SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST

EXECUTIVE SUMMARY
REPORT TO THE BOARD OF DIRECTORS
HELD ON 17th JULY 2013

Subject	Robotic Surgery at STH
Supporting TEG Member	Kirsten Major, Director of Service Development Neil Priestley, Director of Finance
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Status[1]	A*

PURPOSE OF THE REPORT

- To present and seek Board of Director support for the CIT and TEG-approved multi-directorate business case for robotic surgery;
- To provide a potential timeline for implementation in the context of Commissioner involvement;
- To request authorisation for purchase contingent upon Commissioner support and available capital funds.

KEY POINTS

- The February Capital Investment Team (CIT) meeting approved the attached Full Business Case for the purchase of a da Vinci Robotic Surgical System (dVSS) at the capital cost of £2.6 million under the proviso that final authorisation was required from both the Trust Executive Group and the Board of Directors.

- The Trust Executive Group recommended the referral of the full business case to the Board of Directors on 10th July 2013, recommending its approval.

- Surgical procedures use open or laparoscopic techniques. Laparoscopy is termed a minimally invasive procedure due to the small size of incisions required to perform the operation. However, minimal access surgery (MAS) is technically challenging, time-consuming, physically exhausting and potentially morbid even for the most proficient laparoscopic surgeons.

  The use of surgical robots to assist with these more complex operations has been evolving over the past 30 years and more recently MAS performed with the 'assistance' of the dVSS makes these complex aspects potentially simpler, safer, quicker and more effective to perform. The dVSS is the most advanced robotic technology available today and it has the ability to improve upon traditional open and laparoscopic surgery in several ways:

  1. The improved handling speeds up the performance of complex surgical procedures in hard to access areas such as the pelvis, retroperitoneum and oral cavity.
  2. The improved ergonomics and reduced operating times leads to less operator fatigue and reduced incidence of repetitive strain injury.
  3. The technology allows the learning curves of complex procedures to be shortened by a log factor (compared with standard laparoscopy), leading to reduced operating time and improved outcomes earlier in the adoption process.
  4. Improves training facilities for more junior surgical trainees.

  All of the above translate into improved clinical outcomes with more cost-effective use of the limited human and operating theatre resources available. For patients, this translates into improved functional outcomes, less blood loss (and associated transfusions), decreased length of hospital stay (LoS), less pain and quicker return to normal activities. For the Trust, it translates into better long-term utilisation of operating theatre facilities, reduced risk of litigation for poor clinical outcomes, reduced risk of occupational injury to the surgical workforce and improved status as a Cancer Centre: the operative precision and high-definition vision that the robot allows is particularly pertinent for cancer surgery as the oncological aims of en bloc tumour removal (with negative margins), regional lymph node dissection and reconstruction, whilst maintaining low morbidity, are all readily achievable.

  There are 29 dVSS systems in the UK, with further planned. Of the 28 cancer networks in England, 16 currently have a dVSS. The cities/ towns in England, with a dVSS installed include Liverpool, Manchester, Leeds, Newcastle, Wolverhampton, Oxford, Cambridge, London, Stevenage, Canterbury, Chelmsford, Barnet, Torbay, Reading and Bristol, with further installations approved in Bradford, Derby and Sunderland.

The STH Business Model is a collaboration across five surgical specialties (Urology, Gynaecology, Colo-rectal, Endocrine and Head & Neck Surgery) and the Department of Oncology (University of Sheffield). Given the trends in increasing demand driven by an ageing population, public awareness and choice, it is anticipated that within 3 years, the annual volume of NHS cases going through the robotic facility will exceed 500 cases.

The focus of the use of the technology will mainly be for cancer patients with procedures and diagnoses including radical prostate cancer surgery, radical cystectomy for bladder cancer, hysterectomy, throat cancer and colo-rectal cancer. Based on the data available from meta-analyses, dVSS-assisted surgery has demonstrated safety and outcomes that are at least equivalent to those of open surgery in terms of mortality and oncological safety, with the advantages of MAS of reduced morbidity.

The dVSS would be located in a dedicated theatre at the Royal Hallamshire Hospital and will be permanently available for use (at least) 5 days (10 sessions) a week.

- CIT also stipulated that Commissioner (NHS England and CCGs) support be secured given their liability for the additional cost of robotic consumables which are classified as cost per case tariff exclusions. The additional cost to Commissioners over the 3-year period required to reach full robotic capacity will be:

Year	Cases	Consumable Cost to Commissioners
1	310	£510,100
2	416	£693,360
3	481	£804,360

There are however cost savings to Commissioners from robotic surgery. These are difficult to estimate and extrapolate, however they include reduced intervention for erectile dysfunction and incontinence post-prostatectomy and reduced adjuvant radiotherapy and lifelong androgen deprivation therapy resulting from decreased positive surgical margin rates.

- The Business Case was presented to the Regional Cancer Board (Strategy Group) on 5th July requesting that the group consider the business case put forward by STHFT, consider the priority of this development, and provide advice and or recommendation to CCG / South Yorkshire Commissioners.

- If Commissioner and Board of Director support is forthcoming, an October 2013 installation of a dVSS would be targeted.

- Given experience of similar installations elsewhere, positive media coverage is anticipated and Communication Team support is likely to be required.

IMPLICATIONS[2]

AIM OF THE STHFT CORPORATE STRATEGY 2012-2017		TICK AS APPROPRIATE
1	Deliver the Best Clinical Outcomes	✓
2	Provide Patient Centred Services	
3	Employ Caring and Cared for Staff	
4	Spend Public Money Wisely	✓
5	Deliver Excellent Research, Education & Innovation	✓

RECOMMENDATIONS

The Board of Directors is asked to approve the purchase of the dVSS contingent upon Commissioner support and available capital funds.

