A realist process evaluation of robotic surgery: integration into routine practice and impacts on communication, collaboration and decision making: Protocol (v1)

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Summary of Research

The aim of this project is to understand how and in what circumstances robotic surgery produces both intended and unintended outcomes. This will be achieved through a process evaluation, running alongside ROLARR (RObotic versus LAparoscopic Resection for Rectal cancer), a randomised controlled trial (RCT) comparing laparoscopic and robotic rectal cancer surgery for the curative treatment of rectal cancer. Realist evaluation,[1] which is concerned with understanding for whom and in what circumstances complex interventions work and involves building, testing and refining the theories of how the intervention is supposed to work, provides an overall framework for the study (a fuller description of realist evaluation is given on page 7). In Phase 1, grey literature will be reviewed to identify theories concerning (i) how robotic surgery becomes embedded into surgical practice; (ii) how robotic surgery impacts on communication, teamwork and decision making in the operating theatre (OT) and how this is affected by the process through which the technology is introduced; and (iii) subsequent impacts on outcomes such as operation duration, conversion to open surgery, and complications. These candidate theories will be refined and added to through interviews conducted with staff at different levels of the organisation across ten NHS hospital Trusts that are using robotic surgery for rectal cancer resection (both Trusts that are participating in the trial and those that are not), along with a review of documentation associated with the introduction of robotic surgery. In Phase 2, a multi-site case study will be conducted across four NHS hospital Trusts (three that are participating in the trial and one that is not) to test and refine the candidate theories. Data will be collected using multiple methods. Observation using the structured observation tool OTAS (Observational Teamwork Assessment for Surgery)[2] and video recordings of operations will be combined with ethnographic observation and interviews. In Phase 3, interviews will be conducted at the four case sites with staff representing a range of surgical disciplines, to assess the extent to which the results of Phase 2 are generalisable and to refine the resulting theories to reflect the experience of a broader range of surgical disciplines. Findings will be fed back to all four case sites in interactive sessions, feedback from which will assist in the production of actionable guidance concerning how to support integration of robotic surgery into surgical practice and how to ensure effective communication and teamwork when undertaking robotic surgery.

Background and Rationale

The past two decades have seen a revolution in general surgical practice. In the 1990s, traditional open surgery was challenged by the introduction of laparoscopic techniques, initially for benign conditions, but later extended to the treatment of cancer. Instead of large abdominal wounds, the surgeon is able to perform operations using small 'key-hole' incisions, through which cameras and instruments are passed. This effectively removes much of the abdominal access trauma. The clinical benefits were soon realised, including less postoperative pain, shorter hospitalisation, quicker return to normal function, and improved cosmetic effect.[3-5] These benefits were outlined in 2007 by Lord Darzi in *Saws and Scalpels to Lasers and Robots – Advances in Surgery*, who also pointed to how such less invasive techniques allow for increased use of day surgery, helping to cut waiting times for operations.[6] Use of laparoscopic surgery is promoted in *Delivering enhanced recovery – Helping patients to get better sooner after surgery*.[7] Similarly, in *Improving Outcomes: A Strategy for Cancer*, encouraging uptake of less invasive techniques is highlighted as an important part of ensuring improved access to high quality surgery.[8] In addition to patient benefits, laparoscopic surgery is also cost-effective for healthcare providers,[9] the increased operating costs offset in part by shorter inpatient stay and decreased wound care costs.[5]

The restricted abdominal access inherent in the laparoscopic approach does nonetheless come at a price. Laparoscopic operations are technically more challenging than open surgery, as a result of the 2-dimensional operative image, instrumentation with limited freedom of movement, and lack of tactile feedback. The uptake of laparoscopic surgery has therefore been slow; in 2003, the uptake in colorectal surgery was 5% and had increased to only 40% over the 9 years to 2011,[10] despite being recommended by NICE since 2006.[11]

Robotic surgery offers to solve some of the limitations of the laparoscopic approach. A surgical cart carries four robotic arms, one of which holds the camera, while the other arms hold a variety of surgical instruments. These robotic arms are controlled by the surgeon remotely. The robot provides a stable camera image with 3-dimensional field of view, with Endowrist® instruments which provide increased freedom of movement, and a digital platform that enables intuitive instrument handling, tremor elimination, and motion scaling. This enables the surgeon to achieve greater precision and control and simplifies many of the tasks that are difficult with traditional laparoscopy.

The first purchase of a da Vinci® robot (Intuitive Surgical, California, USA), currently the only commercially available robotic platform, by an NHS hospital occurred in 2001.[12] Robotic surgery is primarily used in urology; in 2011 over 50% of radical prostatectomies in the UK were carried out using robotic surgery. Robotic surgery is rapidly expanding across the surgical disciplines, also being used in gynaecology, ear nose and throat, colorectal, cardiology, and paediatrics. There are now 27 robots in use in England and it is anticipated that the number of surgical robots purchased by NHS Trusts will continue to grow.[13,14] Robotic surgery is put forward as an example of new technology supporting delivery of more effective patient care, helping to meet the goals set out in *High Quality Care for All*.[15]

Despite this enthusiasm for robotic surgery amongst clinicians and policy makers, there is evidence that surgical robots already purchased by NHS Trusts are being underused, suggesting potential benefits of robotic surgery for patients are not being realised.[16] This reduces the cost effectiveness of robotic surgery which depends on the number of operations for which the robot is used.[17]

Integrating robotic surgery into surgical practice

Robotic surgery is a complex intervention, by which we mean that it is an intervention aimed at producing change in the delivery and organisation of healthcare services and which comprises a number of separate components that may act both independently and interdependently.[18,19] These components are not only technological but also organisational and social, and they can all impact the extent to which the technology is successfully introduced and subsequent process and patient outcomes.

Successful introduction of technology involves interactions between individual clinicians and their work environment until the technology becomes embedded (routinely incorporated into everyday work) and integrated (sustained over time) into routine practice, a process known as 'normalisation'.[20] Factors impacting integration of healthcare technologies include skill mix and motivation of users, acceptability of technology to clinicians and patients, training, division of labour and workload, organisational culture, and whether introduction of the technology was clinician-led.[21,22]

Where there is a mismatch between the technology and the work practice of the users, users may, both individually and as a group, adapt the technology (system tailoring) and the way that they work (task tailoring), a behaviour that has previously been reported in the OT.[23] Such 'work arounds' can often lead to a variety of 'unintended consequences' which may result in processes and outcomes that are undesirable and/or were unanticipated when the technology was introduced.[24-27]

Normalisation Process Theory suggests that for successful integration to occur, there are four key constructs that need to be considered: Coherence: sense making – where individuals make sense of the new technology and how it differs from existing practice; Cognitive Participation: the process of engaging individuals with the introduction of the technology; Collective Action: how the work processes are adapted and altered to make the intervention happen; and Reflexive Monitoring: the formal and informal appraisal of the benefits and costs of the intervention.[20,28,29] This suggests that if members of the OT team have been able to 'make sense' of robotic surgery, have been engaged in the process of implementation, have been able to adapt their work processes and/or the technology to fit with practice and are able to identify potential benefits to its introduction, it is more likely to become embedded into surgical practice, being used routinely and successfully for surgical operations where it offers benefits to the patient.[30]

Reports of the use of robotic surgery suggest a number of factors are important for successful integration, such as having a highly motivated[31] and/or dedicated robotic team[32-34] and additional staff.[35] Reports of technical failures and difficulties resulting in conversion to open surgery[36,37] have also led to recommendations that surgeons learn to troubleshoot problems with the robot.[38] OT staff consider teamwork skills are critical for easing the integration of robotic surgery, as is having predefined protocols and explicit communication in the event of deviation from the protocol.[39] There is also acknowledgement that there is a learning curve for the whole team,[40] not just the surgeon, and that the whole team requires training.[41] However, such recommendations come from small case series (descriptive non-randomised studies) undertaken in single institutions, typically by dedicated robotic surgery enthusiasts,[5] so that little is known about the contextual factors that are necessary for the successful integration of robotic surgery more broadly.

