



Improving surgical research



Mr John Black, President, Royal College of Surgeons of England

“High quality research, whether related to surgical practice and teaching, audit or clinical trials, plays a fundamental role in a modern surgical service that delivers the best care for patients. In recognition of this, the Royal College of Surgeons has long supported the surgical community in identifying and highlighting innovative practice, promoting its evidence base and encouraging widespread adoption.

Despite huge investments in health research and that almost half of care episodes are surgical, historically only a small percentage of funding has gone into research in surgery. There is a critical opportunity in the wake of the NHS Next Stage Review to make the case for more funding for surgical research. It should be remembered that the vast majority of those cured of the common

solid cancers have an operation as their definitive treatment. Minor improvements in surgical techniques can alter outcomes and may be at least as effective as most adjunctive oncological treatments.

Many methodologies can support research into surgical advancements, breaking new ground and providing evidence for improving patient outcomes.

In surgery it is often not appropriate to use exactly the same measurement tools as are used in pharmaceutical interventions. There is a need for an overarching framework for the safe evaluation and dissemination of innovative procedures. This framework needs to be based on an understanding of the nature of surgery and what can be measured to help improve and evaluate outcome measures specific for individual surgical procedures, and if effective, disseminate their appropriate use widely within the healthcare environment. It would also mean individuals or groups of surgeons are able to get recognition for innovative procedures or interventions that they have developed.

The NIHR HTA programme has an important role in surgical research by identifying and funding high quality research projects that span surgical specialties. The College continues to encourage surgeons to work with the HTA programme and other NIHR research programmes and for the NIHR to recognise the barriers and difficulties facing surgeons who need to retain their clinical skills whilst dedicating time to research. The HTA programme is helping to drive this forward as it is able to quickly and effectively evaluate surgical procedures and improve the evidence base. The smaller number of surgical trials that have previously taken place reflects the need to encourage effort in this area.”

The NIHR HTA programme has invested over £73 million in surgical research since its inception, funding both evidence syntheses and primary research, including randomised controlled trials. It is also supporting the work of the Balliol Collaboration to develop solutions to issues around surgical research (see pages 4-5 for more details).

Make an impact on the NIHR HTA programme's research agenda and help ensure more research is commissioned into important surgical areas by submitting research suggestions. Visit www.hta.ac.uk/suggest

A word from.... *Professor Jonathan Michaels, Chair of the Interventional Procedures Panel*

“Research is crucial to help develop and improve surgical techniques and interventions in the NHS. The NIHR HTA programme plays an important role adding to the evidence base through funding ground breaking research in this area. Recent research includes clinical trials into surgery for gastro-oesophageal reflux disease (see page 3), surgery versus non-surgical interventions for patients

with severe lower limb ischaemia and treatment for tears of the rotator cuff (see page 3).

Surgery and other interventional procedures have previously been under-represented in the HTA portfolio due to difficulties in conducting research in these areas. Clinical trials of invasive procedures present particular ethical problems and there

may be a lack of clinical academic staff or research infrastructure. It is often difficult to time the research in relation to the introduction of a rapidly developing new technology and there are usually learning curves associated with the use of new devices and procedures. The HTA programme is investing in clinical research to help improve this and the new Interventional Procedures Panel

continued . . .

has been created to help progress research into surgical and other interventional therapies (defined as those which involve entry into the body).

The panel is made up of clinical experts who review suggestions and identify priority areas where there is a gap in the evidence base. Researchers are then invited to submit research proposals in these areas. This system enables the programme to commission research that produces physician-relevant and patient-centred results which can often be directly applied to practice.

To identify areas of genuine uncertainty it is important to communicate with those who work in the field. The HTA programme encourages the submission of suggestions for research at all times through its webform (www.hta.ac.uk/suggest).