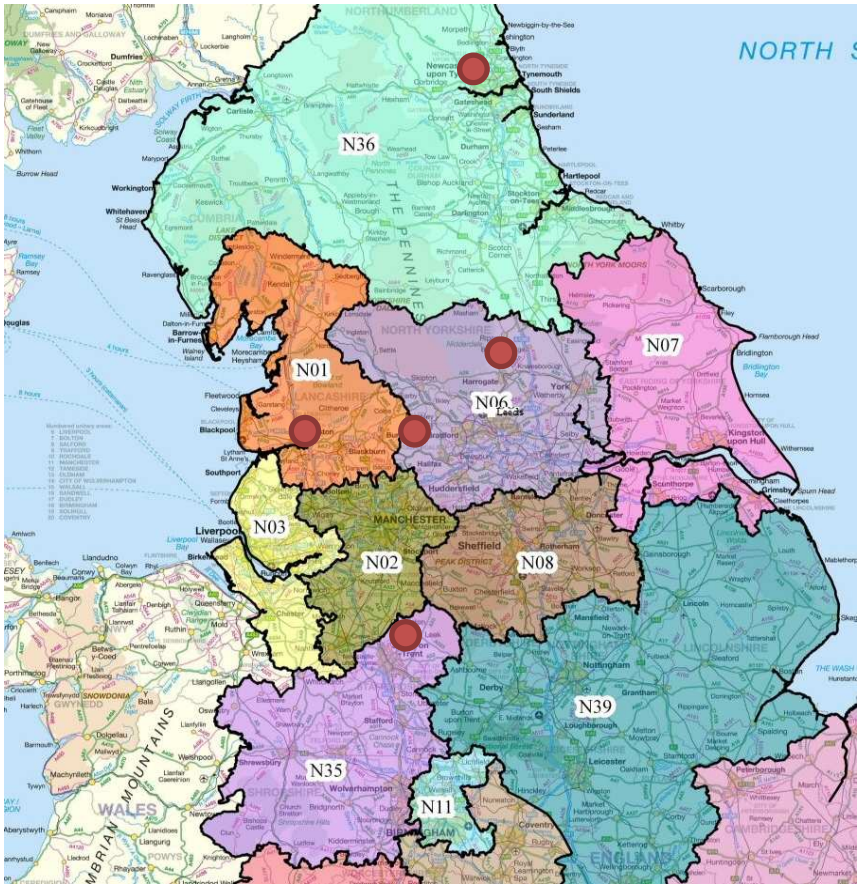
APPROVAL PROCESS

Meeting	Date	Approved Y/N
Capital Investment Team	February 2013	Y
Trust Executive Group	July 2013	Y

[1] Status: A = Approval
A* = Approval & Requiring Board Approval
D = Debate
N = Note

[2] Against the five aims of the STHFT Corporate Strategy 2012-2017

Sheffield Teaching Hospitals NHS Foundation Trust Business Case for the Provision of Robotic Surgery in South Yorkshire



May 2013

Sheffield Teaching Hospitals NHS Foundation Trust
Business Case

General Information

Project Provision of Robotic Surgery in South Yorkshire

Project Leads Chris Powell-Wiffen, Deputy General Manager, Surgical Services
Derek Rosario, Senior Lecturer and Hon. Consultant Urologist

Project Sponsors Kirsten Major, Director of Strategy and Planning
Michael Harper, General Manager, Surgical Services
Julie Ward, General Manager, Head/Neck/Gynaecology

Colo-rectal Surgery
Mr Shwan Amin,
Mr Keith Chapple
Mr Steve Brown

Endocrine Surgery
Mr Saba Balasubramanian

Gynaecology Oncology
Mr Alan Gillespie
Miss Fiona Kew
Mr John Tidy
Dr Julia Palmer

Benign Gynaecology
Mr Andrew Baxter

Head and Neck Surgery
Mr Afshin Yousefpour
Mr Ala Jebreel

Urology
Mr Derek Rosario
Mr Neil Oakley
Mr James Catto
Mr Mark Haynes
Mr David Yates

Clinical Directors of Respective Directorates:

Mr Jaydip Ray, ENT
Mr Paul Skinner, General Surgery
Mr Andrew Farkas, Obstetrics, Gynaecology & Neonatology
Professor Ian Brook, Oral & Dental
Mr Ken Hastie, Urology

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Minimal Access Surgery and Surgical Robotic Technology

With the development of the rod lens system by Harold Hopkins in 1966, the era of minimal access surgery (MAS), designed to reproduce the results of the traditional open major procedures, dawned. Initially limited to Urological procedures (transurethral resection of the prostate - TURP) and gynaecology (diagnostic laparoscopy), interventional MAS became mainstream with the adoption of laparoscopic cholecystectomy as the standard of care for gallstones. Despite the absence of clinical evidence of benefit, the demand for MAS increased throughout the late twentieth century, with a laparoscopic equivalent to most common surgical procedures described in the medical and lay press. The use of surgical robots to assist with more complex operations has been evolving over the past 30 years. A number of technologies have been introduced, starting in 1991 with the PUMA/ProBOT system for TURP, through to 1995 with the AESOP system to assist laparoscopic surgery and to 1998 with the ZEUS system developed by *Computer Motions*, which consisted of 3 robotic arms. In 2000, the FDA in the United States approved the da Vinci Surgical System (dVSS), developed and marketed by *Intuitive Surgical.* In 2003, *Intuitive Surgical* acquired *Computer Motions*, with the combined research and innovation budget being dedicated to further development of the dVSS. The dVSS has undergone several modifications following the first ever description of a robotic-assisted radical prostatectomy performed with it in Paris in 2000, although no dramatic change has taken place in the past 3 years.

The most advanced robotic technology available today, the dVSS enables surgeons to perform delicate and complex operations through small incisions with increased vision, precision, dexterity and control. The latest dVSS model is the 4-arm Si system, introduced in April 2009. The dVSS Si comprises a surgeon's console (with dual console capability), a robotic cart with four arms manipulated by the surgeon at the console and a HD 3D vision system. Articulating surgical instruments mounted on the robotic arms are introduced into the body through traditional laparoscopic style 'ports'. The system detects and filters out tremors in the surgeon's hand movements, so as not to duplicate them. The camera (mounted on a robotic arm) gives stereoscopic images that transmit to the surgeon's console. The surgeon at the console controls both the camera arm and instrument arms. Remote monitoring of system performance is provided via network links with Intuitive Surgical and as such potential problems can often be identified before they manifest themselves.

