Institution: University of Leeds		
Unit of Assessment: 2		
Title of case study: Shaping the future of robotic surgical systems for rectal cancer		
Period when the underpinning research was undertaken: 2010-2018		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Julia Brown	Professor of Clinical Trials Research	1996-present
Claire Hulme	Professor of Health Economics	2007-2018
Period when the claimed impact occurred: 2016-present		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact (indicative maximum 100 words)

Robotic systems were introduced into surgical practice in 2001 at high cost and with no evidence of clinical benefit. Over 2011-15, the ROLARR trial randomised 471 patients with rectal cancer from 40 worldwide centres, to robotic or laparoscopic surgery. Robotic surgery was safe, with similar oncological outcomes and conversion rates. ROLARR has changed NICE guidance and focused surgical practice on technically difficult cases more likely to benefit from robotic surgery.

Economic analysis showed that robotic surgery was £1000 more expensive per case, driven by higher consumable costs and longer operating times. This influenced commercial thinking and on-going research, informing the design and evaluation of more versatile, affordable robotic systems.

2. Underpinning research (indicative maximum 500 words)

Robotic surgery was introduced into clinical practice in 2001, driven by commercial pressures, clinical enthusiasm, and promises of increased market share for healthcare providers. There was no evidence regarding clinical outcomes or cost effectiveness to inform international policy. The uncontrolled introduction of such an expensive technology (~£1.5M per robot) drew strong criticism and divided the clinical community.

The NIHR EME ROLARR trial (£1.2M, 2009-2016) addressed this evidence gap. It was led by a Leeds interdisciplinary research team with expertise in complex trials (Brown), surgical trials (Jayne in UoA1), and health economics (Hulme). ROLARR was an international study involving 40 surgeons from 29 sites in 10 countries providing, for the first time, a randomised evaluation of robotic versus laparoscopic surgery for rectal cancer – one of the main indications for robotic surgery [**1**].

The short-term outcomes from ROLARR, published in JAMA in 2017, showed that robotic rectal cancer surgery was as safe as laparoscopic surgery with similar oncological outcomes and functional outcomes [**2**]. Conversion to open surgery, the primary endpoint, was 8.1% robotic v 12.2% laparoscopic (adjusted odds ratio 0.61, 95% confidence interval 0.31 to 1.21), the complication rate was 33.1% for robotic v 31.7% for laparoscopic (OR 1.04; 95% CI 0.69 to 1.58); and resection margin positivity was 5.1% robotic v 6.3% laparoscopic (OR 0.78; 95% CI 0.35 to 1.76). Potential benefits were observed in technically difficult cases (males, obese patients, and low rectal cancer).

Robotic surgery was more expensive than laparoscopic surgery, with a mean difference in costs of

£1,000 per case and little difference in quality adjusted life years, making system and operating costs the main blockers to wider adoption [**3**]. However, costs were much lower than reported in non-randomised studies and included modifiable factors – increased operating time and expensive robotic instruments – highlighting the scope for making robotic surgery more affordable within the context of an NHS tariff of £15,000.

Importantly, sensitivity analysis explored the effect of surgeon learning curve on outcomes and revealed that the treatment-effect odds ratio decreases by a factor of 0.34 (95% CI 0.12 to 0.96) per unit increase in log-number of previous robotic operations performed by the operating surgeon. The odds ratio for conversion to open surgery for a patient whose operating surgeon had the mean experience level in ROLARR (152.5 previous laparoscopic, 67.9 previous robotic operations) was 0.40 (95% CI 0.17 to 0.95) [**4**]. This work defined the learning curve for robotic rectal cancer surgery as approximately 90 cases, much higher than previously reported.

Alongside the ROLARR RCT, funding was secured to explore the human factors associated with robotic and laparoscopic surgery using realist methods (Randell in UoA3). This defined the ideal conditions for system deployment and surgical team working to facilitate optimal implementation and utilisation [**5,6**].

