BMJ Open Does the healthcare system know what to cut under the pandemic emergency pressure? An observational study on geographic variation of surgical procedures in Italy

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ABSTRACT

Objectives During 2020 many countries reduced the number of elective surgeries to free up beds and cope with the COVID-19 outbreak. This situation led healthcare systems to prioritise elective interventions and reduce the overall volumes of treatments.

The aim of this paper is to analyse whether the pandemic and the prioritisation policies on elective surgery were done considering the potential inappropriateness

highlighted by the measurement of geographic variation. Setting The setting of the study is acute care with a focus on elective surgical procedures. Data were analysed at the Italian regional level.

Participants The study is observational and relies on national hospitalisation records from 2019 to 2020. The analyses refer to the 21 Italian regional health systems, using 48917 records for 2019 and 33821 for 2020. The surgical procedures analysed are those considered at high risk of unwarranted variation: coronary angioplasty, cholecystectomy, colectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping.

Primary and secondary outcome measures Primary measures were the hospitalisation rate and its reduction per procedure, to understand the level of potential inappropriateness. Secondary measures were the SD and high/ low ratio, to map the level of geographic variation.

Results For some procedures, there is a linear negative relationship (eg, tonsillectomy: $\rho = -0.92$, p<0.01; vein stripping: $\rho = -0.93$, p<0.01) between the reduction in hospitalisation and its starting point. The only two procedures for which no significant differences were registered are cholecystectomy ($\rho = -0.22$, p=0.31) and hysterectomy ($\rho = -0.22$, p=0.33). In particular, in all cases, data show that regions with higher 2019 hospitalisation rates registered a larger reduction. **Conclusions** The Italian data show that the pandemic seems to have led hospital managers and health professionals to cut surgical interventions more likely to be inappropriate. Hence, these findings can inform and guide the healthcare system to manage unwarranted variation when coming back to the new normal. This new starting point (lower volumes in some selected elective surgical procedures) should be used to plan elective surgical treatments that can be cancelled because of their high risk of inappropriateness.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- \Rightarrow This study is based on observational routinely collected hospital discharge records of a national single-payer healthcare system.
- \Rightarrow This study can be easily replicated in other healthcare systems.
- \Rightarrow The analysis is limited to a selection of eight elective surgical procedures.
- \Rightarrow The analysis is limited to administrative health data.

INTRODUCTION

Protected by copyright, including for uses related to text The COVID-19 outbreak has led many and countries to reduce the number of elective surgeries, to free up beds (both in ICU and ð acute care wards) and healthcare professionals (mainly anaesthesiologists) to cope with the acute care treatments for patients with COVID-19.¹⁻⁴ This situation led countries, regions, and counties (in the case of ≥ decentralised healthcare systems), as well as providers, to prioritise treatments and reduce overall volumes. The policies adopted aimed **g** to (1) ensure urgent treatments and timedependent diseases such as stroke and Acute simi Myocardial Infarction (AMI); (2) identify the elective treatments to be protected and ensured because they are not deferrable or are life saving, like surgical cancer interven-tions and (3) postpone deferrable elective osurgery.

In particular, elective surgery has been investigated for almost a century because of its variation. For instance, in the first decades of the 20th century, Sir James Allison Glover in his speech at the English epidemiology and state of medicine on the 27 May 1938 cited studies of geographic variation in tonsillectomy; in the last decades of the 20th century, Wenneberg re-launched studies on the geographic variation in use-rates, promoting

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the Dartmouth Atlas of Variation⁵⁶ for several services; vet, in the first decades of this century, scholars have reported wide variation in tonsillectomy hospitalisation rates among different geographic areas in different countries.^{7 8} Nowadays, the pandemic has boosted the importance of geographic variation studies in the rebound stage of elective surgery, supporting health systems to plan a more appropriate new start.

Significant geographic variations have been revealed for several very common elective surgical interventions.⁶ 9-13 In some cases, like a tonsillectomy, there is consensus on the opportunity to reduce the rate, especially in geographic areas presenting high hospitalisation rates. Instead, in other cases, the right rate and the determinants of variation are still discussed. Following revision of Wenneberg's categories by Nuti and Seghieri,⁸ variation in elective surgery may occur in the following situations: (1) when there are clinically proven effective services (eg, volumes of specific surgical procedures such as hip fracture operated within 2 days)in this case, differences in quality should be avoided; (2) when services are delivered according to care settings determined by organisational choices (eg, in-patient admissions for interventions which could instead be performed on a day surgery basis)-in this case, differences may not have an impact on outcomes; (3) when variation reflects patients' different needs or preferences or when it often reflects physicians' discretionary choices and (4) when variation depends on supply (supply-sensitive services), which occurs when the number of services available increases (ie, number of beds, number of specialists, etc.).

