EVIDENCE BASED PUBLIC HEALTH POLICY AND PRACTICE

Impact of regionalisation of cardiac surgery in Emilia-Romagna, Italy

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Study objective: Assessment of the impact of the regionalisation of cardiac surgery through the organisational form of a hub&spoke model introduced in the year 2000.
Design: Case mix adjusted before (1998–1999)—after (2000–2002) comparison of: (a) in-hospital and 30 days mortality rates; (b) proportion of patients timely (within one day) referred for surgery from spoke to hub centres; (c) patients' waiting times to surgery.
Setting: Emilia-Romagna, an Italian region with four million residents.
Patients: 16 512 patients aged ⩾18 years and referred to cardiac surgery over the period 1998–2002.
Main results: Overall, taking into account differences in case mix across the whole study period, the implementation of the regionalisation policy was associated with a 22% reduction (OR: 0.79, 95%CI: 0.66 to 0.93) in in-hospital mortality rate. The corresponding figure for 30 day mortality was 18% (OR: 0.82: 95%CI: 0.69 to 0.98). The individual centres' volume of cases changed over the study period for all hospitals but two, and the biggest reduction in mortality was seen at the centre with the largest increase in caseload.
Conclusions: This study provides additional evidence on the benefit of regionalisation of cardiac surgery interventions. The system allowed each centre to reach the minimum caseload required to assure good quality of care. These findings suggest that policies aimed at increasing cooperation rather than competition among health service providers have a positive impact on quality of care. Timely referrals for surgery increased by 21% (95%CI: 1.12 to 1.31), and mean waiting times were reduced by 7.5 average days (95%CI: −10.33 to −4.71).

Cardiothoracic surgery has been attracting a great deal of attention from health service researchers, with a number of studies reporting wide inter-hospital variation in mortality rates and a strong relation between patient outcomes and hospital or surgeon case volume.

In particular, the many observational studies attesting that low volume hospitals show higher mortality rates, even after taking into account differences in patient case mix,[1–6] stimulated policy makers to the implementation of regulatory policies aimed at promoting an increasing degree of concentration of patients in a few high volume centres.

This process of regionalisation in the delivery of cardiac surgery interventions has been undertaken also in Emilia-Romagna, an Italian region with four million residents, where cardiac surgery is provided by six centres, two of which are public trusts, while the remaining four are private clinics whose activity is regulated by annual contracts between the regional government and their owners.

In this context the regionalisation took the organisational form of ''hub & spoke'' model, gradually implemented since 1998 through the assignment to each centre (hub) of a well defined catchment area, including a network of cardiology departments and wards (spokes) with explicit referral mechanisms in place. While the overall number of cardiac surgery interventions required at the regional level (that is, for the resident population) is estimated on a yearly basis, one of the initial goals of the hub and spoke system was to assure that each centre could gradually achieve and maintain a case volume sufficient to assure good quality care.[1–6 7–9]

Although individual patients enjoy full freedom in choosing their preferred cardiac centre, pre-defined referral pathways and organisational relations have been established between the network of spokes of a specific geographical area and their corresponding hub, these are aimed at assuring a timely access to surgery according to explicit and agreed upon clinical guidelines stating when surgery was recommended and with what priority.

In short, such a system was expected to have an impact on (a) the centres' clinical performance, through a balanced distribution of patient caseload across the six centres; (b) the efficiency of the referral mechanisms from cardiology to surgical centres, through formally defined coordination and cooperation; (c) the accessibility of surgery, reducing patient waiting times.

In this paper, we assess the impact (on the three aspects mentioned above) of this regional organisational policy, gradually developed since 1998 and then officially implemented in 2000.

