European Journal of Public Health, 1–5

doi:10.1093/eurpub/ckv237

Improving clinical outcomes through centralization of rectal cancer surgery and clinical audit: a mixed-methods assessment

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Background: The aim of centralizing rectal cancer surgery in Catalonia (Spain) was to improve the quality of patient care. We evaluated the impact of this policy by assessing patterns of care, comparing the clinical audits carried out and analysing the implications of the healthcare reform from an organizational perspective. **Methods**: A mixed methods approach based on a convergent parallel design was used. Quality of rectal cancer care was assessed by means of a clinical audit for all patients receiving radical surgery for rectal cancer in two time periods (2005–2007 and 2011–2012). The qualitative study consisted of 18 semi-structured interviews in September–December 2014, with healthcare professionals, managers and experts. **Results**: From 2005–2007 to 2011–2012, hospitals performing rectal cancer surgery decreased from 51 to 32. The proportion of patients undergoing surgery in high volume centres increased from 37.5% to 52.8%. Improved report of total mesorectal excision (36.2 vs. 85.7), less emergency surgery (5.6% vs. 3.6%) and more lymph node examinations (median: 14.1 vs. 16) were observed ($P < 0.001$). However, centralizing highly complex cancers using different critical masses and healthcare frameworks prompted the need for rearticulating partnerships at a hospital, rather than disease, level. **Conclusion:** The centralization of rectal cancer surgery has been associated with better quality of care and conformity with clinical guidelines. However, a more integrated model of care delivery is needed to strengthen the centralization strategy.

Introduction

European health systems are increasingly developing centralized care models as a way to improve quality of care for complex procedures and rare cancers.[1] Some experiences have attested that centralizing procedures can improve clinical outcomes,[2] increasing compliance with clinical practice guidelines (CPGs)[3] and organizational recommendations from cancer plans.[4] In Catalonia, Spain, the centralization strategy has been accompanied by a build-up framework, consisting of the designation of authorized centres (ACs) and the use of clinical audits to monitor outcomes. The policy encompasses care for 10 cancers; among these, rectal cancer should be considered a sentinel disease because of its incidence and the need for a multidisciplinary approach, including multimodal therapy. The early policy positioning on rectal cancer stemmed from both the efforts made in the development and update of CPGs in 2003 and 2008, and the performance of a clinical audit in 2010 that focused on the quality of surgery.[5] The audit reported a higher adherence to CPGs and better clinical outcomes in high-volume centres, supporting the concentration of rectal cancer surgery.

These developments have also been influenced and complemented by work elsewhere. For instance, the European Registration of Cancer Care (EURECCA) has established guidelines as well as a European framework for clinical audit.[6] The Spanish Society of Surgery has also run the Viking Project for rectal cancer since 2006; it includes an extensive training component for specialists and has shown a local relapse rate comparable to that of Norway in participating hospitals.[7]

Two years after the implementation of centralized rectal cancer surgery in 2012, a second audit assessed the immediate effect on clinical outcomes. However, the new regionalized model of cancer care also entailed multiple implications and challenges for clinicians, providers and healthcare system managers. We evaluated the impact of rectal cancer care centralization by means of two complementary research goals: assessing patterns of care based on a comparison of clinical audits between the two time periods, and understanding the reform and its implementation from an organizational perspective.

Methods

Study context and overview

The centralization strategy was implemented to improve patient access to expert care,[8] displacing the traditional model of cancer care delivery, which allowed smaller hospitals to provide specialized procedures requiring extensive clinical expertise with little to no coordination with tertiary hospitals. A 2010 retrospective cohort study (for 2005 and 2007) reported that the wide scattering of specialized surgical procedures for rectal cancer concealed poor outcomes among many public providers. A specific regulation underpinned on this assessment led to a surgery-centred centralization, based on the following conditions: authorization of reference centres performing at least 11 surgeries per year, with a referral system for those not authorized to provide the service; non-reimbursement if the procedure is carried out in unauthorized centres; and a ban on ‘adding up patients’ between centres in order to reach the threshold for authorization. After the regulation was enacted in 2012, a three-month period for implementation was allowed. Moreover, the results of the 2010 audit were communicated individually to each of the participating centres in order to point out specific processes and results requiring improvements.

