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Project Title

Reorganising specialist cancer surgery for the 21st century: a mixed methods evaluation (RESPECT-21)

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Contents

ABSTRACT

Current proposals to centralise specialist cancer services in two regions of England provide an opportunity to study the implementation and outcomes of such changes. *London Cancer* (a network of providers across North Central and North East London, and West Essex; population 3.2 million) and *Manchester Cancer* (covering Greater Manchester and East Cheshire; population 3.1 million) plan to centralise specialist surgical pathways for prostate, bladder, kidney, and oesophago-gastric cancers, so that specialist aspects of these services are provided through a smaller number of hospitals. The centralisations in both areas are anticipated to be implemented by December 2015.

This study combines a health technology assessment approach measuring impact of centralisation in terms of clinical processes, clinical outcomes, cost-effectiveness, and patient experience ('what works?') with a qualitative analysis of development, implementation and sustainability of the centralisations ('how and why'). This mixed methods evaluation will use a controlled before and after design, and parallel qualitative study of implementation processes. We will use a framework developed by the research team in a study evaluating centralisation of acute stroke services, structured around key interrelated processes of service reconfigurations, covering: 1) reaching a decision to change; 2) developing and agreeing the new service models; 3) implementing the new models; 4) adherence to the new models throughout the system; 5) impact on provision of care; 6) impact on outcomes (including clinical outcomes, patient experience, and costs). The qualitative analysis will draw on findings from a recent review of large-scale transformation initiatives which identified five 'simple rules' likely to enhance 'successful' implementation [1] relating to: leadership approaches, feedback and learning; history of change; and engagement of professionals, patients and families. Members of the research team have developed these 'rules' further through our study of centralisations of acute stroke services in London and Greater Manchester [2], identifying the importance of combining 'bottom up'-led change with 'top down' central leadership, and of understanding of the social and political context of the changes and their impact on outcomes.

Our research questions are:

RQ 1. What were the key processes in centralising specialist cancer surgery services in London Cancer and Manchester Cancer?
RQ 2. What is the impact of the centralisations on provision of care, in terms of clinical processes and outcomes?
RQ 3. What are the cost and cost-effectiveness of the changes?
RQ 4. What is the impact on patient experience, including choice and continuity of care?
RQ 5. What is the impact on staff and healthcare provider organisations, including ways of working, skill mix and approaches to collaboration?
RQ 6. What are patient, public and professional preferences in relation to these centralisations?
RQ 7. How might lessons from centralising specialist cancer surgery services be applied in future centralisations of specialist cancer services and other specialist settings?

Quantitative methods will include analysis of local and national data on clinical processes and outcomes (RQ 2), as well as joint comparison of costs and effects to allow consideration of the cost-effectiveness of the transformation (RQ 3) and National Patient Experience Survey data (RQ 4). Qualitative methods will include documentary analysis (RQ1), stakeholder interviews and non-participant observations of meetings (RQs 1, 4, 5). We will also conduct a Discrete Choice Experiment to examine patient, public and professional preferences for centralisations of this kind (RQ 6). Finally, we will hold a workshop for those involved in planning centralisations of specialist cancer services elsewhere, and those involved in centralising other types of specialist service. These will include providers, commissioners and patients/patient groups. The workshop will focus on how these lessons might apply more widely, and we will incorporate this feedback into our final conclusions (RQ 7).

This multi-site study covering specialist surgical pathways for four cancers in two large conurbations in England will address established gaps in the evidence on centralisations of specialist cancer surgery, including processes, impact, and cost-effectiveness of changes, and patient, public and professional preferences.

The research team is from London and Manchester, and draws together patients, clinicians, and researchers with the knowledge and expertise necessary to conduct an evaluation of this scale and complexity. Optimising the configurations of specialist services to maximise patient benefit and efficiencies will remain a priority in the English NHS over the coming years. Lessons from this study will be of value to those who commission, organise and manage specialist services, not just by providing evidence on how changes of this kind might benefit patients, but also in terms of giving insights on how service changes of this kind are developed and implemented, and what contextual factors are influential. Further, through a stakeholder workshop we will ensure these lessons will be of use in a wide range of specialist healthcare settings

1. BACKGROUND

Centralising services to improve quality of care and patient outcomes

There is an association between high volume and better outcomes in many clinical settings: for example, recent research by members of the research team has indicated that centralising acute stroke services into a smaller number of high-volume units is associated with significantly better provision of evidence-based clinical interventions[3], and significantly better clinical outcomes, including patient mortality[4]. High volume is associated with better outcomes in specialist surgery for OG cancers[5] and urological cancers[6]. However, the strength of this relationship varies between specialties[7].

There are longstanding recommendations to centralise specialist services[8-10], citing potential to reduce variations in access, increase patient volumes, and improve patient outcomes by increasing the likelihood of patients receiving care in hospitals that have a full range of experienced specialists and equipment to support provision of care. Recent guidance indicates that centralising specialist services will remain a priority in the English NHS in the future[11, 12]. However, little is known about the processes by which services are centralised, the impact of changes on patients and staff, and which factors influence implementation[13]. Recent research indicates that there is limited evidence of the cost impact of centralising

cancer services [13, 14], and limited evidence on patient, public and professional preferences in relation to centralisations of this kind[15, 16]. Research indicates that centralisation of cancer services is likely to place increased travel demands on patients and families, and may limit people's access to quality care[17]. A review of research evidence indicates patients are more willing to travel for a number of reasons: for specialist care; to a hospital with a good reputation; if a condition is serious or urgent; if of a higher socioeconomic status; in contrast, older patients and frequent users of services are less willing to travel further[18]. A recent study suggests that while cancer patients are willing to make more frequent journeys to services if it means they will receive care that is slightly more effective or associated with fewer side-effects, similar effects are not reported for longer journeys[19].

Specialist surgical services for urological and oesophago-gastric cancers in London Cancer and Manchester Cancer

Networked cancer systems London Cancer (covering North Central and North East London, and West Essex (population 3.2 million)) and Manchester Cancer (covering Greater Manchester and East Cheshire (population 3.1 million)) are at present working towards centralising specialist surgery services separately for a number of cancers[20, 21]. This study will evaluate changes conducted in four surgical cancer pathways that are being centralised in both areas: prostate, renal, bladder, and oesophago-gastric (OG) cancers. There are over 60,000 new cases of these cancers in the UK every year[5, 22-24]. Prostate cancer is the second highest cause of cancer deaths in men [22]. Five year survival rates for bladder and renal cancers range from 50-60%[23, 24], 12% for oesophageal cancer and 16% for gastric cancer[5].

Current pathways

In Manchester, patients are referred to a local cancer centre and, depending on diagnosis, either remain at that service for staging or palliative care, or are referred to a specialist centre for specialist surgery, chemotherapy and/or radiotherapy (Figure 1). Specialist centres are located across the Greater Manchester region, and take patients referred from nearby hospitals; certain aspects of urological care (e.g. robotic surgery) are provided by the Christie Hospital. While there is broad agreement in process across the pathways, there exist variations in the protocols used for referral to specialist centres. Across specialist centres, patient volumes are substantially lower than recommended, and there are variations in access to technology (e.g. robotic surgery), innovative techniques, and opportunities to participate in research. At present, all surgeons provide all types of radical surgery within their specialty (e.g. urologists offer all specialist surgery for bladder, prostate and kidney) and there is limited opportunity for greater 'subspecialisation' (e.g. a urologist becoming expert in radical prostatectomy).

In London Cancer, potential cancer patients are referred to their local cancer centre for diagnosis, and either remain there or are referred to a specialist centre. The care received by patients varies across specialist centres. For example, prostate and bladder patients can only receive robotic surgery in certain specialist centres; the majority of renal surgical patients undergo surgery in a local non-specialist centre (performed by a specialist or general urologist – Figure 1), rather than a specialist centre (potentially limiting the surgical options afforded these patients); and OG patients are not guaranteed to see a specialist out of hours or at weekends. Similar to Manchester, there is substantial variation in patient volumes across specialist centres.

Centralisations proposed by London Cancer and Manchester Cancer

In both areas, it is proposed that specialist surgical services for these cancers should be centralised in a reduced number of centres. Patient pathways will be standardised, reducing variations in care. Increased patient volume will permit greater specialisation of staff, and greater experience and expertise across teams, and specialist services will offer a full range of surgical technologies (e.g. robotics), and equal access to innovative techniques, such as less invasive procedures. Local units will continue to provide much patient care closer to home, including diagnosis, ongoing radiotherapy and chemotherapy. However, post-centralisation, local units will benefit from closer involvement of specialist centre staff, e.g. joint multi-disciplinary teams (MDTs), and specialists providing training and delivering some outpatient care, thus improving quality of care across the whole system. Both centralisations emphasise the importance of continuity of care.[20, 21] Table 1 provides an overview of the proposed changes in terms of the number of cases and specialist centres for each type of cancer.

