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Review

Cost effectiveness and the role of the National Institute of Health and Care Excellence (NICE) in interventional radiology

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Healthcare expenditure is continually increasing and projected to accelerate in the future, with an increasing proportion being spent on interventional radiology. The role of cost effectiveness studies in ensuring the best allocation of resources is discussed, and the role of National Institute of Health and Care Excellence (NICE) in determining this. Issues with demonstrating cost effectiveness have been discussed, and it has been found that there is significant scope for improving cost effectiveness, with suggestions made for how this can be achieved. In this way, more patients can benefit from better treatment given limited healthcare budgets.

Importance of evaluation of cost effectiveness in healthcare

Pre-COVID-19, approximately 10% of UK gross domestic product (GDP) was spent on healthcare, with planned spending for Department of Health and Social Care for 2019/20 being £140 billion: contrast this with the 3.5% of GDP spent for the first full year of the NHS in 1948 (£373 million; approximately £13 billion in today's money).[1] The impact of COVID-19 to the national economy has been estimated to add at least £70 billion to government borrowing in 2020 alone.[2] Clearly, there is currently extreme pressure on spending on public finance, so it is important to spend on healthcare as effectively as possible, and demonstrate that this has been done. NICE (the National Institute of Health and Care Excellence) was set up to help with this (Box 1).

Cost-effectiveness studies (CES) can be helpful [3] in guiding how we should spend public resources, as[1]: CES provide an objective system to compare the complete range of relevant alternatives, from invasive treatments to conservative management. Costs for the same procedure can vary widely, e.g., the "Getting it Right First Time" (GIRFT) Vascular Surgery report noted that reported cost for elective endovascular aortic repair (EVAR) varied between £2,251 and £19,690 for no apparent reason and with no indication that lower cost procedures were less effective [2,4]; CES encompass a wider societal perspective than just the clinician's or patient's point of view alone, helping demonstrate equitable resource allocation in a publicly funded service[3]; CES allow evaluation of short- and long-term costs and benefits, which are often under- or overestimated; and[4] CES provide an explicit and accountable framework for decision

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Box 1. Role of NICE

National Institute for Health and Care Excellence (NICE).

The Department of Health proposed the formation of NICE in 1997 with the aim of creating consistent evidence based guidelines and end unevenly distributed local rationing of treatment (postcode lottery), brought about by several issues:

1. There had been increasingly rapid growth in the breadth and depth of medical knowledge, making it difficult for clinicians, patients, and commissioning groups to draw meaningful comparisons and conclusions;
2. There were multiple conflicting and incomplete local guidelines for management of clinical problems, e.g., prostatism, heavy uterine bleeding;
3. There were no agreed consensus criteria to compare different technologies, e.g. angioplasty versus vascular surgery, or open hysterectomy versus uterine artery embolisation versus laparoscopic surgery;
4. There was no future horizon scanning of medical technologies. NICE was launched originally as the National Institute for Clinical Excellence in April 1999, by the Health Secretary, Frank Dobson. The first Chair was Sir Michael Rawlins, a Professor of Clinical Therapeutics.

NICEs remit in IR is to assess the efficacy of procedures, and conduct cost-effectiveness assessment with a view to formulating guidelines for management of clinical conditions. Where the data are sparse or insufficient, NICE will recommend further studies, registries, and ongoing audits to gather further information.

NICE carried out its first health technology appraisal in 2000, and set up the Interventional Procedures Advisory Committee in 2002; the first meeting of which considered uterine artery embolisation for fibroids. Committees to consider new medical technologies and devices were set up in 2009, and in 2015 for highly specialised technologies, which particularly include interventional radiology. By 2018, NICE had published its 500th technology appraisal.

making, which can be re-examined as data accumulate, particularly important with evolving techniques and experience as in interventional radiology (IR).

Increasing costs of healthcare

Healthcare costs continue to grow faster than the economy as measured by GDP: since 1978 public spending on health in the UK has increased by 3.8% per annum on average while GDP has grown by 2.2%, with similar trends in other European countries ,[5,6] due to: demographic change, chronic medical conditions and rising cost of medical infrastructure and medical technology.

