Advice on the Development of Robotic Assisted Radical Prostatectomy in England

Prostate Cancer Advisory Group

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Foreword:

With thanks to the Prostate Cancer Advisory Group, BAUS is pleased to acknowledge this guidance on the development and commissioning of robotic surgery, and particularly robotic prostatectomy in England. An increasing number of robotic systems have been put in place over the past few years. We are particularly aware that to achieve the best outcome from radical prostatectomy the experience of the surgeon and the hospital is a critically important feature. This applies as much to robotic surgery as it does to conventional laparoscopic or open prostatectomy.

This document contains advice that we hope will be helpful to commissioners in the different cancer networks who are considering how best to improve the quality of care for men with prostate cancer. We of course await the outcomes in the longer term of randomised trials comparing surgery and other methods of treatment for men with localised prostate cancer. In the meantime it would seem to us that commissioners should ensure that their patients go to high volume centres and high volume surgeons in order to ensure the best outcomes.

Developed on behalf of the Prostate Cancer Advisory Group.
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1. Introduction, purpose and scope

Introduction

1. Improving Outcomes: A Strategy for Cancer (January 2012) sets out the Coalition Government's aim to deliver cancer outcomes that are among the best in the world. Through the approaches the Strategy sets out, the Government aims to save an additional 5,000 lives a year by 2014/15, aiming to narrow the inequalities gap at the same time.

2. Ensuring that all cancer patients receive the appropriate treatment, delivered to a high standard, is critical to improving cancer outcomes. The benefits of successful surgery are clear: improved survival, improved quality of life and reduced ongoing costs from treatment required to treat cancer, which has spread. In order to deliver improved access to high quality surgery, the NHS needs to promote the uptake of effective new surgical techniques, whilst ensuring that the existing surgical workforce receives the appropriate training to do this. This document fulfils our commitment to publish advice and guidance to commissioners and providers on robotic surgery for prostate cancer.

Purpose

3. The purpose of this document is to review the likely need for robotic prostatectomy and address questions that should be considered by commissioners and providers where implementation is planned.

Scope

4. This document does not to address the question of whether surgery in its various forms (open, laparoscopic and robotic assisted); radiotherapy in its various forms (external beam, brachytherapy); active surveillance or active monitoring represent the best and most cost effective treatment. These questions are the subject of current clinical trials such as the **Pro**state **te**sting for **c**ancer and **T**reatment (ProtecT) study and others, National Institute for Health Research (NIHR) Health Technology Assessment (HTA) systematic reviews and the recent PIVOT study. It also does not address the role of novel therapies such as cryoablation and High-Intensity Focused Ultrasound (HIFU), the early results of which were published this year.

2. Executive Summary

- Significant improvements have been made in radical prostate surgery since the introduction of the NICE Improving Outcomes Guidance in Urological Cancers, and there is evidence of increasing high volume activity comparing 2008/09 to 2009/10. However, some men continue to undergo surgery by surgeons doing very few procedures **(Annex A),** potentially reducing the chance of high quality outcomes.

- There is a strong argument for further concentration of radical prostatectomy to fewer centres and in the hands of fewer surgeons

- Robotic surgery for localised prostate cancer is an established therapy, and in most countries is now replacing conventional laparoscopic prostatectomy

- The present distribution of da Vinci systems across England is not equitable by geography or population density

- If commissioners wish to support the establishment of robotic programmes, they should consider for reasons of cost-effectiveness setting up fewer very high volume centres with two robots

- Given a likely increase in incidence in prostate cancer over the next five to ten years, we estimate that for radical prostatectomy around 40 robots would be required in England

- We offer guidance as to how to measure the success of local programmes in performance of radical prostatectomy and to indicate what factors should be defined in commissioning such services.

3. Prostate cancer and the potential demand for surgery

Current position

Around 5,000 radical prostatectomies are done in England each year **(Annex B)**
The number of prostatectomies is rising markedly. Between 2008/09 and 2009/10 the total increased from 4,100 to 4,900 – a 20% increase **(Annex B)**
In 2009/10 just over half (52%) of procedures were open prostatectomies, and 48% were laparoscopic with 20% being robot-assisted and 28% being not robot-assisted **(Annex C)**
Around 28 units have da Vinci robots. Most of these are in the southern England **(Annex E)**
Most radical prostatectomies are now undertaken in NICE IOG compliant centres. In 2008/09, 65% of all cases were done in centres doing more than 50 cases a year, but around 5% of operations were done in centres doing fewer than 20 a year. This latter figure fell to 3% in 2009/10 **(Annex F)**
The number of robot-assisted procedures is rising rapidly, with just over 80% increase between 2008/9 and 2009/10 **(Annex F)**

1. In 2008 in England, 30,893 men were diagnosed with prostate cancer. Increasingly men are being diagnosed at a localised stage when the disease is identified, through blood sample testing for prostate specific antigen (PSA). When considering the current rates of radical prostatectomy, it is important to understand that in England the levels of PSA testing of men at risk to identify those with localised prostate cancer (8%[1]) are considerably lower than those in the United States (over 65%) and many other Western European countries (between 30% and 60%).