Figure 1. Simplified models summarising specialist cancer surgery – before and after centralisation

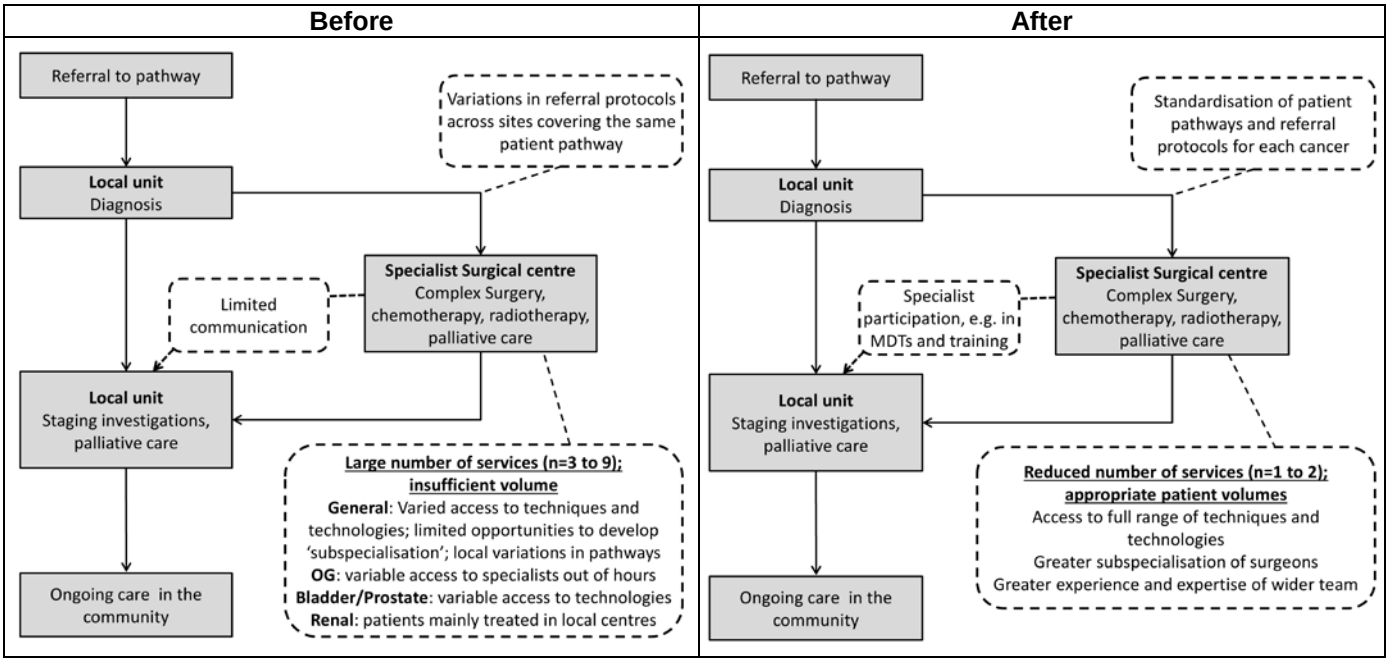


Table 1. Overview of specialist surgical services – number of cases and number requiring complex surgery, and number of specialist services pre and post centralisation (total cases and numbers requiring surgery are annual figures)

Cancer	London Cancer				Manchester Cancer			
	Total cases	Require Surgery	Specialist centres		Total cases	Require surgery	Specialist centres	
			Before	After			Before	After
Prostate & bladder	1900	350	4	1	2500	400	5	2
Renal	250	190	9	1	400	250	8	2
Oesophago-gastric	500	150	3	2	800	150	3	2

London Cancer figures [20, 25]; Manchester Cancer figures [21, 25]

Current status of centralisations

Implementation of the Manchester Cancer centralisation of specialist surgical services for urological cancers is anticipated by December 2015 at the latest. A decision on the OG cancer services competitive tender is expected by August 2015, with full implementation

anticipated by March 2016 at the latest. The London Cancer centralisations have been agreed, and are anticipated to be implemented between July-December 2015.

2. AIMS AND OBJECTIVES

This study will use qualitative and quantitative methods to evaluate centralisation of specialised cancer surgery services in two regions of England, and identify lessons that will guide centralisation work in other areas of specialist services. The objectives of this study are to:

- identify factors influencing development, implementation, and sustainability of centralisations of specialist cancer surgery;
- analyse the impact of changes on patient outcomes and processes of care;
- analyse the impact of changes on staff skill mix, patient choice, patient experience, and continuity of care;
- analyse the relationship between processes of care and outcomes;
- analyse incremental cost and cost-effectiveness of the changes;
- examine preferences for centralisation, the most important attributes of services that affect these preferences, and how these preferences vary between patients, the public, and professionals;
- present lessons on centralising specialist cancer surgery services that might be applied in future centralisations of specialist cancer services and other specialist settings.

To address these objectives we will conduct a mixed method evaluation of the processes, impact, and costs of the centralisations of specialist surgical pathways for four cancers by London Cancer and Manchester Cancer, using a controlled before and after design and parallel qualitative study of implementation processes. The four surgical pathways (prostate, bladder, renal, and oesophago-gastric) have been selected because they are being centralised in both areas, permitting analysis of how such changes occur in different contexts. There is also potential to analyse different scales of change, as the 4 pathways vary in relation to the extent of the centralisation planned, as follows:

- High: Renal - Manchester Cancer (MC) 8 to 2 centres, London Cancer 9 to 1
- Medium: Prostate and bladder - MC 5 to 2, LC 4 to 1
- Low: OG - MC and LC both 3 to 2

Analysing these different extents of centralisation will allow comparison of: the work involved in developing and implementing them (e.g. do different extents of centralisation require different levels of planning? Are the political issues different in these different cases? Is there more resistance to the 'high' centralisation cases?); their level of impact on organisation and quality of care, clinical outcome, patient experience, and costs; and the relationship between effort expended and impact achieved (e.g. do the different scales of change have equivalent impact on quality, outcomes and experience?). Quantitative methods will include analysis of local and national data on clinical processes and outcomes (RQ2), as well as joint comparison of costs and effects to allow consideration of the cost-effectiveness of the transformation (RQ 3) and National Patient Experience Survey data (RQ4). Qualitative methods will include documentary analysis (RQ1), stakeholder interviews and observations of relevant meetings (RQ1,4,5). We will also conduct a Discrete Choice Experiment to examine patient, public and professional preferences for centralisations of

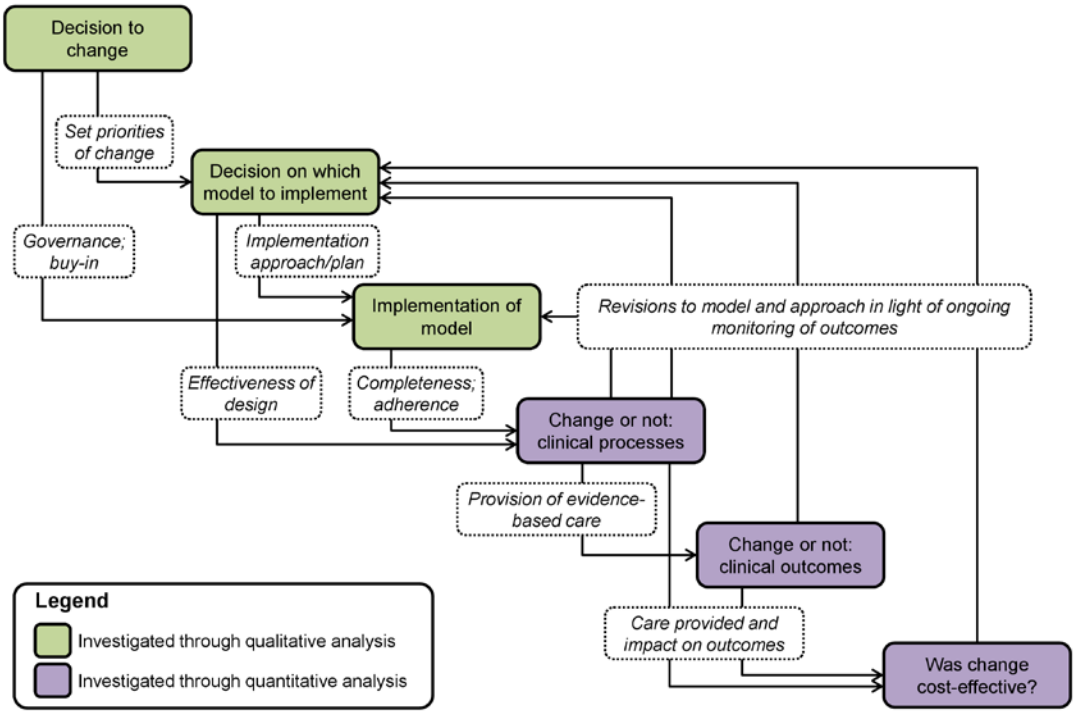
this kind (RQ6). Finally, we will hold a workshop for people planning centralisations of specialist cancer services elsewhere, and people centralising other types of specialist service. It will focus on how these lessons might apply more widely, and we will incorporate this feedback into our final conclusions (RQ7).

