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RESEARCH ARTICLE

Mapping the Diffusion and Implementation of Breast Units: Lessons Learned from the Case of Italy

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ABSTRACT

The paper examines the diffusion and implementation of breast units (BUs) in Italy as a paradigm of pathology units. Through a case study methodology, the article analyses both European and Italian requirements for the identification of BUs and conducts a comprehensive census of active BUs in Italy, by reconciling data from four distinct databases. The analysis reveals variations in requirements between the national and the European level, indicating a process of adaptation while adopting European guidelines and underscoring the complexity of harmonizing BU identification criteria. Furthermore, the census of active BUs provides an estimate of the total number of BUs in Italy and assesses adherence to the recommended population coverage standard (one breast unit per approximately 250,000 inhabitants) at the regional level in Italy. Indeed, the analysis shows geographical disparities in the diffusion of BUs across Italian regions. Additionally, this study highlights the challenge deriving from the lack of a unified national database displaying the total number of active BUs in Italy, a limitation that extends to the European context. The paper ends by offering some insights for future research in this area, emphasizing the need for standardized data collection.

1. Introduction

Specialisation and integration serve as the primary design principles for the organisational structure of healthcare organisations. The enduring presence of the functional model testifies the recognised relevance of work specialization criteria, which in healthcare have traditionally been grounded in the domains of medical-scientific disciplines^{1,2}. Over time, many interventions have challenged traditional functional-type organisational configurations, by promoting interventions aimed at the integrated management of entire care processes and their components such as Integrated Care Pathways, care networks³⁻⁵, departments comprising related specialties (e.g. surgical departments), and models based on the intensity of care⁶. However, it is worth noting that specialisation within the medical field has also changed, and medical-scientific disciplines have evolved into a series of both intra and interdisciplinary hyper specialisations. In this context, organisational models characterized by the integration of healthcare services specialized on specific targets of population (generically called “pathology units” or “centres”) have emerged. These are organisational choices that aim to integrate services with a highly specialised vocation, to improve the effectiveness of interventions and the efficiency of delivery models⁷. Pathology units focus on the concentration of caseloads by improving clinical competence through dedicated teams⁸ and high safety conditions; they activate multidisciplinary models to align primarily clinical perspectives between specialists⁹ and protect the usability of care, thanks to service formulas designed for the specific needs of the populations they address¹⁰. Oncology offers several examples of pathology units that aggregate services from different disciplines in order to manage the outcome of a target population affected by a specific pathology (breast unit - hereafter BU -, lung unit, prostate unit, etc.). This article focuses on the diffusion of BUs, intended as a paradigm of pathology units. The debate around BUs is very broad, and their development has received significant impetus at the European level through specific resolutions of the European Parliament in 2003 and 2006. In particular, the 2006 European Parliament resolution called on Member States to establish a network of breast centres by 2016. In 2017, the Joint Research Centre - JRC¹¹ assessed the state of implementation of BUs in the Member States and other European countries, based on a questionnaire sent to the National Contacts of the European Commission Initiative on Breast Cancer (ECIBC), a JRC-coordinated initiative, and to the National Representatives of Europa Donna, a European non-

profit organisation focused on breast cancer, with members consisting in affiliated groups from countries throughout Europe. The report reveals challenges at the European level in the establishment of networks of BUs and heterogeneity in approaches between different countries. First, BUs are required by law only in two countries (Italy and the Czech Republic), although they are recommended in 17 of the 30 countries considered in the report, and there is a mandatory accreditation or certification system for BUs in only four countries (Bulgaria, the Czech Republic, Italy and the United Kingdom). Furthermore, the four requirements deemed mandatory for BUs according to the 2006 European Guidelines¹² turn out to be obligatory only in two countries (Italy and the Czech Republic). Mandatory requirements encompass: (i) a minimum volume of treated cases; (ii) the composition of the BUs’ core team; (iii) specific breast cancer training of core team members; (iv) continuous professional training of core team members. In 2020, Europa Donna provided an overview of the spread and distribution of BUs in 34 European countries through a survey sent to representatives of the national Europa Donna groups¹³. From the report it emerges that only the 55% of considered countries have implemented BUs as organisational model, and that in the 53% of cases BUs are not well distributed throughout the territory and do not cover the entire population (for an optimal population coverage there should be one BU per approximately 250,000 inhabitants).