Demographic change

As mean population age has risen due to increasing life expectancy and falling fertility rates, so has healthcare expenditure. The precise reasons for this are complex, but broadly divide into the “Sisyphus effect” [7] (more elderly expect to be fit and independent into older age, requiring more medical resources, creating more elderly), and the “multimorbidity hypothesis” (decreasing mortality rates create a larger pool of less fit multimorbid elderly [8]). Most costs arise in the last 6 months of life regardless of age,[9,10] where IR may be a highly acceptable substitute for surgery; for example, embolisation for gastrointestinal bleeding, or an useful option for symptom palliation, such as placement of ascitic or pleural drains.[11,12]

Chronic medical conditions

Accelerating rates of obesity and diabetes worldwide are significantly increasing the incidence of vascular disease and cancer. The number of adults with diabetes is projected to increase worldwide by 48% by 2045.[13] The risk of peripheral arterial disease in patients with diabetes is increased by a factor of 2.72, more than smoking (1.88),[14] with a prevalence of 30% in those aged >50 yearshttps://paperpile.com/c/e2SMlw/2hzYS,[15] and more diffuse and infrapopliteal disease, which is challenging to treat.[16] The increasing demand for rapid diagnosis, treatment, and palliation means interventional oncology is now regarded as a vital and highly cost-effective component of cancer care.[17]

Rising cost of medical infrastructure and medical technology

About half of the increased overall healthcare expenditure in high-income countries is due to increasing costs of medical technology, including equipment and drugs.[6,18–21] When analysed in more detail, costs have actually fallen in some conditions but increased disproportionately in conditions with high-technology interventions, including IR.[22]

These factors indicate increased demand for, and cost of, IR in the future.

CES

CES can consider not only costs to the healthcare system, but also costs incurred by the patient, such as loss of ability to look after family, and wider societal costs. The benefits calculated have developed from unadjusted life years to quality adjusted life years (QALYs) gained, where quality of life is gauged using questionnaires such as EQ-5D or SF-6D,[23,24] and multiplied by years of survival, so that 1 QALY= 1 year of perfect health, reducing to 0.5 for poor health and zero for death. QALYs provide a consistent and transparent means of comparing the outcomes of different surgical, IR, or medical procedures.

CES often show states of health using decision trees (Fig 1). These represent the points of treatment decision or choice (with probability of choice) as *decision nodes*, leading to various outcomes represented by *branches*, which each lead to a *chance node* with probabilities of different clinical outcomes, repeating until the patient has no further decisions or changes in risk, represented by a *terminal node*. Costs and health outcomes are ascribed to each branch. The tree thus generated can be “rolled back” to calculate the overall costs and outcomes for each treatment option.[25]

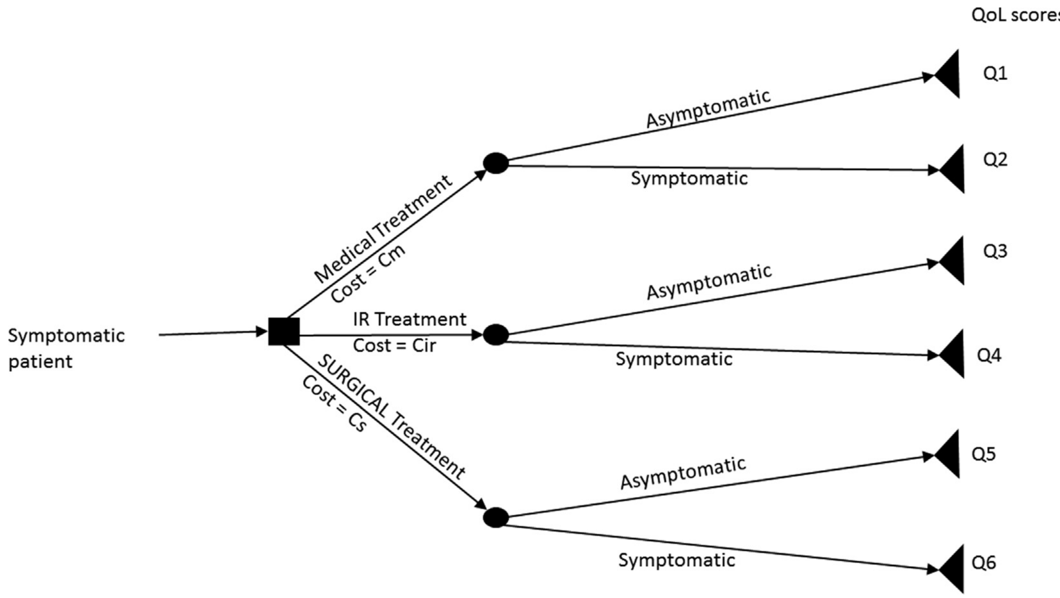

Figure 1 Illustration of the decision tree used in health economics assessments. The patient's treatment journey is mapped out using various decision points, with costs and Illustration of a Markov model showing the probability of transitioning between health states, over fixed periods of time outcomes assigned to each branch.