METHODS

Indicators of impact of the regionalisation policy

The impact of the policy was assessed on three grounds:

- on cardiac surgery outcomes, expressed in terms of in-hospital and 30 day mortality rate, both for individual centres and overall;
- on the efficiency of patients' referral from spoke to hub centres, estimating for each study year the proportion of patients timely (that is, within one day) referred for surgery after completion of the diagnostic investigation at a spoke cardiology centre;
- on patients' access, expressed in average waiting times. The length of waiting lists was retrospectively measured as the time interval between diagnosis and surgery.

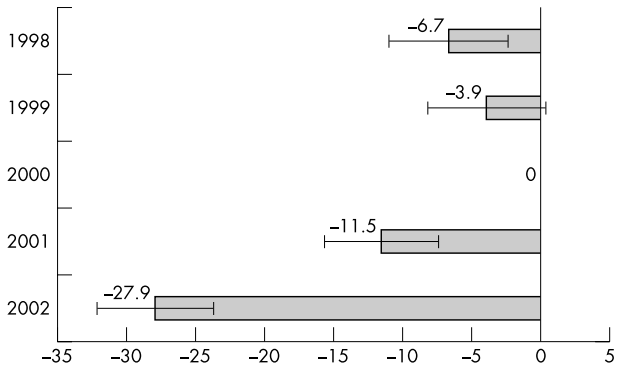

Figure 1 Change in number of mean days, 95% CI, weighted for each study year in comparison with year 2000, when the H&S policy was introduced. Estimates take into account differences in patient case mix across over the study period.

Statistical analyses

The indicators mentioned above were estimated based on 16 512 patients aged ⩾18 undergoing cardiac surgery over the period 1998–2002. Patients were identified in the regional hospital discharge database (SDO) from the ICD-9-CM codes for cardiac surgery procedures (35.xx for valve surgery; 36.1x for bypass surgery; 37.1x, 38.xx, 39.xx mixed surgery, only if together valve and/or bypass codes). The SDO database provides information on patient age, sex, primary and secondary diagnoses, main diagnostic and surgical procedures, and in-hospital mortality. Information on a patient's surgical risk according to the Euroscore system of classification[10] has been also available since the year 2000.

Lastly, information on a patient's vital status 30 days after surgery was drawn from the regional mortality register. However, when these analyses were conducted this information was not yet available for patients cared for the year 2002.

Univariate analyses were carried out to assess differences in patients' case mix across the five study years, using the χ^2 test for trend or analysis of variance for categorical and continuous variables, respectively.

Yearly mortality and referral rates were adjusted through a logistic regression model[11] including as covariates; patient age, sex, comorbidity (measured with the Charlson comorbidity index[12]), type of surgical intervention (elective versus urgent), degree of risk (assessed on the presence of key clinical conditions: diagnosis of acute myocardial infarction, cardiac catheterisation on the same day of the intervention, percutaneous transluminal coronary angioplasty (PTCA) on the same day of intervention), type of surgery. For each study year the number of expected deaths was then estimated, as well as the ratio between observed and expected events (O/E). Year specific adjusted mortality rates were calculated by multiplying O/E by the overall mortality rate observed over the whole study period. The same process was undertaken in estimating case mix adjusted referral rates.

The impact of the regionalisation policy was assessed including in the regression model a dummy variables, representing the after period (2000–2002) its official adoption occurring in year 2000. Therefore, the policy effect is expressed in terms of odds ratios (OR) with 95% confidence intervals (95%CI).

Lastly, a multivariate linear regression[13] was used in assessing changes over the study period in patients' waiting times, adjusting for the same set of covariates mentioned above.