Organisational models such as BUs must be promoted and diffused, as they generate better outcomes for patients. Based on these premises, the purpose of this paper is to examine the implementation of European indications and the diffusion and distribution of BUs in Italy. The objective of the paper is twofold: on the one hand, to analyse European and Italian guidelines that define the requirements for a BU to be official recognized, with the aim of identifying potential differences in the requirements; on the other hand, to conduct a comprehensive census of the BUs active in Italy, by consolidating information from all available sources. Both objectives are of significant importance: the analysis of the indications provides insights into whether a process of national adaptation has occurred when implementing European indications at the national level. Simultaneously, the mapping of BUs represents the first exercise of its kind in the literature, given the absence in Italy of a single database containing the total number of active BUs. This census also serves to verify the adherence to BU standards – especially those related to the average number of inhabitants per BU, thereby allowing an assessment

of the equitable accessibility of services across the country.

2. Methods

2.1 STUDY DESIGN

This contribution adopts a case study methodology, one of the most widely used forms of research in the social and managerial fields. This methodology is preferentially chosen when certain conditions are met, including (i) the research questions delve into the “how” and “why” of a phenomenon, extending beyond linear causality¹⁴; (ii) the phenomena are current or not distant in time, (iii) the adopted approach is naturalistic, meaning there is no attempt to modify the observed reality but rather to interpret it. The case study methodology allows the examination of a phenomenon within its context of occurrence, using multiple sources of information and mixed methods of measurement¹⁵. The use of multiple sources and techniques in the data collection process is a significant strength of the case study method as it ensures its internal validity, which is the main criterion for evaluating the robustness of the applied methods. The case study implemented in this paper is instrumental, as the object under consideration is selected as typical and emblematic in order to enable the development of a series of generalizations¹⁶.

In particular, the contribution analyses the case study of Italy, which holds particular interest due to Italy’s unique position as one of the two countries, alongside the Czech Republic, with dedicated law requiring the establishment of BUs and making the four requirements of European Guidelines for BUs compulsory. Furthermore, BUs serve as a paradigmatic example in Italy, as they are present in all types of healthcare facilities (public and private, Local Health Authorities, Scientific Hospitalization and Treatment Institutes and Hospitals/Universities). Italy’s healthcare system is a regionally based national healthcare system, which operates on a decentralized structure providing universal and largely free of charge coverage for all citizens, without restrictions. This system is structured into three tiers: the national level, the regional level, and the local level. At the national level, the Ministry of Health, supported by various specialized agencies, establishes the fundamental principles, general objectives, and health system goals. Regional health governments hold exclusive authority for planning and delivering healthcare services. They coordinate and deliver healthcare services through a network of population-based “local health authorities” known as Aziende Sanitarie Locali, as well as public and private accredited healthcare providers. This high level of

regional autonomy offers a unique opportunity to study the implementation of both European and national regulation. It also allows Regions to adapt national requirements to address the diverse healthcare needs of their residents, considering the significant disparities in size, population, and economic development levels among Italian Regions¹⁷.

2.2 DATA COLLECTION

Data supporting our analysis were collected through desk research. The aim of this data collection phase was to:

1. Identify sources containing the requirements and indications related to BUs at both European and Italian levels;
2. Identify the BUs active in Italy, taking into account four freely accessible online databases: 1) the EuropaDonna Italia census¹⁸, which maps the BUs identified through Regional Resolutions; 2) the list of BUs affiliated with the national network called “SenoNetwork” (a non-profit organisation that coordinates a network of breast centres in Italy)¹⁹; 3) the list of BUs holding the Eusoma (European Society of Breast Cancer Specialists) certification²⁰; 4) the data from the National Outcomes Programme (PNE) on the volume of admissions for breast cancer surgeries. PNE is a tool for measuring, analysing, evaluating, and monitoring the clinical and healthcare performance of Italian healthcare facilities, developed by the National Agency for Regional Healthcare Services on behalf of the Ministry of Health²¹. This analysis is based on the PNE 2021 edition data, referring to the year 2020. The mapping of active BUs in Italy was initially conducted by the authors in 2020²² and subsequently in 2022 for the purpose of this paper.