In tandem with this the programme's researcher-led workstream offers ongoing opportunities to submit research proposals. Some surgical and interventional trials that have been commissioned through this route include outpatient polyp treatment for abnormal uterine bleeding, and the management of vaginal wall prolapse. To submit a proposal visit www.hta.ac.uk/funding/clinicaltrials

I urge staff of all disciplines and professions to consider submitting suggestions for research or a research proposal relating to an interventional procedure that is important to them and the NHS. //

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Cardiac surgery

For some people with heart disease, surgery is the best treatment option currently available. Each year more than 30,000 people have cardiac surgery in the UK.

The NIHR HTA programme is continuing to expand its portfolio in this area and has funded a trial into elective cardiac surgery. The study will test the theory that adding a modified maze procedure to elective cardiac surgery in patients with atrial fibrillation (AF) will improve their quality of life as well as being cost-effective.

Both complications and treatment of AF can reduce the patient's quality of life and are very costly for the NHS. The maze procedure (cutting and stitching the atrial wall to redirect electrical signals) can stop AF but is not widely used due to its complexity. Ablation devices, consisting of a probe and energy source, can be used to make the maze procedure simpler, quicker and safer.

"The use of these devices is creeping into practice but has not been rigorously evaluated," says principal investigator Mr Samer Nashef of Papworth Hospital. "We need to know whether adding this costly technology to routine heart surgery is worthwhile for the patients and the NHS."

For more details visit www.hta.ac.uk/1705

Another trial underway is assessing whether blood transfusions can be given at a lower threshold following cardiac surgery. Blood is an increasingly scarce and expensive resource and unnecessary blood transfusions increase healthcare costs and complications.

This clinical trial, led by Professor Barney Reeves of the University of Bristol, is being carried out in several UK hospitals. Patients whose haemoglobin (Hb) level drops



below the level at which transfusion is conventionally given will be randomised to be transfused: (a) on the basis of a 'liberal' protocol (more or less as at present), or (b) only when the Hb level drops to a lower, 'restrictive' level. Researchers will measure the number of infectious (septicaemia, wound or chest infection) and ischaemic (stroke, heart attack or kidney failure) complications that occur during the first three months after surgery.

Professor Reeves says, "We believe that withholding transfusion until the lower Hb level is reached will reduce both complications and hospital costs."

To view the full project details visit www.hta.ac.uk/1729

Research published in the area of cardiac surgery includes a review evaluating the ventricular assist device programme. Ventricular assist devices (VADs) were first used to support transplant candidates with rapidly failing circulation who were considered unlikely to survive until a suitable organ could be found.

The study which published in 2006, found that while VAD implantation can be justified for selected cases, there is currently no cost-effectiveness argument for widespread dissemination of the technology. For more details visit www.hta.ac.uk/1256

Surgery for gastro-oesophageal reflux disease

A £1.1 million clinical trial published by the NIHR HTA programme has found that early surgery is beneficial for patients with chronic symptoms of gastro-oesophageal reflux disease (GORD) although its cost-effectiveness is still uncertain.

Currently, the management of people with GORD at the more severe end of the spectrum is primarily through the use of drugs in the form of tablets, with relatively few patients having surgical treatment. However, GORD may be a lifelong condition, and so could require 20-30 years of medical therapy if a patient is young when diagnosed.

Led by Professor Adrian Grant of the University of Aberdeen, researchers recruited 810 people from 21 hospitals across the UK. They compared the clinical, cost-effectiveness, and safety of a

policy of relatively early 'key-hole' laparoscopic surgery, compared with continued medical management.

The results showed that surgical treatment was more effective than long-term drug therapy, especially in patients with the most troublesome symptoms, certainly up to one year after the procedure. A surgical policy is, however, more costly than medical management and it is uncertain whether it would be cost-effective in the long-term. For this reason the HTA programme is now funding the follow-up of participants to at least five years after surgery.