3. DESIGN

This is a multi-site study of centralisation of specialist surgical pathways for four cancers in two large conurbations in England. It will combine a health technology assessment approach of measuring impact of centralisation in terms of clinical processes, clinical outcomes, cost-effectiveness and patient experience, using a controlled before and after design ('what works?') with a parallel qualitative analysis of the development, implementation and sustainability of the centralisations ('how and why?').

These approaches will be combined in a framework that has been developed as part of the current HS&DR funded evaluation of stroke service centralisations (REC reference 11/LO/1396; protocol[2]) (Figure 2). This framework reflects key processes of centralisation, and how they are inter-related. It covers: 1) reaching a decision to change; 2) developing and agreeing the new service model; 3) implementing the new model; 4) adherence to the new model throughout the system; 5) impact on provision of care; 6) impact on outcomes (including clinical outcomes, patient experience, and costs) (NB ordering these factors should not be taken to imply a linear relationship between them).

Figure 2. Summary of framework for analysing centralisations



There are important differences between the context in which this framework was developed and the context in which it will be applied in this study. Whereas stroke is a healthcare event that requires immediate response, specialist cancer surgical services operate at a different pace, and thus offer greater opportunities for service providers to engage with the patient and family regarding treatment choices. Therefore, different factors may influence the decision to change, and different types of model may be implemented.

Both of these considerations might influence the way in which change progresses. There is much potential to examine how the key components of large scale change interact in different contexts.

To interpret the qualitative components of the study, we will use a case study approach[26-28]: in each area, we will analyse the overarching governance, pathway-specific governance, and for each cancer a specialist unit, a local unit, and a hospital that no longer provides services. We will draw on findings from a recent review of evidence on large-scale transformation initiatives, which identified five 'simple rules' likely to enhance 'successful' implementation. These rules suggest the importance of blending designated and distributed leadership approaches; supporting feedback and learning; awareness of history of change; engagement of professionals; and inclusion of patients and families[1]. We have developed these 'rules' further through our study of centralisations of acute stroke services in London and Greater Manchester. Our analysis has drawn out the importance of combining 'bottom up'-led change with 'top down' central leadership, and of understanding of the social and political context of the changes and their impact on outcomes (paper in preparation).

Our research questions are:

RQ1. What were the key processes in centralising specialist cancer surgery services in London Cancer and Manchester Cancer?
RQ2. What is the impact of the centralisations on provision of care, in terms of clinical processes and outcomes?
RQ3. What are the cost and cost-effectiveness of the changes?
RQ4. What is the impact on patient experience, including choice and continuity of care?
RQ5. What is the impact on staff and healthcare provider organisations, including ways of working, skill mix and approaches to collaboration?
RQ6. What are patient, public and professional preferences in relation to these centralisations?
RQ7. How might lessons from centralising specialist cancer surgery services be applied in future centralisations of specialist cancer services and other specialist settings?

We will address these questions using qualitative and quantitative methods:

Documentary analysis (RQ1)

Documentary analysis (e.g. of project plans, meeting minutes, and local press) will be conducted to develop a clear understanding of what processes were carried out, and when, to develop and implement the centralisations of specialist cancer surgery.

Stakeholder interviews and non-participant observations (RQ1,4, 5)

We will interview a range of stakeholders related to the centralisation of specialist cancer surgery in Manchester Cancer and London Cancer, including cancer patients and their carers. Interviews will focus on the drivers for change, and factors influencing the centralisations at key stages (such as agreeing the case for change, selecting the service model, planning and implementation of changes, and their impact on quality of care). To examine issues associated with implementation and sustainability of the changes, we will observe meetings related to the governance and implementation of the centralised services.

Clinical processes, clinical outcomes, and patient experience (RQ2, 4)

It is important that the evaluation establish the extent to which changes were implemented, how this was reflected in provision of clinical interventions, and the impact of centralisation on clinical outcomes. We will assemble data from hospital episodes statistics and national audit data to analyse the impact of selected cancer surgery service centralisations on a range of outcomes (e.g. mortality, readmission, length of stay) and care process measures (e.g. surgeon grade and experience, surgical technique), and also to delineate the association between the outcomes and the care processes. To examine further the impact of the centralisations on aspects of patient experience, we will analyse National Cancer Patient Survey data, with a focus on such key issues as patient choice, confidence in staff, communication, teamwork, and access.

Cost-effectiveness (RQ3)

We will also evaluate the costs of the centralisations, and their value for money. This will be reported as an incremental cost per quality-adjusted life year gained and incremental cost per outcome gained as informed by the Discrete Choice Experiment (RQ6).

Discrete Choice Experiment (RQ6)

The proposed centralisations are likely to represent a significant change in how patients experience care, with many having to travel further to receive surgery or specialised investigations, but with a greater choice of treatments, and with potentially better outcomes. To examine the acceptability of such changes to patients, the public, and professionals, we will conduct a discrete choice experiment (DCE)[29-31], which will examine preferences for centralisation; relative importance of attributes of surgical services; and how preferences vary between stakeholders. The DCE will follow international best-practice guidelines[31].

Stakeholder workshop (RQ7)

In order to draw out the lessons from our findings for the centralisation of other specialist services, we will share our findings at a workshop for those involved in planning centralisations of specialist cancer services elsewhere, and those involved in centralising other types of specialist service. These will include providers, commissioners and patients/patient groups. Based on feedback from this workshop we will provide an analysis of factors influencing the generalisability of our findings to other specialist services, and based on this learning develop lessons that will be of use in these settings.

SAMPLING

Much of the data collected will relate to the areas undergoing centralisation. However, changes of this kind must be understood in a wider context, and we will thus also collect/obtain national data where appropriate.

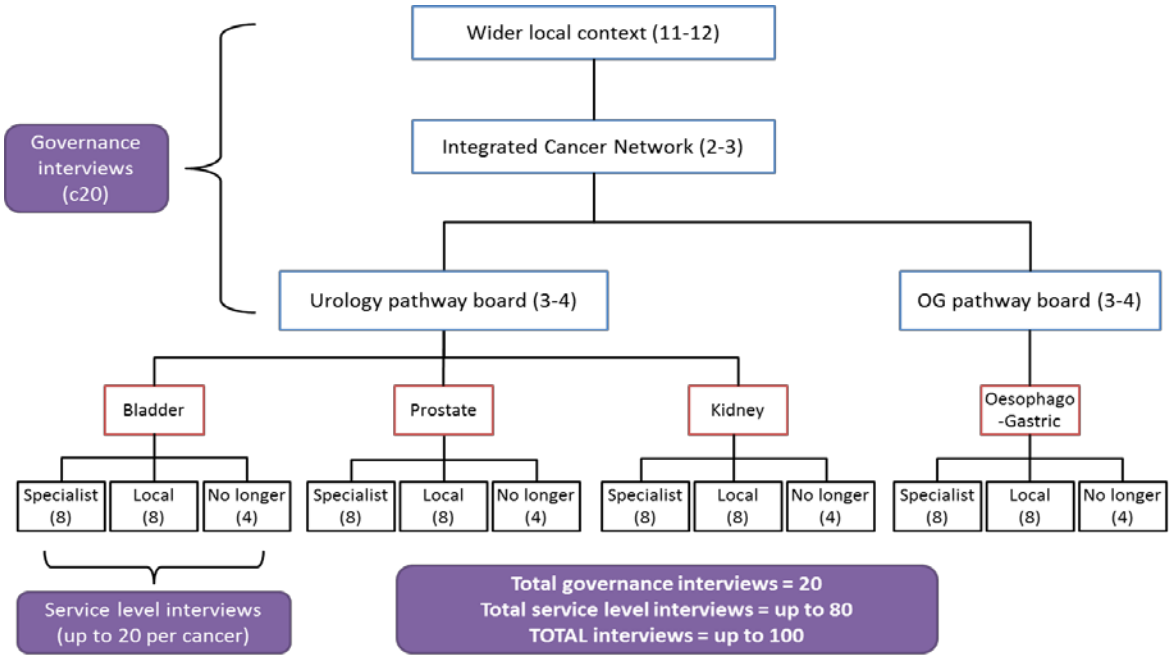
Documentary analysis

We will collect documentation related to development, planning and implementation of the centralisations in London Cancer and Manchester Cancer. We will also collect data on national contextual factors, such as policy and press coverage. We anticipate analysing relevant local and national documentation covering a time period from 2006, when the Royal College of Surgeons of England launched a consultation on centralisation of surgical services[32], through to the end of the data collection period (month 40).