Based on this stream of literature, when geographic variation does not depend on patients' preferences or needs,¹⁴ it can be classified as unwarranted.^{5 6 15} Several studies^{9 10} have reported that patient characteristics and preferences do not completely account for geographic variation in the provision of elective surgery; rather, greater influence is exerted by clinicians' behaviour and judgement. This classification and consideration have to be taken into account when planning the volumes of (appropriate) elective surgery to be ensured, especially in Beveridge-like systems where unwarranted variation can be seen as a signal of horizontal equity (because of the same level of patient need, variation may highlight disparities in resource allocation, the quality of care or access to the services across its territories)¹⁶ also known as 'postcode lottery'.¹⁷

This seems particularly relevant in this period related to the planning of rebound activities. While some scholars have reported how to deal with the growing backlog of healthcare procedures related to non-communicable diseases during the pandemic crisis¹⁸⁻²¹ (such as the delay in cancer procedures and especially in the timedependent intervention²²), there has still been poor debate stimulated on the relationship between the reduction of elective surgeries and unwarranted geographic variation.

Indeed, this unprecedented situation can be considered as an opportunity to revise the intervention priority list

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bin the aim to reduce (or at least freeze) potential inappropriate interventions, thus freeing up resources (operating rooms and professionals) that can be employed in bouncing back the (appropriate) interventions that had been postponed. The paper discusses the opportunity of managing my and empirical evidence from Italy. Relying on primary data from Italian hospital discharge records from 2019 and 2020, this paper analyses whether the pandemic and the prioritisation policies for elective surgery have had an impact on regional geographic variation. In particular, considering the extant Italian regional differences in providing elective surgery, the issue investigated is whether the healthcare system grabbed the opportunity to prioritise beds to reduce potential inappropriate elective surgery. Closing remarks have been formulated for the rebound stage. toring regional budgets. Meanwhile, regional govern- 3 ments are responsible for the organisation and delivery of health services through the local health authorities and public and accredited private hospitals, and can also raise **≥** local taxes and fund additional health services.

Because of the joint responsibility for healthcare, both the national and regional health systems monitor performance using tools; mainly three have been identified by the 2016 European Report²⁵ with specific characteristics: LEA grid; National Outcome Programme (known by the acronym PNE) and Inter-Regional Performance Evaluation System (IRPES).

All three systems highlight that geographic variation occurs across and within regions on different dimensions: access, quality, appropriateness and efficiency. While the g LEA grid does not have specific indicators to monitor **g** elective surgery variation, PNE and IRPES monitor some common elective surgery procedures known to have a high degree of variability, often because of the lack of standards. Figure 1 shows, as an example, that the hospitalisation rates for tonsillectomy can be as much as four times higher in one region compared with another.

In 2020, overall elective surgery at the national level was reduced by up to 28% with respect to 2019 volumes. Mild differences were registered across regions. Larger

Hospitalization rate for tonsillectomy, 2019



Figure 1 Hospitalisation rates for tonsillectomy across and within Italian regions in 2019. Source: PNE, 2019. Pie (Piemonte); VdA (Valle d'Aosta); Lom (Lombardia); PAB (Provincia Autonoma di Bolzano); PAT (Provincia Autonoma di Trento); FVG (Friuli Venezia Giulia); Lig (Liguria); E-R (Emilia Romagna); Tos (Toscana); Umb (Umbria); Mar (Marche); Laz (Lazio); Abr (Abruzzo); Mol (Molise); Cam (Campania); Pug (Puglia); Bas (Basilicata); Cal (Calabria) and Sic (Sicilia).

differences show up when comparing single surgical procedures such as oncological interventions.²⁶

METHODS

The RECORD guidelines²⁷ were applied to conduct the study. This study did not involve human participants and ethics committee approval was not required. The RECORD checklist has been included in the supplementary materials (see online supplemental material 1).