"Extending the use of laparoscopic fundoplication to people whose GORD symptoms require long-term medication would provide better quality of life. Like all surgery, fundoplication has some risks, but the more troublesome the

symptoms, the greater the potential benefit from the operation," says Professor Grant. "We believe our research can help to better inform the management of patients with chronic symptoms of GORD."

To view the full results visit www.hta.ac.uk/1134

An editorial in the *BMJ* has praised this trial as an "excellent model of how to design and conduct a robust and pragmatic randomised trial within the complexity of the NHS." www.bmj.com/cgi/content/full/337/dec15_2/a2747

Treatment for rotator cuff tears

HTA-funded research is underway to compare surgery versus non-surgical treatment for tears of the rotator cuff. Every year about one per cent of UK adults aged over 45 present with a new episode of shoulder pain. Approximately 70 per cent of these cases involve the rotator cuff.

Surgery can take two main forms, an open repair or an arthroscopic repair (where the tear is repaired through key-hole surgery). Non-surgical treatment can be through injection or home-based exercise. There is wide variation in treatment practices across the UK and it is unclear which approach provides the best results for patients.

The £1.9 million trial, led by Professor Andrew J Carr of the University of Oxford, is assessing arthroscopic surgery or open surgery with a 'rest then exercise' management approach. Over 600 patients are being recruited from

around 60 centres across the UK, and randomised to receive one of the three treatments.

All participants are placed on the NHS waiting list for surgery including those allocated to the 'rest then exercise' programme. However, if they feel their shoulder has improved after completing the programme, they are then given the opportunity to decline surgery.

Patients will be followed up for two years with questionnaires on shoulder pain and function, as well as their general health. Twelve months after surgery patients will also receive an MRI scan to check the repair is intact. Alongside this, researchers will assess the cost-effectiveness of each procedure.

"Tears of the rotator cuff are one of the most common causes of shoulder pain and dysfunction, but evidence on the most effective treatment is



limited," says Professor Carr. "With the development of arthroscopic techniques it is important that this research is conducted now to help identify the best procedure for patients."

This study is also being supported by the British Elbow and Shoulder Society. To view the full project details visit www.hta.ac.uk/1551

Advancing surgical knowledge

Research in surgery has traditionally been a challenging area due to a number of issues, not least the recruitment of surgeons as well as patients, achieving clinical equipoise, and the often complex nature of surgical interventions. The NIHR HTA programme is helping to address some of these issues, and we talked to a leading expert in this field, Professor Jon Nicholl, Director of the Medical Care Research Unit at the University of Sheffield, and Chair of the HTA Commissioning and Clinical Evaluation and Trials Boards. Professor Nicholl has also been closely involved in the work of the Balliol Collaboration, which was set up to discuss the problems facing surgical research and surgical innovation and to identify solutions to help further future research.

The evidence base for surgery

Patients' expectations of the quality and effectiveness of the treatments they receive through the NHS continue to rise. Well-trained staff, published surgical outcomes and low risks of harm are key to the issues of governance, safety and quality in healthcare. High quality research by surgeons must support any innovation in surgery in order to reassure patients and demonstrate to NHS policy makers that new techniques and interventions are safe and both clinically and cost-effective.

The need for scientifically robust evidence in surgery has been highlighted in recent years, particularly by the rapid developments of new surgical technologies and techniques, and with the benefits of future advances expected to be less apparent there is likely to be a greater need for high quality randomised controlled trials (RCTs).

In 2006 only eight per cent of publications in leading surgical journals were of RCTs, with a large proportion of the literature being made up of case series. Case series provide the weakest evidence for assessing the efficacy of a treatment.

Experts such as those contributing to the Balliol Collaboration are trying to encourage greater understanding of the importance of surgical research to clinical practice. It has been recognised that more pragmatic trials are needed to determine the acceptability, effectiveness, and efficacy of new interventions by comparing them with current preferred treatments.