We used a mixed-methods approach based on a convergent parallel design, independently collecting and analysing quantitative and qualitative data and then combining the findings in the final interpretation.[9] Qualitative analysis was added sequentially as a second strand in order to provide a more comprehensive account of the centralization strategy for rectal cancer surgery,[10] by giving a sense of process and contextual understanding to the quantitative results of the clinical audit.[11]

Clinical audit assessment

We assessed quality of rectal cancer care by means of a clinical audit for all patients undergoing rectal cancer surgery with a radical intent in two time periods (2005–2007 and 2011–2012). We defined quality of care as adherence to the Catalan CPG,[12] which incorporate the EURECCA recommendations. The methodology used has been described in detail elsewhere.[5] Differences in patterns of care quality between the two time periods were assessed using the *U*-Mann–Whitney test for continuous variables and the χ^2 test and Fisher's exact test for categorical variables. Two-sided *P* values below 0.05 were deemed statistically significant. All analyses were performed using SPSS software (version 21.0, 2012). We used the Catalonian Hospital Discharge Minimum Basic Data Set to collect data from 2014.

Qualitative evaluation

The qualitative portion of the study consisted of semi-structured interviews conducted from September to December 2014, with healthcare professionals involved in rectal cancer care ($n = 9$), hospital and health system managers ($n = 7$) and experts from academia ($n = 2$). The following criteria were used for selection of informants and composition of the purposive sample: three healthcare areas (Barcelona, Lleida and Manresa); ACs and non-ACs; and different specialties including pathologists, gastroenterologists, surgeons and medical and radiation oncologists. Snowball sampling was also used, especially among healthcare professionals.[13]

A semi-structured, one-on-one interview (by JP and PM) ensured that all critical points were addressed and that the 45–60 min sessions were flexible enough to enable participants to volunteer information on topics relevant to them. Interviews were audio-taped, transcribed and then compiled into an anonymized documentary record. We examined interview data inductively, applying thematic analysis criteria to emphasise meaning and facilitate the interpretation of the text's thematic content.[14] The development of inductive data codes ensured that recurring views and experiences were obtained.[15] Saturation of information was achieved.[16] The Atlas-ti 6.2 software programme facilitated a systematic process of data-treatment analysis.[17] We checked coding and interpretation consistency during analysis by reviewing the transcripts at different points in time.

Results

Quantitative assessment

From 2005–2007–2012, the number of hospitals performing rectal cancer surgery decreased from 51 to 32 centres. Between the two study periods, the number of centres whose yearly volume of surgical patients was more than 40 increased from 6 to 10, and the proportion of patients receiving care in these centres rose from 37.3% to 52.8%. By contrast, the number of centres with fewer than 11 surgeries per year decreased from 25 to 6 (see figure 1). Key surgical and pathology characteristics are shown and stratified by study period in table 1: first ($n = 1831$) and second study period ($n = 1949$). No significant differences were identified in the distribution of included and excluded patients. With regard to surgery, no global change in the distribution of types of operation occurred. The report of total mesorectal excision (TME) from pathologists improved. The proportion of complete mesorectum increased among the patients with reported mesorectal excision. Also, patients having at least 12 lymph nodes examined improved, as the median and mean number of lymph nodes examined increased. Regarding circumferential radial margin (CRM), both proportions of negative and positive resulting margins increased between periods, and the proportion of missing values decreased ($P < 0.001$).

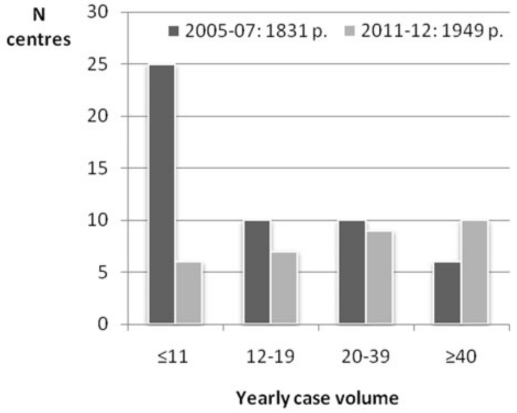

Figure 1 Distribution of centres, by annual volume of surgical patients and time period

Of the six centres with fewer than 11 cases in 2012, three have recently received authorization and have increased their volume (due to the assignment of a larger catchment area and population), while the other three have seen their authorization rescinded and have stopped offering this procedure. Thus, two years were necessary to achieve nearly full compliance to the regulation. According to administrative data, 1039 patients underwent surgery in 32 centres in 2014. Of these, 10 centres had a case volume exceeding 40 per year, and 2 handled fewer than 11 cases.

Qualitative assessment

Most of the stakeholders involved expressed a favourable view towards the centralization of rectal cancer surgery. Far from being a neutral process, however, numerous implications emerged in relation to the use of clinical audits and the reconfiguration of cancer services following the reform.