In relation to the aim and objectives of this project, key questions that arise are:

- *What are the components on which successful integration of robotic surgery depends?*
- *What contextual factors impact integration of robotic surgery?*

Communication and teamwork in the OT

The successful performance of a surgical operation is dependent on collaboration amongst staff from different professional groups. In the UK, the team that is brought together to perform a particular operation will include the surgeon, an anaesthetist, a scrub nurse, a circulating nurse, one or more operating department practitioners (ODPs), and often a trainee surgeon. There is a complex division of labour that requires the various team members to use their different skills to collaboratively accomplish a single, principal activity.[42]

Communication and teamwork in the OT is a topic that has received much attention over recent years, due to failures in communication and teamwork being identified as key factors in adverse events in the OT.[43] An analysis of communication breakdowns that resulted in injury to surgical patients in 60 malpractice claims found that in 49% of cases information was never communicated and in 44% of cases information was communicated but inaccurately received.[44] More generally, communication in the OT has been found to be variable in terms of quality and quantity, with a lack of formal exchanges between staff about essential information and completion of basic procedural tasks.[45] There is considerable distraction and interruption in the OT,[46] which may negatively impact communication and teamwork.[47] Communication in the OT may suffer from poor timing, missing or inaccurate information, failure to resolve issues, and exclusion of key individuals.[48] Even when communication and teamwork failures do not result in an adverse event, they can negatively impact the surgical team's ability to compensate for a major event,[49] whereas effective teamwork in the OT can reduce the number of small problems and prevent them from escalating to more serious situations.[50] Thus, teamwork and communication are both considered to be markers of surgical excellence.[51]

While such work on the relationship between communication and teamwork in the OT and patient safety has been important in highlighting the significance of this area, a limitation of existing work is that too often the emphasis has been on applying the label of failure, rather than seeking to understand and explain, with the terms communication and teamwork often being used interchangeably.[52] The ‘workplace studies’ literature provides an alternative view of communication and teamwork in the OT. Drawing on ethnographic data and naturalistic video recordings, workplace studies are concerned with the interplay of talk, visual conduct and the use of tools and technologies in the achievement of work in complex settings.[53,54] Such studies emphasise the careful collaboration and coordination that is an essential part of surgical practice and illustrate how oral communication is just one strategy that is used for ensuring smooth coordination amongst team members.[42] For example, one of the roles of the scrub nurse is to provide assistance by passing the correct surgical instruments to the surgeon as they are required and there are a number of strategies that scrub nurses draw on to ensure the smooth passing of instruments in a safe and timely manner. Before the operation, the scrub nurse will organise potentially relevant instruments, positioning and orientating so that they can be grasped or handed safely. During the operation the scrub nurse will pay attention to the actions of the surgeon and may reorganise the instruments according to when, based on the sequence of actions observed, the nurse anticipates they will be required, which also enables the surgeon to take the instrument from the table directly.[42] Through this careful attention to the ongoing work, the scrub nurse is also able to anticipate when an instrument is required, obviating the need for an oral request from the surgeon. Such coordination is considered to be a team level behavioural marker of surgical excellence.[51]

Such studies also point to the operation as a moment of training and the embodied conduct that is used for this purpose; surgeons combine talk and gesture to enable trainees to follow and make sense of a surgical procedure, supported by timely and relevant contributions from other members of the surgical team, and draw on the trainee’s talk and gesture to determine their level of understanding.[55] In studies of laparoscopic surgery, despite all team members having access to the same view of the surgical site, talk and gesture are required to ensure that the others see what the surgeon sees.[56] At the same time, an important aspect of training and part of developing ‘professional vision’[57] is learning to read the implications of others’ actions based on an understanding of how those actions fit within specific sequences of action, thereby enabling smooth coordination in the OT.[58]

Key to these communication and collaboration activities is that they are spatially embodied practices continually organised in situ with respect to the spatial configuration of team members, patient, tools and technologies, and information resources. Recent studies have highlighted the impact of spatial configuration on communication and collaboration behaviours in the OT and have demonstrated the way in which the introduction of new technologies can demand particular spatial configurations, with both positive and negative impacts on communication and collaboration.[59,60]

Robotic surgery significantly changes the spatial configuration, with the surgeon at a distance from the patient and team. While the team works with a 2D image of the operative field, the surgeon’s visual attention is focused on the 3D image provided by the robot, prohibiting face-to-face communication during the operative part of the procedure. More generally, the size of the robot introduces physical space constraints, resulting in a new choreography of movement around the patient.[39]

The impact of this change in spatial configuration on communication and teamwork in the OT is not a topic that has been explored in evaluations of robotic surgery. Such studies typically focus on the role of the surgeon.[61] There is an acknowledgement that robotic surgery requires increased collaboration between the operating surgeon and the surgical assistant (typically the surgical trainee) while at the same time the challenges of collaboration are increased.[62,63] The surgical assistant’s close proximity to the robotic arms makes him physically vulnerable to quick movements, so he has to learn to pre-empt movements of the robotic arms, while also ensuring that his instruments do not impede the movement of the robotic instruments. It is suggested that the surgical assistant’s familiarity with both the surgeon and the operation is important, so that less verbal communication is needed.[61] What has not been considered is the interaction between the surgeon and the broader team and the consequences of this for the performance of the operation.

Two small studies have looked specifically at differences in communication between laparoscopic and robotic surgery. One study compared communication in 8 operations using laparoscopic surgery (4 cholecystectomies and 4 prostatectomies) and 12 using the da Vinci robot (5 cholecystectomies and 7 prostatectomies).[64] The other study compared communication in 2 cholecystectomies, 1 using laparoscopic surgery and 1 using the LaproTek surgical robot, where it was the first experience for both the surgeon and nurse of using the robot on a patient.[42,43] Both studies found a significant increase in verbal communication between the surgeon and the rest of the team in robotic surgery, particularly in relation to the orientation and localisation of organs and the manipulation of instruments,[64-66] with the effect found to be more pronounced in teams which have less experience of robotic surgery.[64] What these studies do not provide is a consideration of the non-verbal coordination that has been shown to be an important aspect of teamwork in the OT or the strategies the OT team employ to manage the differences in communication and teamwork. Neither do they explore the additional contextual factors beyond the technology that affect communication and teamwork.