Stakeholder interviews and non-participant observations

Reflecting the proposed centralisations, we will sample up to 200 stakeholder interviewees purposively from a range of settings (up to 100 in London Cancer, up to 100 in Manchester Cancer, summarised in Figure 3). These will include the overarching governance of the centralisations, for example the London Cancer and Manchester Cancer boards, cancer-specific pathway boards, and representatives of the wider community in which the changes take place (including commissioners, health and wellbeing boards, Strategic Clinical Networks, Academic Health Science Networks, and patient and carer representative groups). For each cancer, we will interview clinical staff (surgeons, doctors, nurses, therapists) and management (at service and board level) for specialist cancer centres, local cancer centres, and services that no longer provide care (with each representing a case study).

Figure 3. Anticipated interviewee recruitment (example covers single area)



Note: numbers in brackets reflect upper estimate of anticipated interviewees: where studied services are based in the same organisation, data collection may reduced, in terms of overlapping managerial and clinical staff

Over the data collection period, researchers will observe meetings related to the ongoing governance and implementation of the centralised services, for example pathway board meetings organised by London Cancer and Manchester Cancer, and training sessions and multidisciplinary team meetings within cancer services.

Clinical processes and outcomes, and patient experience

Table 2 presents the datasets we will access, the time period covered, and the numbers of cancer patients likely to be available per year in these datasets.

Table 2. Summary of datasets to be sampled (further detail on datasets, in terms of request processes, completeness, and coverage are provided in Appendix A)

Dataset	Year change occurs	Years sampled	Mean number of patients per year, by area	Notes
Prostate cancer				
National Prostate Cancer Audit	2015	2014-2017	*Incidence of prostate cancer:* London Cancer=1600 Manchester Cancer=1879 Rest of England=30,637	Audit commenced 2014 Mean annual incidence of prostate cancer from UK Cancer Atlas data 2008-2010[25]
Post Radical Prostatectomy Outcomes - Oncology & Function (PROOF)	2015	2014-2017	London Cancer=500 Manchester Cancer=300 Rest of England=500	Estimated figures from collaborator Caroline Moore, lead of PROOF project
National Cancer Patient Experience Survey	2015	2014-2017	London Cancer=276 Manchester Cancer=307 Rest of England=5002	National Cancer Patient Experience survey (2013)[33]
BAUS Radical prostatectomy dataset	2015	2014-2017	BAUS audit participation (national)=2093	BAUS Radical Prostatectomy Audit report (2012)[34]
Bladder cancer				
HES	2015	2014-2017	Patients undergoing cystectomy (national)=1360 *Incidence of bladder cancer:* London Cancer=628 Manchester Cancer=372 Rest of England=7895	From NCIN analysis of 2005-2007 bladder cystectomies[35] Mean annual incidence of bladder cancer from UK Cancer Atlas data 2008-2010[25]
National Cancer Patient Experience Survey	2015	2014-2017	London Cancer=321 Manchester Cancer=410 Rest of England=6327	National Cancer Patient Experience survey (2013)[33] NB these are overall figures for urological cancers – will be disaggregated by ICD10 code.
Renal cancer				
BAUS audit of nephrectomies	2015	2014-2017	BAUS audit participation=5851 *Incidence of renal cancer:* London Cancer=282 Manchester Cancer=407 Rest of England=5930	From BAUS nephrectomy Audit report (2012) Mean annual incidence of renal cancer from UK Cancer Atlas data 2008-2010[25]
National Cancer Patient Experience Survey	2015	2014-2017	London Cancer=321 Manchester Cancer=410 Rest of England=6327	National Cancer Patient Experience survey (2013).[33] NB these are overall figures for urological cancers – will be disaggregated by ICD10 code.
OG cancer				
AUGIS national audit[1]	2015	2014-2017	Patients undergoing oesophagectomy and gastrectomy (England)=1967 *Incidence of OG cancer*: London Cancer=868 Manchester Cancer=566 Rest of England=11529	From AUGIS OG audit report (2013)[36] Mean annual incidence of OG cancer from UK Cancer Atlas data 2008-2010[25]
National Cancer Patient Experience Survey	2015	2014-2017	London Cancer=221 Manchester Cancer=202 Rest of England=3860	National Cancer Patient Experience survey (2013).[33] NB these are overall figures for upper GI cancers – will be disaggregated by ICD10 code.

Table 3. Summary of primary and secondary outcomes, process measures, and mediating factors for each cancer

Prostate cancer	
Primary outcome	• Radical prostatectomy: Proportion of men treated by primary surgery who remain continent (pad free) at 12 months (research indicates range of 80-92%, depending on procedure)[37]
Secondary outcomes	• Radical prostatectomy: proportion of men treated by surgery with pre-operative erectile function who have erections sufficient for penetration at 12 months • Length of stay • Readmission • Surgical complications (conversion to open surgery, rectal injury, bowel injury (other than rectal injury), blood transfusion) • Post-operative complications (anastomotic leak and prolonged dependence on a drain, ileus, deep vein thrombosis, or compartment syndrome (in particular related to length of procedure)) • Diagnostic outcomes: proportion of men diagnosed with clinically significant prostate cancer (using number of men biopsied as the denominator) • Patient experience, including choice of treatment, access to services, confidence in staff, communication, effectiveness of teamwork and opportunity to participate in research
Bladder cancer	
Primary outcome	• 30 day post-operative mortality (national figure (2012)=2.4%)[38]
Secondary outcomes	• Length of stay • Proportion of patients offered neo-bladder reconstruction • Proportion of patients receiving neo-bladder reconstruction • Surgical complications (measured by Clavien-Dindo grading) • Patient experience, including choice of treatment, access to services, confidence in staff, communication, effectiveness of teamwork and opportunity to participate in research
Renal cancer	
Primary outcome	• 30 day post-operative mortality (anticipated figure=10.5%)[39]
Secondary outcomes	• 30 day readmission • %of cases of T1a tumours having nephron sparing surgery • Length of stay • Surgical complications (measured by Clavien-Dindo grading) • Conversion from laparoscopic (including robotically assisted) to open surgery • Patient experience, including choice of treatment, access to services, confidence in staff, communication, effectiveness of teamwork and opportunity to participate in research
OG cancer	
Primary outcome	• 30 day post-operative mortality (national figure (2013)=1.7%)[36]
Secondary outcomes	• % of patients offered endoscopic resection for tumours staged as T1a • Length of stay • % Complete R0 resection (i.e. full removal of tumour) • Surgical complications – anastomotic leak • Patient experience, including choice of treatment, access to services, confidence in staff, communication, effectiveness of teamwork and opportunity to participate in research
Process measures (all)	
	• Waiting times (within 62 days of referral, 31 days of decision to treat) • Number of patients seen by surgeon • Case volume per surgeon • Proportion of cases where surgery is an emergency procedure
Mediating factors (all)	
	• Patient characteristics (age, gender, ethnicity, socioeconomic status) • Cancer stage • Whether procedure is a salvage procedure

Table 3 presents key measures for the quantitative analyses. Clinical members of the research team identified primary and secondary outcome measures, process measures, and mediating factors for each type of cancer. Our patient co-applicant led the process of identifying items in the National Cancer Patient Experience Survey for analysis, covering e.g. patient choice of treatment, access to services, confidence in staff, communication, effectiveness of teamwork and opportunity to participate in research.