As things stand, and have stood for the past 12 years, *Intuitive Surgical* has a monopoly market position, with no similarly capable technology visible on the horizon. The dVSS was approved by the US FDA in 2000 and has been awarded a European CE mark. Given the lead-time between emergence of technological innovations and acquisition of clinical outcome data, as well as the time taken for regulatory-authority approval, it is unlikely that any competitor with similar capability, and the ability to provide a platform that can be upgraded, will emerge within the next 5 to 10 years.

The dVSS has the ability to improve upon traditional open and laparoscopic surgery in several ways:

5. The improved handling speeds up the performance of complex surgical procedures in hard to access areas such as the pelvis, retroperitoneum and oral cavity.

6. The improved ergonomics and reduced operating times leads to less operator fatigue and reduced incidence of repetitive strain injury.

7. The technology allows the learning curves of complex procedures to be shortened by a log factor (compared with standard laparoscopy), leading to reduced operating time and improved outcomes earlier in the adoption process.

8. Improves training facilities for more junior surgical trainees.

All of the above translate into improved clinical outcomes with more cost-effective use of the limited human and operating theatre resources available. For patients, this translates into improved functional outcomes, less blood loss (and associated transfusions), decreased length of hospital stay (LoS), less pain and quicker return to normal activities. For the Trust, it translates into better long-term utilisation of operating theatre facilities, reduced risk of litigation for poor clinical outcomes, reduced risk of occupational injury to the surgical workforce and improved status as a Cancer Centre: the operative precision and high-definition vision that the robot allows is particularly pertinent for cancer surgery as the oncological aims of en bloc tumour removal (with negative margins), regional lymph node dissection and reconstruction, whilst maintaining low morbidity, are all readily achievable.

The Clinical Case for a dvSS

Surgical procedures use open or laparoscopic techniques. Laparoscopy is termed a minimally invasive procedure due to the small size of incisions required to perform the operation. However, more complex procedures that require suturing, extensive dissection and reconstruction are technically challenging, time-consuming, physically exhausting and potentially morbid even for the most proficient laparoscopic surgeons. Minimally invasive surgery performed with the 'assistance' of the dVSS makes these complex aspects potentially simpler, safer, quicker and more effective to perform. All existing experienced surgeons require a period of training to be able to perform a competent robot-assisted laparoscopic operation.

Although the initial introduction of laparoscopic surgery was not associated with any clinically-proven benefits, in the era of evidence-based medicine, data have been collected to establish whether or not the introduction of the dVSS is associated with clinical benefit. Analyses of large mature datasets have demonstrated significant clinical advantages with published evidence of its safety, benefits (patient and surgeon) and decreased learning curve. A recent meta-analysis of 286,876 patients who had undergone open, laparoscopic or robotic-assisted radical prostatectomy (for prostate cancer) in the USA has shown significant benefits for robotic surgery in terms of operative time, cancer clearance (as shown by negative surgical margins) and peri-operative complications. A recently published (late 2012) systematic review (Health Technol Assess. 2012;16(41):1-313. doi: 10.3310/hta16410) entitled "A Systematic review and economic modelling of the relative clinical benefit and cost-effectiveness of laparoscopic surgery and robotic surgery for removal of the prostate in men with localised prostate cancer" identified 2,722 potentially relevant titles and abstracts, from which 914 reports were selected for full-text eligibility screening. The review:

- Demonstrated that the outcomes were better for robotic than for laparoscopic surgery for major adverse events such as blood transfusion and organ injury rates and for rate of failure to remove the cancer. The predicted probability of a positive margin was 17.6% following robotic prostatectomy compared with 23.6% for laparoscopic prostatectomy;
- Concluded that robotic prostatectomy had lower perioperative morbidity and a reduced risk of a positive surgical margin compared with laparoscopic prostatectomy.
- Suggested via its economic analysis that the reduction in positive margins for robotic radical prostatectomy was associated with an incremental cost per quality-adjusted life-year lower than threshold values typically adopted by the NHS (£30,000) and is further reduced in high volume centres.
- Concluded that although Robotic prostatectomy is more costly to the NHS because of the fixed capital and maintenance charges for the robotic system, the excess cost can be reduced by maintaining a high case volume for each robotic system of at least 100-150 procedures per year.

Similar results have been described in Gynaecological surgery and more recently in colo-rectal surgery and head and neck surgery, where results with the DvSS are being found to be superior to conventional open surgery and to conventional laparoscopic surgery for more complex tasks.

The NHS outcomes framework (Improving Outcomes: a strategy for cancer (DoH Jan 2011)), requires providers to improve outcomes for patients and begins to describe a different set of outcomes, for example the speed at which a person recovers from surgery or resumes being economically active following surgery. Acquiring a Surgical Robot will assist particularly in achieving improvements highlighted in **bold** in the table below:

Outcome	Indicators	Areas for Improvement
Preventing people from dying prematurely	One-year and five-year cancer survival rates	• **mortality from cancer** by age • cancer patients diagnosed as an emergency admission or attendance (proxy for survival) • proportion of cancer diagnosed at stage 1 and 2 • inequality gaps between different populations • active treatment rates • **31 and 62 day waiting time standards for Cancer**
Enhancing quality of life for people with long term conditions	Prescribing rates for drugs for erectile dysfunction	• **Cancer PROMs and surveys of cancer survivors** • **proportion of working age cancer survivors who are able to work and are in work** • **proportion of children or young people cancer survivors in education or employment** • **proportion of survivors living independently** • GP usage of diagnostic tests
Helping people to recover from episodes of ill health or following injury	Average return to work following MAS	• **recovery after cancer surgery** • **return to normal activities** • less ill health associated with cancer treatment • proportion of people reporting unmet psychological support following cancer treatment
Ensuring people have a positive experience of care	Patients choose surgical method they want	• **annual cancer patient experience surveys** • experience of patients at Trust level • surveys of bereaved relatives (proxy to assess quality of care given at the end of life)
Treating and caring for people in a safe environment and protecting them from harm	Quicker recovery and return to normal activities	• 90-day mortality following completion of radical or adjuvant radiotherapy • 30-day mortality following palliative radiotherapy • wrong route chemotherapy • 30-day mortality following chemotherapy • **death or severe disability following surgery** • **case mix adjusted 30-day mortality post surgery and morbidity post surgery**

Training Implications of the dVSS

The place of MAS in surgical training is procedure and specialty dependant. For example, in general surgery, laparoscopic cholecystectomy is considered a core index operation for certificate of completion of training (CCT) whereas in Urological surgery, laparoscopic procedures are considered to be outside the requirements for CCT. In any case, complex pelvic surgery in Gynaecology, Colo-rectal surgery and Urology are all post-CCT cases, learned by trainees in post-CCT fellowships. Whereas laparoscopic fellowships were extremely popular 10 years ago, the current crop of trainees are more focussed on Robotic

fellowships, namely to train on a dVSS. Several such fellowships exist in North America and Continental Europe, with increasing numbers now being offered in England, as the number of dVSS systems in place increases.