If use of robotic surgery interferes with standard practices of coordination among the OT team, the achievement of seamless, efficient and timely teamwork may be hampered. Communication and teamwork around robotic surgery are likely to be influenced by processes associated with the introduction of robotic surgery, such as training and changes in team structure, but equally the integration of robotic surgery in surgical practice may be dependent on the extent to which it supports existing practices for coordination. It is also important to assess the extent to which robotic surgery impacts on training, how it transforms the ways in which surgeons are able to guide others through the operation and how it impacts the opportunity for trainee surgeons to develop an understanding of the sequences of action. This in turn may affect the extent to which robotic surgery becomes embedded in surgical practice.[34]

In relation to the aim and objectives of this project, key questions that arise are:

- *How does communication and teamwork differ between laparoscopic and robotic surgery and what are the causes of those differences?*
- *What are the consequences of differences in communication and teamwork for outcomes such as operation duration, conversion to open surgery, and complications?*
- *What strategies do the OT team employ to manage the differences in communication and teamwork?*
- *What is the impact of robotic surgery on training in the OT?*

Decision making in the OT

Decision making is an important component of surgical expertise.[67] Despite flexible decision making strategies being a behavioural marker of surgical excellence,[51] there is a paucity of research on decision making in the OT, much of which focuses solely on the decision making of the surgeon.[68,69] Factors that affect the surgeon's decision making in the OT include instrument complexity,[69] although the decision making strategy used (rapid, intuitive mode versus deliberate comparison of alternative courses of action) is not affected by whether the surgery is open or laparoscopic.[70] Quality of the surgeon's decision making is dependent on situation awareness,[68] better situation awareness of the surgeon being associated with fewer surgical errors.[71,72]

The spatial configuration of team members and technology in the OT influence the gathering of information that is used to inform decision making.[59,60] For example, positioning imaging systems around the edge of the OT can make it difficult for the surgeon to access these while remaining at the patient bedside without support from a colleague, affecting how these images are able to be used and interacted with.[59,60] More generally, the spatial configuration of OT teams is not arbitrary but affords particular views of the patient, the rest of the team, and different tools and technologies, with the result that different team members have access to different information to inform their decision making.[73]

That different team members have different views of the patient makes communication and pooling of information essential for ensuring the surgeon's situation awareness.[73] It is also important that there is shared situation awareness amongst all members of the OT team.[74] However, several studies highlight discrepant perceptions of the quality of communication and teamwork in the OT, with surgeons typically rating intra-operative teamwork and communication more favourably than anaesthetists and nurses,[75-79] suggesting that surgeons may perceive the team members as being well-informed when in fact they are not.[76]

The nature of the decision making tasks of the OT team may be impacted with robotic surgery. Surgeons report a sense of both physical and psychological isolation from the patient in robotic surgery.[39] As the surgeon is not able to see the patient directly, he/she is more dependent on the rest of the team communicating the status of the patient to maintain situation awareness.[39,80] Consequently it has been argued that decision making in robotic surgery is essentially collaborative.[80] As the surgeon is no longer in the sterile field, more of the burden falls on the rest of the team to respond in the event of a complication, increasing the importance of the team having a shared situation awareness of what is happening in the operative field and how far they are through the procedure.[39]

Because of the importance of shared situation awareness in the OT, interest has emerged in large surgical displays that integrate diverse sources of information[81,82] which could have benefits in the context of robotic surgery. However, this requires an understanding of what information each member of the team needs to work effectively and safely and how that information can best be communicated.[83]

In relation to the aim and objectives of this project, key questions that arise are:

- *How does the nature of decision making differ between laparoscopic and robotic surgery?*
- *What information does each member of the OT team require to enable effective decision making and coordinated action in robotic surgery?*

Summary

In summary, we currently know the following about the introduction of robotic surgery and its impact on communication, collaboration and decision making:

- Successful integration of technology depends on a range of factors, not just technological but also organisational and social;
- Healthcare technologies such as robotic surgery are complex interventions that can have unintended consequences;
- Effective communication and teamwork in the OT is essential for patient safety;
- Quality of decision making in the OT is dependent on situation awareness; and
- In robotic surgery, the surgeon is physically separate from the patient and the rest of the team, potentially impacting communication, teamwork, and situation awareness.

What is not currently known is:

- What factors are associated with successful integration of robotic surgery into routine surgical practice;
- How the reconfiguration of the surgeon, patient, and team impacts communication, teamwork, and situation awareness; or

- How to ensure effective communication, teamwork, and situation awareness when undertaking robotic surgery.

Evidence explaining why this research is needed now

Robotic surgery offers many potential benefits for patients, but these are currently not realised to the full extent because of underuse of the surgical robots. This has cost implications for the NHS, with the most recent da Vinci® robot model costing £1.7 million to purchase, and £140,000 a year for maintenance.[12] There is a desire to accelerate adoption and diffusion of innovations across the NHS, outlined in *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*, and minimally invasive surgery is highlighted as an example of innovation that transforms patient outcomes.[84] Enthusiasm for robotic surgery is expressed by both clinicians and policy makers and it is anticipated that the number of surgical robots purchased by NHS Trusts will continue to grow. However, for robotic surgery to provide most benefit for patients and the NHS, it is first necessary to understand the organisational and social factors that support the successful integration of robotic surgery, by which we mean it becomes embedded into surgical practice, being used routinely and successfully for surgical operations where it offers advantages to the patient. This is a topic that has not been explicitly considered by existing studies of robotic surgery, with most evaluations of robotic surgery being single-institution case series undertaken by dedicated robotic surgery enthusiasts.[5]

Existing evaluations of robotic surgery also fail to consider the impact of robotic surgery on communication, teamwork and decision making in the OT. Robotic surgery is a complex intervention with potential for unintended consequences and there is already some evidence that it impacts communication. This is concerning because of the well-documented relationship between communication and patient safety in the OT. It is necessary to understand those impacts of robotic surgery and how OT teams manage them, to produce guidance for OT teams on how to ensure effective communication and teamwork when undertaking robotic surgery. This understanding will also be able to inform the design of tools and technologies to support teamwork and decision making when undertaking robotic surgery.

This work will be undertaken alongside an existing trial. ROLARR is an international multi-centre RCT comparing laparoscopic and robotic surgery for the curative treatment of rectal cancer, funded by the MRC Efficacy and Mechanism Evaluation programme.[85] The process evaluation will be able to take advantage of the relationships already built up with NHS hospital Trusts participating in the trial, enabling the research to start quickly, while the findings of the process evaluation will provide data that will support the interpretation and reporting of the trial results.

Aims and objectives

The aim of this project is to understand how and in what circumstances robotic surgery produces both intended and unintended outcomes. This will be achieved through a realist process evaluation, running alongside an existing RCT comparing laparoscopic and robotic rectal cancer surgery for the curative treatment of rectal cancer. The study has the following research objectives:

1. To contribute to the interpretation and reporting of the trial results by investigating how variations in implementation of robotic surgery, and the context in which it is implemented, impact on outcomes such as operation duration, conversion to open surgery, and complications;
2. To produce actionable guidance for healthcare organisations on factors likely to facilitate successful implementation and integration of robotic surgery;
3. To produce actionable guidance for OT teams on how to ensure effective communication and teamwork when undertaking robotic surgery; and
4. To provide data to inform the development of tools and technologies for robotic surgery to better support teamwork and decision making.

To achieve these objectives, the research will answer the following research questions:

1. What are the components on which successful integration of robotic surgery depends?
2. What contextual factors impact integration of robotic surgery?
3. How does communication and teamwork differ between laparoscopic and robotic surgery and what are the causes of those differences?
4. What are the consequences of differences in communication and teamwork for outcomes such as operation duration, conversion to open surgery, and complications?
5. What strategies do the OT team employ to manage the differences in communication and teamwork?
6. What is the impact of robotic surgery on training in the OT?
7. How does the nature of decision making differ between laparoscopic and robotic surgery?
8. What information does each member of the OT team require to enable effective decision making and coordinated action in robotic surgery?

Research Plan/Methods

Design and conceptual framework

We will undertake a realist process evaluation which will run alongside ROLARR. ROLARR is an international, multicentre prospective, randomised, controlled, unblended parallel-group trial comparing laparoscopic and robotic rectal cancer surgery for the curative treatment of rectal cancer. The primary outcome is conversion to open surgery, as an indicator of technical difficulty. Presently 17 centres are participating, from the UK, France, Germany, Italy, Denmark, the US, Singapore, South Korea, and Australia. A total of 400 patients (200 in each arm) will be recruited, with each centre having predicted capability to recruit a minimum of 15 patients per year to the trial. It is anticipated that recruitment of patients to the trial will continue until the end of July 2014 and that data analysis will take place between February and August 2015, providing adequate time for the research proposed here to be undertaken and feed into the reporting of the trial.

