assessed, as it removes the source of the symptoms. However, hysterectomy is a major surgical procedure with a small but significant major morbidity and mortality.

Uterine Artery Embolisation (UAE), also called Uterine Fibroid Embolisation (UFE) is an alternative to hysterectomy. It is an image-guided technique which blocks the blood supply to uterine fibroids causing them to shrink and become asymptomatic. A small catheter is introduced via the common femoral artery under local anaesthetic and using x-ray guidance the catheter is manipulated into the uterine arteries on both sides and an embolic agent is injected to occlude them. The procedure is carried out by an interventional radiologist under sedation.

Over 100,000 cases of UAE have been performed worldwide since its first description as a stand-alone procedure in 1995. Recent published guidelines support the use of UAE as an alternative to myomectomy (surgical removal of fibroids) and hysterectomy in women who have symptomatic fibroids less than 3 cm in size.

UAE is reported to be only available in forty-eight NHS and three private hospitals in the UK. Most of the availability is in London and the South East of England. Out of an estimated total of 2,050 UAE procedures for fibroids performed in the UK to date, only 200 (10%) have been performed outside London or the South East.

Key clinical data

In 2004, NICE supported the use of UAE as an alternative to myomectomy and hysterectomy in women who have symptomatic fibroids smaller than 3 cm and where there is a desire to maintain the uterus. In 2007, NICE gave their support for the use of UAE for heavy menstrual bleeding where the indication is fibroids smaller than 3 cm in diameter. The guidelines suggest UAE as a first-line treatment if there are other significant symptoms including pain. The procedure is particularly recommended for women who want to retain their uterus and/or avoid surgery.

In 2006, a study examined the long-term outcomes of UAE in 172 women. All women were between 5 and 7 years post UAE and showed satisfactory, subjective improvement in menstrual flow and fibroid-related symptoms. The study reported that UAE was associated with a low risk of complication, a high satisfaction rate from patients and only a 16% risk of requiring a subsequent procedure for fibroids.

The Randomised Control Trial of Embolisation versus Surgical Treatment for Fibroids (REST) Working Group (2007) examined RCTs in 27 UK hospitals where women were assigned in groups from November 2000 to May 2004. They concluded that UAE is associated with significantly faster recovery (including resumption of usual activities). A 12 month follow up was completed in Sept 2005. One hundred and fifty seven women were randomly assigned to UAE (n=106) or surgery (n=51) with symptomatic fibroids. At 12 months it was reported that the percentage of women who would recommend their treatment to a friend was high in both treatment groups. The median hospital stay after UAE was significantly shorter than that after surgery (1 day vs. 5 days) and the median time until patients could resume all recorded activities was significantly lower in the UAE group. At 12 months there was no difference in

quality of life measures, although 10 out of 106 in the UAE group had required a secondary intervention for persistent or recurrent symptoms.

A study involving 28 Dutch hospitals compared hysterectomy with UAE for treatment of menorrhagia caused by uterine fibroids in 177 patients randomised to UAE (n=88) or hysterectomy (n=89) and concluded that UAE is a valuable alternative treatment for symptomatic uterine fibroids, but when patients seek absolute certainty for a cessation of bleeding problems, then hysterectomy remains the treatment of choice.

The 2007 HOPEFUL study reported the outcome of a multicentre, retrospective cohort study that compared the experiences of two representative groups of women who had either hysterectomy (n=450) or UAE (n=649) with an average follow up of 4.6 years. More women in the hysterectomy cohort reported relief from fibroid symptoms (96% versus 85%) and feeling better (96% versus 84%) but that fewer complications were experienced by women receiving UAE (19% versus 26% hysterectomy). There was a 23% chance of requiring further treatment for fibroids after UAE. Twenty-seven women who had UAE reported 37 pregnancies after treatment resulting in 19 live births.

Key cost data

Economic modelling indicates that UAE is a cost effective treatment with significant savings over open surgery at one year with older patients being less likely to require re-intervention. Wu et al (2007) agreed that UAE was the less costly option and could be highly cost effective for women who preferred to keep their uterus. Their base case analysis illustrated that UAE was associated with substantially lower mean cost £1,677 for UAE versus £3,282 for hysterectomy.

Post Partum Haemorrhage

Primary PPH is the most common form of major obstetric haemorrhage within 24 hours of the birth of a baby. Secondary PPH is defined as abnormal or excessive bleeding from 24 hours to 12 weeks postnatal. In developed countries 2% of postnatal women are admitted to hospital with this condition, half of them undergoing uterine surgical evacuation.

Haemorrhage remains a significant cause of maternal mortality in the UK and it is the third highest direct cause of maternal death. Haemorrhage is also the major cause of severe maternal morbidity in almost all “near miss” audits in both developed and developing countries. The 2004 Confidential Enquiry into Maternal and Child Health noted that maternal death from haemorrhage had increased. The Health Care Commission reported on the maternal deaths at the unit in the Northwick Park Hospital in 2006 and identified a lack of IR as being a factor in a number of unexpected maternal deaths.