In Urological training programmes, Robotic fellowships are now being offered and being taken up by the most able senior trainees. Fellowships for training in complex laparoscopic procedures are no longer as freely available, thus recruitment in the near future of trained laparoscopic surgeons will not be possible.

For surgeons 'in-training', the assistance of the dVSS shortens the learning curve for a variety of operations. Taking ventral rectopexy as an example (correction of a rectal prolapse), it takes between 50 and 100 supervised cases, depending on previous experience, to master a laparoscopic ventral rectopexy. During this time, supervision by another trained specialist is necessary to maintain standards. With the dVSS, this learning curve is reduced to fewer than 15 cases. This has a dual benefit, allowing earlier independent surgical activity with good results in the novice, whilst releasing the experienced 'mentor' from time-consuming supervision. A recent UK systematic review has demonstrated a significantly reduced learning curve for robotic radical prostatectomy surgery versus standard laparoscopy (30 cases versus 250 cases). In Sheffield, where approximately 100 radical prostatectomies are carried out annually, this translates to having 2-3 fully-trained surgeons within a year, rather than taking 3-4 years for a fully trained laparoscopic surgeon to develop.

It must also be noted that complex laparoscopic operations are usually long procedures with surgeons stood, often in poor ergonomic positions, for protracted periods of time. This leads, over time, to musculo-skeletal problems with spine, shoulders, neck and lower limbs. There is evidence to indicate that the use of a robot removes the strain on the musculo-skeletal system and thus will potentially prolong the number of years of surgical activity for an individual surgeon.

The Strategic Case

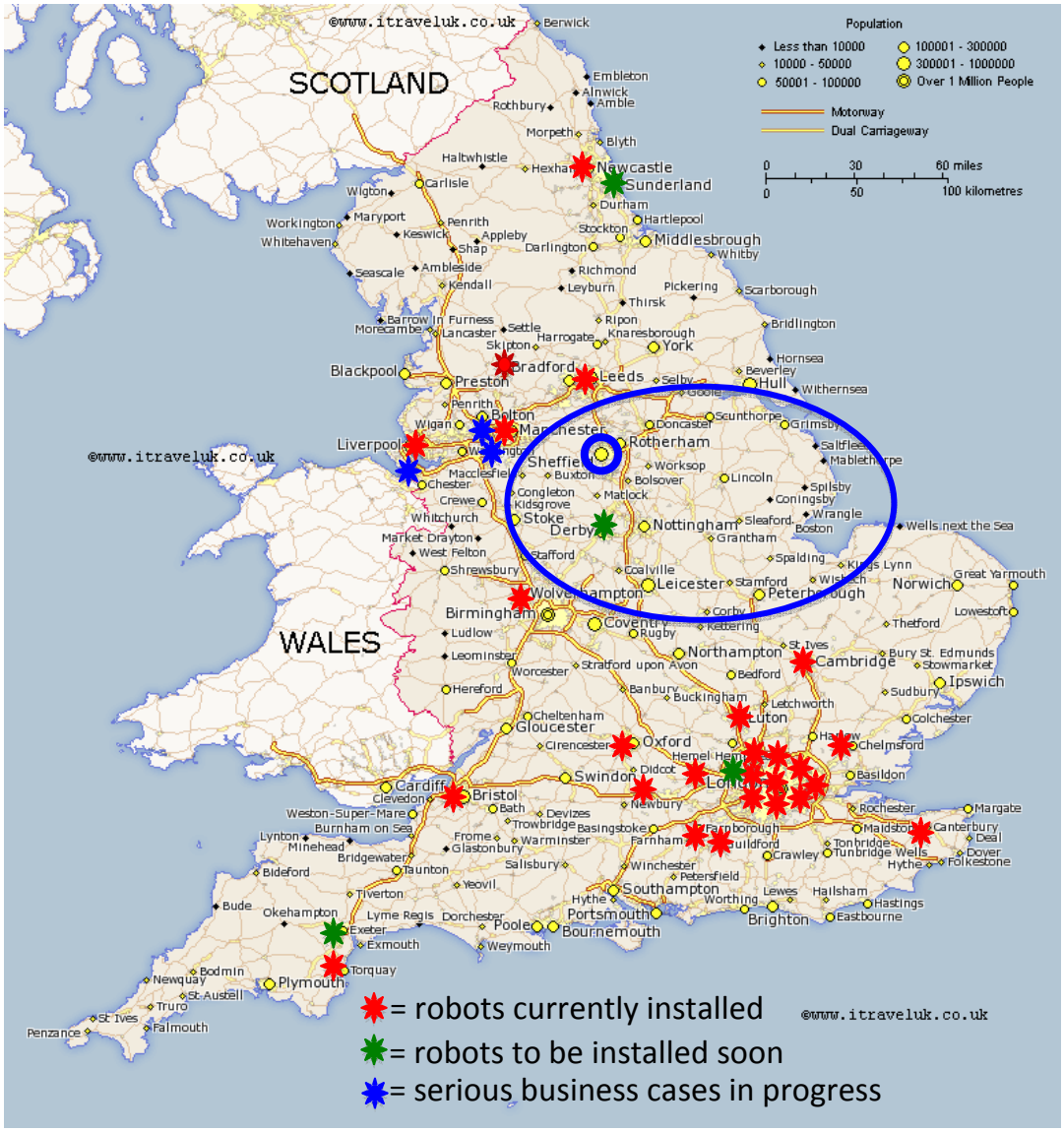
No other 'robotic' device has the track record, worldwide adoption and acceptance, international regulatory approval and advantages specific to the dVSS. There has been an exponential rise in the number of dVSS installed worldwide. To date a total of 2,132 have been installed, 1,548 in the USA, 372 in Europe (29 in UK) and 212 in the rest of the world. In 2011, 534 dVSS were sold compared to 441 in 2010. Approximately 360,000 operations across all surgical specialties were performed using a da Vinci robot in 2011, the greatest volume in Urology and Gynaecology. In the USA, 85% of radical prostatectomies in 2011 were performed using the dVSS compared with 5% in 2000.