Process evaluations are predominantly qualitative studies that are typically undertaken alongside a trial, but may be undertaken in preparation for a trial or after a trial,[86] and explore how the intervention is implemented.[87] Process evaluations are recommended when evaluating complex interventions because, although the RCT design remains as the most reliable method of determining effectiveness,[18] it is necessary to understand the mechanisms through which the intervention achieves its outcomes.[88] This involves defining the active components of the intervention and investigating contextual factors that affect the implementation of the intervention.[87] Without this, effective aspects of the intervention may go unmeasured, raising concerns about the validity and reliability of the results of an evaluation[89] and preventing replication.[90] For example, an important component of robotic surgery may be the training delivered to the OT team but if this element of the intervention is not reported and described, healthcare organisations may introduce robotic surgery without an equivalent level of training and are unlikely to achieve the same impact. Process evaluations are particularly important in multicentre trials where the intervention may be implemented in different ways.[87] Understanding how the components of the intervention and the context vary across sites can assist in interpreting differences in results.

Evaluation of complex interventions requires a strong theoretical foundation.[29] Realist evaluation[1] offers a framework for understanding for whom and in what circumstances complex interventions work. It involves building, testing and refining the underlying assumptions or theories of how the intervention is supposed to work. Realist evaluation does not employ particular methods of data collection, although a mixture of qualitative and quantitative methods is encouraged, to gather data on the processes and contexts of an intervention as well as its impacts.[91] While general qualitative approaches can only provide a catalogue of possible contextual factors thought to impact the process and outcomes of interest, the advantage of the realist approach is that it explains how different contexts trigger particular mechanisms which, in turn, give rise to certain outcomes. Thus it increases the specificity of our understanding of the relationship between context, mechanisms and outcomes. Realist evaluation has been used for studying the implementation of a number of complex interventions in healthcare.[92-94]

The implicit assumption underlying the introduction of robotic surgery is that the increased precision and control offered to the surgeon through use of the robot will result in improved patient outcomes. This focuses on the technical skills of the surgeon, neglecting a wide range of factors that have been found to be important in achieving safe, high-quality surgical performance,[95] as has been described above. It fails to consider how use of the robot impacts communication, teamwork, and decision making and the subsequent impact on patient outcomes and other outcomes such as education and training. Evaluations of healthcare technologies need to consider not only the micro-level, but also the dynamic macro-level context (e.g. political, economic) and the different meso-level contexts (e.g. organisations, professional groups, clinical areas) that impact on their success.[96] Figure 1 presents an initial model of robotic surgery, based on: existing knowledge presented above regarding how technology becomes embedded into healthcare practice and the nature of communication, teamwork, and decision making in the OT; consideration of the broader surgical safety literature;[95,97] and preliminary discussions with OT staff and the ROLARR team. It lists a range of factors that could potentially influence the processes and outcomes of robotic surgery. Through the creation, testing and refinement of Context Mechanism Outcome (CMO) configurations,[1] this research will enable identification of the key factors and provide a better understanding of how they influence processes and outcomes in the context of robotic surgery.

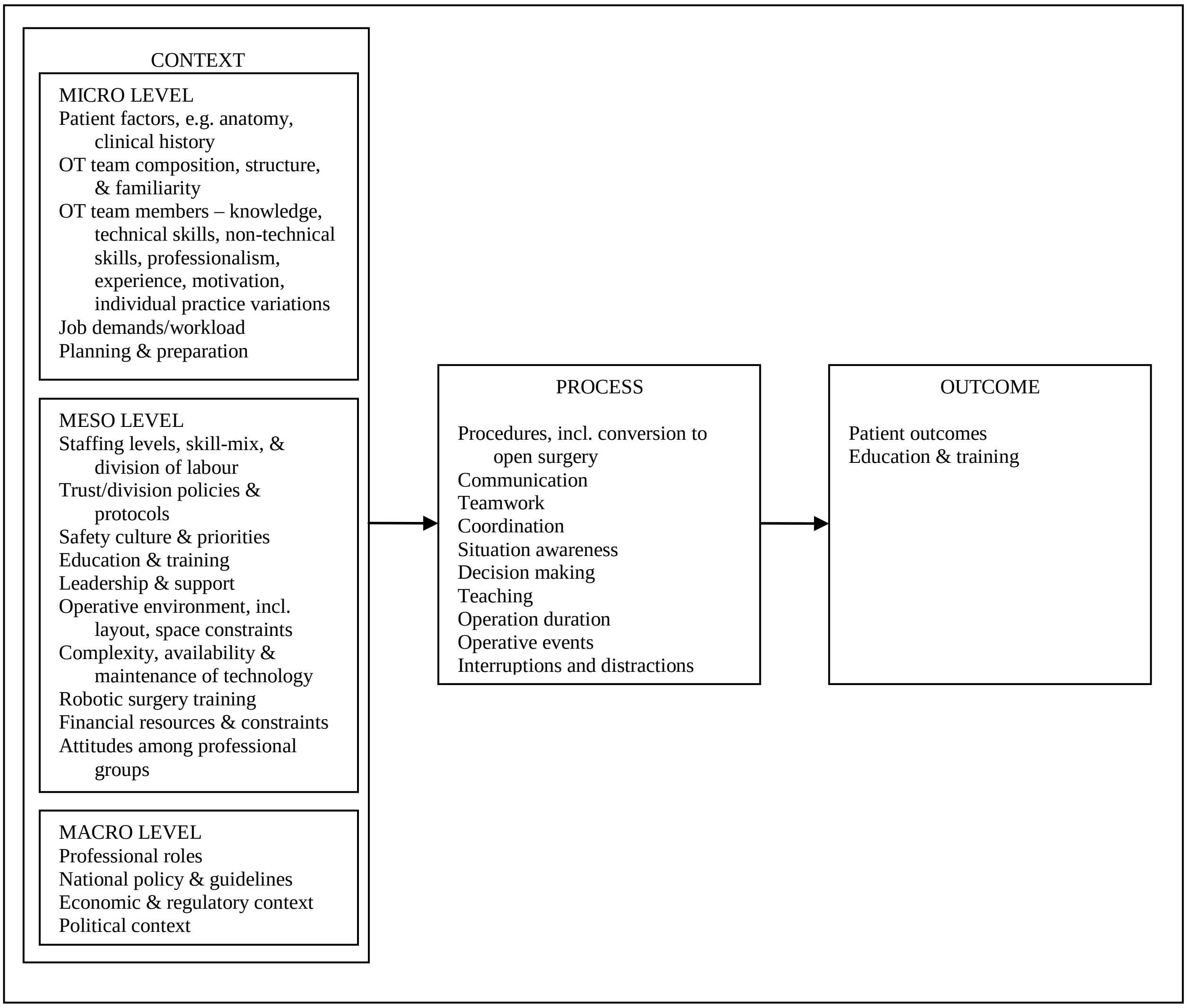

Figure 1: An initial model of robotic surgery

Drawing on this initial model, we have identified six candidate theories for further exploration which set out why and in what circumstances robotic surgery produces or fails to produce particular outcomes:

1. When the OT team is less experienced in robotic surgery, they have more difficulties in setting up and positioning the robot which can reduce the ease with which OT team members have access to the patient on the operating table, resulting in increased operation duration, conversion to open surgery and complications;
2. If the whole OT team can feel the advantages of robotic surgery outweigh its disadvantages and are involved in the decision to introduce it, they will be more motivated to work together to develop solutions to problems that may arise when they are using it to carry out operations;
3. When the surgeon is separated from the rest of the OT team, the team is less aware of the surgeons' actions, making it more difficult to coordinate their actions during the operation and so the operation takes longer;
4. When OT teams are motivated to use robotic surgery and as they become more familiar with the equipment through repeated use, they are better able to develop strategies to overcome difficulties created in this reconfigured environment, resulting in effective co-ordination, teamwork and communication and reduced operation duration;
5. When surgeons and trainees have different views of the operative field, it is harder for the surgeon to explain what is happening and monitor the trainee's understanding, resulting in the trainee not learning as much as they would in other forms of surgery;
6. When the team is more experienced in robotic surgery, they understand that the surgeon's situation awareness is dependent on them orally communicating information and they respond by using more oral communication about the patient's state which in turn improves the surgeon's situation awareness.