For prostate cancer, we would need a sample size of 582 patients to have a 80% chance of detecting, as significant at the 5% level, a decrease in the primary outcome (proportion of men treated by primary surgery who remain continent at 12 months) from 80% to 70% (https://www.sealedenvelope.com/power/ [09 September 2014]). For bladder and OG cancers we would need a sample size of 4634 patients for the same statistical power as above to detect a decrease in 30 day post-operative mortality (the primary outcome selected by our clinical collaborators in each case) from 2% to 1%. For renal we would require a sample size of 2850 patients to have a 80% chance of detecting, as significant at the 5% level, a decrease in in 30 day post-operative mortality from 10.5% to 7.5%.

Length of stay was selected as an important secondary outcome in every case by clinical team members. We would need a sample size of 256 patients to have a 80% chance of detecting a one day decrease in length of stay (i.e. from 9.2 to 8.2 for specialist surgery for bladder cancer, from 5.1 to 4.1 for specialist surgery for kidney/prostate cancer, and from 6.0 to 5.0 for specialist surgery for OG cancer) as significant at the 5% level, assuming a standard deviation (SD) of 2.8 (baseline length of stay and SD derived from national figures[40]).

Based on the figures in Table 2 we expect our datasets to contain information on primary outcomes for approximately the following number of patients per year: prostate cancer 1,300; bladder cancer 1,400; kidney cancer 6,000; OG cancer 2,000. For each cancer we will have at least four years of data (2014-2017), suggesting that the required sample sizes are feasible.

Cost-effectiveness

Using our links with providers and commissioners, we will obtain information on the costs associated with the process of centralisation and implementing changes. Although some of these costs may represent one-off, sunk costs to providers and commissioners, they will be important in informing other organisations as to what the potential cost of centralisation might be. We will also attempt to quantify any impact on cost per procedure and in-patient hospital costs that may have occurred as a result of the centralisation, for example as a result in change in patient case-mix and complexity, changes in bed management practices or as a result of the way theatres are being booked and used. The cost-effectiveness of the centralisations will then be reported as an incremental cost per quality-adjusted life-year gained and incremental cost per outcome gained as informed by the Discrete Choice Experiment.

Discrete Choice Experiment

The DCE will elicit preferences for the way in which cancer surgery services are organised for three sub-groups: patients; the general public; and professionals (surgeons, specialists, GPs, nurses). The DCE will include a nationally representative sample from each group. Sample

size calculations for DCEs are not straightforward but depend on the question format, the complexity of the choice tasks, the desired precision of the results, the degree of heterogeneity in the target population, the availability of respondents, and the need to conduct subgroup analyses. A sample size of 300 is commonly recommended[41], and this will be exceeded here, with 100 in the professional and public subgroups, and 200 in the patient subgroup (100 London and Manchester, 100 from elsewhere).

4. DATA COLLECTION

Documents

Much of the documentation covering development and implementation of the centralisations will be obtained through engagement with Manchester Cancer and London Cancer, and staff in other participating organisations. We will supplement these data with online searches for local and national documentation, including relevant policy, guidance and media reports. Physical documents will be stored for analysis in locked cupboards in a secure, pass-protected environment, while electronic documents will be stored on a secure server on password-protected computers.

Stakeholder interviews and observations

Semi-structured interviews will be conducted with a range of stakeholders. Topic guides will be developed in collaboration with patient and clinical team members to focus on key aspects of the centralisations, including the decision to change, selection of the model, processes of planning and implementing the changes, perceived impact and sustainability of changes (e.g. on ways of working, service quality, continuity of care, and patient choice and experience), and influential factors (such as local and national context). Interviews will be digitally recorded for professional transcription, and will only be conducted with written, fully informed consent. All interviews will be digitally recorded for transcription in full. Non-participant observations will be recorded as fieldnotes. Data will be stored securely and fully anonymised.

Clinical processes, clinical outcomes, and patient experience

Formal requests for national datasets will be made through the relevant organisations (specified in Table 2). These requests have been accounted for both in terms of time and funding. The research team is experienced in successfully obtaining data of this kind, and has already contacted several of these organisations to confirm how best to obtain the data.

Cost-effectiveness

We will use clinical process, clinical outcomes, and patient experience data along with data from published sources to populate the cost-effectiveness models described in Section 6. Additional data to be collected will include:

- Probabilities and disease progression (obtained from systematically reviewing epidemiological and other literature)
- Unit costs (obtained from NHS Reference Costs, previous studies http://www.crd.york.ac.uk/CRDWeb/), British National Formulary (http://www.bnf.org/bnf/index.htm), Unit Costs of Health and Social Care (http://www.pssru.ac.uk/project-pages/unit-costs/2013/)
- Utilities (obtained from CEA registry https://research.tufts-nemc.org/cear4/)

Discrete Choice Experiment

We will establish preferences for the scenarios included in the analysis by asking respondents to complete the survey. The survey tool will be designed as follows:

1. We will identify key attributes for cancer surgery services that may be affected by centralisation. A long list of attributes will be drawn from the published literature. The final list of attributes to be included in the analysis will be derived from focus groups with patients, the public and professionals. Potential attributes will include clinical outcomes and care processes as described above, plus travel distance, frequency, time, and cost, NHS cost per patient and potential unit closures.
2. We will assign levels to these attributes based on clinically feasible ranges derived from systematic literature reviews.
3. We will design the DCE questionnaire. At this stage we will use a pairwise choice framework and will compile a set of pairwise scenarios that describe the feasible combinations of levels and attributes of centralised versus non-centralised cancer surgery services. The number of pairwise choices will be reduced to a practical number for participants to answer using an orthogonal fractional main effects design[42].

Combining the methods

Combining our evaluation methods throughout the lifespan of the study will benefit the research in terms of data collection, analysis, and the resultant lessons. In terms of data collection, interview topic guides will in the first instance be informed by the documentary analysis and primary measures used in the process, outcome and patient experience analyses, and latterly incorporate initial findings from the process, outcome, and patient experience analyses. The process and outcome analyses will in part be guided by documentary analysis (e.g. in terms of specifying when centralisation took place and identifying relevant measures). Potential sources of cost data will be partly identified through interviews and documentary analysis (e.g. issues related to staffing and resource use), while the focus of the cost-effectiveness analysis will be guided by the results of the outcomes analysis. The attributes used in the DCE will be informed by data from interviews with professionals, patients and the public, and the patient experience survey data.

5. RECRUITMENT

Interviews

All potential staff interviewees will be approached by a study researcher: in the first instance, contact, including provision of information sheets, will be made through e-mail and telephone. Staff will have at least 48 hours to consider the contents of information sheets and will be free to ask any questions about the research. Staff will only be interviewed once they have given written, fully informed consent. Participants will be free to withdraw at any time, up to and including the actual interview.

Non-participant observations

We aim to observe ward activity and relevant meetings in participating services. We anticipate that staff participants are unlikely to experience any risks from this component of the study.

On ward observations, researchers will not directly observe patients at any time, but rather staff activity as patients pass through specialist cancer services. Therefore, we will not recruit patients to the observation component of the study. It will not be possible to seek individual consent during the observations of ward activity. However, before commencing any observations, the researcher will attend staff meetings to discuss the research and to obtain consent from team members. Further, posters explaining the purpose of the observations will be displayed in the clinical areas, the presence of the observer will be announced and the researcher will be clearly identified with a badge. When accompanying ward rounds, the researcher will ask permission of the staff involved and ensure copies of the information sheets are available for distribution. This approach is based on recruitment methods applied in an observational study of care provided in maternity services approved by an NHS Research Ethics Committee (NHS REC reference: 08/H0808/178) and a study of 24/7 working in London Hyperacute Stroke Units (NHS REC reference: 14/LO/0355).

Permission to observe meetings will be obtained from the Chair in advance of the meeting taking place. The participant information sheet will be circulated with meeting papers to all attendees. On the first attendance, the researcher will brief attendees on the study's aims, what participation entails, and that they may decline to participate at any time; at subsequent meetings, the researcher will announce him/herself as a non-participant observer, and confirm that he/she is happy to answer any questions in relation to the research. Agreement for observation to proceed will be recorded in meeting minutes. If participants do not agree to participate, any contributions they make to the meeting will be excluded from the researcher's field notes, or the researcher will withdraw from the meeting if more appropriate. Staff participants will be granted anonymity, and will not be identified by name in any reports.