Using clinical audits as a service improvement guidance

Clinical audits embody the quality control system of the centralization strategy, and different perspectives arose with regards to their use. First, as critical mass is only a surrogate marker of quality, many participants recommended reinforcing and specifying the quality indicators to be used in clinical audits. For instance, data show that multidisciplinary teams (MDTs) assessed 73% of patients were assessed by multidisciplinary teams (MDTs), but it is unknown whether this was before any treatment was delivered. Likewise, 12% of patients received neoadjuvant chemotherapy by a non-AC's team prior to surgery, but it is unknown whether the surgical team agreed with such a decision. Complementary to auditing data by centre, interviewees mentioned the need to carry out internal controls, specifically disambiguating the results by surgeon and other key professionals, and to develop a more managed approach with regard to suboptimal clinical outcomes, which should lead to increased oversight or even rescission of the centre's authorization. Also, more cooperation should be fostered between nearby centres just surpassing the cut-off point in order to share expertise and integrate clinical practice for

Table 1 Indicators of rectal cancer surgery by audit period

		2005/07		2011/12		*P*
		n	%	*n*	%	
Cases included (*n*)		1831		1949		
Treatment						
Type of surgery	Emergency	103	5.6	71	3.6	<0.001
	Elective	1721	94.0	1878	96.4	
	Missing*	7	0.4	–	–	
Surgical operation[1]	Anterior resection	615	34.2	527	28.4	<0.001
	Low anterior resection	715	39.7	842	45.4	
	Abdoperineal resection	385	21.4	404	21.8	
	Hartmanńs procedure	85	4.7	80	4.3	
Pathology (pathology report)						
Mesorectal excision	Reported	656	36.2	1606	85.7	<0.001
	Not reported	1158	63.8	268	14.3	
Quality of mesorectal excision	M. Complete	419	63.9	1262	78.6	<0.001
	M. Nearly complete	74	11.3	130	8.1	
	M. Incomplete	85	13.0	175	10.9	
	Missing*	78	11.9	39	2.4	
Lymph nodes examined	≥12	983	56.8	1213	66.5	<0.001
	<12	749	43.2	611	33.5	
Lymph nodes examined	Mean ± SD; median	14.1 ± 9.6; 12		16.0 ± 9.6; 14		<0.001
Lymph nodes affected	Mean ± SD; median	1.9 ± 4.6; 0.0		1.4 ± 3.5; 0.0		0.009
Lymph nodes index (affected/examined)	Mean ± SD; median	11.6 ± 21.5; 0.0		9.0 ± 18.4; 0.0		0.003
Circumferential resection margin	Negative	1468	84.7	1479	87.6	<0.001
	Positive	113	6.5	138	8.2	
	Non assessed/missing	152	8.8	71	4.2	

both critical masses of patients. Overall, while centralization ameliorated a significant part of existing therapeutic inequities, half of the interviewees, regardless of their specialty or geographic location, recommended raising the threshold set at 11 annual cases. Although comparisons are problematic, the centralization carried out for rare tumours such as sarcoma—restricted to 3 ACs, contrasts with the high number of 32 ACs in rectal cancer, with the latter model seen as being hindered by a significant scattering of therapeutic procedures.

Another important issue was the difficulty in assessing quality of care when centralization was based on a specific procedure. Perceptions varied about whether rectal cancer is mainly surgeon-dependent or if diagnostic and/or therapeutic procedures are also key elements for clinical success. Thus, the clinical role assumed by ACs and non-ACs, and the clinical criteria used to refer patients (especially when lacking formal coordination mechanisms) showed a significant variability. In this regard, most professionals from ACs asserted the importance of pathology and imaging results being assessed by the MDT undertaking treatments, especially in the case of patients with advanced disease. On the contrary, professionals from non-ACs argued the need to diagnose and stage patients in their centres, in part to reduce waiting times in reference hospitals. They also denounced the lack of devolution of patients for follow-up in the non-ACs. On the other hand, most agreed on the need to properly cope with acute complications and avoid a model of care delivery based on the displacement of a skilled surgeon (currently performed in paediatric or plastic surgery).

Regionalization of rectal cancer care and organizational innovation

The top-down definition of a patient flow map prompted hospitals to regionally create or reinforce inter-organizational relations in order to manage the workflows. Before centralization, these connections lacked a specific pattern, varied by cancer type and were mainly based on informal relations between physicians of the same specialty, especially medical oncologists and surgeons. In this context, our study revealed two factors that gradually made the interface of ACs and non-ACs a key management issue: first, the possibility to increase the critical mass of patients by establishing agreements with hospitals that were not originally considered in the referral map; and second, an explicit cultural shift in the customer-provider management, addressing both patients' transition and clinical engagement between professionals from different providers. Examples of such organizational innovation, not only limited to rectal cancer, are described in table 2. Interviewees identified multicentre tumour boards and cross-cutting groups as the most successful organizational mechanisms for achieving integrated care. Importantly, both examples depend on an institutionally supported clinical leader to foster multicentre, win-win strategies and create shared ground for partnership on treatment for rectal cancer patients. On the contrary, unsatisfactory experiences led some non-ACs to pressure central health system managers to change the foreseen path, or they directly referred patients to other ACs.