Starting from the hospitalisation records of the Italian National Health Service provided by Agenas, the paper analyses geographic variation for the procedures selected by Nuti and Seghieri,⁸ which usually present wide unwarranted geographic variation across and within countries: coronary angioplasty, cholecystectomy, prostatectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping (details about ICD9CM (International Classification of Diseases, 9th revision - Clinical Modification) and DRGs (Diagnosis Related Group) are reported in the Appendix, in online supplemental material 2. Additional information can be requested from the authors). These procedures have also been used by other authors, both separately and combined.^{28–30}

These crude rates (number of procedures per 100000 inhabitants) were indirectly standardised by age and sex using SAS 9.4 software and then put into a relationship with the reduction of surgical hospitalisation rates for the two consecutive years 2019 and 2020.

Overall, the analyses refer to 48917 records for 2019 and 33821 for 2020 that represent the entire database

population for the selected 8 elective surgery procedures. The variables used in the study were those considered mandatory at the national level so the record can be accepted as a valid one. These data were put in relation to the population information gathered from the National Institute of Statistics (Istat). Data matching was carried out at the regional level. No record linkage at the person level was executed.

Following the Expert Panel on Effective Ways of Investing in Health definition of resilience,³¹ the percentage reduction of non-COVID-19 services can be used to assess the capacity of healthcare systems to be resilient. In fact, one specific characteristic of resilience is the capacity to adapt to shocks and structural changes, to sustain required operations and to resume optimal performance as quickly as possible.³¹ In this perspective, the reduction of volumes of surgical procedures can be seen as the potential for interventions to rebound after the emergency.

The matrix combining the 2019 hospitalisation rates with the percentage reduction of volumes in 2020 compared with 2019 has been used to graphically understand whether the pandemic has had any effect on the unwarranted regional variation of the selected elective surgery procedures.

The Pearson correlation has been also executed, showing the p value at 1%, 5% and 10%.

A cut-off was introduced to the absolute volumes per procedure. The cut-off was set at 10 volumes for the year 2019 to reduce the variability linked to the occurrence of a low number of cases.

High/low ratio

4.20

1.74

11.42

2.64

2.08

3.39

18.82

4.29

Table 1 Descriptive statistics for selected elective surgery hospitalisation rates in 2019						
Hospitalisation rate	Mean	SD	Minimum	Maximum		
Coronary angioplasty	76.27	24.86	27.22	114.44		
Cholecystectomy	158.47	18.85	120.37	209.29		
Hysterectomy	3.11	2.77	1.00	11.42		
Prostatectomy	145.22	31.94	90.24	238.07		
Knee replacement	155.87	27.49	102.33	212.95		
Hip replacement	342.90	106.27	176.63	598.78		
Vein stripping	46.62	34.22	7.19	135.31		
Tonsillectomy	197.63	74.72	81.63	350.37		
Elaboration of authors on 2019 data	1.					
Patient and public involvement Patients and the public were conduct, reporting or dissemin The analysis is based on aggr at this stage of the analysis, t patient and public lay actors.	not involved in th aation plans of our egated administra he authors did no	ne design, research. ative data; ot involve	Concerning the sele reports a chart of ho ence between 2019 an The charts exhibit a linear negative rela hospitalisation and it	ected elective spitalisation r id 2020. that for some tionship betw s starting poi		

RESULTS

Starting from the hospitalisation records of the Italian National Health Service provided by Agenas, we display in table 1 the descriptive statistics for the selected procedures in 2019.

Table 1 shows wide variations across geographic areas (Italian regions). Moreover, regions with high (low) rates in one procedure have not been found to be associated with high (low) rates in another, most likely reflecting autonomous practices and failures in adhering to shared guidelines and protocols among professionals.

Considering the overall reduction in elective surgery of 28%,²⁶ table 2 reports that the mean reduction for the selected elective surgeries sometimes is lower but registers a wide variation across Italian regions. In some cases, regions enhanced their volumes concerning 2019. Specifically, in 2020, Valle d'Aosta increased the interventions in coronary angioplasty by 3% while Piemonte increased hysterectomy by 24%.

Protected by copyrigh procedures, figure 2 rates and their differ-

<u>ה</u> procedures, there is een the reduction in int. In particular, the 🖪 scatter plots of hospitalisation for vein stripping and tonsillectomy present a clear negative relation: regions with higher 2019 hospitalisation rates registered a larger reduction. ſe ated to te

The Pearson correlation confirms that there is a statistically significant negative correlation between the hospitalisation rates and the reduction in 2020 in all the charts analysed.