Table 1 Characteristics of patients receiving cardiac surgery over the period 1998–2002 in Emilia-Romagna

			Official H&S policy			
	1998	1999	2000	2001	2002	
	(n = 2979)	(n = 3134)	(n = 3450)	(n = 3505)	(n = 3444)	p Value*
Demographic characteristics	%	%	%	%	%	
Female	28.8	29.5	30.5	29.9	27.8	0.4752
65–69	20.5	21.3	19.7	18.1	18.5	0.0009
70–75	23.3	21.6	22.4	23.7	23.0	0.4801
75–80	14.5	17.2	17.2	19.5	18.5	<0.0001
>80	3.2	4.3	5.2	5.4	6.6	<0.0001
Age (mean)	65.8	66.6	66.7	67.3	67.4	<0.0001
Comorbidity conditions	%	%	%	%	%	
Diabetes	14.7	16.6	19.8	20.6	20.4	<0.0001
Chronic obstructive lung disease	0.6	0.8	0.6	0.7	0.6	0.6553
Congestive heart failure	19.6	18.1	19.3	20.7	18.7	0.7573
Cerebrovascular disease	3.2	4.0	4.4	4.7	4.3	0.0104
Peripheral vascular disease	10.5	11.6	10.8	12.1	12.3	0.0217
Renal failure in previous admissions	2.3	2.6	2.5	2.3	2.1	0.4233
Absence of comorbidity	36.8	36.5	36.4	35.9	39.1	0.1028
Admission	%	%	%	%	%	
Elective	93.0	81.5	77.6	78.6	76.0	
Urgent	7.0	18.5	22.4	21.4	24.0	<0.0001
High risk clinical conditions	%	%	%	%	%	
Diagnosis of AMI	1.0	1.3	0.7	0.8	0.8	0.1026
Cardiac catheterisation on same day of surgery	2.1	0.5	0.1	0.3	0.6	<0.0001
PTCA on same day of surgery	0.3	0.4	0.8	0.4	0.9	0.0036
Intra-aortic balloon pump before surgery	0.2	0.3	0.2	0.4	0.6	0.0171
Euroscore (mean)	NA	NA	5.1	5.3	5.6	<0.0001
Type of surgery	%	%	%	%	%	
CABG alone	66.3	64.7	61.9	61.7	59.6	<0.0001
Valve alone	21.3	20.9	22.5	22.1	22.4	0.1333
CABG+valve	7.9	8.9	9.4	10.6	11.3	<0.0001
Other cardiac surgery	4.6	5.5	6.1	5.6	6.7	0.0008
Length of stay (mean)	13.6	13.4	14.1	14.0	14.4	0.0002

*p Values have been obtained: for categorical variables from Mantel-Haenszel χ^2 test for trend; for averages from *F* test for linear trend, for medians from Wilcoxon test.

Table 2 Overall performance of the regional cardiac surgery system in Emilia-Romagna over the whole study period

	Official H&S policy					
	1998	1999	2000	2001	2002	
	(n = 2979)	(n = 3134)	(n = 3450)	(n = 3505)	(n = 3444)	p Value*
Clinical outcomes						
Crude mortality rates						
In-hospital	4.6	3.9	3.1	3.5	3.6	0.0382
30 days	5.1	4.6	3.5	4.5	NA†	0.0013
Centres in-hospital and (30 days) mortality						
Centre 1	6.8 (7.9)	3.4 (4.3)	2.8 (3.7)	4.8 (7.3)	3.1 (NA)†	0.0489‡
Centre 2	4.3 (4.6)	3.6 (4.3)	4.6 (5.1)	4.1 (4.8)	4.3 (NA)	0.8834‡
Centre 3	7 (11.6)	5.9 (7.6)	3.3 (3.7)	2.6 (3.0)	3.0 (NA)	0.0451‡
Centre 4	2.4 (2.5)	2.8 (3.6)	2.1 (2.7)	2.5 (3.2)	2.6 (NA)	0.9487‡
Centre 5	4 (4.3)	3.3 (3.6)	2.5 (2.5)	2.7 (3.8)	3.7 (NA)	0.7924‡
Centre 6	6.6 (7.5)	5.5 (6.1)	3.8 (4.1)	4.7 (5.7)	4.8 (NA)	0.1380‡
Efficiency						
Patients referred from spokes to hubs within one day	19.9	22.9	24.8	24.9	22.0	<0.0001
Centres supply share						
Centre 1	14.9	11.2	9.4	10.1	9.3	<0.0001
Centre 2	22.4	19.3	17.1	18.6	16.2	<0.0001
Centre 3	1.4	7.6	7.1	6.6	6.9	<0.0001
Centre 4	27.0	22.4	24.6	23.0	24.8	0.1549
Centre 5	15.0	20.3	21.9	21.2	23.5	<0.0001
Centre 6	19.3	19.3	20.0	20.5	19.3	0.6246
Accessibility						
Waiting time in days (median)	(n = 2763)	(n = 2839)	(n = 3102)	(n = 3267)	(n = 2959)	
From last diagnosis to surgery	14	15	19	13	11	<0.0001