In another vein, some clinicians pointed to the fact that removing competences on rectal cancer surgery disregarded the distribution of clinical expertise in the case of both skilled surgeons and other professionals, arguing that 'clinical expertise across the health system is not limited to the staff working at authorized centres'. This led some ACs to engage surgeons from non-ACs within an ongoing process of *satellitization* between clinical departments/MDTs from different centres. Respondents also suggested taking advantage of specialist expertise at a healthcare system level by optimizing their scale of operation (e.g. tumour-site expert pathologists).

Discussion

This study showed the two sides of centralization: improved quality of cancer care, but also difficulties and debate on implementation at the professional and management levels. In Catalonia, centralizing rectal cancer surgery changed the prevailing healthcare patterns, reducing the service providers from 51 to 32 hospitals. The number of centres whose volume of surgical patients was under 11

Table 2 Types of healthcare reorganization between authorized (ACs) and non-authorized centres (non-ACs) in streamlining professional expertise and continuity of care

Healthcare reorganization type	Specific practices
Multicentre tumour boards	• Involvement of clinicians from non-ACs within multicentre tumour boards in ACs, including the presentation of patients to be referred • Involvement of clinicians from ACs in non-AC tumour boards, to provide expert advice and visit patients eligible for referral
Coordination of the process of care between ACs and non-ACs	• Development and adoption of a pathology-based clinical protocol in both ACs and non-ACs • Agreement on the clinical management roles to be played by ACs and non-ACs throughout the diagnostic, staging, treatment and follow-up phases, in order to better deal with fragmentation of care • Definition of scenarios between ACs and referring centres in order to better tackle the management of complications, emergencies, secondary effects and treatment sequels
Pooling services and exchanging professionals	• Pooling cancer services by involving expert clinicians in other ACs in order to activate local staff competencies • Exchange of professionals to maintain clinical skills and expertise
Clinical accountability and information	• Annual report by ACs to non-ACs on clinical performance for referred patients • Common use of pathology-based clinical databases between ACs and non-ACs • Identification of clear gatekeepers in ACs for patients and professionals, granting full access to clinical and care information along the process of care, reporting specific changes in treatments and elaborating a final report before devolution. • Exchange of publications between and among professionals in ACs and non-ACs

decreased from 25 to 6, while high-volume centres (>40 surgical patients per year) increased from 6 to 10 and eventually assumed surgical care for over half of the patients. The Netherlands,[18] Norway,[19] and Sweden[20] have also launched similar initiatives. For instance, the number of providers in Norway dropped from 56 hospitals in 1993–97–36 in 2007–10; in the latter period, 69% of patients underwent surgery in hospitals that performed > 25 operations per year. In Sweden, this figure rose from 50% in 1995–90% in 2012. Likewise, indicators for both surgical outcomes and pathology processes in Catalonia improved after centralization; for example, emergency surgical interventions decreased to levels similar to those achieved in the Dutch Surgical Colorectal Audit.[18] Overall, there were no changes in the proportion of sphincter-preserving surgery, probably due to its perceived high value as a therapeutic target. In fact, the proportion of conservative surgery in both study periods is higher than the one obtained in other similar studies.[21] This is consistent with the high value assigned by patients to this strategy in southern European countries.

Some data indicated a clear improvement in the quality of rectal cancer care between the two periods. For example, TME is considered the cornerstone of optimal surgical management for patients with locally advanced rectal cancer, consistently related to lower local recurrence rates;[22] in our study, more pathologists explicitly reported the performance of TME, which was especially requested by health authorities after the first audit. Although results seem positive, we cannot conclude that the quality of the technique itself has improved due to the high proportion of missing values in the first period. Pathological reporting of CRM, which is associated with both risk of local recurrence and patient survival,[23] has also improved. Also because there was a higher proportion of missing values for CRM in the first audit than in the second, it is difficult to assess the outcome related to CRM, as the relative proportion of both negative and positive CRMs increased. However, the finding observed in the last audit is consistent with the Dutch audit[18] and slightly higher than that of the Norwegian Rectal Cancer project.[19] Finally, the proportion of patients with a least 12 lymph nodes examined, as recommended by TNM and NICE for correctly staging rectal cancer, increased significantly.[24] The mean and median number of lymph nodes analysed increased significantly in the second period of study. Furthermore, considering that prognosis improves for every negative lymph node found, the reduction of the lymph node ratio to 2 between the two study periods translates to a substantial improvement in quality of care.