Between 1995 and 2005, the number of laparoscopic radical prostatectomies for prostate cancer was increasing, driven by the demand for MAS. Since 2006, almost no standard laparoscopic radical prostatectomies are currently being performed in the USA. The first dVSS was installed in the UK in 2004 and uptake in the UK has been slower than in the USA and continental Europe. Nevertheless, it seems likely that the trends seen on both sides of the Atlantic will be repeated here, driven in this case by a combination of patient-demand and the demonstration of superior clinical results. Internationally, robot-assisted hysterectomy (dVH) is the highest volume robotic procedure performed worldwide, with volumes growing from approximately 110,000 cases in 2010 to approximately 146,000 cases in 2011, of which approximately 39,000 were for the treatment of cancer and the remaining 107,000 related to benign conditions.

Intuitive Surgical has installed 29 systems in the UK, with a further handful being planned (Figure 1). Of the 28 cancer networks in England, 16 currently have a dVSS. The cities/ towns in England, with a dVSS installed include Liverpool, Manchester, Leeds, Newcastle, Wolverhampton, Oxford, Cambridge, London, Stevenage, Canterbury, Chelmsford, Barnet,

Torbay, Reading and Bristol, with further installations approved in Bradford, Derby and Sunderland.

Figure 1- dVSS 'robots' Installed in England as of Dec 2012



To date, 29 robots installed in UK, covering 16/28 cancer networks.

As illustrated, a robot at STH could strategically open up potential referrals to STH from a large non-STH population

The Research Case

Investment in Robotic Surgery would bring with it an increased potential for research. For example, the dVSS facilitates the use of 'near infrared fluorescence imaging' which is being increasingly used as an aid to intraoperative assessment and complete resection of cancer in a number of different organs. The Endocrine Surgery Sub-Specialty is beginning a study in collaboration with Fluoptics, in quarter 2 of 2012/13. This project will assess use of this technology in open endocrine surgery. However, there are clearly trends to use this approach in laparoscopic and robotic cancer resections as well.

Moreover, given the dearth of randomised control trials examining the impact of robotic surgery, there is a clear opportunity for patients in South Yorkshire to contribute to this field of research.

The Business Model at STH

The STH Business Model is a true collaboration across five surgical specialties (Urology, Gynaecology, Colo-rectal, Endocrine and Head & Neck Surgery) and the Department of Oncology (University of Sheffield). In 2011, approximately 360,000 surgical procedures were performed world-wide with the da Vinci Surgical System, up approximately 29% compared to 2010. Given the trends in increasing demand driven by an ageing population, public awareness and choice, it is anticipated that within 3 years, the annual volume of NHS cases going through the robotic facility will exceed 500 cases.

There is strong evidence that the benefits to patient care (reduced blood loss, length of stay and recovery) are applicable to all these specialties. The focus of the use of the technology is mainly for cancer patients with procedures and diagnoses including radical prostate cancer surgery, radical cystectomy for bladder cancer, hysterectomy, throat cancer and colo-rectal cancer. Based on the data available from meta-analyses, dVSS-assisted surgery has demonstrated safety and outcomes that are at least equivalent to those of open surgery in terms of mortality and oncological safety, with the advantages of MAS of reduced morbidity. Index procedures for the dVSS in Urology include robotic-assisted radical prostatectomy (RARP), robotic-assisted radical cystectomy (RARC) and Partial Nephrectomy (RAPC). Index procedures in gynaecology include Hysterectomy, Myomectomy and Sacral Colpopexy. Target procedures in general surgery include da Vinci Colon Resection within Colo-rectal and Trans/Retroperitonal Adrenalectomy in Endocrine surgery. Lastly, in Head and Neck surgery, they include da Vinci Trans-oral Robotic Surgery (TORS).

The dVSS would be located in a dedicated theatre at the Royal Hallamshire Hospital and will be permanently available for use (at least) 5 days (10 sessions) a week. The theatre robot timetable has been devised over 2 weeks (20 sessions) and sessions have been allocated according to specialty caseload and robot demand.

Multi-Specialty Utilisation

1. Urology

The target Urology cases for robotic surgery include robotic-assisted radical prostatectomy (RARP), robotic-assisted radical cystectomy (RARC), partial nephrectomy (RAPN) and pyeloplasty. RARP is the 'index' case appropriate for the dVSS and this is reflected in the fact that in 2011, 85% of radical prostatectomies in the USA were performed robotically compared to 5% in 2000. In 2011, 113,000 RARPs were performed worldwide, compared to 98,000 in 2010. The majority of the 2011 worldwide RARP growth came from European markets, led by Germany and France. It is envisaged that 90% of the Trust's radical prostatectomies will be performed robotically within the first year. The default position for any male patient needing a prostatectomy will be a RARP unless precluded by specific adverse disease or patient parameters. After Year 1, we will commence a RARC program and predict that 40-50% of our radical cystectomies will be appropriate for a robot-assisted procedure. In terms of partial nephrectomy (PN), the robot platform makes significant advances on both open and laparoscopic methods. It is superior to open PN as it removes the need for a large painful potentially morbid (neuralgia, hernia, cosmesis) loin incision. It is also preferable to laparoscopic PN as the dexterity and precision of the robot instruments allow for much more time efficient suture haemostasis with all the benefits of lower blood loss and preserved renal function. The dVSS HD 3D vision also allows for more accurate tumour excision and the robot increases the threshold for more complex larger masses to be treated by robotic partial nephrectomy.