2. Recent studies of screening demonstrate clearly that PSA testing saves lives, but at the price and cost of over diagnosis and over treatment [2]. Current evidence does not support the introduction of national screening; this remains under review by the UK National Screening Committee. The Prostate Cancer Risk Management Programme (PCRMP) indicates that men should be counselled about the pros and cons of PSA testing. The number of cases diagnosed will increase significantly in the coming years if the rate of PSA testing in the UK rises to approach that currently seen in other European countries. Screening may eventually gain popularity based on the updated results of the European Randomised Controlled trial (ERSPC).

Figure 1: age-standardised incidence and mortality of prostate cancer (CRUK) (2008)

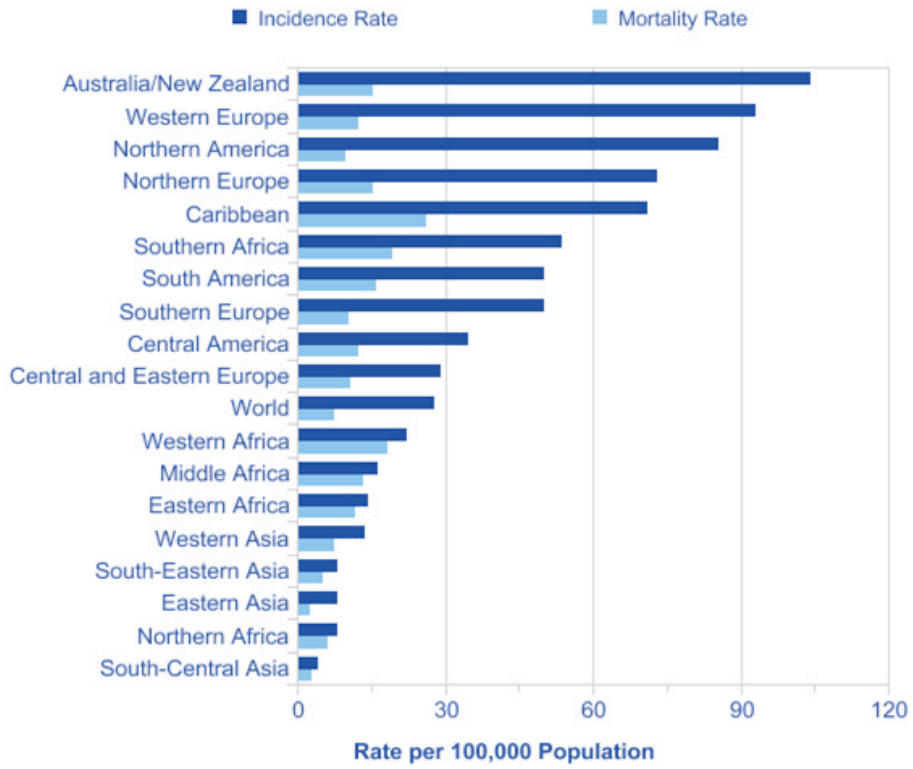
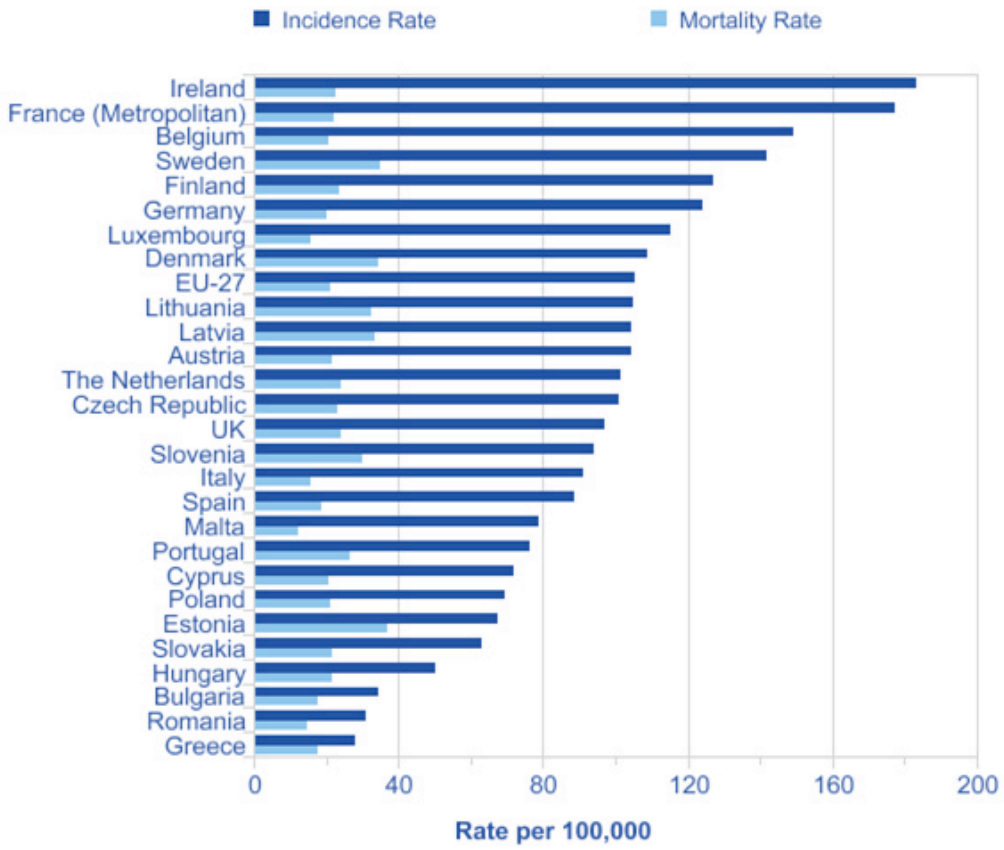