In Phase 1 of the research, these theories regarding how robotic surgery leads to positive and negative outcomes and what needs to be in place for the positive impacts to be achieved will be refined, developed and added to through a supplementary review of the grey literature and semi-structured interviews across ten NHS hospital Trusts that are using robotic surgery for rectal cancer resection (both Trusts that are participating in the trial and those that are not) with staff at different levels of the organisation. In Phase 2, a multi-site case study will be conducted across four NHS hospital Trusts (three that are participating in the trial and one that is not) to test and refine the candidate theories. Data will be collected using multiple methods, including observation, interviews and video recordings of operations. In Phase 3, interviews will be conducted at the four case sites with staff representing a range of surgical disciplines, to assess the extent to which the results of Phase 2 are generalisable and to refine the resulting theories to reflect the experience of a broader range of surgical disciplines. Figure 2 illustrates how these activities answer the research questions outlined above.

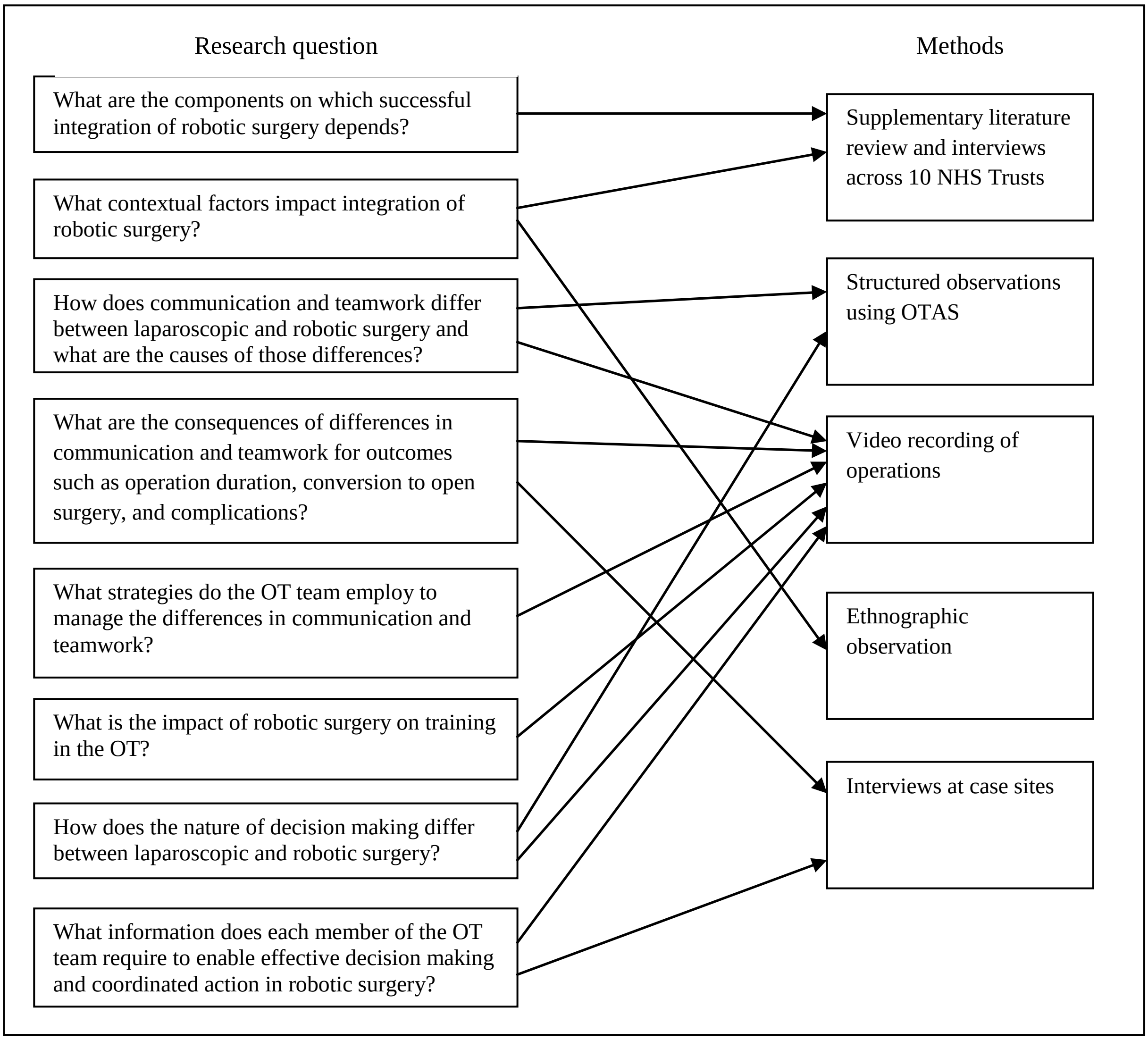

Figure 2: Outline of study design

Phase 1: Formulation of CMO configurations

Aims

- To refine the candidate theories of how, and in what contexts, robotic surgery achieves it intended and unintended outcomes by drawing on grey literature and stakeholder knowledge; and
- To gather data on the different ways in which robotic surgery has been implemented, in terms of components of the intervention.

Summary of method

The unit of analysis in realist evaluation is not the intervention but the theories concerning the mechanisms through which the intervention produces certain outcomes in particular contexts. A first task is to identify these theories. Above we presented a series of candidate theories based on our understanding of the relevant literature and initial discussions with OT staff and the ROLARR team. In Phase 1, a supplementary literature review will be undertaken. This review will comprise the first 'theory elicitation' stage of a realist synthesis and will be designed to surface the theories underlying the implementation of robotic surgery and its impact on teamwork and coordination. Such theories are to be found in guidance documentation (e.g. for robotic surgery), position papers, professional journals such as the Health Service Journal and the Nursing Times, publications of the Royal Colleges, blogs, thought pieces, advocacy pieces, and critical pieces and so the review will focus on this grey literature. In addition, the broader surgical literature will be consulted to develop a model of the procedural components of surgery, to understand how robotic surgery changes these components. Thus the outputs of the review will be: (1) a logic map of the implementation chain of robotic surgery; and (2) additions or refinements of our existing candidate theories. These candidate theories will be presented to members of the OT team and other staff members involved in the introduction of robotic surgery in interviews where they will be asked to refine, develop and add to the theories based on their direct experience of robotic surgery. A refined set of theories will then be presented to the Project Advisory Group (PAG) and Patient Panel (both described on page 15) who will assist in the selection of key theories that will guide the fieldwork during Phase 2.