2.3 DATA ANALYSIS

Three researchers conducted independent comparison of the sources containing requirements and indications related to BUs, in order to highlight the common and distinctive elements that qualify BUs, and to pinpoint any differences in the requirements. Afterwards, they separately estimated the number of BUs active in Italy by reconciling the four abovementioned databases and removing duplicates arising from the intersection. During two 90-minute meetings with an extended team of researchers, results from both the comparison of the requirements and the estimation of the number of BUs were examined, discussing any discrepancies in the assessment and drafting the common and final results, arriving at a consensus.

3. Results

3.1 THE REQUIREMENTS FOR BREAST UNITS

Through the analysis it was possible to identify the main sources that define BUs which are: i) the Eusoma indications (2000, 2013, and 2020²³⁻²⁵) that, by identifying their requirements, lay the foundations for subsequent literature; ii) resolutions of the European Parliament (2003 and 2006^{26,27}) that aim to give relevance to the topic of BUs by setting specific objectives for the Member States; iii) the guidelines on the organisational and care models of the network of Breast Centres approved by the Italian State-Regions Conference in December 2014²⁸, which incorporates the indications of the previous sources and introduces the concept of functional coordination. The information deriving from SenoNetwork and those provided by EuropaDonna Italia complete the Italian panorama on the subject.

The article “The requirements of a specialist Breast Unit Centre”²³, updated in 2013 by Wilson et al.²⁴ and subsequently in 2020 by Biganzoli et al.²⁵, constitutes the representative document of the Eusoma standards on Breast Centres (BCs), which will then be taken up internationally by various countries, including Italy. This document outlines the requirements of BCs, proposing a specific organisational model for breast activity: the multidisciplinary nature of the professionals (to be activated in all phases of the clinical pathway) is the pivotal element, together with their specialist expertise and the minimum standards of dedicated resources. Requirements of the BCs according to Eusoma include that the BC must treat at least 150 new cases of primary breast cancer per year and 50 cases of metastatic breast cancer per year. In a 2003 resolution²⁶ the European Parliament endorses Eusoma’s recommendations and calls on Member States to prioritise the fight against breast cancer, sustaining the building of a capillary network of certified BCs following the Eusoma example. The European Parliament resolution of 2006²⁷ invites Member States to ensure compliance with EU guidelines and establish a network dedicated to breast pathology by 2016.

At the Italian level, the indications on BUs come from the ministerial document approved by the State-Regions Conference in December 2014²⁸, which incorporates both the Eusoma indications and those of the European Parliament, introducing the theme of functional coordination. In fact, it defines the BC as a centre that functionally brings together all the simple, complex, or departmental operating units or services that are involved in the diagnosis and treatment of breast pathology, and that contribute to guarantee the multidisciplinary nature of the diagnosis, treatment, and rehabilitation of breast cancer patients.

SenoNetwork contributes to the definition of BUs by indicating the requirements to join its network. Indeed, to become a member of SenoNetwork, a BU needs to perform at least 135 first surgeries on incident breast cancer, as it is required by the 2018 fulfilments on the essential care levels (Livelli essenziali di Assistenza - LEA) defined by the Italian Ministry of Health.

Finally, EuropaDonna identifies two types of BUs²⁹: the structural BUs and the functional BUs. In the first case, a Breast Unit organisational responsibility is formally defined in the organisational chart of the healthcare organisation (with objectives and resources), and it groups together a series of core services for the patient clinical pathway, in order to guarantee their integration and quality of care. In the functional model, on the other hand, no organisational responsibility is defined, and the integration of services is obtained through the coordination between operational units and professionals, who collaborate throughout the clinical pathway.