Figure 2: incidence and mortality in Europe per 100,000 men (CR UK) (2008)



3. According to figure 2, the current annual incidence of prostate cancer in the UK is around 97/100,000. It is likely to increase to ~ 130/100,000 within 5 years which will result in an increase from 30,000 cases to over 40,000 cases in England. Of these approximately 14,000 will have the personal and disease characteristics that will require curative treatment to be offered.

4. The standard ways of managing localised prostate cancer include active surveillance / monitoring, radiotherapy (external beam and brachytherapy) and surgery. High intensity focused ultrasound (HIFU) and cryotherapy are being tested but are not yet accepted as standard care. The early results of HIFU have recently been published but medium to longer term outcomes are awaited before it is established as an alternative therapeutic option for localised disease.

4. Prostatectomy and da Vinci Prostatectomy

What is radical prostatectomy?

1. The operation of radical prostatectomy aims to cure men with localised prostate cancer whilst minimising the risk of adverse effects particularly urinary incontinence and erectile dysfunction. At present there is uncertainty as to which of the available methods; open, laparoscopic, or robotically assisted laparoscopic; referred to in this document as 'robotic', is the most effective and cost-effective.

2. In England there are approximately 5,000 radical prostatectomies carried out annually (HES data for 2009/2010). This is in contrast to France where ~ 25,000 such operations are performed for a broadly similar population. It is therefore likely that the numbers of men undergoing radical prostatectomy will increase in the future in England and it is sensible for the NHS to plan for an increase in the number of such operations. If we continue with an annual growth of 20% to 30%, within five years, the numbers of operation would have increased to over 12,000. A very conservative estimate would be that within 5 years the numbers will increase to 8,000 to 10,000.

Volume and outcomes in radical prostatectomy

3. It is clear from several studies that functional and cancer related outcomes are strongly related to the individual surgeon who does the operation. A recent view of standard laparoscopic prostatectomy showed that the benefit of greater surgeon experience in reducing risk of cancer recurrence continued up to at least 750 cases [3]. However, it is also now clear that for the learning curve to begin to plateau in open surgery a significant number of cases is required – in excess of 250. [4]

4. Volume of cases is not the only factor since there is also variation in outcome between surgeons of similar experience. Without specific prospective studies, it is difficult to correct for different patient demographics and disease severity factors. There is also variation in methods of assessment of longer term adverse effects such as incontinence and erectile dysfunction. [5-7] Despite these problems with available evidence, it is highly likely that in order for a patient to gain the best results from any type of radical prostatectomy, the operation should be done by a surgeon (and team) who have achieved stable results in terms of cancer cure and minimisation of adverse effects (in practice in excess of several hundred operations).

5. The National Institute for Health and Clinical Excellence (NICE) Improving Outcomes Guidance (IOG) began the process of

centralisation for radical pelvic surgery. It is likely that the significant capital costs associated with establishing robotic prostatectomy in a centre, together with the number of cases required to achieve the best result, and the training requirements for all sorts of prostatectomy will result in further concentration of procedures in fewer centres.

6. Following IOG, the intention was that all complex pelvic cancer surgery (cystecomy and prostatectomy) would be done in centres doing more than 50 cases per year. Significant progress is being made year on year, and even between 2008/ 2009 and 2009 / 2010 more of these operations are being done in high volume centres.

7. However, the current situation in England for some men is still far from this ideal. In 2008 / 2009, 5% of men underwent surgery in hospitals doing < 20 a year and these Trusts accounted for 39% of the hospitals doing this operation. This figure reduced to 3% in 2009 / 2010, but this means that almost 1 in 5 men is undergoing this surgery in units doing fewer than 50 cases a year, where many of the surgeons are doing low numbers.