Sampling of interviews

There is no consensus regarding how many interviews are necessary to provide an adequate understanding of attitudes and experiences within a particular setting.[98] It is dependent on the range of participants to be included, the purpose of the interviews, and whether other forms of data will be gathered. It is necessary to balance the desire for data saturation with the need to keep the data set to a manageable size. Interviews will be conducted with staff in ten NHS hospital Trusts, both Trusts that are participating in the trial and those that are not. It is anticipated that by this time there will be eight Trusts participating in ROLARR and indications from Intuitive Surgical suggest that a further three NHS Trusts will be introducing robotic surgery in 2013. All Trusts in the ROLARR trial will be invited to participate. Trusts that are not participating in the trial will be identified by the ROLARR team (Trusts that expressed interest in participating but were not eligible to participate because of inadequate experience with robotic surgery – to participate in the trial, a surgeon must have undertaken a minimum of ten rectal cancer resections with robotic surgery) and through personal contacts of one of the co-applicants (DJ). In this way, the Trusts involved in the trial will have a range of experience of robotic surgery. All Trusts in the ROLARR trial introduced robotic rectal cancer surgery prior to their involvement in the trial, so there is likely to be variation between Trusts in the process through which this occurred. It is essential that the study captures the perspectives of all professional groups that make up the OT team.[80] At each Trust, six interviews will be conducted (total n=60), providing a substantial data set.[98] Interviews will first be held with one of the surgeons (in most Trusts, there are one or two surgeons participating in ROLARR) and through them we will identify other members of the OT team to interview (surgeons, anaesthetists, theatre nurses, ODPs, trainee surgeons) as well as division and Trust level staff who were involved in the introduction of robotic surgery into the Trust.

Data collection

Interviews: Interviews will be undertaken by telephone. Telephone interviews do not differ to face-to-face interviews in the amount and quality of data gathered[99] and have been used successfully in previous studies of attitudes of healthcare professionals,[100,101] so are a cost-effective alternative to face-to-face interviews. Interviews will be semi-structured and conducted using the 'teacher learner cycle'.[102] Here, the interviewer describes, through their interview questions, the candidate theories to the interviewee who is then invited to comment, expand and discuss the theories based on their experience of the intervention. For example, theory 2 would lead to questions regarding the process of introducing robotic surgery into the hospital, whether they were involved in the decision to introduce robotic surgery, and the training that they received. This would be followed by questions regarding what impact the interviewee thought the process of introduction had and why, and whether there are any other elements of the process of introducing robotic technology that they consider impact how it is now used. Through this process, the interviewer channels the interviewee's responses to the task of developing and refining the theories. The interviewer proceeds to formalise the interviewee's theories, based on the information they have given, and the interviewee is then invited to comment on that formalisation. Consequently, the interview is a vehicle for enabling key participants to revise and expand the theory. An interview topic guide will be established, with the research team agreeing revisions to the guide in light of emerging themes. All interviews will be audio recorded and transcribed verbatim.

Documents: Copies of materials such as protocols and training guides concerning the use of robotic surgery and business cases justifying the introduction of robotic surgery will be requested from each Trust at the time of the interviews.

Data analysis

An iterative approach to data collection and analysis will be taken in this phase, to support the gathering of further data on emergent themes. Data for analysis will consist of interview transcripts and documents which will be entered into a qualitative software programme (NVivo 9) for indexing.

Thematic analysis will be used to analyse the data.[103] Following the realist strategy, indexing of the data will focus on identifying interviewees' accounts of how outcome patterns are formed by mechanisms and contexts.[92] Continuing with the example of theory 2, interviewees' responses regarding how robotic surgery was introduced will provide details of the context, while their accounts of the impact and why that impact occurred will provide details of the outcomes and the mechanisms that generated the outcomes. In addition, both codes derived from the research questions and codes developed inductively will be used to index the data. The process will follow accepted good practice guidelines for ensuring quality in qualitative research.[104,105] Multiple members of the research team will undertake the indexing and the inter-rater reliability of the indexing will be measured at several time points.[106]

Once all the data has been indexed, matrix displays will be created in a format similar to the one presented in Figure 3 below, to build up a picture of the data as a whole.[107] This involves abstraction and synthesis of the data but referencing the original text. The matrices will be used to support both within-case comparisons (similarities and differences according to e.g. role) and between-case comparisons, returning to the original data where necessary. Similarities and differences in the stakeholder theories will be identified and used to further refine the emerging CMO configurations. Because of the range of participants involved in the interviews, we anticipate that we might encounter conflicting CMO configurations. However, realist evaluation allows for, even encourages the testing of multiple, contradictory CMO configurations, so the intention is not to remove or ignore such conflicting configurations.[93] A refined set of theories will then be presented to the PAG and Patient Panel who will assist in the selection of key theories for testing in Phase 2 in light of the objectives of the research project and the questions it seeks to answer.

Outputs

- A set of candidate theories, expressed as CMO configurations, to be tested in Phase 2; and
- An account of the different ways in which robotic surgery was implemented in the ten sites, in terms of components of the intervention.

Phase 2: Empirical testing of CMO configurations

Aim

- To collect and analyse the data necessary to test the CMO configurations selected in Phase 1.

Summary of method

The next stage of a realist evaluation involves collecting data that will enable the testing of the selected CMO configurations. Here we present a plan for data collection and analysis based on the six candidate theories presented above. These are outlined in Figure 3 below, which also indicates what data will be used for testing each theory. Data will be collected using a range of methods, which are flexible enough to allow exploration of a variety of CMO configurations. However, the data collection protocol will be revised and further specified at the end of Phase 1 in light of the theories to be tested.

Observation using a structured observation tool and video recording of operations will be combined with ethnographic observation and semi-structured interviews. This reflects the growing acknowledgement within the surgical safety literature of the need to study work 'as performed' rather than 'as imagined.'[108] At each case site, contextual data will also be collected (e.g. description of the case site, staffing levels, experience of staff, structure of teams).

Teamwork during operations will be assessed using OTAS.[2] We have chosen to use OTAS rather than other non-technical evaluation tools related to surgery such as NOTSS (Non Technical Skills for Surgeons) because of its emphasis on evaluating teamwork that goes beyond individual teamwork skills.[109] OTAS has been shown to be applicable to various branches of surgery[2] and has demonstrated construct validity,[110] content validity,[111] and reliability, minimising error and bias in data collection and therefore increasing confidence in the validity of the findings.[43] OTAS has also demonstrated good inter-rater reliability with short-term training.[112] Such training will be an important part of establishing the validity of the assessment, ensuring assessments are truly comparable within the study but also comparable with existing studies.[43]

To facilitate a close consideration of robotic surgery in use, we will adopt the workplace studies approach,[54,113] collecting video recordings of action and interaction in the OT. The value of video recordings is that they capture the dense richness of social conduct, including talk, gesture and tool manipulation.[114] Video recordings are permanent which facilitates a thorough and systematic examination of key events by the researcher. They also facilitate collaborative analysis in ways that other qualitative data prohibit and the permanence of the record enables the research team to share key episodes with others, to present, discuss and evidence analytic claims. The workplace studies approach has been recently and successfully applied by a number of internationally-leading research groups who have considered aspects of collaboration and training in and around the OT.[55,58,115-117] More generally, video recording has been highlighted as an important tool for understanding safety in the OT[108] and has been used successfully in a number of studies concerned with the impact of communication and teamwork on surgical performance.[118-120] These studies provide a useful set of background materials with which to compare and contrast our findings. They also provide insights into the practicalities of data collection and analysis in the OT.

Ethnography, the study of people in their environments where the researcher participates in the setting in order to collect data,[121] has been argued as an essential approach for studying the introduction of technology into healthcare settings.[122] It is an important complement to the structured observations, allowing unanticipated yet significant behaviours and interactions that fall outside the scope of the observation tool to be recorded in the researcher's field notes. In addition, ethnographic observation is important for getting a sense of how what happens in the OT fits within the broader context of work[58,123] and for capturing those aspects of the context that cannot easily be measured, such as the culture of an organisation. The researcher's field notes can assist in the analysis of the video data, highlighting points in the operation to focus on. It is also necessary to record in the field notes any critical conduct that evades the cameras. Finally, interviews are an important complement, providing an opportunity for the researcher to ask questions about aspects of practice that might not be immediately intelligible to an observer, as well as for gaining interviewees' perceptions of the impact of robotic surgery.