3. References to the research (indicative maximum of six references)

[**1**] Collinson FJ, Jayne DG, Pigazzi A, Tsang C, Barrie JM, Edlin R, Garbett C, Guillou P, Holloway I, Howard H, Marshall H, McCabe C, Pavitt S, Quirke P, Rivers CS, **Brown JM**. An international, multicentre, prospective, randomised, controlled, unblinded, parallel-group trial of robotic-assisted versus standard laparoscopic surgery for the curative treatment of rectal cancer. Int J Colorectal Dis. 2012; 27: 233-241. DOI: 10.1007/s00384-011-1313-6

[**2**] Jayne D, Pigazzi A, Marshall H, Croft J, Corrigan N, Copeland J, Quirke P, West N, Rautio T, Thomassen N, Tilney H, Gudgeon M, Bianchi PP, Edlin R, **Hulme C, Brown J.** Effect of robotic-assisted vs conventional laparoscopic surgery on risk of conversion to open laparotomy among patients undergoing resection for rectal cancer. JAMA 2017; 318: 1569-80. DOI: 10.1001/jama.2017.7219

[**3**] Jayne D, Pigazzi A, Marshall H, Croft J, Corrigan N, Copeland J, Quirke P, West N, Edlin R, **Hulme C**, **Brown J**. Robotic-assisted surgery compared with laparoscopic resection surgery for rectal cancer: the ROLARR RCT. Efficacy Mech Eval 2019; 6(10). DOI: 10.3310/eme06100

[**4**] Corrigan N, Marshall H, Croft J, Copeland J, Jayne D, **Brown J**. Exploring and adjusting for potential learning curve effects in ROLARR: a randomised controlled trial comparing robotic-assisted vs. standard laparoscopic surgery for rectal cancer resection. Trials. 2018; 19: 339-350. DOI: 10.1186/s13063-018-2726-0

[**5**] Randell R, Honey S, Hindmarsh J, Alvarado N, Greenhalgh J, Pearman A, Long A, Cope A, Gill A, Gardner P, Kotze A, Wilkinson D, Jayne D, Croft J, Dowding D. A realist process evaluation of robot-assisted surgery: integration into routine practice and impacts on communication, collaboration and decision-making. Health Serv Deliv Res 2017; 5(20). DOI: 10.3310/hsdr05200

[**6**] Alvarado N, Honey S, Greenhalgh J, Pearman A, Dowding D, Cope A, Long A, Jayne D, Gill A, Kotze A, Randell, R. Eliciting context-mechanism-outcome configurations: Experiences from a realist evaluation investigating the impact of robotic surgery on teamwork in the operating theatre. Evaluation 2017; 23(4): 444-462. DOI: 10.1177/1356389017732172

4. Details of the impact (indicative maximum 750 words)

The ROLARR study was undertaken during a period of great uncertainty about the benefits of robotic surgery and whether it offered value for money and should be more widely adopted. The work was presented at the world's foremost surgical congresses, including the American Society of

Colon and Rectal Surgeons (ASCRS; USA, 2015), the European Society of Coloproctology (Hungary, 2015), the Asian Robotic Camp for Colorectal Surgeons (S Korea, 2018), and the Association of Coloproctology of Great Britain and Ireland (UK, 2016), and is regarded as an exemplar study by the IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the Quality of Research in Surgery) Collaboration (UK, 2018).

ROLARR galvanised the robotic surgical community, clarified international opinion and put robotic surgery in the public spotlight through national media coverage. The JAMA manuscript [**2**] was named "Paper of the month" by the European Society of Coloproctology in January 2018 [**A**] and to date has been cited 324 times on Web of Science, indicating its importance to the surgical community.

Patient and healthcare provider impact

The most important beneficiaries of robotic surgery are patients. Demonstration that robotic rectal cancer surgery was safe, with good oncological and functional outcomes [**2**], and evidence of factors enabling safe technology adoption [**5**,**6**], provided reassurance to clinicians and patients. Although robotic surgery was more expensive than laparoscopic surgery, the differential costs were less than previously reported [**3**], providing encouragement to healthcare providers to invest in the technology and widening access for patients to benefit from minimally invasive surgery [**B**].