Discrete Choice Experiment

As design of the Discrete Choice Experiment forms an early part of the project, participant information sheets, informed consent forms, and any recruitment materials will be developed in the early stages of the project and submitted to the REC as an amendment for approval prior to use. These materials will be developed in collaboration with patient and clinical team members. Survey data will subsequently be collected by a mixture of online survey tools and hard-copy postal questionnaires from the three stakeholder groups as follows:

- For patients, data will be collected from patients waiting for surgery in London, Greater Manchester and the rest of England, identified through clinical centres, local cancer-specific patient associations run through participating hospitals and other local independent patient and carer support groups (including groups focusing on hard to reach people, e.g. through BME-specific patient associations), and national patient organisations, e.g. the Prostate Cancer Charity, Orchid, Urostomy Association, Kidney Cancer UK, and the Oesophageal Patients Association.

Information about the Discrete Choice Experiment will be made available in service settings, but researchers will not directly approach or recruit potential participants. Recruitment will take place through implied consent associated with the return of online survey or postal questionnaire.

- For the general public we will recruit respondents to the survey using a number of approaches. We will advertise the survey online via the study page and through the communications offices of London Cancer and Manchester Cancer. Also, the Directors of NIHR CLAHRC North Thames and NIHR CLAHRC Greater Manchester, which are developing databases of members of the public who are interested to take part in healthcare research, have indicated they will support recruitment for this research.
- For professionals (surgeons, nurses) we will recruit respondents via newsletters distributed by Royal Colleges and professional organisations, e.g. the British Association of Urological Surgeons (BAUS), and the Association of Upper Gastrointestinal Surgeons (AUGIS), and at professional meetings.

As design of the DCE forms an early part of the project, participant information sheets, informed consent forms, and any recruitment materials will be developed in the early stages of the project and submitted to the REC as an amendment for approval prior to use. These materials will be developed in collaboration with patient and clinical team members. Once approved, participant information sheets will be given to all prospective participants. Information sheets will describe clearly the purpose of the DCE, how long completing the survey tool is estimated to last, and will state that any (personal or research) data will be stored securely and not used for any purpose beyond this analysis. The forms also state that participation is entirely voluntary, that participants may withdraw at any time, and that completion of the survey tool implies consent to participate. For the online survey tool, an opening page will provide equivalent information and consent details; to begin the survey, participants will have to press a button stating “I understand - click here to take the survey”.

6. DATA ANALYSIS

Documentary analysis

The documentary analysis will draw on our conceptual framework (Figure 2) and reflect key processes related to changes of this kind (agreeing the case for change, planning the changes, implementation), and influential factors (e.g. governance structure, local and national policy context). This information will be used to produce detailed timelines of the changes and narrative summaries of centralisations based around this framework.

Stakeholder interviews and non-participant observations

Interview transcripts and observation field notes will be managed with NVIVO software. Ongoing iterative and thematic analysis of all data will be undertaken concurrently, following established procedures of constant comparative analysis [43]. Initial analysis and category building will be led by the London and Manchester qualitative researchers and will include category mapping and constant comparison; the analysis will be developed with a subgroup of co-investigators who have qualitative expertise; and interpretation of findings will be contributed to by the whole research team. Validity will be assessed in relation to Patton’s four criteria of validity in qualitative research: verification, rival explanations, negative cases and triangulation [44].

Clinical processes, clinical outcomes, and patient experience

We will aggregate risk-adjusted patient level data by Trust and time (quarter) and use between-region difference-in-differences regression analysis to investigate the impact of the centralisations on the clinical process, clinical outcome, and patient experience measures described above. The risk adjustment will be based on patient-level regressions.

We will risk-adjust the observed patient outcomes using expected outcomes that are obtained from patient level regression models. In the case of the primary outcomes (pad free at 12 months, 30 day mortality) we will use patient level logistic regressions. For each type of cancer, the binary outcome at the patient level will be regressed against a series of covariates including: gender; age (measured in five year bands); interactions between age and gender; cancer diagnosis using the first four digits of the full primary ICD-10 diagnosis code; Charlson index derived from secondary ICD-10 diagnostic codes; presence of 16 comorbidities included in the Charlson index; ethnic group; deprivation quintile based on area of residence; and rural Urban classification based on area of residence. The patient-level regressions will be run only on patients who had surgery before the reorganisations so that the risk adjustment will not be contaminated by the changes. The regression coefficients (derived from the logistic regressions for the pre-implementation periods) will then be used to predict the probability of the outcome for every patient (in both pre- and post-implementation periods). These will then be aggregated to create a dataset of the actual outcomes (actual percentage of patients who were pad free at 12 months or who had died by 30 days) and the expected outcomes by admitting hospital and quarter (from the logistic regressions).

For each outcome and type of cancer we will construct a Trust-by-quarter dataset covering the whole of England where possible containing data on the clinical outcomes and care processes plus covariates. We will then regress the risk adjusted outcomes, measured at the Trust level in each quarter, against a variable denoting cancer surgery service centralisations, controlling for Trust and time fixed effects. This two stage approach (patient level risk adjustment followed by between-region difference-in-differences analysis on aggregate Trust-by-quarter data) is consistent with Medical Research Council guidelines for using natural experiments to evaluate population health interventions[45] and has been used previously in the evaluation of the Advancing Quality initiative in the North West of England[46], and the centralisation of stoke services in Greater Manchester and London[4]. In the regression analysis of the aggregate data the regression model is

$$y_{jt} = \alpha_1 + u_j + v_t + \delta_1 D^1_{jt} D^2_{jt} + e_{jt}$$

where *y* is the risk-adjusted outcome of interest (e.g., mortality, readmissions, LOS; actual minus expected values with expected values based on the aggregated patient level risk adjustment model), *j* indicates Trust, *t* indicates quarter, α is a constant term, *u* are Trust fixed effects and *v* are time (quarter) fixed effects. D^1 is a variable taking the value 1 if the provider Trust is in London Cancer/Manchester Cancer and 0 otherwise, D^2 is a variable which equals 1 if the observation belongs to the time period after the reconfiguration and 0 otherwise. Sample weights based on patient numbers in each Trust/quarter will be used. We are particularly interested in the sign and statistical significance of the coefficient δ_1, which quantifies the changes in risk-adjusted outcomes over time in London Cancer and Manchester controlling for the changes over time in the rest of England. We will run pre-

trends tests to examine whether the outcomes had a different linear trend in London Cancer and Manchester Cancer compared with the rest of England before the reconfigurations.

We will undertake a secondary analysis using synthetic controls, defining a control group that closely resembles regions in which centralisation occurred in terms of the outcomes in the period before the reforms. To do this we will create synthetic controls[47-50] using a weighted combination of Trusts from the rest of England to approximate pre-centralisation outcomes in London Cancer and Manchester Cancer. Trends in outcomes between London Cancer and Manchester Cancer and their synthetic controls will then be compared over time using an adapted version of the regression model described above.

We will also use patient-level regression analysis to relate the care processes to the clinical outcomes.

Cost-effectiveness

We will construct de novo cost-effectiveness models to test whether centralisations reflect good value for money 30 days and 1 year post-surgery. A before and after decision analytic model will be constructed for London and Manchester, with a different model for each type of surgical cancer centralisation. Where possible we will construct a decision analytic model of an urban region in England that has not been centralised as a control comparator to determine what change may have occurred if no centralisation had taken place. The models will be constructed using data described above along with data from published sources to calculate NHS and personal social services costs and outcomes of surgery pre and post-centralisation, with the aim of providing policy makers, commissioners and providers with information on the value for money of centralisation in surgical cancer as described above. We will include information and descriptive statistics on surgery, in-patient stay, follow-up, readmission, centralisation and implementation resource use and costs. Where possible we will report costs available from providers or commissioners. If this information is not available costs will be based on national published sources. Special attention will be paid to specific analysis of fixed and variable costs and where assets have been purchased versus staff costs so as to provide an accurate assessment of mean cost per patient before and after.

Outcomes will be modelled as quality-adjusted life years (QALYs). We will assess the feasibility of calculating QALYs from patient level patient reported and clinical outcome measures. If this information is not available utility scores of health states for calculating QALYs will be obtained from the CEA registry (https://research.tufts-nemc.org/cear4/). Cost-effectiveness will be calculated as mean cost difference between before and after centralisations, divided by mean difference in outcomes before and after, to give incremental cost-effectiveness ratios. In addition to reporting the mean incremental cost per QALY we will report the mean incremental cost per outcome gained as informed by the Discrete Choice Experiment described below. We will conduct probabilistic and deterministic sensitivity analyses to explore effects of uncertainty. Where provider or commissioner costs have been used and national published values are available, we will conduct sensitivity analyses of the impact on the results of using national versus local values. Cost-effectiveness acceptability curves will be created comparing the net monetary benefit (the willingness to pay for an outcome gained multiplied by the incremental increase

in outcome minus the incremental cost), for each of the centralisation options after compared to before. We will assess the feasibility of constructing before and after life-time models for each cancer centralisation, extrapolating the results of survival and re-admission data described above, collected as part of the evaluation. We will also assess the feasibility of calculating the cost to primary care of the different centralisation models. However, this is unlikely to be viable, owing both to issues associated with accessing the necessary data, and to the additional resources that would be required to collect this information.