8. As noted above as well as the volume of cases done in a centre, the number done by individual surgeons is also important to achieve best outcomes. At present only four NHS hospitals in the country have two or more individual surgeons doing more than 50 cases a year. Whilst the global figures for the individual NHS hospitals look reasonable in that 4 of 5 men undergoing radical prostatectomy are treated in hospitals doing more than 50 cases a year, in many of these Trusts there are several surgeons doing relatively few cases.

9. The evidence is that very few men are being treated by surgeons who are on the relatively flat part of the learning curve and therefore further concentrating this operation in fewer hospitals and in the hands of fewer surgeons would be beneficial.

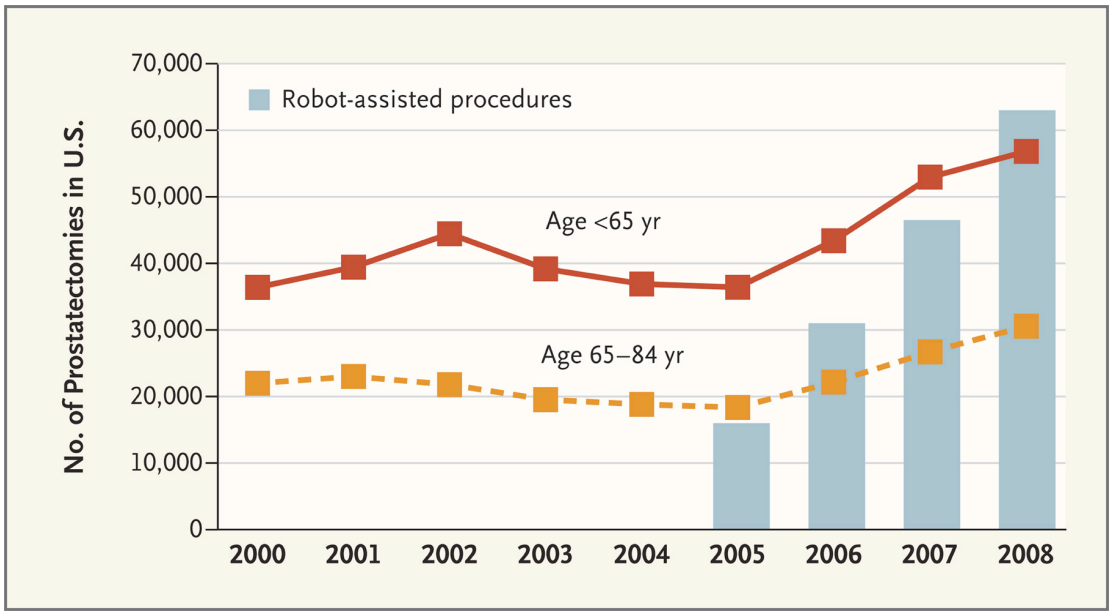
Da Vinci prostatectomy

10. Intuitive Surgical introduced the Da Vinci® system in 1999 and it received FDA approval in 2000. The first robot- assisted prostatectomy was performed in Frankfurt in May 2000. The robot is essentially a master-slave manipulator rather than a true robot and remains under the control of the operating surgeon at all times. The system allows servo-assisted control and 3-D vision leading to very fine control over movement of specifically designed laparoscopic-type instruments inserted into the patient. The most recent version, the Da Vinci Si has 1080 dpi 3D-HD vision and the possibility of controlling the robotic arms from dual consoles thus enhancing the supervision of a surgeon in training by an experience mentor.

11. In the United States in the past several years, and in many European countries, a number of pressures including patient choice, surgeon and institutional preference and commercial marketing have led to an increasing number of men with localised prostate cancer having the operation carried out by robotically assisted techniques.

12. This has grown to such an extent that currently in the US approximately 80% of all radical prostatectomies are now carried out robotically and this is associated with a decreasing role for laparoscopic surgery in that country. Intuitive Surgical Incorporated based in California, USA remains the sole manufacturer of the robotic system under the brand name 'Da Vinci'. The pattern and use of robotic prostatectomies in the USA is shown in Figure 3. Currently around one in four operations in England are done robotically, and this trend is likely to increase.

Figure 3: use of robotic prostatectomy in the US [8]



13. Open and laparoscopic prostatectomy carry different tariffs being higher for laparoscopic procedures to reflect extra instrument costs. Robotic prostatectomy also carries a higher tariff reflecting capital costs, service charges and costs of disposables. The length of hospital stay is longest for open prostatectomy with an average of 4.9 days, but similar for laparoscopic and robotic procedures with an average of 2.8 days. Carefully managed care pathways can reduce hospital stay further with an average for robotic prostatectomy of 1.3 days reported by the Cambridge service for example. Whilst scientific evidence is lacking concerning the relative effectiveness and cost-effectiveness of laparoscopic and robotic surgery, the international trends are clear; provision and implementation of a robotic system into a health service

results in a marked reduction in use of standard laparoscopic surgery.