Arterial embolisation and other endovascular techniques have become the second line therapeutic option for the management of intractable obstetrical and gynaecologic bleeding. It

is a fast, safe, and effective minimally invasive alternative to hysterectomy when medical treatment fails to control uterine bleeding. Moreover, it preserves the uterus with little or no significant impact on future pregnancies or fertility.

Key clinical data

A small study looked at 10 women with PPH (n=7) and post abortion haemorrhage (n=3). The vaginal bleeding resolved in all patients without any ischaemic complications after eight underwent UAE. Microcoil devascularisation was performed in the remaining two patients. At follow up all patients who underwent UAE had normal menstruation and three subsequently gave birth to full term health babies.

A further study followed up 31 patients who had had UAE for PPH. Their results suggest that women who undergo arterial embolisation for obstetric haemorrhage should expect to have a return of normal menses with preservation of future fertility and successful uneventful pregnancies.

Systematic reviews looking at all RCTs of treatment for primary PPH found that selective radiological embolisation of the bleeding vessel is a successful therapeutic option but a Cochrane review in 2008, found no information available from RCTs to inform the management of women with secondary PPH.

Appendix B – Case Studies

Emergency drainage for treatment of abscess by an on call interventional radiologist

An elderly lady was admitted on a Saturday morning to ITU septic and unstable with a collection of pus in the gallbladder. She was considered too unwell for open surgery. The non-interventional radiologist on call for this weekend had not done an ultrasound-guided drain insertion for several years. The on call interventional radiologist inserted a percutaneous drain under ultrasound guidance. Within a couple of days the patient was well enough to be transferred to the general surgical ward.

This was a life-saving procedure that had to be done and the general radiologist was able to have an interventional colleague to call upon to perform it. With an established interventional on call service non-interventional radiologists have a formal process for arranging and performing abscess drainages or nephrostomy insertions on sick patients at the weekend and during the evenings.

Emergency interventional radiology for post partum haemorrhage

A 23 year-old female had a healthy child delivered by caesarean section. She bled post-operatively and went back to theatre. She continued to bleed and required 24 units of blood. The on call IR team was called at approx 02.45hrs and an angiogram revealed a bleeding vessel which was embolised. There was no further uterine bleeding. The procedure took 15 minutes and the patient rapidly stabilised requiring no further treatment. She now plans to have a third child.

Without IR the likely outcome would have been hysterectomy.

Emergency stent graft insertion requiring patient transfer to a specialist IR unit

A middle-aged patient underwent laparoscopic hernia repair in a rural district general hospital. She became hypotensive during the procedure. This was attributed to an anaesthetic reaction and the procedure was abandoned. She was discharged that day. A few days later, on a Friday evening, she presented to the emergency department with abdominal pain. Emergency CT showed an acute traumatic fistula between the aorta and the inferior vena cava.

The patient was transferred by air ambulance early on the Saturday morning to the nearest centre where there was availability of on call vascular surgery and IR. The surgeon and radiologist together inserted an aortic stent-graft, successfully sealing the fistula.

Trauma and the need for a full on call IR team

A 36 year-old male was involved in a road traffic accident on a Sunday evening and suffered multiple pelvic fractures. He was haemodynamically unstable and embolisation was considered. There was no formal IR on call service but the radiologists were happy to attend on an ‘ad hoc’ basis. One of the consultant radiologists was contacted. He was able to find a willing radiographer but none of the radiology nurses were available. The interventional radiologist was therefore not able to carry out the procedure.

The patient underwent a laparotomy and pelvic packing. He remained unstable overnight. By this point the patient had received large volumes of blood products. The ITU consultant commented that they did not expect the patient to survive for more than a few hours. Embolisation was performed on the Monday morning by an interventional radiologist and fully trained team following which he became haemodynamically stable. After a long period of rehabilitation the patient was discharged home.

GI Bleeding and integrated services with IR involvement

A 75 year-old man, who had recently undergone a coronary artery bypass graft, was admitted with bright red rectal bleeding at midnight, and was unstable and hypotensive.

The patient had an emergency CT scan which showed rectal bleeding. He was transferred to the IR suite where embolisation of the bleeding point was undertaken. He was discharged home 3 days later slightly anaemic on iron supplements.

The case was discussed at an MDT meeting. Failure to perform proctoscopy by the junior surgical staff was discussed. It was recognised that with the associated co-morbidity this patient was still best managed by minimally invasive embolisation.

A review of the literature and review of the unit’s data were presented at the Trust weekly surgical conference. Amendments to the surgical protocol for the management of life threatening GI bleed were instituted.

Appendix C – References

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