Discrete Choice Experiment

The DCE will allow estimation of the preferences held in pre-defined populations and the weighting of the relative value attached to attributes determining these preferences. It will also provide an indication of people's willingness to trade between attributes. We will analyse preference data using conditional logit regression analysis. The results will indicate which attribute is most important to respondents and how this compares with the other attributes. Data will be analysed for all respondents jointly and separately for each of the three subgroups. To explore the trade-offs participants were willing to make between attributes, we will calculate the marginal rates of substitution. We will also use the regression results to calculate the predicted probability that different combinations of the attribute levels used in the experiment would be selected. This allows us to rank centralised versus non-centralised services in terms of their order of preference by the participants[51], and to explore how this ranking varies by sub-group.

Combining the data

We will conduct a multi-method case study approach to combine the above methods, with cases defined as governance of the changes in both areas (overarching and at pathway level), and for each cancer pathway a specialist centre, a local centre, and a centre that no longer provides services (see Figure 3). The case study method permits development and testing of theories on how change processes interact with the context in which they take place; a multiple case study approach – in this case, the overarching governance and implementation and impact at service level of the centralisations in Manchester Cancer and London Cancer – allows the analysis to be conducted in different organisational contexts[26-28]. The analysis will present rigorous quantitative data on the impact of these centralisations on provision of care, clinical outcomes, cost-effectiveness, and patient experience. However, such findings alone are of limited benefit, as they leave unanswered the important questions of how these impacts were achieved, and what factors were influential. In-depth qualitative analysis of approaches taken in planning, implementing, and sustaining these changes will be used to develop potential explanations of their impact on quality of care, while the focus on contextual influences will support generalisability beyond the specialist cancer surgery settings under investigation. Finally, the DCE will provide valuable insights on the priorities of a range of key stakeholders in relation to changes of this kind, which will guide the cost-effectiveness and qualitative analyses. Taken together, we will generate compelling lessons for future centralisations of specialist services, in terms of engaging key stakeholders, planning and implementing change, and potential impact on quality and outcomes of care.

7. STUDY ADMINISTRATION AND ETHICAL ISSUES

Ethics

Interviews

When interviewed, staff engaged in planning delivering specialist cancer services may feel reluctant to raise criticisms of services provided. The Participant Information Sheets make clear the independence of the researcher conducting interviews, the importance of identifying challenges as well as successes, and that any information will be anonymised fully.

Non-participant observations

The non-participant observation component of this research is extremely important to understanding how these new specialist cancer services operate. We recognise that staff may be sensitive about being observed, and that they may be concerned that observations may interfere with provision of high quality care. Following the approach taken in an observational study of maternity services (NHS REC reference: 08/H0808/178) and a study of 24/7 working in London Hyperacute Stroke Units (NHS REC reference: 14/LO/0355), we will seek to ensure that staff are fully aware of the research both before and during these observations (e.g. through presentations to staff meetings and posters within the services to be observed), that staff have the opportunity to provide informed consent, and that they are assured that the researcher will withdraw from any situation where it is felt that observation is not appropriate or might interfere with provision of care.

Discrete Choice Experiment

The DCE may raise issues for our anticipated participant groups in different ways. For members of the public, and especially patients who have previous experience of cancer services, the hypothetical situations described in relation to care preferences (e.g. distance to services versus care options) may cause distress, as individuals revisit previous experiences of cancer care. For staff respondents, it is possible that the situations presented might cause distress in terms of raising personal concerns in relation to potential changes to their own services, or in terms of their own concerns in relation to quality of cancer care. To address this concern, our patient and clinical team members will review the survey tools, to ensure that the hypothetical scenarios are presented in a sensitive fashion. Further, the participant information sheets will make clear the (hopefully minimized) risk of distress, and make clear that participation is voluntary, and that participants may withdraw at any stage.

Management arrangements

As Chief Investigator, NF will provide overall leadership of the project team, lead the qualitative analysis, manage the London-based qualitative researcher, and provide expertise on healthcare policy and evaluation. SM will lead the quantitative analysis and DCE, manage the quantitative researcher and the DCE researcher, and provide expertise on health economics and statistical methods. RH will lead the cost-effectiveness analysis, manage the health economist working on this analysis, and provide expertise on health economics and statistical methods. RB will manage the Manchester-based qualitative researcher, and expertise on organisational change and evaluation. KPJ will provide expertise on the London centralisations. JH will provide expertise on the London centralisation of urological services.

DS will provide expertise on Manchester centralisations. NC will provide patient expertise on all aspects of the study. AR will provide expertise on healthcare evaluation; will support fieldwork and analysis of qualitative, quantitative, and DCE elements.

To ensure effective management across the different institutions, formal project management will be provided by London Cancer, Manchester Cancer, and UCL (further detail on how they will contribute is provided under 'expertise and justification of support required').

The research team will meet on a monthly basis throughout the study to discuss the status of the centralisations, support progress with data collection and analysis, and to ensure effective dissemination of findings and stakeholder engagement. These meetings will be chaired by NF; administration will be provided by a project manager; teleconference facilities will be used to optimise participation. The research team meeting will take place in person once per year.

Ad hoc subgroups of the project group will be formed to lead on particular aspects of data collection and analysis. For example, NF, RB, AR, and the qualitative researchers will form a subgroup to support development of interview topic guides and coding frameworks, for final approval by the wider research team.

Study Steering Committee

During the 6 months preceding project launch, the research team will recruit members of the Study Steering Committee (SSC). The SSC will have an independent Chair. In addition to members of the research team, the SSC will be composed of a wide range of stakeholders from London and Manchester, including representatives of service users and carers, commissioners, and academics with expertise in qualitative and quantitative methods (including health economics).

Patient and Public Involvement

Patient representatives played a significant role in developing this study. Patient and public involvement will continue to benefit the study in the following ways: ensuring the research focuses on issues that are of importance to service users; ensuring that this focus is reflected in our aims, objectives, and research questions; ensuring that these are operationalised suitably in our approach to data collection and analysis; and ensuring that our findings are disseminated effectively and in a manner that is meaningful to patients and the public.

Our patient co-investigator will participate in monthly team meetings, attend the annual Study Steering Committee meetings, and comment on study documents such as participant information sheets, interview topic guides and summaries of findings. Our patient collaborators will provide expertise on all aspects of the project, e.g. commenting on study documents, and will be invited to attend annual SSC meetings.

We have budgeted to support our patient representatives in all these activities. To support effective participation, we will ensure that documents relating to meetings and events are distributed in a timely fashion. Also, a member of the team will be identified as primary contact with whom patient representatives may raise any issues or concerns.

Recommendations on effective involvement and payment of patients and public will be followed[52-55].

8. INSURANCE

UCL's insurance policy provides for negligent and non-negligent harm for all studies but in line with current sponsor's arrangements, non-negligent harm insurance is only covered for all CTIMP's and other non-CTIMP interventional studies. All other studies will be covered for negligent harm cover only. However, if this study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is a NHS Trust or otherwise.

9. DATA MANAGEMENT

Data transfer (handling, processing and storage)

Quantitative data (HES, audits, patient experience, DCE)

Electronic data drawn from national datasets (e.g. HES , national clinical audits, National Patient Experience Survey) will be transferred securely in accordance with the systems approved by the data owners. Electronic data provided as part of the DCE online survey will be transferred securely using the FTP process within the UCL Data Safe Haven. All electronic data will be stored, handled and analysed within the UCL Data Safe Haven (IDHS - see https://www.ucl.ac.uk/isd/itforslms/services/handling-sens-data/tech-soln). This is a secure electronic environment that has been certified to the ISO27001 information security standard and conforms to the NHS Information Governance Toolkit. It has a mechanism that enables information to be transferred simply and securely.

Any paper-based quantitative data – such as completed hard copy surveys – will be stored in locked filing cabinet in security card protected office space at the UCL Department of Applied Health Research. These data will be transferred to electronic format and also stored and analysed within the IDHS.