14. The pros and cons of laparoscopic and robotic surgery continue to be debated and are the subject of a National Institute for Health Research (NIHR) Health Technology Assessment (HTA) systematic review. There is no question that laparoscopic and robotic prostatectomy are associated with lower blood loss and transfusion rates compared to open prostatectomy and shorter hospital stays [9 10]. There is some evidence that compared to conventional laparoscopic approaches the learning curve is shorter for robotic prostatectomy. This may lead to patient benefit particularly during the early implementation phase as the technology becomes established within a unit.

Current Provision of da Vinci Robotic Systems in England

15. There are currently 28 robots installed in UK and Ireland, but the geographical and population density localisation is uneven. Most are located in London and the South East. A number of systems have also been recently installed in smaller centres, some without designation as the pelvic cancer centre for the Local Cancer Network. Here they tend to be used for kidney, colorectal and gynaecological surgery.

5. Future models of care

1. As noted previously, the demand for radical prostatectomy in England will almost certainly rise to 8,000 per annum and beyond in coming years.

2. Expert opinion suggests that each surgeon should ideally be undertaking at least 50-100 cases per annum to maintain skill and to deliver the best possible outcomes. This would suggest that operations should be undertaken by no more than 80-160 surgeons in England. For mentoring, cross-cover and skill development reasons it is recommended that each centre should have at least 2 surgeons. This would suggest a need for around 40 centres carrying out robotic prostatectomy in England. The da Vinci system is also currently being used for kidney, bowel and gynaecology surgery and there is early experience with head and neck and bladder surgery. One model therefore would be that the centre could reserve use of its robotic system for prostatectomies on 2 days a week to allow at least 160-200 procedures per year with the remaining time used by other specialties. This is highlighted by the Canadian HTA published in September 2011, which showed that in order to be cost-effective, robotics needs to be multi-disciplinary and concentrated in high volume centres. The maintenance costs of the Da Vinci system remain high and utilisation on most days of the week over a number of specialities, tends to make the system cost efficient [11]. A systematic review also demonstrated that reduced hospital stay alone is not enough to offset the capital investment and running costs of the Da VInci system [12].

3. There are different models that might be considered in a centrally managed system such as the NHS. Another approach would be to develop a smaller number of very high volume centres which could provide continued training for both surgeons and the whole care team; this would ease replacement of team members who leave or retire. Given that many patients can be brought in on the day of surgery and that most stay around 24 hours, travelling some distance to the nearest centre is eminently possible for this group of men who by definition will be relatively fit and otherwise healthy. This larger volume would also concentrate support required from anaesthesia and peri-operative service. Taking into account use of the robot for other procedures we estimate that provision of one robotic surgical centre for a two million population a reasonable option, which argues further for careful thought to be given to the location of these systems.

4. Given the relatively high capital and running costs it would make financial sense to ensure that each robot was used 5 days per week,

and indeed there would be merit in fewer centres having two robots to avoid down-time for maintenance and repair. A possible service configuration for NHS England would be twenty centres with two robotic systems each and three to four surgeons performing 100 radical prostatectomies per year. This arrangement may help optimise functional and cancer related outcomes for men treated, financial cost control for the hosting NHS organisations and ensure future supply of well-trained clinical teams.

5. Commissioners are advised to take account of the underlying configuration of cancer centres within their network in terms of where they commission services, although they are free to commission services from other networks.

System and Set up Costs

6. Clearly there are significant capital, and on-going cost implications and this raises the question of whether a limited number of appropriately resourced national training centres for this operation would be the best service configuration.

7. The system itself has a capital installation cost of approximately £1.5 million. It is therefore also financially important that systems are well positioned to maximise usage and achieve the benefits of scale and controlled use.

Workforce, Training and Mentoring

8. The optimal duration of mentoring/proctoring is not clear. An early adopter of the robotic system, Dr Mani Menon in Detroit, was mentored for the first 100 cases, although he was at that time very much developing and standardising the technique.

9. The history of an introduction of complex new technology in surgery has not always been a happy one. When laparoscopic cholecystectomy was introduced there was a significant increase in the rate of bile duct strictures and it is possible that the introduction of robotic assisted prostatectomy or laparoscopic prostatectomy may also result in increased complication rates. There is evidence from a number of centres that careful mentoring and proctoring is required. A centre aspiring to adoption and implementation of the technology should ensure that the following programme of team training is carried out:

10. We would recommend that when the procedure is introduced, the lead surgeon should be supported by another surgeon colleague. Mentoring should be carried out until the colleague surgeon was competent.

11. The surgeon should be competent in basic laparoscopic skills. The whole team should visit a centre which carries out these procedures regularly. This team should include the anaesthetist, the principal training surgeon, another surgeon from the institution, the theatre nurses, a ward sister and a nurse practitioner from the clinic. The Urology Foundation (TUF) funds a number of national and international robotic preceptorships in collaboration with King's College London to support the safe training of individual surgeons and their teams [13].