In the healthcare scenario, the patient may have a relapsing or recurrent condition and can transition back and forth from different health states, e.g., remission and active disease, so decision trees that only allow one-way progression become unmanageable; these are better demonstrated by Markov models (Fig 2), which allow two-way progression and map the health states and the probability of transitioning between these states after an intervention during a given time cycle. The time spent in each health state is associated with a cost and outcome, and these can be aggregated to calculate overall costs and QALYs for each treatment option.[26]

The incremental cost effectiveness ratio (ICER) is calculated as the difference in cost divided by difference in QALYs between different strategies, compared to an alternative. For

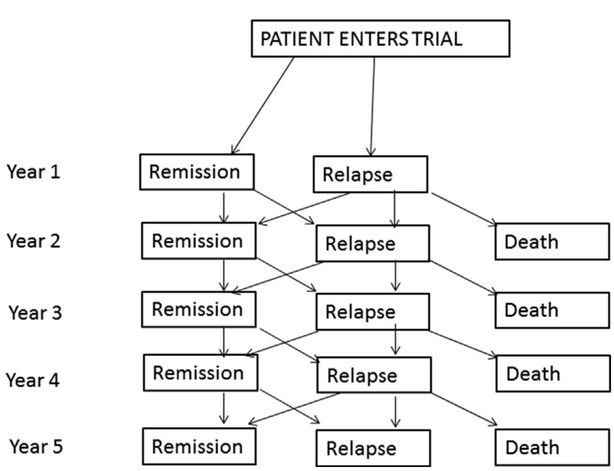

Figure 2 Illustration of a Markov model showing the probability of transitioning between health states, over fixed periods of time.

example, the EVAR1 and DREAM trials showed an ICER of £8,579 per QALY for EVAR in patients unfit for surgical repair.[27] In the National Health Service (NHS), a ICER threshold of £20,000 to £30,000 per QALY (and up to £50,000 for end-of-life treatments) has been considered reasonable to decide whether a treatment is cost effective versus baseline, and although it has been emphasised by NICE that thresholds are not fixed,[28] they have attracted attention for seeming to put an arbitrary price on health, or being associated with rationing of resources.[29] There is no explicit rationale for the cost per QALY, although some commentators relate it to the share of GDP per person in an economy, or average household income. The threshold can cause issues with new IR technologies where initial prices may be higher reflecting development costs or low volume production runs.[30] Notably the Affordable Care Act in the USA forbad the use of cost per QALY as a threshold, to counter accusations of enacting "big-government healthcare" or setting up "death panels".[31]

Fig 3 illustrates the ICER cost-effectiveness plane, which plots cost in pounds sterling against effect in QALYs. The ICER threshold represents the acceptable threshold to decide whether the increased effect of a procedure justifies its cost. Compared to the baseline procedure O at the origin, treatments A and B are more effective but more costly, C is more costly and less effective, D is less costly and less effective, but above the threshold, and E is less costly and more effective, so the clear winner. The usual situation is A or B: in this case, it can be seen that B would be preferable as it is below the ICER threshold.

Sensitivity analyses (SA) vary key inputs (e.g., probability of treatment efficacy or price of equipment) where there is uncertainty of real or estimated parameters and can determine which factors in the model are the main drivers

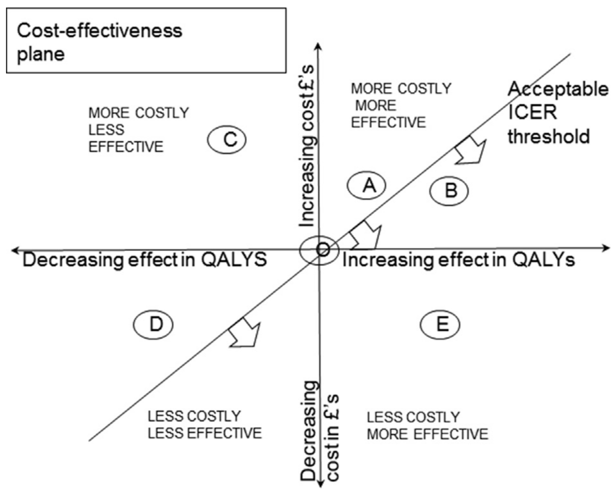

Figure 3 Illustration of ICER (incremental cost-effectiveness plane) and derivation of ICER threshold.