To help develop the evidence base in surgery the HTA programme has supported the work of the Balliol Collaboration and has funded many rigorous systematic reviews and evidence syntheses as well as new clinical trials. To date the programme



Professor Jon Nicholl

has invested over £73 million on 100 surgical research projects which range from trials comparing surgical techniques for the repair of abdominal aortic aneurysms to a range of different treatments for varicose veins and an evaluation of weight loss surgery.

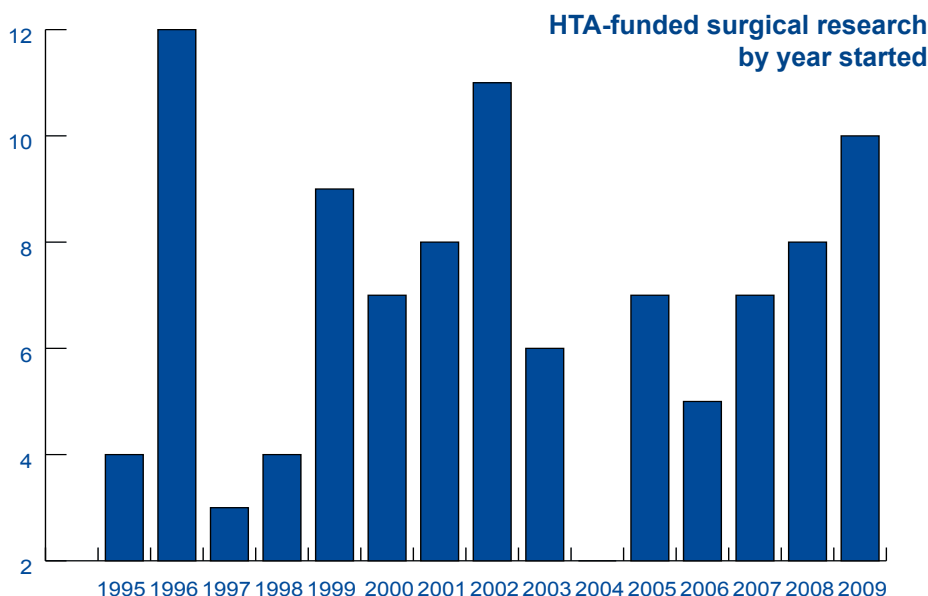
Issues facing surgical research

The Balliol Collaboration has identified a number of challenges associated with surgical research.

Study design is a key area for surgical trials and one where many issues have been highlighted. Historically, there has been a lack of infrastructure and guidelines to help surgical researchers generate evidence that is well planned, well conducted, and meticulously reported. The NIHR has been working through the HTA programme with Clinical Trials Units (CTUs) and NIHR Research Networks to help tackle these issues and provide researchers with more support.

RCTs are the gold standard for evaluating interventions, but they are not always appropriate or possible. For example, if conducted too early before the innovation has been optimised an RCT could hinder innovation and delay development. However, if too late, clinical equipoise may be lost, as the majority of surgeons may have formed a strong preference to one procedure over the other and decline to participate in any study, thus limiting patient recruitment.

Other challenges are posed by the complexity of surgical interventions. A surgical procedure can consist of a number of different components that cannot be evaluated separately, often surgical treatments have a learning curve or are influenced by other aspects of healthcare delivery.



These aspects, and not just the knowledge and skill of a surgeon, will vary between centres and may significantly affect health and research outcomes.

What is the HTA programme doing?

To ensure that research funded by the HTA programme is both important to the NHS and scientifically robust, the programme identifies areas of clinical uncertainty, prioritises them through panels of clinicians and then invites researchers to submit proposals for studies in these areas. Proposals received through all HTA funding routes are peer-reviewed by a number of experts, as well as being evaluated by senior colleagues through the programme's commissioning boards.

The HTA programme is also continuing to support the developing role of CTUs through its management of NIHR funding to strengthen CTU capacity for conducting clinical trials.