*p Values have been obtained: for categorical variables from Mantel-Haenszel χ^2 test for trend; for averages from *F* test for linear trend, for medians from Wilcoxon test; †30 day mortality not available for year 2002; ‡test referred to in-hospital mortality, similar results are obtained for 30 day mortality rates.

RESULTS

Table 1 outlines the characteristics of patients undergoing cardiac surgery in each study year. Patients' age increased over time (the proportion of those >75 increased from 17.7% in 1998, to 25.1% in 2002; p<0.0001), and comorbidities such as diabetes (from 14.7% to 20.4%; p<0.0001) and cerebrovascular disease (from 3.2% to 4.3%; p = 0.01) were more frequently reported.

While the proportion of patients with high risk clinical conditions did not show important differences over time, the rate of urgent admissions increased, sharply from 7% in 1998 to 18% in 1999, being 24% in the last year (p<0.0001).

As for type of surgery performed, there was a decrease in isolated CABG procedures (from 66% to 60%; p<0.0001)), while interventions represented by the combination of more than one type of surgery increased (p<0.0001).

Impact of the regionalisation policy

Crude (that is, unadjusted) in-hospital and 30 day mortality rates are reported in table 2, showing a reduction of 22% and 12%, respectively.

Corresponding figures for individual centres remained comparatively stable over time, with the exception of centre 1 and centre 3, both showing for in-hospital mortality a statistically significant reduction of 54% (p = 0.05) and 57% (p = 0.05), respectively.

As for the aspects relating to the efficiency of the system, the proportion of patients referred from spokes to hubs within one day increased from 19.5% in 1998, to 22% in 2002 (p<0.001).

Moreover, over time most of the six centres had their share of the overall regional supply changed (see table 2). In particular, centres 4 and 6 remained stable, while centres 3 and 5 increased their share of the overall caseload (from 1.4% to 6.9% (p<0.0001) and from 15% to 23.5% (p<0.0001), respectively), and the others had their volume of activity reduced (p<0.0001).

The trend in patient waiting times to surgery was less clear (table 2), with an increase between 1998 and 2000 (from 14 to 19 days median), and then a reduction in 2002 (11 days median). Case mix adjusted mean waiting times for each study year as compared with year 2000 are shown in figure 1. From year 2000 to 2001 patients experienced a reduction of about 11 days (95%CI −15.6 to −7.4) in accessing cardiac surgery, while the differences in the year 2002 is 27.9 days (CI −32.2 to −23.6).

Overall, the case mix adjusted effect of the regionalisation policy is reported in table 3, as well as in figure 2 and figure 3.

Regionalisation was associated with a 22% reduction in in-hospital mortality rate (95%CI: 0.66 to 0.93), and with an 18% reduction in 30 day mortality (95%CI: 0.69 to 0.98). Timely referrals for surgery increased by 21% (95%CI: 1.12 to 1.31), and mean waiting times were reduced by 7.5 average days (95%CI: −10.33 to −4.71) (table 3).

DISCUSSION

In this study, we explored the impact of a policy of regionalisation of cardiac surgery in Emilia-Romagna.

Basically, one of the key assumptions of such a policy was that better clinical outcomes could be achieved if clinical practice was regulated in such a way as to assure that each surgical centre had a volume of cases sufficient to maintain the required clinical competence.