2. Gynaecology Oncology

Mr Alan Gillespie introduced laparoscopic surgery into the Department of Gynaecological Oncology following his consultant appointment in 2003. Numerous surgical procedures have been safely introduced including laparoscopic hysterectomy, laparoscopic radical surgery and bariatric gynaecological surgery. Accompanying service developments have ensured that the laparoscopic work performed by the Gynaecological Oncology team is now recognised as being amongst the best in the country in terms of length of stay.

The surgical Gynaecological Oncology Team currently consists of four members of whom two perform substantive laparoscopic surgery. Informal subspecialisation within the surgical team maximises the potential for offering MAS to appropriate patients. However, given: (a) the overall Gynaecological Oncology capacity / workload; (b) the framework of cancer management guidelines; (c) current surgical skill mix, there is currently no capacity to further expand the number of patients benefitting from MAS without investment in a dVSS.

Mr Gillespie is Clinical Lead for the Surgical Robot in the Obstetrics and Gynaecology Directorate. He is also the Lead Clinician for Gynaecological Oncology. In addition to the expected background work visiting established robotic surgical centres and attendance at national and international robotics meetings, he has prepared the Gynaecological Oncology Team for the introduction of the Surgical Robot by (a) becoming a founder member of the European Society of Robotic Surgeons (SERGS); (b) becoming a founder member of the British and Irish Society of Robotic Surgeons (BIARGS); (c) negotiating and facilitating the Robotic Surgery training of the previous Gynaecological Oncology Subspecialty Trainee, the first such fellowship in the UK; (d) provisionally agreeing a training package with Intuitive Surgical to ensure surgical competency and safe introduction of the Robot in Gynaecological Oncology; (e) publishing a review article on the Gynaecological utilisation of the Robot with the President of BIARGS.

As stated, the Gynaecological Oncology Team at STH is recognised as having the lowest length of stays for laparoscopic work of any comparable unit in the country. Further reductions in length of stays with the use of the Surgical Robot would be anticipated with a change in service configuration of peri-operative care with the aim of achieving a routine day case hysterectomy service. All members of the surgical team have now indicated that they would wish to train in the future in laparoscopic assisted robotic surgery. A formal agreement between the Team members would be forthcoming that in achieving such training the aim of the Specialty would be to offer MAS to all appropriate patients falling within its remit.

Benefits would include an increase in longevity of the MAS surgical team members; enhancement of STH's reputation as a forward thinking Cancer Centre; and increased ability to attract high quality trainees in the future.

3. Benign Gynaecology

STH has a long and established history of laparoscopic surgery within benign gynaecology, especially in the areas of reproductive medicine and in the treatment of endometriosis.

Mr Andrew Baxter took up his Consultant post in 2002 having completed a Fellowship in minimal access surgery. He undertakes laparoscopically assisted and laparoscopic subtotal hysterectomies for benign conditions and laparoscopic pelvic floor surgery. His major interest however is the surgical treatment of endometriosis and he is responsible for the laparoscopic and open management of the women with severe, recto-vaginal endometriosis within the unit. These procedures are performed in conjunction with Mr Ian Adam, Consultant colo-rectal surgeon.

Current practice is to manage bowel adhesiolysis or disc excision cases laparoscopically. When bowel resection is required, the cases are converted to open surgery. The main advantage of introducing robotic surgery into endometriosis surgery therefore is to convert these open bowel resection procedures into MAS ones, delivering the established benefits of reduced morbidity, pain levels and quicker recovery for our patients. It is also anticipated that some procedures currently being performed laparoscopically will be converted to robotic ones, with the subsequent surgical advantages.

Converting these cases of severe recto-vaginal endometriosis to MAS will allow STH to become a National Endometriosis Centre. This network of units in the UK has been established by the British Society of Gynaecological Endoscopy to optimise the treatment and evaluation of women with severe endometriosis. Membership is limited to units who deal with these cases laparoscopically, as it is thought the MAS approach represents best practice. In becoming such a centre, we will ensure that our surgical data and patient outcomes are prospectively audited and compared to national and international benchmarks, allowing us immediate and prospective monitoring of our practice on the robot.

Internationally, robot-assisted hysterectomy (dVH) is the highest volume robotic procedure performed worldwide, having surpassed RARP in 2010. dVH procedure volume grew from approximately 110,000 cases in 2010 to approximately 146,000 cases in 2011, of which approximately 39,000 were for the treatment of cancer and the remaining 107,000 related to benign conditions. It is also achieves excellent outcomes for sacrocolpopexy and endometriosis. Furthermore the robot will increase STH's credentials as a centre of MAS excellence, increasing the Trust's ability to attract high quality trainees.

4. Endocrine Surgery

The current approach to the resection of adrenal tumours is open (for large tumours) and minimally invasive (either transperitoneal or retroperitoneal) for smaller tumours; the latter constitute the majority of adrenalectomy procedures being performed in Sheffield. Robotic Adrenalectomy is emerging as a viable alternative to these techniques and has the potential to reduce the volume of surgery being performed with the open technique. Robotic adrenalectomy has been shown to be associated with shorter operative time and less pain when compared to the traditional laparoscopic approach. Moreover, the use of a robotic approach for large adrenal tumours has the added advantage of a lower 'conversion to open' rate.

The use of the robot for adrenal surgery has the potential to increase referrals for adrenalectomy from outside the region and may also facilitate the introduction of robotic surgery for other retroperitoneal procedures such as the retroperitoneal sarcoma and retroperitoneal lymph node dissection.

5. Head & Neck Oncology

Head and neck squamous cell carcinomas are the 6th most common cancer worldwide. There is increasing incidence of the disease and a shift in demographics to a younger population that is typically high functioning with lower rates of co-morbidities. The overall disease-free survival rates in this patient group are better than previously observed, so long-term quality of life considerations are increasingly important.

Surgical treatment of tumours of the tongue base involves major resective and reconstructive surgery, involving significant morbidity. The suffering associated with facial disfigurement and oral dysfunction is a considerable burden following surgery.

TORS is an emerging treatment option for the treatment of head and neck malignancies, particularly for base of tongue tumours. Preliminary studies have demonstrated excellent

oncologic and functional outcomes. Emerging evidence suggests that effective primary surgical management of these malignancies may provide an opportunity for less aggressive adjuvant treatments, with resultant improvements in patient's quality of life.