12. The team-based approach allows accurate counselling of men in the clinic with the provision of accurate information regarding their own expectations, and the expectations that the patient will mobilise very quickly and will be intending to be out of hospital within approximately 24 hours.

13. There is a need for the anaesthetist to go to ensure that the correct approach with anaesthesia is adopted to allow early recovery and avoiding high dose of opiates and high rates of fluid infusion. It is difficult to recommend a precise number of operations that should be seen at an experienced centre by the visiting team but one would have thought around 10 to 20 would be reasonable.

14. The training surgeon should then go on an advanced laparoscopic training course involving model systems including porcine models – this is of necessity required to be done out of the United Kingdom, although cadaver models now available in the UK may prove useful.

15. There seems to be a consensus that to carry out the operation within a reasonable time frame and with an acceptably low rate of complications, somewhere between 20 and 50 operations are required to be performed by the training surgeon closely supervised by the trainer surgeon. After this time the surgeon is then capable of proceeding on their own to complete their training and experience. Clearly, this carries serious cost implications, which is why the NHS should consider resourcing one or more training centres for robotic surgery. Surgeons and robotic centres are encouraged to submit their data prospectively to the **BAUS Nuvola database** to demonstrate commitment to national audit.

Case Study

A recent paper describing the process of setting up and mentoring the Cambridge team in robotic prostatectomy [14] showed the benefit of a very experienced robotic team invited into an NHS practice allowing safe introduction of the procedure, provided there was on site support from experienced laparoscopic surgeons. The Cambridge experience was that around 40 cases were required for its safe introduction provided there was on site supervision from an experienced laparoscopic or robotic surgeon. This was also the experience of the Manchester team.

At present the Cambridge series is the only UK publication on this topic and data are now available on 500 men with an average age of 62 years who have undergone robotic assisted laparoscopic prostatectomy[9].

After approximately 50 cases both principal surgeons reached a stable operating time of around 120 minutes on the robot, and the positive surgical margin rate stabilised at 10% for pT2 case and 25% for patients with pT3 disease after approximately 100 cases.

Audit of the first 100 cases from Manchester supports these data, with a 50% reduction in the pathological margin rate for cases operated on by the same surgeons undertaking open surgery and with similar selection criteria within the first 50 cases.

In terms of functional outcome for continence it probably requires more cases to reach the best possible rate of continence. This evidence is supported by data from large centres in the United States and also local data from Cambridge. In the last 200 patients from Cambridge, 80% of men were fully continent at 6 weeks and at 10 months over 90% were completely continent.[9]

1.

7. Criteria for selecting patients suitable for robotic surgery

1. When the centre's robotic programme is set up it would seem sensible to recommend a number of criteria used for selecting initial patients for the surgery in the early implementation phase. This would mean that some men would still need to be operated on during this period using the prevailing method of open or standard laparoscopic prostatectomy.

2. Ideally these men:

   - should have a Body Mass Index (BMI) less than 30;
   - would have not had previous abdominal surgery or mesh hernia repair;
   - would not have had a previous transurethral prostatectomy;
   - would have a prostate size somewhere between 30 and 50 g
   - would have a prostate cancer of low or intermediate risk[15].

3. Ideally, the early patients would accept the high risk of erectile dysfunction given that preservation of erectile function is difficult to achieve for the first 100 or so cases.

4. The patient should be counselled carefully that the hospital is introducing a new procedure and that the surgeon is competent but not heavily experienced in the technique. Nurse-led pre operative counselling and patient focused user groups are highly effective in managing patient expectations and post-operative results. This is demonstrated by excellent functional outcomes [15] from Guy's whereby nearly 80% of previously potent men were able to achieve erections sufficient for intercourse 18 months after bilateral nerve sparing prostatectomy and penile rehabilitation, which was shown to them before their operation [16].

7. Clinical Audit

7.1 There should be a programme of continuous audit of each set of cases for each surgeon probably analysed in successive cohorts of between 30 to 50 patients, and the outcome should include audit of the elements set out in the box.

Cancer control

Positive margin rates (stratified for risk category and pathological stage)

Rate of biochemical recurrence (PSA rise)

Mortality – within hospital, 30 days, 90 days, 120 days

Morbidity

Operative

blood loss and need for blood transfusion

Bowel injury

Conversion to open/laparoscopic

Return to theatre

Long term

Rates of urinary continence at 12 months following surgery

Rates of adequate sexual function when preservation was aimed for

8. Conclusion

1. We await the outcomes of trials comparing active monitoring/active surveillance, surgery and radiotherapy to determine the most effective treatments for men with localised prostate cancer.

2. In the meantime current evidence suggests that the best outcomes in terms of cancer cure, continence and preservation of erectile function in men undergoing radical prostatectomy are best when treated by high volume surgeons in high volume centres.

3. Further thoughts should be given by commissioners to making sure that men are treated in centres that can demonstrate accepted benchmark rates of cancer control, and preservation of continence and erectile function.