The overall number of surgical interventions required for the resident population is established at the regional level, setting an explicit ceiling that the overall caseload should not exceed. Therefore, individual centres are allowed to expand their own volume of cases freely, only attracting non-resident patients. Thus, one of the implications of regionalisation was that the overall regional caseload had to be redistributed across hospitals, with some of them implicitly required to

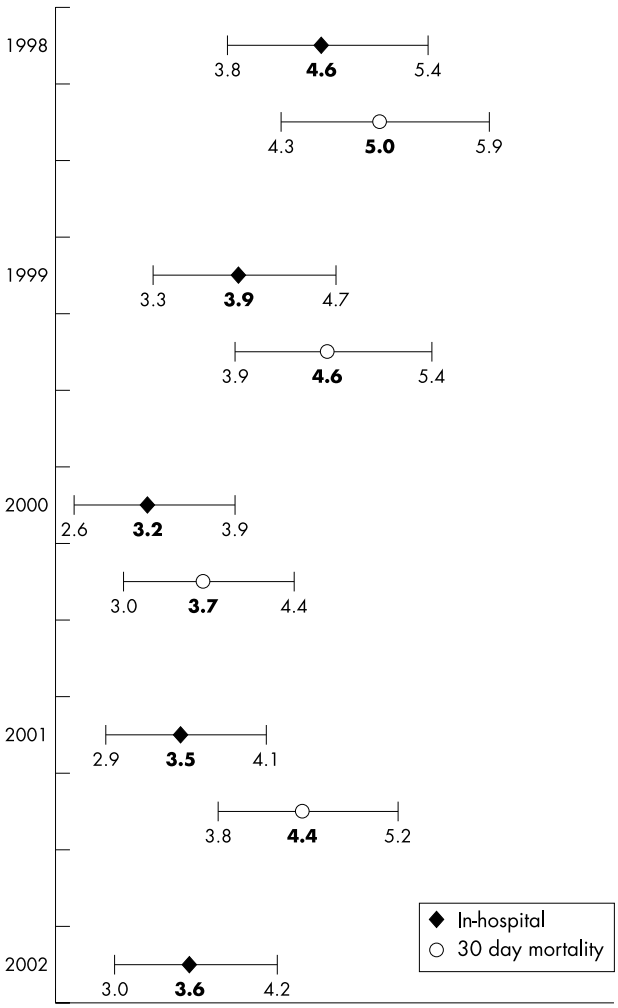

Figure 2 In-hospital and 30 day case mix adjusted mortality rates over the whole study period.