Table 1 compares the indications related to the professional figures of a BU from Eusoma, the 2014 Italian ministerial document, and the entry criteria of SenoNetwork. The table highlights the standards that are most widely observed among the 3 sources with respect to the number of professionals, the working time (WT), and the number of services performed (e.g. number of ultrasound scans, mammograms or surgeries). As depicted in the Table, the expected forms of specialisation are, on average, defined around 50% of the WT and reach 100% only in the case of the nurse.

Table 1 Comparison of regulatory sources on the number of core team professionals and specialisation requirements

	EUSOMA		ITALIAN MINISTRY OF HEALTH		SENONETWORK	
	No.	Specialisation	No.	Specialisation	No.	Specialisation
Radiologist	2	50% WT 1000 mammograms/per year, 200 ultrasounds/per year, 50 MRIs/per year, 50 breast guided interventions/per year	NA	50% WT 1000 mammograms/per year, 250 ultrasounds, 100 cytology and micro histological procedures + 25 VABB procedures, 50 MRIs/per year	1	50% WT
Radiographer	2	1000 mammograms/per year	NA	NA	NA	NA
Surgeon	2	50% WT Primary surgery on 50 newly diagnosed breast cancers/per year	2	50% WT (the responsible professional) 50 new interventions/per year (both)	1	50% WT
Pathologist	2	50% WT 50 preoperative samples/per year, 50 early resections/per year, 25 metastatic breast cancer surgical specimens/per year	2	1° 50% WT, 2° 25% WT 50 resections/per year, 100 cytological examinations from FNAC, and 100 histological examinations from core biopsy	1	50% WT
Medical oncologist	2	50% WT 50 early and 25 metastatic breast cancer patients treated/per year	2	50% WT At least 5 years of experience in the medical treatment of breast cancer	1	50% WT
Radiation oncologist	2	50% WT 50 early breast cancer patients treated/per year	2	40% WT	1	40% WT
Nurse	2	100% WT 50 early and 25 metastatic breast cancer patients seen/per year	2	100% WT	NA	NA

Source: Authors' elaboration on Eusoma, Italian Ministry of Health and SenoNetwork

3.2 THE CENSUS OF BREAST UNITS IN ITALY

As highlighted in the methodology, in the absence of a single national database, the mapping of BUs has been carried out through the analysis of the 3 databases of BUs managed respectively by EuropaDonna, SenoNetwork, and Eusoma, which are not in complete overlap. In addition, the PNE data on the volumes of admissions for breast cancer surgeries has been considered for the mapping.

First, the periodic census of EuropaDonna shows 188 BUs identified by a Regional Resolution. As of 2022, there has been a Regional Resolution to activate BUs in 90% of the Italian regions. SenoNetwork has 149 BUs registered in the network, 141 of which are identified by Regional Resolution. Finally, Eusoma reports the list of 24 BUs that have obtained a Breast Centre Certification. This is a voluntary certification process that follows the international regulations of ISO/IEC 17065 certification. All 24 BUs with Breast Centre Certification are also identified by Regional Resolution. Additionally, considering the PNE data referring to 2020 on volumes of admissions for breast cancer surgeries, it is possible to identify other 4 facilities treating more than 150 breast cancer cases per year (the threshold is derived from the European and Eusoma requirements for the definition of a BU, as well as from the thresholds introduced by the Ministerial Decree 70/2015 on hospital standards). These 4 additional units are absent in the other databases (see Table 2 and Table 3) and could be identified only merging and combining data from multiple units. This is because PNE considers data only at the operating unit/ward level. However, there are intra-organisational BUs where the operating units of the core disciplines are spread across several hospital sites within the same healthcare organisation, or inter-organisational BUs, which are units whose services are distributed

across different healthcare organisations. Therefore, it is worth noting that not all facilities would be detectable solely by imposing the 150-case threshold in the PNE database. This discrepancy arises from the fact that the requirements specify only the number of cases without further clarification regarding whether this number pertains to the volume of activities at the hospital level or at the unit level. In the former case, only high-volume units capable of concentrating numbers in one facility can be identified. In the latter interpretation, intra-organisational BUs, composed of multiple surgical units within the same hospital, and inter-organisational BUs, consisting of surgical units from separate hospitals, can also be recognized. The lack of clarity is one of the key takeaways from this analysis.