in cost effectiveness.[3] If the ICER varies little when inputs are varied, the findings can be considered more robust. SA can yield unexpected insights into cost effectiveness and are thus a powerful tool in designing pathways to maximise benefits gained for a given budget and improve a procedure's ICER. For example, contrast-enhanced follow-up post-EVAR with abdominal radiography and ultrasound has been shown to be more cost-effective than computed tomography (CT).[32]

Although widely used, QALYs are inherently subjective as they are based on valuing the patient's quality of life (QoL), raising ethical, methodological, and disease-specific issues.[33,34] Ethical issues include valuing another's QoL when one can have no experience of having the specific physical disorder. Methodological issues involve relating this subjective judgement to one or more of many different health utility scores, which introduces further intra- and interobserver variability (e.g., varying among different age groups, nationalities). Disease-specific issues arise in less common conditions where estimates of the impairment caused vary widely. Uncertainties also arise in costing items, such as time off work after surgery or an interventional procedure is highly variable between patients and difficult to quantify.

The rapid growth in health CES has created the need for a checklist to ensure that different CES are complete and contain enough information to be compared and combined with each other for meta-analysis. The CHEERS (Consolidated Health Economic Evaluation Reporting Standards) checklist [35] is recommended when planning CES to ensure quality and completeness. Many recent radiological studies assessed by this checklist are incomplete.[36]

The quality of the conclusions drawn from CES are only as robust as the data used, and if these are drawn from a wide range of disparate studies, or are biased or not generalisable, this will limit the strength of the study. Choice of control groups or comparison strategies will influence the ICER and sensitivity results. The time horizon will also have a large effect, especially because of compound discounting.

Cost effectiveness in IR

There are already some conditions where IR has been shown to provide a more cost-effective solution (Table 1). Areas where IR can improve and better demonstrate its cost effectiveness are discussed below.

Improving evidence base

Robust trials with clear outcomes are the basis of CES, and many trials comparing IR are underpowered or incomplete for the following reasons: study power, recruiting team factors, and non-robust outcome measures.

Study power

Recruitment into trials is often expensive and difficult,[47] and many fail to achieve planned recruitment.[48] NIHR found that less than one third of clinical trials achieved their recruitment target. From 2000 to 2013, 11% of cardiovascular trials registered on ClinicalTrials.gov terminated early,[49] mainly due to poor recruitment or high patient dropout. The latter often arises as some patients prefer a specific option, often what they perceive as more "active" treatments such as angioplasty or stenting over medical therapy, e.g. in the EXACT (Exercise versus Angioplasty) only 6% of screened patients agreed to be randomised and the trial was terminated early.[50] Other reasons are unwillingness to undergo treatment regarded as "experimental", and non-compliance with follow-up.[51–53] Complex trial protocols increase non-completion rate. Recruitment may also prove prohibitively expensive: a 2016 study[54] on peripheral arterial disease demonstrated a wide range of recruitment cost from $4 (at a Community event) to more than $18,000 (radio advertising) per randomised participant: the same study spent more than $340,000 on recruiting 171 participants, a mean of approximately $2,000. A business model approach can help to improve recruitment, retention, and trial completion[55] (Table 2). Specialist research nurses can make a significant contribution in recruiting, retaining, and following up patients.

Recruiting team factors

Research teams often have to balance research and clinical commitments. Clinician participation may be

Table 1
Examples of interventional radiology procedures proven more cost effective than surgery.

Tumour ablation	Liver metastases https://paperpile.com/c/e2SMlw/BJe9+Ctuh+YPj9+5VMv [37–40]
	Hepatocellular carcinoma (single or multiple nodules <3 cm) https://paperpile.com/c/e2SMlw/O4BE+Vszk+5VMv [40–42]
	Renal cell carcinoma <4 cm https://paperpile.com/c/e2SMlw/PaUH+tCl1 [43,44]
Embolisation	Uterine fibroids *initially* although equipoise after ~ 5 years https://paperpile.com/c/e2SMlw/tkkc [45]
Endovascular aortic repair	Ruptured abdominal aortic aneurysm https://paperpile.com/c/e2SMlw/CrHpz [46]

Table 2
Improving the evidence base: a marketing approach.