It took two years for regional hospitals to comply with the new regulations, reflecting the complexities (including financial constraints) that this kind of policy measure inevitably entails. A reconfiguration of rectal cancer services based on regional linkages emerged and shaped the centralization strategy, with clinical audits serving as the cornerstone of the reform. The audits not only provided the scientific basis for centralization but also influenced the established model of clinical accountability, henceforth subject to formal standards and policy monitoring. Indeed, the impact of the auditing process itself in improving clinical practice was quite important. Other authors have observed that integrating auditing into the national quality assurance policy helped standardise the measurement of quality of care.[18] Certainly, there is a significant association between high-volume hospitals and improved 5-year survival for rectal cancer,[25] although it has not been possible to establish a specific case threshold that is associated with better clinical outcomes.[26] As other authors have stated, critical mass appears to depend on indirect and complex links between high case volumes and better outcomes.[21] However, considering the importance of such a measure, some cancer plans have explicitly set up minimum volume thresholds.[27] The critical mass in our case was largely considered to be too low, so a substantial variability in outcomes may still exist. Quality assessment is further complicated by the fact that diagnosis and multimodal therapy is fragmented by centre. In this regard, the fact that only 11 Catalonian hospitals provide radiotherapy shows the need to disperse patient care when pre-operative radiochemotherapy is required; this was true for 55% of all cases in our study (stages II–III).

The challenges encountered stimulated considerations on the need for a territorial rearticulation based on partnerships between hospitals rather than between specialist units regarding highly complex diseases or procedures. Divergent views revealed a potential clash with regard to different organizational options; while some interviewees defended centralizing treatment delivery in a limited number of hospitals, others believed that creating a network structure could better improve clinical outcomes and management of elderly and comorbid patients. Other issues included facilitating access to MDTs and site specialists,[28] allotting time for MDT meetings,[29] avoiding specialist isolation and enabling hospitals to treat patients admitted on an emergency basis (especially as 30–45% of European patients are diagnosed when their cancers are too advanced to be curable).

Some strengths and limitations must be taken into account when assessing the results of this study. One limitation in the quantitative data relates to its retrospective nature. This aspect was addressed by equipping a trained team of professionals with purpose-designed instruments to ensure highly accurate data collection from patients' medical charts. For both study periods, hospital results were individually presented to the respective centres, and their feedback validated the results. Patients treated in private centres were excluded. Also, clinical audits did not include data on waiting times and travel distances, although they are very relevant in the patient experience of care. However, future audits will assess these measures. One strength of the qualitative study was the criteria used for the composition of the sample, which included interviewees from different specialties, healthcare areas and ACs and non-ACs. Snowball sampling helped avoid bias in favour of clinicians with opinions favourable to the reform. However, the limited number of participants implicitly ruled out the possibility of capturing all the best practices that might exist in the health system. By using a qualitative strand after the clinical audit analysis, we intended to add dimension to the quantitative findings.[10]

In conclusion, centralizing delivery and integrating a clinical audit component to rectal cancer surgery has been associated with better quality of care and conformity with clinical guidelines. However, further policy criteria and measures should consider the challenges in centralizing care for different cancers through different critical masses and healthcare frameworks. Developing the current system of authorized and non-authorized centres towards a more coordinated setting, especially considering the use of a network approach, is envisaged as a proper response.

Acknowledgements

We would like to thank all the health professionals and managers who so unstintingly gave their time to share their experiences and thoughts with us. Further, we are grateful to Meggan Harris for her editorial support.

Funding

It should be acknowledged Carlos III Institute of Health (Instituto de Salud Carlos III/ISCIII) for its support for the Cancer Research Network (co-funded by FEDER funds / European Regional Development Funds, ERDF) (RD 12/0036/0053), and the support from the Agència de Gestió d'Ajuts Universitaris i de Recerca (AGAUR, 2014SGR0635).

Conflicts of interest: None declared.

Key points

- Centralizing delivery and integrating a clinical audit component to rectal cancer surgery has been associated with better quality of care and conformity with clinical guidelines.
- The process of centralizing cancer diseases is not neutral from a healthcare system organization perspective. Together with quality of care outcomes, our study examined its implementation at the professional and management levels.
- Centralizing highly complex cancers using different critical masses and healthcare frameworks prompt the need for rearticulating partnerships at a hospital, rather than disease, level.

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