Based on the intersection of all the sources, it can therefore be estimated that there are about 200 active BUs in Italy that satisfy at least one of the following conditions: identification through a Regional Resolution, registration within SenoNetwork, volume of cases greater than 150 per year. This is an average of one BU every 295,000 inhabitants, not far from, though not coinciding with, the reference of the State-Regions Agreement, which provides for one every 250,000 inhabitants.

Notably, there has been an overall increase in the total number of BUs with respect to 2020, year in which there was an average of one BU per approximately 318,000 inhabitants. Only through the PNE data fewer BUs were detected in 2022 compared to 2020. Since the PNE data considered in the paper refers to 2020, it can be assumed that the emergency situation related to the Covid-19 pandemic had a negative impact on the number of cases treated within the BUs.

Table 2 Distribution of BUs in Italian Regions (thousands of inhabitants per BU and total BUs) in 2022

Region	Inhabitants (thousands) per BU	Total BUs
Abruzzo	319	4
Basilicata	271	2
Calabria	464	4
Campania	402	14
Emilia Romagna	369	12
Friuli Venezia Giulia	239	5
Lazio	336	17
Liguria	302	5
Lombardy	249	40
Marche	297	5
Molise	292	1
Piedmont	266	16

Region	Inhabitants (thousands) per BU	Total BUs
Apulia	302	13
Sardinia	397	4
Sicily	302	16
Tuscany	262	14
AP of Bolzano	533	1
AP of Trento	541	1
Umbria	215	4
Aosta Valley	123	1
Veneto	231	21
Total	295 (318 in 2020)	200 (190 in 2020)

Source: Authors' elaboration on data from Istat, PNE, regional resolutions, SenoNetwork and Eusoma

Table 3 Distribution of BUs in Italian Regions (detail of total BUs) in 2022

Region	Total BUs	BU identified by the Region	BU registered in SenoNetwork	BU with Eusoma certification	Additional units >150 cases (PNE)
Abruzzo	4	4	2	1	0
Basilicata	2	2	2	0	0
Calabria	4	4	3	0	0
Campania	14	10	6	0	3
Emilia Romagna	12	12	12	6	0
Friuli Venezia Giulia	5	0	5	3	0
Lazio	17	17	15	1	0
Liguria	5	5	5	0	0
Lombardy	40	40	32	8	0
Marche	5	5	2	0	0
Molise	1	1	0	0	0
Piedmont	16	16	15	0	0
Apulia	13	12	10	0	0
Sardinia	4	3	2	0	1
Sicily	16	16	8	1	0
Tuscany	14	14	11	1	0
AP of Bolzano	1	1	1	1	0
AP of Trento	1	0	1	0	0
Umbria	4	4	4	0	0
Aosta Valley	1	1	1	0	0
Veneto	21	21	12	2	0
Total	200 (190 in 2020)	188 (173 in 2020)	149 (135 in 2020)	24 (20 in 2020)	4 (8 in 2020)

Source: Authors' elaboration on data from PNE, regional resolutions, SenoNetwork and Eusoma

Table 3 shows the total number of BUs as emerges from the intersection of the four sources considered. Since 141 of the 149 BUs registered in SenoNetwork are also identified by Regional Resolution and all the 24 BUs with Breast Centre Certification are also identified by Regional Resolution, the total number of BUs is not the sum of the number of BUs contained in each of the four sources. Indeed, the total number of BUs is the sum

of the 188 BUs identified by Regional Resolution, the 8 BUs registered in SenoNetwork but not identified by Regional Resolution and the 4 additional units identified through the PNE.