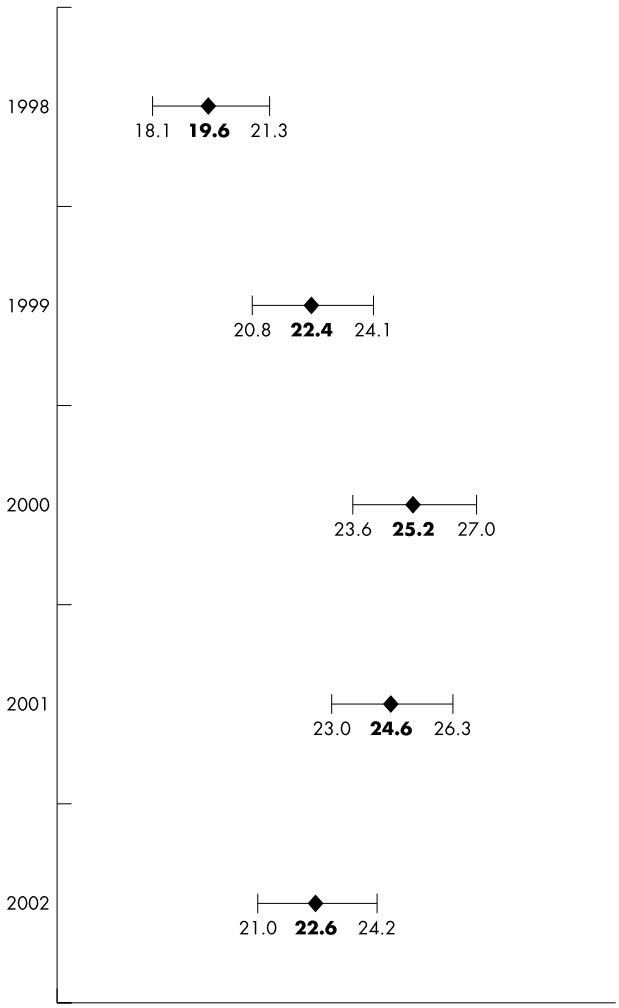

Figure 3 Case mix adjusted of timely (within one day) referrals from spoke to hub centres, over the whole study period.

increase their caseloads, while others decrease them or, alternatively, rely on their ability to attract patients from other regions.

Over the period 1998–2002, the number of patients from other regions remained quite stable (around 22% of all the cardiac surgery interventions performed). Thus apparently individual centres—including the four private clinics—only moderately took advantage of this opportunity to expand their productive capacity.

Nevertheless, our findings show that the regionalisation policy induced a redistribution of the overall caseload among the six centres, and that this corresponded to a concurrent improvement in clinical outcomes (expressed as in-hospital 30 day mortality rates).

Over a five year time frame, each centre achieved a caseload of 250 interventions at least, and there was a reduction in both in-hospital and 30 day mortality rates. While the greatest reduction in mortality rates was observed in the hospital with the largest increase in caseload, the fact that this positive trend was common also to those whose yearly caseload decreased, indicates that the regionalisation process apparently did not have unwarranted effects, jeopardising the performance of hospitals that had their volume of interventions reduced.

Table 3 Case mix adjusted effect of the adoption of the hub&spoke policy in Emilia-Romagna

	ORs and 95% CI
Clinical outcomes	
Mortality rates	
In-hospital	0.79 (0.66 to 0.93)
30 day	0.82 (0.69 to 0.98)
Efficiency	
Patients referred from spokes to hubs within one day	1.21 (1.12 to 1.31)
Accessibility	
Waiting time in days (median)	−7.52 (−10.33 to −4.71)

Policy implications

- Regionalisation of health care is much more than simply referring patients to few highly specialised centres. It implies the adoption of a ''hub & spoke'' model, with specialised centres (hubs) serving a well defined catchment area, and cooperating with a network of services (spokes) with explicit referral mechanisms in place.
- To avoid unwarranted side effects from the regionalisation process, cooperation should exist also among hub centres.
- Regionalisation of health care implies the establishment of functional relations based upon cooperation and integration among health services, rather than on competition.
- Monitoring of the impact of regionalisation policies on quality of care should be broad enough to explore the different aspects on which the policy may have an effect: patients' clinical outcomes, accessibility of the system, and efficiency of referral procedures.

These reassuring findings are in line with those reported by others[5 7 14] who assessed the impact of regionalisation policies for cardiac surgery.

More recently, the effect on coronary bypass surgery mortality rates of the adoption in the USA of the federal certificate of needs procedure has been assessed,[8] showing that a regulatory policy aimed at balancing surgical supply with local demands was associated with better clinical outcomes. This finding could be reasonably attributed to the concentration of patients in comparatively highly specialised centres.

Consistent with these results, we also observed in this study that a policy inducing a balanced distribution of patients across the six centres providing cardiac surgery was associated with a reduction in mortality rates, both overall and for each individual centre.