4. Robotic prostatectomy does appear to be stably adopted by many countries worldwide although technology is likely to continue to advance. In most countries conventional laparoscopic prostatectomy is declining in favour of robotic prostatectomy for a number of reasons. Whilst surgeons are on the learning curve for either procedure they will be exposed to increased rates of complications and side effects.

5. This document offers advice on the implementation of a robotic programme including systems of audit and mentoring and we commend it to commissioners. It would appear that provision of radical prostatectomy and in particular robotic prostatectomy for the NHS is a circumstance where collaborative action by different commissioning teams would help ensure that men with localised prostate cancer get the best chance of the most effective surgery and would also help with cost-containment for the NHS as a whole.

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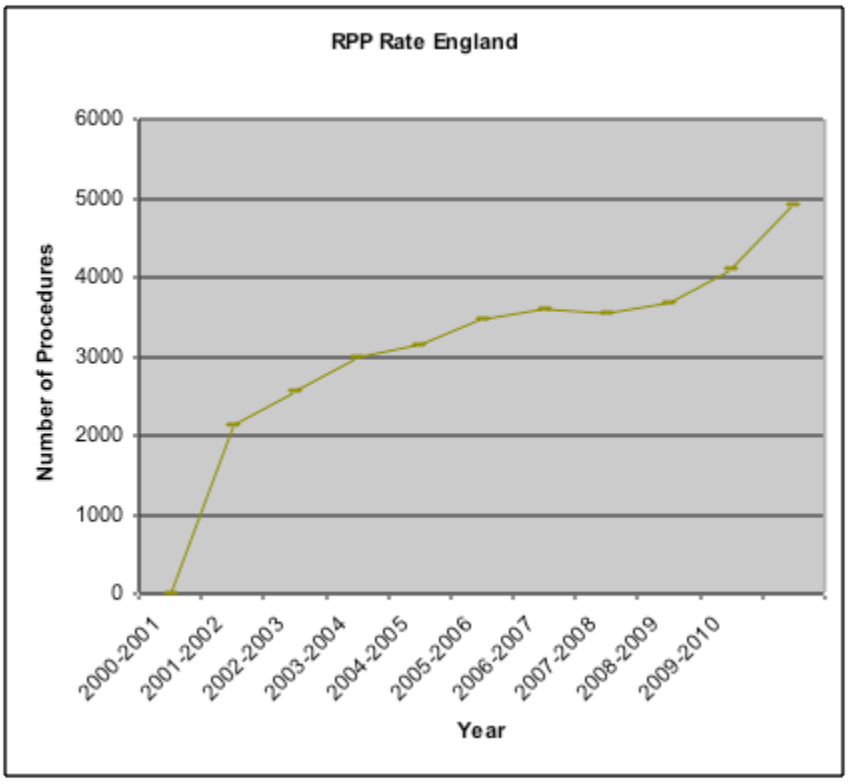
Annex A

Summary chart detailing range of number of cases performed per Trust in 2008/2009 and 2009/10 (source: HES data)

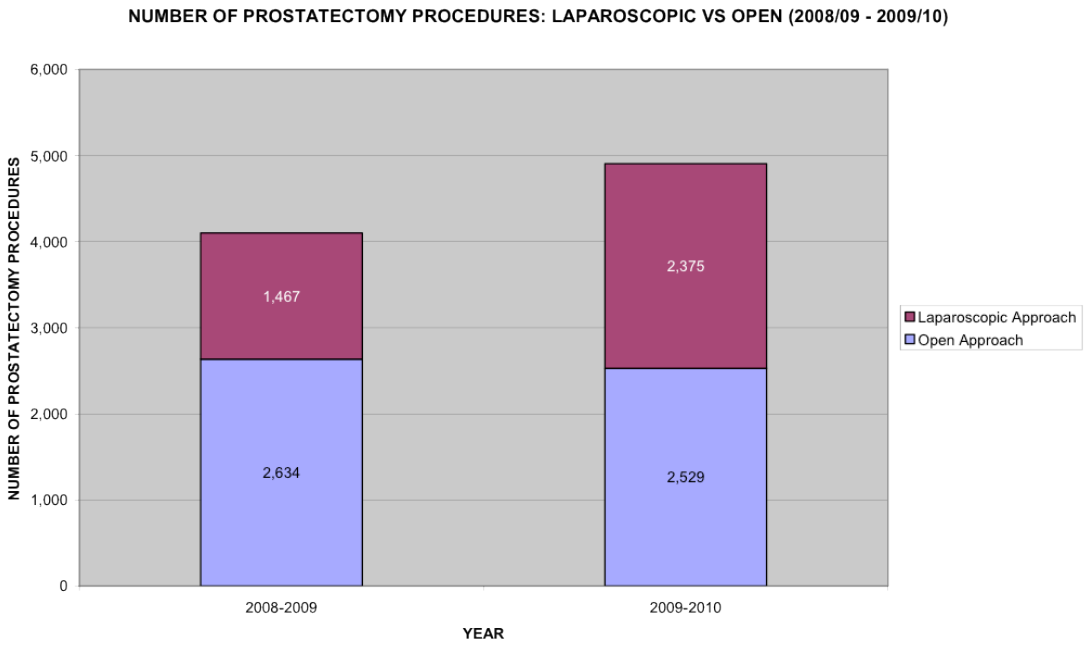
Annex B

Annual number of radical prostatectomies carried out in England 1997- 2010 (source: HES data)