It is also one of a few national research programmes to have a pro-active monitoring process to help projects identify and address any problems that might arise during a study. This support helps surgical researchers to conduct and complete robust and high quality clinical research. An example of this is the HTA-funded REFLUX trial which compared early key-hole laparoscopic surgery with continued medical management for the treatment of gastro-oesophageal reflux disease. The trial was noted in the *BMJ* as an "excellent model of how to design and conduct a robust pragmatic randomised controlled trial within the complexity of the NHS" (see page 3).

Although pragmatic trial-based research might not currently be a driver in the development of surgery, it is increasingly important to patients and policy-makers as well as surgeons themselves. Research to ensure new surgical interventions are evidence-based is important in helping to support the development of the specialty as well as the issues of clinical governance, safety and the quality of healthcare. The HTA programme is committed to expanding the surgical research portfolio and working with professionals in the field to achieve this. //

The work of the Balliol Collaboration has been highlighted in a series of articles in *The Lancet* 2009; Vol 374, Issue 9695. They provide a framework for future high quality surgical research through their examination of the 'top ten' challenges faced in surgical research, the strengths and weaknesses in surgical studies, and give insights and solutions to further the future quality of surgical research and evaluation. Visit [www.thelancet.com/journals/lancet/issue/vol374no9695/PIIS0140-6736\(09\)X6093-9](http://www.thelancet.com/journals/lancet/issue/vol374no9695/PIIS0140-6736(09)X6093-9)

HTA-funded research published in the *BMJ* suggests that transurethral resection, the most common operation for benign prostatic enlargement (BPE), remains a clinically and cost-effective treatment for the condition.

Researchers at the University of Aberdeen, led by Professor James N'Dow, examined existing data to determine the risk factors and clinical and cost-effectiveness of minimally invasive treatments for BPE compared with the current standard of transurethral resection. These included 'tissue ablative' treatments such as holmium laser enucleation of prostate (HoLEP); transurethral vaporisation; and 'minimally invasive' techniques such as laser coagulation, microwave therapy and transurethral needle ablation. They also looked at the overall long-term benefits to patients.

The research team concluded that transurethral resection provides a consistent, high level of long-term symptom improvement. Improvements in quality of life and urinary flow were also observed. However, the risks associated with the minimally invasive interventions were generally lower than transurethral resection, with fewer adverse events, such as the need for a blood transfusion. The need for repeat surgery was more common with the newer technologies.

The evidence also suggests that HoLEP could offer some advantages over transurethral resection (such as equally good urine flow but shorter hospital stay and reduced bleeding) although long-term follow-up data is needed.

"Overall, our findings do not support a change in surgical treatment of BPE and suggest that transurethral resection of the prostate should remain the standard approach," says Professor N'Dow. "Which minimally invasive intervention is most promising is unclear and good quality randomised controlled trials are needed to prove whether they are superior. Until then, personal preference will influence choice of procedure, with some patients choosing minimally invasive treatment options for their decreased morbidity."

To view the *BMJ* papers visit

www.bmj.com/cgi/content/abstract/337/oct09_2/a1662

www.bmj.com/cgi/content/abstract/337/jun30_1/a449

To view the full results in *Health Technol Assess* 2008; Vol. 12:35 visit www.hta.ac.uk/1468



HTA research informs policy



The NIHR HTA programme is continuing to support the work of the National Institute for Health and Clinical Excellence (NICE) through the commissioning of Technology Assessment Reports. Many of these reports are surgically based and help inform NICE's guidance, as well as taking forward its priority recommendations for research.

In 2008, a study to determine the safety, clinical and cost-effectiveness of circular stapled haemorrhoidopexy (haemorrhoidectomy) was commissioned by the HTA programme on behalf of NICE to inform guidance TA128: www.nice.org.uk/Guidance/TA128.

This review suggests that stapled haemorrhoidopexy is a reasonable alternative to conventional, excisional, haemorrhoid surgery for people with prolapsed internal haemorrhoids, where surgery is considered to be a suitable treatment option. The procedure is carried out using a circular stapler specifically designed for haemorrhoid surgery.