In addition, we showed that the establishment of a policy of cooperation among centres providing the same type of service, was instrumental to the achievement of an increased degree of efficiency in the relation between spoke and the hub centres represented by the proportion of patients timely referred for surgery, although with a less clear trend (possibly because of the gradual implementation of the referral mechanism required by the H&S model), over time also waiting times became shorter keeping the level of supply constant. These positive findings for cardiac surgery are consistent with those already observed where the impact of regionalisation was analysed on patterns of use and clinical outcomes of percutaneous coronary interventions.[9] In this context the trend in the proportion of patients referred for urgent indications could be also seen as a further indirect indicator of better efficiency of the system. The fact that after an abrupt change (from 7% to 18%) between 1998 and 1999 urgent referrals increased over time at a much lower rate, could be explained by the increased degree of explicitness and transparency required by the referral system under the H&S model. Indeed, one of the features of the model adopted from the very beginning of its implementation process, has been the development of explicitly criteria for the identification of ''urgent'' patients.

Our study has several limitations that have to be acknowledged.

Firstly, in our evaluation we focused only on those aspects that were comparatively easy to measure, not necessarily representative of all the relevant dimensions of good quality care. In our study, because of the limitations of the sources of information available, we have not been able to assess the appropriateness of use of the surgical operations. Likewise, patients' satisfaction with care has not been considered.

However, we tried to be as comprehensive as possible in our approach, identifying the aspects on which the regionalisation policy was expected to have an impact, and attributing to each one a specific indicator measured with the available sources of information.

Furthermore, we did not investigate whether regionalisation was associated, as others recently showed,[15] with increased underuse of surgical procedures. Our study design prevented the opportunity to explore this aspect, our analysis being limited to patients who actually received surgery. Nevertheless, the observed reduction in average waiting times is reassuring, and indicates that the system did not generate an unmet demand. Furthermore, the geographical characteristics of the region are such that it is unlikely that there are underserved areas.

In general, the assessment of the effect of a policy on quality of care represents quite a challenge to health services research. Experimental designs are often inapplicable in the evaluation of the impact of health policies.[16] Random assignment of providers to different policy options is usually politically unacceptable and technically inapplicable, even more so in our comparatively restricted regional context, where the identification of an ''unexposed'' control group sufficiently preserved from the risk of contamination would not have been possible.

In addition, differently from other types of interventions, policies are usually implemented gradually over time, as in our case. Thus, it can be hard to identify a specific point in time in which the intervention was been introduced. Time series analyses and specific statistical techniques may be of some help in addressing these methodological issues,[17 18] but several observations over time are required for their application.

In our study, we only had information over five years available to assess the impact of the regionalisation process, making it particularly hard to disentangle the ''true'' effect of the policy from the other factors.

Nevertheless, we were at least able to control for the major confounding factors, represented in our context by changes in patient case mix over time, which could explain the observed trend in mortality rates.

Lastly, in the analyses presented in this paper we have considered only interventions performed on residents in our region, the main justification being that some of the indicators used to assess the impact of the regionalisation policy, namely those concerning the efficiency and the accessibility of the system, would not have been applicable on patients coming from other regions. However, the results concerning the clinical performance of individual centres and of the system as a whole did not change when interventions performed on non-resident patients were considered.

In conclusion, despite the limitations of a simple observational design, we believe that this study provides additional evidence on the benefit of regionalisation of cardiac surgery interventions. Furthermore, our findings suggest that policies aimed at increasing cooperation rather than competition among health services providers have a positive impact on quality of care.

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APHORISM OF THE MONTH

Achieving change is about more than ticking boxes

The argument about the value of targets is current in the United Kingdom's search for improved health at the present time, yet we know that the battle for hearts and minds for buy-in and ownership are at least as important as an accountancy driven approach to improved performance, and the presentation and packing need to be more than skin deep. When I was at medical school in the 1960s, we used to retreat from anatomy dissection into the bowels of the basement in search of coffee and sustenance from a distant outreach of the Student Union refectory. All that was on offer was beans on toast and tea or coffee. Protests to the head of catering in the Student Union produced a positive response, soon to be followed by a new menu in a glass case on the wall beside the cafe counter—but all you could still get was beans on toast and tea or coffee.

JRA