	CONTEXT	+	MECHANISM	=	OUTCOME PATTERN	DATA
1	Less experienced teams	+	Less able to overcome difficulties in set-up and positioning of the robot	=	Increased operation duration; Increased conversion to open surgery/complications	Operation duration; Video recordings/interviews
2	Whole OT team involved in implementation and all team members receive training	+	OT team perceive benefits for patients and more motivated	=	Improved teamwork	OTAS/interviews
3	Less experienced teams	+	Physical separation reduces team awareness of surgeon's actions	=	Reduced coordination; Increased operation duration	OTAS/video recordings; Operation duration
4	Motivated teams and/or dedicated robotic teams	+	Develop strategies to deal with physical separation	=	Effective coordination, teamwork, communication; Reduced operation duration	OTAS/video recordings; Operation duration
5	Surgical trainee as part of team	+	Physical separation and different views of operative field	=	Harder for surgeon to explain what is happening and monitor trainee's understanding; Reduced satisfaction in robotic surgery as opportunity for training	Video recordings/interviews; Interviews
6	More experienced teams	+	Understand need to support surgeon's situation awareness	=	Increased verbal communication of patient state to surgeon; Increased situation awareness of surgeon	Video recordings; OTAS

Figure 3: Initial theories presented as CMO configurations, with data to be collected

Sampling of case sites

Four case sites will be selected, three of which will be participants in the ROLARR trial and one which is not. Case sites will be purposively sampled to ensure variation in the contextual factors identified as being significant in Phase 1 of the research. These are likely to include: process through which the technology was introduced (Trust led vs. clinician led); level of experience with robotic surgery; and whether dedicated robotic teams are employed. There is no consensus regarding how many case sites to include in a multi-site case study.[124] The number of case sites depends on the number of aspects of the context that are anticipated to impact on the phenomenon of interest,[124] while also involving a trade-off between breadth and depth of investigation.[121] Four case sites were used in a previous multi-site case study concerned with the introduction of new technology that the applicants have undertaken[125] and enabled identification of organisational level factors that impacted the phenomenon of interest while providing confidence in the generalisability of findings that were consistent across sites.

Sampling of observations

There is no consensus regarding how many periods of observation are necessary to provide an adequate overview of current practice within a particular setting.[121] In each case site, we will observe 10 rectal cancer resections (n=40). This is a feasible amount of data to collect within the timeframe of the project and will provide approximately 200 hours of video data, which constitutes a substantial corpus. In each of the ROLARR case sites, while recruitment to ROLARR continues, we will observe operations involving patients in the trial. After recruitment to ROLARR ends, and in the case site that is not participating in ROLARR, we will use the same inclusion and exclusion criteria as the ROLARR trial, to ensure the operations observed are comparable. While we will observe both laparoscopic and robotic operations in each case site, the number of laparoscopic and robotic operations observed in each case site will depend on the extent to which these two techniques are used within the case site and, for case sites in the ROLARR trial, the randomisation of patients to the different arms of the trial.

Sampling of interviews

Five interviews will be undertaken per case site (total n=20). A range of participants (surgeons, anaesthetists, theatre nurses, ODPs, trainee surgeons) will be included. Participants will be those who participated in operations that are observed. We may choose to supplement this with brief, informal interviews at the end of each operation, depending on the specific CMO configurations to be tested.

Data collection

Structured observation: OTAS comprises ratings on five team behaviour constructs: Communication: quality and quantity of information exchanged among members of the team; Coordination: management and timing of activities and tasks; Cooperation and back up behaviour: assistance provided among members of the team, supporting others and correcting errors; Leadership: provision of directions, assertiveness and support among members of the team; and Team monitoring and situation awareness: team observation and awareness of ongoing processes. These behaviours are assessed during observation of the surgery, with each behaviour scored on a 7-point scale. OTAS distinguishes between different subteams in the OT (surgeons, anaesthetists, and nurses) and different phases of a procedure (pre-, intra-, and post-operative). For one operation a total of 45 behavioural ratings are generated (5 behaviour constructs x 3 subteams x 3 phases). Researchers will also record additional information for each operation, such as the team composition, each team member's level of experience of robotic surgery, duration of each phase of the operation, and whether there was a conversion to open surgery. In preparation for data collection, research staff will be trained in using OTAS by Nick Sevdalis, one of the developers of OTAS. Formal data collection will only begin once an acceptable level of inter-rater agreement between the research staff has been reached in pilot data collection.

Video: All operations that are observed will be video recorded. Given the concerns of the project with teamwork, two video cameras will be required in the OT. This will allow for the capture of the surgeon's perspective on the surgical scene and the wider conduct of OT team members. We will use a radio microphone to capture the surgeon's spoken conduct and further microphones to capture the talk of other key participants.

Ethnographic observation: Field notes will record key moments that arise and any critical conduct that evades the cameras, as well as activities that take place before and after the operation, to provide a sense of what happens in the OT in its broader context. Following in the ethnographic tradition, the researchers will, at least in the early stages of the study, keep the scope of the notes wide on the basis that what previously seemed insignificant may come to take on new meaning in light of subsequent events[121] and should give special attention to the indigenous meanings and concerns of the people studied.[126] In addition, the researchers will record incidents of observer effects (e.g. participants asking 'What are you writing?') to allow analysis of whether participants' awareness of the researchers' presence changed over time.[127] Field notes will be written up as soon after data collection as possible.

Interviews: Interviews will be semi-structured and will seek to gather data on those outcomes that cannot be easily gathered by other means, particularly those relating to the perceptions of members of the OT team, e.g. level of enthusiasm for robotic surgery, perceptions of teamwork, and perceptions of robotic surgery as an opportunity for training. In addition, due to the infrequency of such events, we are unlikely to see many conversions to open surgery or complications (conversion to open surgery is expected to occur in less than five per cent of operations), so we will gather OT team members' accounts of the reasons for such conversions. All interviews will be audio recorded and transcribed verbatim.

Data analysis

An iterative approach to data collection and analysis will be taken, to enable ongoing testing and refinement of the CMO configurations and the gathering of further data in light of such revisions. Data for analysis will consist of 1,800 OTAS behavioural ratings, video recordings and ethnographic field notes of 40 operations, and 32 interview transcripts. The overall approach to analysis will involve initial comparisons in the processes and outcomes of interest (i.e. those specified in the CMO configurations) between laparoscopic and robotic surgery, before using the data from the robotic surgery operations to test the CMO configurations. As shown in Figure 2, we will try to draw on multiple sources of data to test each configuration. Thus, it is through the CMO configurations that the various sources of data will be integrated together. While the exact form of this analysis will depend on the CMO configurations to be tested, below we give examples based on the initial theories identified.

OTAS: Initial analysis of OTAS scores will use a mixed model analysis of variance (ANOVA), with case site and sub-team as between-subjects factors and surgery type (laparoscopic vs robotic), phase, and behaviour as within-subjects factors.[2] From this, we will then test the CMO configurations. For theory 2, this would involve checking for a difference in the overall OTAS score in those case sites where the OT team had been involved in implementation and all team members had received training compared to those case sites where this was not the case. In contrast, testing theories 3, 4 and 6 would involve analysing specific behavioural ratings, according to the team's level of experience (theories 3 and 6) and whether they were dedicated robotic teams and/or reported high levels of motivation (theory 4).