Professor Steve Morris (Department of Applied Health Research, 1-19 Torrington Place, University College London WC1E 7HB), will act as the data controller of quantitative data for the study. He will process, store and dispose of all quantitative data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto. Data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the participants' consent.

Qualitative data (interviews and observations)

In the study, interview data will be collected from participants in accordance with the participant consent forms, participant information sheets and Section 5 of this protocol (under *Recruitment*). Interviews will be recorded on an encrypted, password-protected digital audio recorder to which only the researcher knows the password. Data collected by the London researcher will be taken directly to the UCL Department of Applied Health Research (1-19 Torrington Place, University College London WC1E 7HB); data collected by

the Manchester researcher will be taken directly to Manchester Business School, University of Manchester (Booth Street West, Manchester M15 6PB). The data will be anonymised and stored securely for analysis, and the data will be cleared from the digital audio recording device when it has been transferred. Participant identifier codes will be stored in a password-protected file on a secure network to which only named team members have access via password-protected computers at the UCL Department of Applied Health Research. These data will be kept completely separate from study data: interview data will be anonymised and organised by participant codes.

Digital audio recordings of interviews will be appropriately sent to Essential Secretary (http://www.essentialsecretary.co.uk/) for transcription. Digital audio recordings of interviews, anonymised interview transcripts, data for the documentary analysis will be stored for analysis on a secure computer network to which only named team members have access via password-protected computers at the UCL Department of Applied Health Research and Manchester Business School. Only the research team will have access to participants' personal data (i.e. name and status). Any paper-based data – such as signed consent forms – will be stored in locked filing cabinets. In Manchester, data will be stored in a locked office space; in London, they will be stored in security card protected office space at the UCL Department of Applied Health Research.

Professor Naomi Fulop (Department of Applied Health Research, 1-19 Torrington Place, University College London WC1E 7HB), will act as the data controller of such data for the study. She will process, store and dispose of all qualitative data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto. Data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the patients' consent.

Data archiving

Each participating site recognises that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that she will archive the study master file at UCL for 20 years from the study end.

10. RESOURCE REQUIREMENTS

The main resources required in this study are summarised as follows:

- Time provided by stakeholders across the studied specialist cancer pathways in the Manchester Cancer and London Cancer areas, including staff, service users and carers, and members of the public.
- One 50% FTE Research Associate (grade 7 spinal point 32) for the duration of the project to undertake the cost-effectiveness analyses.
- One 50% FTE Research Associate (grade 7 spinal point 32) for 18 months to undertake the DCE
- One 100% FTE health economist for 6 months
- Two 100% FTE Research Associate (grade 7 spinal point 32) for the duration of the project to undertake the qualitative analyses.

- Finance to cover participation in DCE; researchers' travel expenses; professional transcription of interview data; dissemination, e.g. conference to present findings.

All financial and staffing resource requirements are covered by the funding agreed with the NIHR HS&DR Programme.

11. DISSEMINATION AND OUTCOME

To ensure that learning is shared rapidly and effectively, we will employ a similar range of approaches to those employed successfully in our current study evaluating the centralisation of stroke services in London and Greater Manchester[2]. The research team will provide regular feedback to stakeholders, including London Cancer, Manchester Cancer, local commissioners, and NHS England. For example, project researchers will provide verbal updates at meetings in London and Manchester. In addition, accessible briefings covering specific findings will be produced and shared electronically with local stakeholders through key contacts, the Study Steering Committee, and local Clinical Research Networks, for wider distribution. These briefings will be made available on the project website and the websites of London Cancer and Greater Manchester Cancer. We will also engage with people who are leading or developing similar changes in other parts of the country. A key example of such dissemination is the stakeholder workshop, which will be attended by people involved in planning centralisations of specialist cancer services elsewhere, and those involved in centralising other types of specialist service. Participants will include providers, commissioners and patients/patient groups.

We anticipate that our findings will influence approaches to planning, implementing and evaluating centralisations of this kind ('detailed under 'expected output/impact'). Key beneficiaries are likely to include those who commission, organise and manage healthcare services at national and regional level, healthcare staff working in relevant care domains, and patient and carer groups. All stakeholders will be added to a dissemination database, which will be regularly updated so that our findings can be shared as rapidly and effectively as possible. A number of key stakeholders, including the National Director for Cancer, and representatives of local Clinical Commissioning Groups, Commissioning Support Units, and NIHR CLAHRCs, have indicated support for the research and interest in the findings; further, several have volunteered to join our Study Steering Committee (see under *Project Management*).

The final report to NIHR HS&DR will present the overall evaluation, along with lessons and recommendations tailored to relevant stakeholders, for example those who organise healthcare at national and regional level and the national Clinical Reference Groups that advise on specialist services.

Research articles based on key findings will be published 'open access' in high impact peer-reviewed journals related to surgery, organisation and management, and health economics, in order to reach the relevant academic audiences. Two papers in peer-reviewed journals have been identified to be submitted during the study: the analysis of the DCE (estimated submission Month 18), and the analysis of governance-level interviews (estimated submission Month 20). The project team will seek to present findings at national and international conferences related to these same domains. We anticipate that these outputs

will contribute to strengthening the evidence base on centralisations of this kind (detailed under 'expected output/impact').

12. INTELLECTUAL PROPERTY

The research team possesses substantial know-how relating to novel analytic techniques and models including a proprietary framework for analysing reconfigurations (see Figure 2, under 'Design'). The existing framework has been developed by the Chief Investigator (Fulop) and other members of the research team (Morris, Ramsay, Hunter) during their employment at UCL. As such the model is proprietary to UCL and the research team have full rights to use and develop the model over the course of the proposed research and beyond. The project team are familiar with this field of research, and are confident that no freedom to operate issues exist.

This research may generate new intellectual property. Any such product will be dealt with appropriately with guidance from UCL's technology transfer company, UCL Business PLC, and in partnership with the research team's host organisations. During the project we anticipate producing the following:

1. Topic guides for focus group discussions and in-depth interviews that explore the barriers and facilitators to changes of this kind among users and providers;
2. Survey tools for evaluating the preferences of key stakeholder groups (patients and carers, members of the public, and healthcare professionals) for changes of this kind;
3. Short, accessible summaries of lessons on centralising services derived from our findings.

The above will be protected by copyright law, according to the Copyright, Designs and Patent Act 1988. Copyright law protects any work which is written and is original. We will use (c) University College London (followed by the year of creation) to make clear that UCL asserts its right to copyright protection in these works.

Intellectual property generated through this research will be managed by UCL Business, who will work closely with the project team to ensure that any valuable IP is protected by patent filing or copyright as outlined above. Our dissemination plan allows for free and open access publication of the intervention manuals and peer-reviewed journal articles. Should the interventions prove effective and cost effective we anticipate they will be adopted by NHS commissioners across the UK as new models for cancer service delivery.

The aim of the project is to generate knowledge for wider benefit. Nothing we will produce will necessarily generate income and it is likely that all our tools and outputs will be maximally accessible and free at the point of delivery.

13. TIMELINE

TASK	**MONTHS**
ORGANISING the EVALUATION	
Set up SSC	-6 to 3
NHS ethics approval	-6 to 1
NHS local research governance	-6 to 6
Recruit 2 qualitative researchers, DCE researcher, 0.5	-6 to -1

quantitative researcher)	
Recruit 0.5 health economist 22 to 27	22 to 27
SSC meetings	3, 15, 27
Project meetings	Monthly
INTERVIEWS and OBSERVATIONS	
Topic guide development	1 to 6
Data collection	4 to 28
Data analysis	10 to 40
DISCRETE CHOICE EXPERIMENT	
Developing attributes for DCE	1 to 6
Survey distribution and collection	7 to 12
Data analysis	13 to 18
PROCESSES, OUTCOMES, COSTS, and PATIENT EXPERIENCE	
Develop analysis plan	1 to 9
Specifying dataset	10 to 16
Data requests	17 to 34
Process analysis	29 to 42
Patient experience analysis	29 to 42
Outcome analysis	37 to 42
Cost analysis	37 to 42
STAKEHOLDER WORKSHOP	40
DISSEMINATION	
Progress reports to HS&DR	6, 12, 18, 24, 30, 36
Stakeholder newsletters	3, 9, 15, 21, 27, 33, 39
Draft journal articles	15 to 42
Article based on DCE	18
Article based on governance interviews	20
Final report	36 to 42

NB we have planned a 6 month lead-in, covering months -6 to -1, with launch at month 1.

14. REFERENCES

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