In particular, table 3 reports the correlation coefficient and the p value. Tonsillectomy, hip replacement and prostatectomy are the procedures where the correlation is statistically significant at p <0.01, knee replacement is statistically significant at p <0.05, while a lower correlation and a lower significant p value were found for coronary angioplasty (p<0.10). No significant correlation was ٩ found for cholecystectomy and hysterectomy. training, and

DISCUSSION

Considering the selected elective surgery indicators, we found that regions with higher potential inappropriate

Table 2 Volume reduction for selected elective surgery in 2020 compared with 2019					
Procedures	Mean reduction	Minimum reduction	Maximum reduction		
Coronary angioplasty	25%	-3%	57%		
Cholecystectomy	34%	20%	50%		
Hysterectomy	30%	-24%	100%		
Prostatectomy	31%	20%	43%		
Knee replacement	26%	8%	42%		
Hip replacement	25%	20%	36%		
Vein stripping	51%	38%	74%		
Tonsillectomy	54%	27%	68%		

Elaboration of authors on 2020 and 2019 data.

similar technologies



Figure 2 Matrix of 2019 hospitalisation rate and difference in hospitalisation rate between 2019 and 2020 for selected elective surgery procedures. Source: elaboration of authors on 2020 and 2019 data. Y-axis represents the difference in hospitalisation rate between 2019 and 2020. X-axis represents the 2019 hospitalisation rate. Lines represent the linear fit of the values.

elective surgery hospitalisation rates are those that reduced their volumes more.

6

In particular, tonsillectomy and vein stripping, which have been shown to be among the procedures with wider variation across geographic areas, are also those with a

Table 3 Correlation between 2019 hospitalisation rates and hospitalisation rate reduction					
Procedures	ρ	P value			
Tonsillectomy	-0.92	0.00			
Hip replacement	-0.79	0.00			
Prostatectomy	-0.72	0.00			
Coronary angioplasty	-0.38	0.08			
Cholecystectomy	-0.22	0.31			
Hysterectomy	-0.22	0.33			
Vein stripping	-0.93	0.00			
Knee replacement	-0.51	0.01			

Elaboration of authors on 2020 and 2019 data.

Overall, the lower the 2019 hospitalisation rate, the larger the reduction of hospitalisation rates.

larger reduction (in both cases, the correlation coefficient is around -0.9 with a p value of <0.01). These straightforward results seem to support the idea that under emergency pressure, the healthcare system is more likely to provide stricter directions to allocate healthcare resources, preserving them for elective surgical interventions which have stronger clinical evidence. Yet, there is no standard for a number of surgical treatments; in those cases, the 2019 national median can be considered as a reference for all the regional health systems that overcame it in 2019 and the reduction that occurred in 2020 could not be taken into account when planning rebound and new activities. This evidence seems to confirm, at least for the potentially inappropriate hospitalisation rate, the rule of thumb known as Romer's law.

The drop-offs occurred to different degrees. These differences are not strictly linked to the level of variation or the level of use-rates. For instance, in the case of hysterectomy, for which a very high level of geographic variation was registered (as shown in table 1), no significant correlation was found between use-rates and their reduction (as shown in table 3); similarly, relatively lower use-rates of vein stripping (as shown in table 1) were linked to a higher correlation with their drop-offs (as shown in table 3).

Tonsillectomy is the procedure that registered the second highest negative correlation coefficient between use-rates and their drop-offs ($\rho = -0.92$, p<0.01). After the introduction of Italian national guidelines, there was a decrease in the total number of tonsillectomies and their geographical variation.³² However, in 2019, a 4-fold geographic variation was registered (as shown in table 1) and the uneven reduction that occurred across the Italian regions during 2020 seems to confirm that the doubts of the scientific community³³ related to the trade-offs of benefits against risks, discomfort and costs⁷ are not solved yet.

Under the same national recommendation to protect those interventions with the highest degree of clinical relevance, the drop-offs among the procedures were different across regions, and they were not necessarily linked to the level of variation or the level of use-rates. Different healthcare performance between northern and southern regions has already been reported by other authors.^{24 34} Conversely, this study does not report a clear North-South pattern in the high(low) hospitalisation rates analysed (detailed data of the regional use-rates with the North-South area labels are provided in online supplemental material 3). This evidence is in line with that of a recent study on the impact of COVID-19 in Italy which found that the pandemic exacerbated some disparities related to socio-economic or gender issues but there was no clear-cut evidence from the pandemic of a North-South divide for variations either in the quality of service provided during the first year of the pandemic or in the overall hospitalisation rates.³⁵ Disparities instead were exacerbated, in both health and access to healthcare for some fragile population groups, such as the elderly and migrants.³⁵ It is possible that differences in performance between North and South mainly concern resource allocation and management, while variation in medical practice such as that presented in this analysis occurred everywhere. In the former case, regions using a performance measurement system may help to change professional behaviours, while in the latter case the sharing process and a second opinion may provide that help.^{16 36}