For further details on this study visit www.hta.ac.uk/1544

Research commissioned for NICE also includes a systematic review and economic model to determine the clinical and cost-effectiveness of endovascular stent-grafts for repair of infrarenal abdominal aortic aneurysms.

The study has concluded that open repair is likely to be cost-effective compared with endovascular aneurysm repair in patients considered fit for open surgery. These findings have informed NICE guidance TA167 Abdominal aortic aneurysm. Visit www.hta.ac.uk/1678

Other ongoing research informing NICE guidance (TA166) is a systematic review which found that unilateral cochlear implantation is safe and effective for adults and children. The assessment looked at devices used in one or both ears and assessed whether this treatment is

likely to be considered good value for money for the NHS. For more details visit www.hta.ac.uk/1593

Further research has found that bariatric surgery is a more effective intervention for weight loss than non-surgical options. The aim of this health technology assessment was to assess the clinical and cost-effectiveness of bariatric surgery in the obese and update the original NICE guidance, which was assessed in 2002 (TA46). This project published its findings in *Health Technol Assess* 2009; Vol. 13:41. Visit www.hta.ac.uk/1742

Treatments for head injury investigated

It is known that patients with a bleed on the surface of the brain following a head injury benefit from urgent surgery. However, it is not known whether patients with a bleed inside the brain would also benefit from surgery. A £2.3 million clinical trial commissioned by the NIHR HTA programme is investigating this issue.

Researchers, led by Professor David Mendelow of the University of Newcastle-upon-Tyne, will identify patients assessed in the neurosurgical department within 12 hours of a head injury. Those eligible will be randomised to either receive early surgery to remove the blood from the brain or best medical treatment and delayed surgery if they deteriorate.

If the patient is allocated to early surgery, this will be undertaken by

a method of the surgeon's choice within 12 hours of randomisation. If the patient deteriorates, best medical treatment will be allocated and surgery may be undertaken if it becomes appropriate later. Both groups will be carefully monitored according to standard neurosurgical practice and the outcome will be assessed at six months with postal questionnaires.

"This study will be highly successful if a definitive answer is achieved to the question," says Professor Mendelow. "If the study is neutral it will add to the research evidence, as there is no good quality research evidence about surgery for traumatic intracerebral haemorrhage at present."

To view the full project details visit www.hta.ac.uk/1756



Gynaecological surgery focus

The NIHR HTA programme is expanding the evidence base around gynaecological surgery and has invested over £5 million in 10 research projects in this area.

Published research includes a comparison of the safety, clinical and cost-effectiveness of uterine artery embolisation (UAE) against hysterectomy for the removal of fibroids. The researchers suggest that UAE may provide an effective alternative to hysterectomy.

Fibroids can cause heavy painful periods and impair both fertility and urinary functions. Currently, standard treatment for this condition is a hysterectomy. UAE is a less invasive alternative to a hysterectomy and offers women the possibility of remaining fertile. The treatment also reduces hospital stay and recuperation time is much shorter.

Led by Professor Klim McPherson of the University of Oxford, researchers recruited around 1700 women from 20 collaborating hospitals over eight years. They examined participants' hospital records and conducted a follow-up questionnaire looking at complication rates, patient satisfaction, fibroid shrinkage, aftercare treatment and the number of pregnancies following treatment with UAE.

"Hysterectomy is a very invasive technique and so it is important that research is conducted into alternative treatments," says Professor McPherson. "Our research suggests that UAE is a clinically and cost-effective treatment for fibroids providing clinicians and patients with the evidence to make more informed choices, resulting in a healthier female population and better use of NHS resources."