4. Discussion

Any study on the subject of pathology units inevitably raises the question of what is meant by a centre or unit and which are its distinguishing

features. The in-depth study of BUs has shown that the answer to this question is neither trivial nor obvious. Indeed, with respect to the first research objective, the analysis shows the complexity of the recomposition of the requirements for the identification of BUs, as there is no single source indicating the requirements for BUs, but there are several with slight differences between them. In particular, the reconciliation of the different sources containing indications on the subject of BUs points out some differences in the requirements between the national and the European level.

The first difference concerns the requirement on the number of primary breast cancer cases treated per year by the BU to be considered as such. At the European level, according to Eusoma, the BU must treat at least 150 new cases of primary breast cancer per year. At the Italian level, the Ministerial Decree 70/2015, in line with international guidelines, identifies the threshold of 150 first surgical operations per year per BU. In 2018, the LEA fulfilments issued by the Ministry of Health lowered the threshold to 135, which is adopted by SenoNetwork within its network membership requirements.

The second difference regards the indications with respect to the professional figures that must compose the BU team. Indeed, the comparison of the indications from Eusoma, the 2014 ministerial document, and the entry criteria for SenoNetwork shows some differences. While the ministerial document and the Eusoma document always require the presence of at least 2 professionals per medical speciality, SenoNetwork lowers the minimum threshold to 1, bringing into sharper focus the concrete difficulty in gathering such a number of professionals. Furthermore, it can be seen that SenoNetwork does not include the figure of the nurse among the professionals for whom some form of specialisation is required, while the figure of the radiographer is only required by Eusoma. Differences can be seen between Eusoma and the ministerial requirements with respect to the number of services performed per year by the various professionals, whereas SenoNetwork does not state this type of requirements. These differences reveal that a national adaptation process has taken place while adopting European indications at the national level, but also that a lack of clear indications can lead to local interpretation and inequities.

The analysis related to the second research objective has led to the estimation of the number of BUs active in Italy. According to Regional Resolutions, there are 188 BUs in Italy, while by reconciling all the databases they rise to 200, since other units appear, either registered in SenoNetwork or reaching the standard on the minimum threshold of cases (> 150 cases). However,

with respect to the latter, since they cannot be formally classified as BUs, it is complex to intercept the other requirements, such as multidisciplinary. The hypothesis that these facilities can also be classified as BUs could be inferred solely from the number of cases. It could be possible that the entire patient care pathway is not developed within these organisations, even though it is hard to imagine that the case volumes are limited to surgical treatment alone. However, it would be important to assess whether the other requirements are also satisfied within these 12 facilities that, beyond the formal dimension, manage at least 1,680 cases in total per year (8 facilities from SenoNetwork with at least 135 cases each and 4 facilities from PNE with at least 150 cases each).

The census of the BUs active in Italy allows also to evaluate the level of implementation of a BCs network at a regional level within Italy. Although the number of Regions with a Regional Resolution for the activation of BUs has increased since 2020 (from 76% to 90%), there are still some Regions that have not identified BUs with a resolution, in spite of the European indications on the establishment of a network of BUs by 2016. Disparities among Regions emerge also when assessing the average number of inhabitants per BU, considering the total number of BUs. While the national average is equal to one BU every 295,000 inhabitants, this number ranges from a minimum of 123,000 inhabitants per BU in Aosta Valley to a maximum of 541,000 inhabitants per BU in the Autonomous Province of Trento, both Regions having only one BU. Overall, there are only 6 Regions (namely Basilicata, Friuli Venezia Giulia, Lombardy, Piedmont, Tuscany and Veneto) having an average number of inhabitants per BU close – considering a 10% margin – to the reference of the State-Regions Agreement, which provides for one every 250,000 inhabitants. On the other hand, there are 5 Regions (namely Calabria, Campania, Sardinia, Autonomous Province of Bolzano and Autonomous Province of Trento) exceeding the reference threshold by more than 50%. These data reflect a picture of a country in which the level of diffusion of BUs is geographically differentiated and uneven, with some Regions lagging behind with respect to the institution of an adequate number of BUs per inhabitants.