Further research is needed to better understand the role played by the different stakeholders: regional managers or health authority managers, professionals and patients. At first evidence, although fear of the population has affected the surgical reduction, the impact seems to be rather limited; a 2021 survey of the population highlighted that 8% of Italians preferred to postpone or avoid surgical treatments because of the fear of COVID-19.³⁷

As a preliminary study on this topic, this research presents some limitations. First, the study context focused on the Italian healthcare system and its organisational structure so that it cannot be generalised. Nevertheless, geographic variation is a topic investigated in several countries, although with different intensity (eg, the USA

showed double the use-rate for hernia compared with the UK,²⁹ while France showed a lower level of use-rates for some procedures with respect to the USA or UK^{38}). Hence, evidence coming from this study may be analysed and replicated in both high-income, and low-income and middle-income countries.^{29 38 39}

However, this study provides evidence to enlarge the debate on this relevant topic in Italy and also in those countries aiming to analyse what happened in 2020 to the unwarranted variation in elective surgery in their **_** countries.

Second, there could be other indicators as valuable and informative as those included in the analysis. However, we considered the ones selected by a group of Italian regional healthcare managers and already included in two of the three performance evaluation systems used in Italy, IRPES and PNE, as indicators monitoring variation in surgical procedures.

Third, although we used standardised hospitalisation rates, further analyses can be done to better understand if patients' characteristics may have played any role in the reduction in volume. Other investigations could be also useful in understanding if some factors (such as the presence of private providers or patient outflow) may explain variation in the volume reduction.

Geographic variation may be a signal of inappropriateness related to overuse, for supply-sensitive care such as that related to the absence of clinical theories, or to misuse, for preference-sensitive care such as treatment that should be linked to patients' preferences, weak for prostatectomy.⁴⁰

However, we cannot exclude the possibility that underuse may occur. Even if we selected procedures that are often considered as being overused, there is still the possibility that some of the patients who did not receive care ended up not getting the care they needed. Indeed, variation in use-rates is an indirect measure of inappropriateness.^{41 42} To underline the uncertainty due to this indirect way of measuring inappropriateness, we added the adjective 'potential'. Indicators are relevant because the adjective 'potential'. Indicators are relevant because **y** they allow a further step of analysis and a sharing process and discussions among health professionals. **CONCLUSION** COVID-19 led healthcare systems to make hard choices in providing services. A large number of cuts, especially for acute care services have been put in place. That has

for acute care services, have been put in place. That has led healthcare systems to reflect on prioritising access to services, which is certainly an ethical issue but also an opportunity to reduce potentially inappropriate interventions.

This study aimed at providing preliminary evidence on the impact of the pandemic on the geographic variation of selected elective surgery procedures. In particular, the group of oncological surgical interventions belongs to the preference-sensitive categories of Wenneberg mostly influenced by the clinician's decision. Wide variation in elective surgery rarely depends on patients' preferences or needs. In fact, a recent study demonstrated that often reservation of the operating room does not depend on demand or waiting times.¹³ This variation category is also one requiring a deeper involvement of clinicians because it asks them to align their behaviour with clinical guidelines or practices.^{8 16} The Italian data show that the pandemic seems to have led hospital managers and health professionals to cut the surgical interventions more likely to be inappropriate. Hence, these findings can inform and guide healthcare systems to manage unwarranted variation. In fact, when coming back to the new normal after this unpredictable situation given by the pandemic, it is important to use this new starting point (lower volumes in some selected elective surgical procedures) to plan elective surgical treatments that can be cancelled because of their high potential for inappropriateness.

Unfortunately, there are no gold standards for surgical use-rates. Under these circumstances, the public disclosure of information about use-rates among regions (and the risk of surgical intervention) can enable a discussion about appropriate care.^{16 29 42 43}

In particular, once healthcare systems have achieved lower hospitalisation rates for potentially inappropriate treatments, as happened during the pandemic, it is important to reverse the burden of proof in the cases of surgical intervention, which are at high risk of inappropriateness. Hence, it could be useful to investigate if it is right that the region should come back to the past performance for interventions that have uncertain evidence instead of asking for a reduction of these cases.

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