Building brand value and defining purpose of the trial	Gain legitimacy and prestige (coordinated by an academic centre, funding by a non-commercial body, signal worthiness (that benefits to trial participants will outweigh costs)
Marketing and product planning	Adopt an explicit marketing plan with stakeholder engagement, local and regional champions, and strategies for overcoming resistance (address concerns), providing a complete administrative process with easy data collection and transfer
"Making the sale"	Deliver a targeted multi-level approach to multiple different audiences (with appropriate language) and achieving "buy-in" (confirmed commitment), through websites and communications back to trial participants
Maintaining engagement	Especially important when follow-up or supplementary studies are envisaged. Key points: deal with feedback constructively, continue to provide reinforcement, and communicate findings and positive learning points

suboptimal where the clinician feels options are not in equipoise or is unfamiliar with, unconvinced by, or actively resistant to a novel technique. Pseudorandomisation may occur whereby sicker patients with more comorbidities are referred for IR procedures and fitter ones for surgery, thereby introducing bias into the long-term outcomes and decreasing generalisability of the results to the general population.[56] A whole team approach should be used, with wide involvement in auditing, presenting, and publishing the results of the work.

Non-robust outcome measures

Clinical endpoints need to be objective, robust, and verifiable, or bias may be introduced. There needs to be clear guidance of who assesses, when and how. Non-blinded observers have been shown to exaggerate treatment effect by up to 68% versus blinded.[57] Lack of definition of "best supportive care" in oncology studies has been shown to distort interpretation of outcomes.[58]

Lack of long-term follow-up is a common issue in interventional procedures where patients revert back to the original referring consultant for ongoing review. Some EVAR studies found only 50% of patients having complete surveillance as per the protocol.[59,60] IR involvement in follow-up would not only improve the evidence base for long-term efficacy, but would also afford IR the opportunity to advise or intervene if late complications arise.

Improving procedure performance

Learning curve and procedure volume effects

Medical outcomes improve as teams complete a "learning curve" and start performing larger volumes of procedures regularly.[61,62] Interventional radiologists perform a wide variety of emergency and elective procedures, which are being continually developed and elaborated. It is challenging to master and maintain competence in these different procedures, which may be infrequently performed. These factors can reduce outcomes and cause delayed recognition of complications, which may require expensive retreatment and further surveillance,[63–66] thus reducing cost effectiveness.

Two strategies can help here. First, increasingly sophisticated simulation training (ST) has been developed, which provide detailed real time audiovisual and haptic feedback. Simulation training has already been embraced by cardiologists (for arterial puncture and coronary artery catheterisation), neurosurgeons (for neurovascular procedures such as aneurysm coiling and stroke thrombectomy) and vascular surgeons (for renal, carotid and peripheral vascular procedures),[67–73] and ST has been explicitly incorporated into their curricula. ST allows the trainee to experience a standardised set of scenarios designed to cover a range of teaching points and embed useful skills in the most efficient way, without relying on random caseload in a particular centre, at a convenient time and setting conducive to learning, with objective and supportive feedback. It has been shown to reduce procedure time and radiation dose, improve outcomes and patient safety, and operator confidence.[66] The operator can learn at their own pace, and pay attention to areas where they need more training, or where they feel less confident. ST can be particularly helpful to teach the basic skills rapidly, such as arterial puncture and selective catheterisation, allowing the trainee to concentrate on the more advanced aspects of the procedure. It reduces the burden on trainers,[74,75] and increases patient safety. ST can also be valuable for experienced operators to maintain and update their skills, with objective feedback. ST is still expensive, but resources can be shared at a regional or college level, as most trainees only require 1–2 days of practice initially with shorter further sessions as required.

Secondly, *hub and spoke* models with concentration of more advanced services in a hub with higher volumes have been noted by the GIRFT report on Vascular Surgery to achieve better outcomes with better use of healthcare resources and opportunities for cost saving due to improved procurement.[4,61] There is already a tendency for hub and spoke working to provide 24-h IR availability, and increasing use of this model will improve outcomes at relatively minor increased cost, thus improving cost-effectiveness.