Moreover, the reconciliation of the databases for the census of BUs carried out in this article reveals the complexity of such an exercise, deriving from the fact that there is no single database that maps all active BUs in Italy. The absence of a single database containing the number and reference of Italian BUs is clearly a limitation, as it requires carrying out the reconciliation work conducted in this

study whenever there is a need or interest to assess the distribution of BUs at a geographical level or the adequacy of the number of BUs per inhabitant. This limitation persists also when moving from the Italian to the European level. Indeed, it is worth noting that both mappings of BUs cited in the introduction (performed by JRC and Europa Donna) are based on the results of a questionnaire, in the absence of a census that precisely identifies the BUs active at a European level. The presence of such a census would be extremely valuable for policy and decision-makers in order to be able to make detailed considerations on the level of adoption of European indications at national level, and on the geographical distribution of BUs both at European level and within individual countries, assessing their coverage in terms of number of BUs per inhabitant, and the fulfilment of clear standards and certifications. Recognizing the importance of clear standards and quality frameworks for certifying cancer centres aligns with one of the key recommendations suggested by Ferrara et al. in their recent publication³⁰. Collecting this census can prove invaluable also for patients themselves. Having access to comprehensive information about available healthcare services, including data on patient volumes and treatment outcomes, empowers individuals to make informed decisions regarding their care. In today's healthcare landscape, where patients have more options than ever before, being well-informed allows them to choose the most suitable healthcare providers, treatment options, and facilities based on their specific needs and preferences, and factors like proximity. This not only enhances the quality of care they receive but also serve as a vital tool in empowering and engaging patients to take an active role in their healthcare decisions and ultimately leads to better healthcare experiences and outcomes for all^{31,32}.

Such a census would be desirable not only for BUs, but also in all those cases in which a model organised by specialised centres is proposed because they generate better outcomes for patients, such as in the case of other forms of cancer, such as head and neck cancers^{33,34} and gastrointestinal cancers³⁵, or cerebrovascular diseases such as stroke³⁶. The importance of conducting such a census is already recognized, particularly in the case of rare diseases. Indeed, one of the primary objectives underlying the establishment of European Reference Networks (ERNs)³⁷ for rare diseases is the imperative to pinpoint and highlight reference centres that not only adhere to rigorous standards but also possess a wealth of expertise in managing specific diseases. In essence, ERNs serve as a vital mechanism for elevating the visibility and accessibility of reference

centres, thereby enhancing the overall quality of care for patients with rare diseases across Europe, allowing the identification of specialised centres that excel in the diagnosis, treatment, and management of specific diseases. This newfound visibility and accessibility empower patients to make informed decisions about their healthcare journey, ensuring that they receive the highest quality of care from centres that meet stringent standards and possess unparalleled expertise.

The present contribution holds both strengths, being the first exercise of its kind in the literature carrying out a census of the total number of BUs active in Italy, and limitations, related to the fact that the census is carried out only through secondary analysis of existing databases and that the contribution lacks an analysis of the context in which the BUs are located. Indeed, an interesting area for future research is represented by the analysis of the organisational models of BUs, by considering the physical allocation of the core disciplines for breast cancer management, and analysing some of their characteristics, such as the professionals who are part of the BU's team.

5. Conclusion

This contribution has reconstructed the requirements and indications on the subject of BUs both at the Italian and European level, and it has estimated the number of BUs active in Italy through the reconciliation of four different databases. The reconstruction of the requirements has shown that a national adaptation process has taken place while adopting European indications at the Italian level, since some slight differences exist in the requirements for BUs between the national and the European level. The census of active BUs in Italy has, on the one hand, identified additional BUs other than those formally classified as such by the Regional Resolutions, with respect to which it would be important to assess whether all the requirements are met, and, on the other hand, revealed a differentiated and uneven level of implementation of a BUs network at a regional level within Italy. In conclusion, the contribution points out the importance and desirability of developing a single database, mapping the total number of BUs active both in Italy and at the European level, in order to support and facilitate the assessment of the adequacy and equity in the diffusion and distribution of services.

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