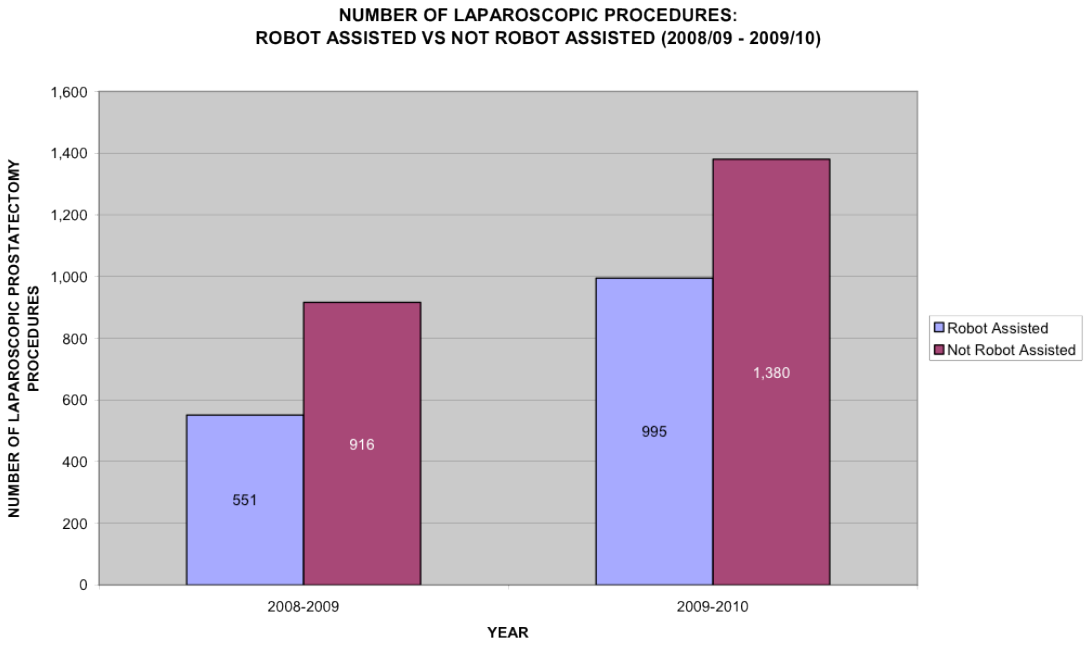


Annex C

Number of prostatectomies (open and laparoscopic) carried out in England – 2008/09 and 2009/10 (source: HES data)



Annex D


NUMBER OF LAPAROSCOPIC PROCEDURES:
ROBOT ASSISTED VS NOT ROBOT ASSISTED (2008/09 - 2009/10)
NUMBER OF LAPAROSCOPIC PROSTATECTOMY PROCEDURES
1,600
1,400
1,200
1,000
800
600
400
200
0
551
916
995
1,380
2008-2009
2009-2010
YEAR
Robot Assisted
Not Robot Assisted

Annex E

Hospitals in UK and Ireland with Da Vinci Robotic system installed (source: Intuitive Surgical Sep 2012)

1. Addenbrooke's Hospital, Cambridge
2. Barnet and Chase Farm Hospital, Enfield
3. Bradford Hospital
4. Broomfield Hospital, Essex
5. Christie Hospital, Manchester
6. Cork University Hospital, Ireland
7. Freeman Hospital, Newcastle
8. Frimley Park Hospital
9. Galway Clinic, Ireland
10. Guys Hospital, King's College London
11. John Radcliffe Hospital, Oxford
12. Kent and Canterbury Hospital, Canterbury
13. Lister Hospital, Stevenage
14. Mater Private, Ireland
15. Princess Grace Hospital, London
16. Royal Berkshire Hospital, Reading
17. Royal Liverpool Hospital
18. Royal Marsden Hospital, London
19. Royal Surrey County Hospital, Guildford
20. Southmead Hospital, Bristol
21. St George's Hospital, London
22. St Mary's Hospital, London
23. St. James's Hospital, Leeds (2 systems currently)
24. The London Clinic, London
25. The Wellington Hospital, London
26. Torbay Hospital, Devon
27. University College London Hospital, London
28. Wexham Park Hospital, Slough

Annex F

Percentage of radical prostatectomy procedures carried out in England in 2008/09 and 2009/10 (source: HES data)