The report published in *Health Technol Assess* 2008; Vol. 12:5. Visit www.hta.ac.uk/1382

There are currently three studies into gynaecological surgery underway. The first includes an assessment of outpatient polyp treatment for abnormal uterine bleeding. Uterine polyps are small, soft outgrowths from the lining of the womb. There are two methods used to remove polyps: with forceps under local anaesthetic or via a general anaesthetic.

Currently, most surgeons only offer the in-patient general anaesthetic option, but potentially more will perform the outpatient polyp treatment. However, it is not known which method is better.



This trial will compare the effectiveness of these two methods at removing polyps. They will also measure reduction in bleeding, patient preference and cost to the NHS. Up to 500 women from 20 hospitals in the UK will be recruited. To view the full project details visit www.hta.ac.uk/1679

A second study led by Professor Siladitya Bhattacharya of

the University of Aberdeen is investigating treatment for heavy menstrual bleeding (menorrhagia), a common problem in women of child bearing age.

"Over the last decade a number of less invasive treatments have been developed, with current guidelines now recommending their use before proceeding to hysterectomy. Yet it is thought that many women with menorrhagia suffer in silence because they are afraid that they will need a hysterectomy," says Professor Bhattacharya.

Researchers are reviewing the existing evidence on hysterectomy, endometrial ablative techniques (microwave endometrial ablation and thermal balloon ablation), and the Mirena® coil to establish which is the most clinically and cost-effective treatment.

They are also aiming to define a treatment pathway that sets out the most effective course of action and to help aid clinical decision-making. To view full details about the project visit www.hta.ac.uk/1616

The third study is a clinical trial is evaluating fetal bladder obstruction in pregnancy. Researchers are assessing the safety, acceptability and the clinical and cost-effectiveness of percutaneous vesico-amniotic shunting compared with monitoring via ultrasound.

Percutaneous vesico-amniotic shunting is the insertion of a catheter into the bladder of the fetus to allow drainage of urine. They are aiming to recruit around 200 pregnant women carrying a male fetus to the trial. Visit www.hta.ac.uk/1732

Procedures for hip replacement assessed

Minimal incision total hip replacement (THR) may have some advantages over the standard procedure when treating arthritis of the hip suggests research by the NIHR HTA programme. The review, jointly commissioned with The Canadian Agency for Drugs and Technologies in Health (CADTH) and the HTA programme, assessed the clinical and cost-effectiveness of minimal incision approaches to THR for arthritis of the hip.

“There were considerable advantages in terms of efficiency and avoiding duplication of research efforts through conducting this research in collaboration with our UK colleagues,” says Professor Coyle from the University of Ottawa.

Osteoarthritis was the primary diagnosis in 94 per cent of THR operations in England and Wales in 2005. Six to fourteen per cent of these operations were reported to

have been mini-incision THRs. With improvements in implant design and longevity, younger patients are also now considered for minimally invasive surgery (MIS).

The project, which was published in June 2008, involved a research team led by Professor Luke Vale of the University of Aberdeen. They reviewed existing literature on the clinical and cost-effectiveness of minimal incision THR (a technique which utilises a three to four inch incision) compared with standard THR (done through an incision that is usually about five to eight inches in length). In addition to this, contact was made with experts in the field and scrutiny of retrieved papers to identify published and ongoing studies.

“Minimal incision THR has small advantages in terms of blood loss and operation time and may offer a shorter hospital stay and quicker

recovery,” says Professor Vale. “It appears to have a similar procedure cost to standard THR, but evidence on its longer term performance is very limited.”

Professor Vale continues, “Further data, particularly on long-term outcomes, is therefore required.”

To view the full project details visit www.hta.ac.uk/1598

CADTH is an independent, not-for-profit agency funded by Canadian governments to provide evidence-based information about the effectiveness of drugs and other health technologies to healthcare decision makers. For further information visit www.cadth.ca/index.php/en/hta/reports-publications/search/publication/794

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The NIHR HTA programme is managed by NETSCC, HTA as part of the NIHR Evaluation, Trials and Studies Coordinating Centre at the University of Southampton

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