The surgical robot offers the benefit of infield optics via the double video endoscope, so line-of-sight issues associated with more traditional transoral techniques are overcome. This factor, combined with the valuable 3-dimensional imagery and tremor filtration allow for accurate dissection of tissue planes in a way not previously possible.

It is estimated that 25 base of tongue cases per year could benefit from TORS. TORS has been shown to have the following potential benefits compared to traditional approaches:

- Avoidance of disfiguring mandibulotomy
- Minimization or elimination of need for chemo-radiation, the current first line treatment
- Avoidance of tracheostomy
- Quicker return to normal speech and swallowing
- Significantly less pain
- Decreased blood loss
- Shorter recovery time and reduced length of stay – from 21 days to 7 days

6. Colo-rectal Surgery

Minimally-invasive surgery with a surgical robot offers potential in rectal resections for Cancer patients and Irritable Bowel Disease (IBD) patients, helping with the technical difficulties in this complex surgery and allowing more surgeons to offer MAS.

Laparoscopic ventral rectopexy is commonly used as treatment for weak pelvic floor function and robot assisted surgery would simplify this procedure, potentially improving outcomes. The literature for robotic versus laparoscopic assisted rectopexy is limited. Data that is available suggests the procedure is equivalent in terms of safety and efficacy. A laparoscopic ventral rectopexy requires a significant learning curve (estimated 50 cases). A robot could reduce this curve substantially (estimated 15 cases) and remove the need for dual consultant supervision.

Currently patients who undergo a laparosopic ventral rectopexy require approximately 2 days hospital stay. It is proposed that the use of a robot would be linked in with a patient pathway that may allow same day or 23 hour discharge. An audit is being carried out to assess reasons for discharge delay (catheter removal, pain relief, patient expectations) and a pathway document including a patient information sheet and pre-assessment documentation will then be completed to allow introduction of such a pathway.

Option Appraisal

In light of the aforementioned strategic and clinical cases combined with the multi-specialty approach, the Project Team explored potential options and identified the benefit criteria. These criteria were developed by the Project Team to cover benefits to the patient, STH and the Clinical Directorates that collaborated on this case. Definitions were derived to test the impact of the benefit and take into account external and internal factors. The benefits were weighted by the team and options scored according to perceived benefits.

4 viable options were identified, namely:

- Option 1 – Do nothing
- Option 2 – Invest in the dVSS system
- Option 3 – Expand traditional Laparoscopic capacity
- Option 4 – Postpone any decision for 2 years.

(A fifth option, to network with another Provider with a dVSS and purchase some capacity was initially considered but discarded as impractical, given the lack of a suitable local provider with sufficient spare capacity to cater for the activity volumes required.)

Option 1 (Do Nothing) carries the risk that patients may choose to travel out with the Network to have their surgery. Currently, 16 of 28 cancer networks in England have a robot and this includes the centres regarded as the major urology centres in England (London, Manchester, Bristol, Newcastle, Cambridge, Oxford). STH is also one of the major Urology centres in terms of procedure volume, held in high regard by the rest of UK Urology due to its high clinical and academic reputation. It is critical given the population size and incidence of cancers that patients are able to access the optimal treatment without onerous travel. There is also a risk that more motivated and informed patients will choose to travel while others would remain within the Network for their treatment.

Option 2 (Invest in the dVSS) entails the installation of dVSS surgical robotic technology into a dedicated operating theatre. The current capital cost for the two console dVSS represents the main risk of this option. The main benefits of this option are strategic and clinical, linked to health benefits such as improved continence and erectile function that the robot is likely to deliver as well as reduced LoS, primarily for those procedures where the operative technique will be converted from Open to Robotic. Furthermore, the dual console system costed in this option provides the ability to teach, train, and attract the highest calibre trainee doctors.

Option 3 (Expand Traditional Laparoscopic Capacity) will result in the need to invest in further laparoscopic capacity (surgeons, theatre teams and equipment), either by training existing surgeons or by new appointments. STH recently appointed an additional laparoscopic surgeon in Urology to keep pace with the demand on the service and has, through this appointment, been able to significantly reduce reliance on taking patients off site for their treatment within the 62 day cancer waiting time standard or to achieve the 18 week waiting time standard. However, increasing demand across all the Surgical Directorates will result in the need to invest in further laparoscopic capacity, either by training existing surgeons or by new appointments.

Analysis of comparative data shows the Trust benchmarks closely with other Trusts in terms of the number of surgeons in post. Comparison with other similar Teaching Centres indicates that the number of surgeons and spells per population in Leeds and Manchester are comparable. This means a case for substantially more surgical consultant posts is not likely to succeed given the level of current investment. Retraining therefore is the better way forward under this approach, however, as has been amply demonstrated, training even a single experienced surgeon in MAS for complex cancer surgery results in a learning curve lasting between 2 and 4 years, depending on volume. Additionally, there will be an impact upon capacity due to slower operating whilst becoming proficient. The costs of treatment for complications during the learning phase of each surgeon cannot easily be quantified but cannot be ignored, nor can the requirement for further treatment in the case of recurrent disease.

Option 4 (Postpone the Decision to Invest by 24 months) carries with it the main advantage of watching the market as technology evolves. The price of the technology may reduce as production efficiencies and technological advances are made or Intuitive Surgical may reduce the price if a competitor releases a rival machine to the market. STH has not seen a wholesale shift in the number of patients seeking care and treatment elsewhere to date and it is arguable therefore that it has already benefitted as an organisation from a period of watchful waiting to observe how the technology progresses. Nevertheless, this approach carries with it the risks inherent in option 1 (do nothing), both strategic and financial, for the period of delay. Furthermore, over recent years, the dVSS has proven itself as the most

advanced surgical robotic technology, with no clear competitor visible, despite extensive horizon scanning. No other so-called 'robotic' device has the track record, worldwide adoption and acceptance, international regulatory approval and advantages specific to the dVSS. Over the past 2 years, Intuitive shares have outperformed those of Apple, with no downwards movement of pricing of either the disposables or the surgical systems. With no immediate economic upturn likely it is difficult to see a fundamentally improved financial position emerging in the foreseeable future that would benefit the Network.