Video: The analysis of video materials has been reported on extensively within the workplace studies literature. We will follow standard methods outlined in the field,[128] which draw heavily on ethnomethodology[129] and conversation analysis.[130] A key role of the video data is in providing a detailed understanding of how the reconfiguration of team members with robotic surgery impacts communication, collaboration, decision-making, and opportunities for learning (theories 3 and 5) and how those impacts are managed (theory 4). The analysis will explore how practices found in laparoscopic surgery are refined in robotic surgery, such as: (a) coordinating the exchange or manipulation of instruments; (b) establishing a common perspective on the operative field; (c) designing instructions; and (d) managing the interplay of teamwork and training. There are four key stages in the analytic approach that we will adopt: (1) A preliminary review of the corpus to identify short episodes of explicit coordination between OT team members under the broad headings noted above. The review will also highlight moments of 'trouble' – ranging from unproblematic 'hitches' in communication through to critical incidents; (2) The detailed transcription of selected extracts using standard orthographies in conversation analysis to detail the temporal organisation of actions and activities – talk, bodily conduct and tool use; (3) A close consideration of the extracts to explore the contexts in which problems emerge and are managed, thus potentially identifying additional CMO configurations; and (4) A further review of the data corpus to identify similar and contrasting examples to enrich the understanding of patterns of interaction. This analysis will be undertaken by multiple members of the research team and team 'video review sessions' will be a routine and regular feature of project work. In addition, the video data will be subject to content analysis, using codes derived from the research questions, e.g. the types of information that are drawn upon and shared (question 8), and from the CMO configurations, e.g. examples of verbal communication of patient state (theory 6). Given the complex and highly specialised character of the setting, specific video extracts and preliminary analytic observations will be discussed with participants at each case site (and the clinical members of the research team) to ensure that the findings are robust, to generate alternative avenues for inquiry and to discuss implications of the findings for practice. To prevent this opportunity to review and reflect on their practice influencing staff behaviour and team performance, video review sessions with participants at each case site will only be undertaken once video recording of all operations has been completed at that case site.

Ethnographic field notes and interview transcripts: Field notes and interview transcripts will be entered into NVivo 9 for indexing and will be analysed using the methods outlined for the analysis of the interview data in Phase 1. This will identify data to support or refute particular CMO configurations (e.g. theories 1 and 5), as well as identifying additional CMO configurations. Multiple members of the research team will undertake the indexing and the inter-rater reliability of the indexing will be measured.

Contribution to interpretation and reporting of ROLARR data: Analysis of the collected data will contribute to interpretation and reporting of ROLARR data in the following ways:

1. Discussions with the ROLARR team suggest that the process evaluation will be able to provide insight to support the interpretation of the trial data in terms of understanding any increase in operation duration in robotic surgery (theories 1, 3 and 4). In addition, the process evaluation may usefully provide data on what leads to conversion to open surgery or to complications. From the analysis of outlined above, we will have data on OT team members' accounts of why conversion to open surgery was necessary, and possibly video recordings of the events leading up to such incidents.
2. A regular and routine feature of the project work will be discussion with those members of the research team who are involved with ROLARR, about emerging findings from the process evaluation. This provides the opportunity for new avenues of inquiry which are of interest to the ROLARR investigators to be explored in the data collection and analysis of this study.
3. Subject to recruitment, from the data collected in Phase 1, we will be able to provide an account of the different ways in which robotic surgery was implemented in all NHS ROLARR sites, in terms of components of the intervention. From the analysis outlined above for Phase 2, we will be able to identify the contextual factors that impact integration of robotic surgery. Inclusion of these findings into the reporting of the ROLARR trial will provide important information for healthcare organisations that are considering introducing robotic surgery. Variation in the components of the intervention and the contexts can assist in interpreting differences between sites.

Outputs

- A series of CMO configurations, with supporting data, detailing how robotic surgery produces particular outcomes, both intended and unintended, in particular contexts.

Phase 3: Production of guidance

Aims

- To assess the extent to which the CMO configurations resulting from Phase 2 are generalisable to other surgical disciplines;
- To translate the results of Phase 2 into actionable guidance for healthcare organisations and OT teams; and
- To explore ideas for tools and technologies to better support teamwork and decision making in robotic surgery.

Summary of method

The third and final phase of the project consists of the following three activities:

1. Interviews will be conducted at the four case sites with participants from different surgical disciplines to assess the generalisability of the CMO configurations that result from Phase 2 and to further refine them to reflect the experience of a broader range of surgical disciplines. The methods for this are discussed below in more detail.
2. Presentations will be given at each of the case sites, reporting the results of the project. These are intended to be interactive sessions, to encourage discussion about the implications of the findings in terms of how to facilitate successful integration of robotic surgery and how to ensure effective communication and teamwork when undertaking robotic surgery. The feedback from these sessions will be used to generate actionable guidance for

healthcare organisations and OT teams.

3. We will hold a one-day workshop at the University of Leeds with colleagues from the School of Mechanical Engineering and Microsoft Research (both have expertise in the design of surgical technologies), and other potential collaborators. We will present our findings in relation to the impact of robotic surgery on teamwork and decision making in the OT and use this as a starting point for generating ideas for how technology could facilitate better teamwork and decision making in the context of robotic surgery.

Sampling of interviews

Eight interviews will be undertaken per case site (total n=32). A range of participants (surgeons, anaesthetists, theatre nurses, ODPs, trainee surgeons) from a range of surgical disciplines where robotic surgery is being used will be included.

Data collection

Interviews will be undertaken by telephone and conducted using the 'teacher learner cycle', as in Phase 1. The interviewer will describe the CMO configurations that result from Phase 2 of the research. The interviewee will be invited to comment, expand and discuss the theories based on their experience of the intervention. Where a CMO configuration does not fit with the interviewee's experience of the intervention, the interviewer will probe to identify the contextual factors that limit the applicability of the CMO configuration to the interviewee's discipline. An interview topic guide will be established, with the team agreeing revisions to the guide in light of emerging themes. All interviews will be audio recorded and transcribed verbatim.

Data analysis

Interview transcripts will be entered into NVivo 9 for indexing and will be analysed using the methods outlined for the analysis of the interview data in Phase 1. This will be used to further refine the CMO configurations from Phase 2 of the research.

Outputs

- Actionable guidance for healthcare organisations on factors likely to facilitate successful integration of robotic surgery;
- Actionable guidance for OT teams on how to ensure effective communication and teamwork when undertaking robotic surgery; and
- Design ideas for tools and technologies to better support teamwork and decision making in robotic surgery, to take forward into pilot projects.

Dissemination and projected outputs

The main outputs of this research will be: Evidence and understanding regarding how and in what circumstances robotic surgery produces both intended and unintended outcomes; Actionable guidance for healthcare organisations on factors likely to facilitate successful integration of robotic surgery; and Actionable guidance for OT teams on how to ensure effective communication and teamwork when undertaking robotic surgery. In addition to collaborative publications with the ROLARR team, dissemination activities will include publication in an open access format and in a range of academic journals and presentation of findings at national (e.g. International Surgical Congress of the Association of Surgeons of Great Britain and Ireland) and international conferences (e.g. Clinical Robotics Surgical Association Worldwide Congress). The project will have a dedicated website which will provide up to date information on the project and its results.

We will work with our Project Advisory Group to create a dissemination plan to promote the resulting guidance. A key activity will be a one-day workshop at the Royal College of Surgeons. This event will be targeted at a range of stakeholders, representing the different professional groups that make up the OT team as well as NHS managers, commissioners, and the Clinical Board for Surgical Safety. In the morning, we will present and discuss our findings in relation to the factors likely to facilitate successful integration of robotic surgery. In the afternoon, we will present and discuss our findings in relation to the impact of robotic surgery on communication and teamwork in the OT and the strategies developed to overcome these impacts. Other activities will include targeted dissemination through professional journals and relevant channels, as well as general publicity through print and broadcast. We also intend to take advantage of new media, such as Twitter and web-based seminars, to support our dissemination.

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