Increased use of day-case and shorter-stay procedures

Interventional procedures lend themselves to shorter length of stay, due to smaller incisions, decreased use of general anaesthetic, and faster recovery times, versus surgical alternatives. This leads to shorter operating time, length of stay in hospital, time away from home and back to work and therefore significant cost savings,[22] especially if one considers an overnight stay costs £400 on a ward, and £1,150 in a critical care unit (NHS reference costs [76]). Thus moving from EVAR with open surgical femoral exposure to percutaneous radiological femoral access was shown to reduce operating theatre time by 19%, length of stay by 50% and overall cost by 23%.[77] The Audit Commission noted in 1990 that switching to day-case surgery nationwide would allow up to 200,000 patients more to be treated annually without extra expenditure,[78] and similar calculations would show significant cost savings from increased use of IR. Furthermore, in the current COVID era, many IR units have been able to continue doing day-case and outpatient treatments without cancellations due to ward or critical care shortages,[79] also helping to reduce waiting lists, which have recently risen sharply.[80]

Kit and technique used

A substantial proportion of IR procedure cost is the kit used, which may be substantially more than the surgical equivalent (e.g., average price of EVAR graft and wires £6,945 versus surgical aortic graft and consumables £429), due to small production volumes and requirement to recoup development costs.[81] The GIRFT Vascular Surgery report noted a nearly 10-fold variation nationwide in cost of EVAR grafts with no apparent difference in effectiveness,[4] implying a massive opportunity to reduce costs with judicious procurement. Equipment prices tend to fall with increasing production and commercial competition (as with coronary angioplasty balloons and stents) so it is important to continually review the market to see if more cost-effective kit or cheaper alternatives become available. With increasing experience, less kit is generally used, which underlines the value of ST as above. Costs vary significantly between countries, e.g., coronary stents cost six-times more in the USA versus UK and Germany,[82] so local costs should be obtained and compared.

Complications, re-intervention, and long term-benefits

Complications can massively increase the cost of a routine procedure, and therefore relatively small additions to a procedure may prove highly cost effective if they reduce complication incidence. This has been an important factor in EVAR, especially in those patients with relatively long lifespan post-procedure, and may easily tip the balance of cost-effectiveness between IR and surgery. Some radiological interventions provide short-term benefit but not long-term durability: for example, in uterine artery embolisation (UAE), the REST trial showed the initial cost benefit of UAE over surgery at 12 months was eroded by a higher rate of treatment failure rate in the embolisation group (32%) versus surgery (4%), which reduced the cost effectiveness to equipoise by 5 years.[83] Similarly, the HOPEFUL study showed improved quality of life initially but with erosion of benefits over time.[84] For aortic aneurysm, EVAR was noted to have short-term benefits, but lack of benefit in the long term (as well as increasing costs from re-intervention) leading NICE to approve it only for acute rupture [46,85] and not elective repair of uncomplicated aortic aneurysms.[86,87]

The reasons for complications and lack of durability need to be acknowledged and addressed. With increasing experience and training, complications can be recognised and mitigated earlier and more cost effectively. Developments in technique frequently occur: for example, in UAE, the role of anastomotic vessels causing regrowth of fibroids has been recognised and can be treated primarily or with re-intervention.[88] Long-term studies can also help define which subgroup of patients are likely to benefit most, so patients can be better informed of the options most likely to suit them and therefore prove cost-effective.[89]

Sometimes a different treatment paradigm may prove more suitable. For example, magnetic resonance imaging (MRI)-focussed ultrasound may prove more effective for certain groups of patients with fibroids,[90] and this is currently being trialled.[91] Similarly, the EVAR strategy of internal graft fixation by radial force and non-abolition of the aneurysm sac may be superseded.[92] So far, different approaches such as endovascular aneurysm sealing (for example with Nellix) have not proved successful, although eventually a hybrid technique with EVAR graft plus sac filling may prove the best solution.[93]

Follow-up

Imaging follow-up adds significant costs, especially if cross sectional, such as CT, which costs three times the cost of ultrasound.[22] Follow-up consultations can often be done more conveniently for patients and IR teams by telephone rather than face to face, and by different team members such as specialist nurses,[22,94] and large societal cost savings can be obtained due to reduced hospital usage, fewer missed appointments, and decreased transport costs.[95] The duration of follow-up for all procedures should be continually under review as better and longer-term data becomes available, and tailored to where re-intervention can make a significant difference.

Conclusion

IR is a rapidly evolving field with many potential clinical advantages for patients and cost-effectiveness advantages for the whole healthcare system. IR can demonstrate and promote its value with high-quality robust long-term data, using criteria developed by NICE, which is recognised worldwide as a leader in objective evaluation of healthcare effectiveness, working in the best interests of patients. The methodology of cost-effectiveness analysis and areas where improvements could be made have been discussed. It is hoped that IR teams will use these and work together to expand this evidence base, which can potentially be of great benefit to all.

Conflicts of interest

The authors declare no conflict of interest.

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