There would be the risk of being isolated from the leading edge of technology, being unable to provide an up-to-date training facility for MAS, potentially losing highly skilled and ambitious staff and, most importantly, the benefits foregone by not being able to offer this surgery to patients.

Scoring of the benefits of each option was carried out and options 1, 2, 3 and 4 were scored at 53, 161, 118 and 63 points respectively, giving the option to purchase the dVSS the highest relative score.

Financial Case

In its assessment of the capital cost (in the region of £2 million with maintenance costs of circa £150k per annum), STH has concluded there is a compelling case to purchase a surgical robot system for Sheffield.

Consumables

The Robotic consumables are multi-use (limited to ten procedures) and comprise 5 instruments at an average of £300 per use per consumable. Therefore the approximate cost per case is £1,500.

Robotic consumable instruments are part of the NHS PbR device exclusion list and therefore CCGs have been asked to consider the case for their separate reimbursement. A formal approach has been made to Commissioners as part of the 2013/14 contractual negotiations seeking acceptance of the robotic consumable costs. The additional cost to Commissioners over the 3-year period required to reach full robotic capacity will be:

Year	Cases	Consumable Cost to Commissioners
1	310	£510,100
2	416	£693,360
3	481	£804,360

Excluding as yet to be confirmed 'Glossectomy' at 25 cases per year maximum

An assessment of 2012/13 HRGs and associated procedure codes for those cases suitable for robotic intervention shows the following Commissioner split:

Commissioner	Proportion
BARNSLEY PCT	9.17%
BASSETLAW PCT	4.04%
DERBYSHIRE COUNTY PCT	9.17%
DONCASTER PCT	8.28%
ROTHERHAM PCT	7.69%
SHEFFIELD PCT	57.99%
OTHER	3.65%
Grand Total	**100.00%**

There are however cost savings to Commissioners from robotic surgery. These are difficult to estimate and extrapolate, however the examples provided below are typical and indicative. The consumable costs should therefore be viewed as a worst case scenario in terms of annual financial impact.

1. Erectile Dysfunction (ED)

dVSS use decreases ED at 12-months by 50% (from 50% to 25%). Assuming 83 men need ED treatment per year with PDE5 inhibitors (from 180 prostatectomies per year), this equates to an annual cost of:

A. £54,770 for Cialis 5mg od or
B. £53,764 for Cialis 20mg PRN twice weekly

Cost saving of dVSS: Approximately £27,000/year (half of either A. or B.) (est. £81,000 over 3 years).

2. Incontinence

dVSS use decreases 12-month pad dependence (from 10% to 5%) and absolute incontinence following prostatic surgery (from 5% to 2.5%) by 50%:

A. Incontinence pad usage: The current annual cost for incontinence pads is difficult to quantify precisely. Extensive discussion and collaboration with community continence service managers suggests an estimated annual cost per patient of £400 for patients in their own home and £550 for patients in a nursing home.

Cost saving of dVSS: Assuming significant incontinence reduced by 50% and an annual radical prostatectomy rate of 180, then the robot would save a minimum (i.e. assuming 100% home usage) of £3,200 per year (8 men x £400) and £9,600 over 3 years.

B. Artificial Urinary Sphincter insertion: Currently, around 9 (5%) men per year have significant incontinence and may require AUS insertion. The cost of the AUS is £8,300 each, equating to a total of around £74,700 per annum.

Cost saving of dVSS: If the robot reduces this potential need by 50% (to 4.5 men), this equates to a saving to the PCT of £37,350/yr approximately e.g. £112,050 over 3 yrs.

3. Cancer Outcomes

Positive surgical margin (PSM) is one surrogate marker for the rate of curative surgery. dVSS use decreases PSM rate by 6% overall (from 24% to 18%). This impacts upon the use of adjuvant DXT and lifelong androgen deprivation therapy (ADT)

A. Adjuvant radiotherapy for PSA: This equates to 11 patients being saved from needing adjuvant DXT. Adjuvant DXT to prostate bed costs approximately £9,000.

Cost saving of dVSS: £9,000 x 11 = £99,000 saved per year, £297,000 over 3 years.

B. ADT: Annual cost to PCT per patient for ADT is £828-940 depending on LHRH used. Assuming 50% of the patients who receive DXT will fail then 6 patients will avoid need for lifelong ADT. The average length of time from PSA failure to death post radical prostatectomy is 13 years so these patients (and PCT) will be spared ADT for this duration.

Further cost savings will be for men failing ADT who would receive systemic chemotherapy. These men will be spared expensive and morbid treatment. It is difficult to be sure of how many men this would affect (and so we have not included this cost).

Cost saving of dVSS: The robot would reduce the cost of ADT by £5,400 per year, £16,200 over 3 years and £70,200 over the lifetime of the patients.

4. Summary of Cost Savings

Complication	Treatment	1 year	3 year (cumulative)
Erectile Dysfunction		27,000	81,000
Incontinence	Pads	3,200	9,600
	AUS	37,350	112,050
Cancer Outcome	DXT	99,000	297,000
	ADT	5,400	16,200
Total		**£171,950**	**£515,850**

Conclusions / Recommendations

In addition to the clinical and strategic need, this business case, with its multi-specialty approach, demonstrates a model for productivity and efficiency. STH is one of the most successful and recognised trusts in the UK as well as being the designated cancer centre for the North Trent Cancer Network. It is an expectation from patients and referring clinicians that STH has state-of-the-art technology so as to be able to provide excellent contemporary management of patients as standard.

The purchase of a dVSS will be beneficial to the patient, the Trust and the wider healthcare community. However, this relies partly upon Commissioner support in funding for robotic consumables via the exclusion specified in HRG4. Nonetheless, the use of this technology has been demonstrated to be cost-effective should there be sufficient volumes undertaken (150+ cases - http://www.ncbi.nlm.nih.gov/pubmed/23127367). Benefits that will accrue financially to Commissioners will include reduced complications (e.g. incontinence) and lower levels of follow-up, facilitating the roll-out of community-based follow-up for prostate cancer as considered by Cancer Board at its May 2013 meeting.

Providing robotic surgery will ensure patients can access a high quality surgical service and enable STH to continue to be a leading trust and cancer care provider for the patients of North Trent and surrounding localities.