The adoption and utilisation of robotic surgery for rectal cancer has increased markedly since the ROLARR presentations and publications [**2-6**]. In the National Bowel Cancer Audit 2020, 30 NHS Trusts were regularly performing robotic colorectal cancer surgery with the number of cases more than doubling over the previous 4 years [**B**]. Importantly, almost two-thirds of robotic surgery was performed in males and for low rectal cancer – the technically difficult sub-groups identified in ROLARR [**2**]. Similar patterns of robotic adoption have been seen in the US with rates of laparoscopic rectal cancer surgery plateauing at 19%, whilst robotic surgery has increased from 1% to 13% [**C**].

Previous single institution studies have suggested that the learning curve for robotic rectal cancer surgery was ~30 patients. ROLARR showed this to be an underestimate, with the true learning curve, even in experienced laparoscopic surgeons, not plateauing until ~90 patients [**4**]. This has had major implications for robotic training programmes, surgeon accreditation, patient safety, and the future design of surgical technology evaluations. It informed the design of further research exploring the subgroups (males, obese patients, low rectal cancers) identified within ROLARR where there was likely to be maximal benefit, including the European RESET trial aiming to recruit 1300 patients with low rectal cancers [**D**].

Policy and implementation impact

The importance of ROLARR in determining future healthcare policy is illustrated by its inclusion in an NIHR Signal Report [**E**]. NICE guidance on the treatment of colorectal cancer published in 2014 failed to mention robotic surgery. Updated guidance published in 2020 supported the use of robotic rectal cancer surgery within established robotic programmes that have appropriate audited outcomes, affirming the learning curve [**4**] and human factors findings [**5**,**6**] of ROLARR [**F**]. The potential benefits highlighted by ROLARR for increasing patient access to minimally invasive surgery were formalised within the Royal College of Surgeons (RCS) of England "Future Surgery" report [**G**]. Building on the success of ROLARR, RCS England set up a national research initiative to undertake further research to demonstrate the benefits of robotic surgery.

Commercial impact

Presentation of the ROLARR results at the ASCRS meeting in 2015 had an immediate impact on the commercial robotics sector. US financial markets showed particular interest with investor speculation on Intuitive Surgical Inc., the manufacturer of the *da Vinci* system. The markets reacted favourably, reassured by the safety and high quality of robotic surgery [**H**].

Confidence in robotic surgery was reassured, paving the way for the development and commercialisation of other robotic systems. Manufacturers have taken on board the health economic lessons from ROLARR, in particular the need to reduce capital and instrument costs to make the technology more affordable. Companies, such as CMR Surgical (UK) and Distalmotion (Switzerland), have been consulting with the ROLARR team to better understand the implications of ROLARR and how to develop the next generation of more versatile, affordable systems [**I**, **J**]. Specific influences of ROLARR cited by manufacturers include a focus on colorectal surgery as a strategic market, increased investor confidence, use of health economics data to guide market positioning, and the importance of independent clinical evaluation to facilitate EU and US regulatory approvals.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[**A**] European Society of Coloproctology. “Paper of the Month”. January 2018
[**B**] National Bowel Cancer Audit. Annual Report 2020. Available from https://www.nboca.org.uk/content/uploads/2020/12/NBOCA-2020-Annual-Report.pdf
[**C**] Protyniak *et al.* Handbook of robotic surgery, Chapter 10, pages 159-170. Elsevier 2020.
[**D**] Rectal Surgery Evaluation Trial (RESET). https://clinicaltrials.gov/ct2/show/NCT03574493
[**E**] NIHR Signal Report summarising the findings of ROLARR and its implications for implementation of robotic surgery.
[**F**] NICE Guideline NG151. Colorectal Cancer. Published 29 January 2020. www.nice.org.uk/guidance/ng151
[**G**] Royal College of Surgeons. Future of Surgery. 2019. https://futureofsurgery.rcseng.ac.uk
[**H**] Benzinga.com – financial news website speculating on the likely impact of ROLARR on financial markets
[**I**] Supporting letter from CMR Surgical outlining the influence of ROLARR on development of the Versius robotic surgical system
[**J**] Supporting letter from Distalmotion confirming the importance of ROLARR health economics analysis in informing design and marketing of next generation robotic surgical systems.