



Applied nutritional investigation

Patient access to oral nutritional supplements: Which policies count?

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ABSTRACT

Objectives: Oral nutritional supplements (ONS) represent a cost-effective method for treating malnutrition. The aim of this study was to investigate the effects of public policies on patient access to ONS, using the Italian regionalized health care system as a case study, subsequently compared with the centralized British National Health Service.

Methods: Regional policies in the nine largest Italian regions and British policies were gathered through a literature review; interviews with officers responsible for clinical nutrition policies at the regional level in Italy were also conducted. Total ONS regional sales in Italy were gathered from industry sources.

Results: Regulation by Italian regions focused on patient access and local prescribing issues (facilities and specialists allowed to prescribe reimbursed ONS, clinical pathways for malnutrition or disease-related malnutrition, length of prescriptions, and distribution of ONS). British policies focused on organizational issues (clinical governance through multidisciplinary Nutrition Support Teams, Nutrition Steering Committees and Clinical Commissioning Groups), education and referral by health care professionals. Neither per capita reimbursed ONS expenditure nor the proportion covered by public funds seem dependent on policies implemented at the regional level in Italy. There is no cutting-edge evidence that British policies produced broader diffusion of ONS, but they appear to have standardized their use within a more homogenous framework.

Conclusion: As no clear relation between regional policies and variation in patient access to ONS emerges in Italy, national policies should be encouraged to enhance awareness of malnutrition among health care professionals and encourage the diffusion of multidisciplinary nutrition teams in health care organizations.

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Introduction

Prevention and adequate management of malnutrition is increasingly believed to be integral to clinical pathways for various diseases, such as cancer, chronic obstructive pulmonary disease, and dementia, to reduce complications and improve outcomes [1,2]. A need to address malnutrition and undernutrition among elderly,

and especially frail, patients also has emerged [3]. Despite such evidence, attention to malnutrition remains stubbornly low in health care settings [4], a phenomenon also observed in Italy. Suggested actions to address awareness on malnutrition and its management in patients affected or at risk of disease-related malnutrition (DRM) include increasing education for physicians on malnutrition, regular screening for risk for malnutrition, nutritional assessment and management as an integral part of clinical practice, multidisciplinary nutritional work groups, and follow-up [4,5].

Nutrition therapy includes enteral nutrition (EN), parenteral nutrition (PN), and diet enrichment as well as oral nutritional supplements (ONS), medical nutrition products in the form of ready-to-drink liquids or powders that provide macronutrients and micronutrients. Recent systematic reviews and meta-analyses have provided evidence on the efficacy and economic effects of using ONS [6]. Some meta-analyses have estimated a reduction in health care costs associated with treatment with ONS for patients with

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malnutrition of between 5% and 12%, depending on the setting, by reducing complications and the average length of stay for inpatients [7,8]. Other reviews emphasize the need to improve the quality of the ONS studies undertaken, although better quality studies usually correspond with a more favorable economic affect [6].

The aim of this study was to investigate the role played by policies on patient access to ONS, using Italy as a case study of a regionalized system, compared with the British National Health System (NHS).

In Italy, a guaranteed, common benefits basket is centrally defined by the national Ministry of Health, Livelli Essenziali di Assistenza (LEA), and covered by the Italian public health system, Servizio Sanitario Nazionale (SSN); however, the 20 individual regions are responsible for the planning and delivery of health care. The regions may provide services beyond the LEA at their own expense as well as delay access to treatments when health care budget constraints intervene [9,10]. Such discretion can often lead to disparities in access to and quality of care. ONS offer a relevant case in point as they have been included in the 2017 revision of the LEA for public reimbursement only when provided in the inpatient setting [11], whereas EN and PN were included for full reimbursement in the LEA in 2001. The decision to reimburse ONS outside the hospital is left up to the individual regions. There are no national directives regarding nutrition therapy, and guidelines on national scientific association websites have focused on EN and PN. A consequence of this situation is poor attention to malnutrition by specialists, as observed in a recent survey carried out on oncologists in Italy. Only 5.7% of nearly 2400 members of the Italian Society of Medical Oncologists completed the questionnaire; nutritional assessment and support were routinely integrated into patient care for only 28% of respondents; and almost 49% declared that nutritional assessment was carried out only at the patient's request [12].

In Britain, NHS policies have been centrally defined, and a double target approach has been adopted: NHS interventions address both patients and health care professionals—specialists as well as general practitioners (GPs)—who eventually treat malnourished patients by providing proactive consultancy and training.

To the best of our knowledge, the potential and actual role played by policies in guaranteeing access to ONS has not been investigated elsewhere.

Materials and methods

Per-capita public expenditure for ONS and the level of public coverage of the market for ONS were used as a proxy for patient access to ONS in Italy. Data regarding total sales of ONS (only medical nutrition oral supplements, excluding products for dysphagia, thickeners, and vitamin supplements) to individual regions were gathered for the year 2015 from the four industry sources that market ONS directly to the public SSN, comprising the market for reimbursed ONS, shown in Table 1. These products were purchased at the regional or local level (Local Health Authorities [LHAs]) and were subsequently distributed in various settings, including hospitals, territorial facilities and services, through public (district) pharmacies, ambulatory care facilities, clinical nutrition centers or operational units, or sometimes through retail pharmacies but paid for with public funds. Data for ONS sold in retail pharmacies to private citizens were also collected, comprising the "private market" (Table 1). The data cover all ONS producers active in Italy.

Regional policies regarding ONS were mapped in the nine largest Italian regions (Piedmont, Lombardy, Veneto, Emilia Romagna, Tuscany, Latium, Campania, Apulia, Sicily), which correspond to 79% of the entire market for ONS (80% of the private market and 78% of the public market) and 80% of the population (Table 1).

The mapping exercise considered the following aspects of regional and local policies:

- Explicit mention of ONS in regional planning, policy, and regulation regarding clinical nutrition;
- Any indication of the population potentially covered by ONS in settings outside the hospital;

Table 1
Market for oral nutritional supplements in Italy (2015)

Region	Market for ONS procured by LHAs (reimbursed)			Market for ONS procured and dispensed by retail pharmacies (not reimbursed)			Total ONS market		
	Euro	% on total market	Per capita (Euro)	Euro	% on total market	Per capita (Euro)	Euro	% on Italian market	Per capita (Euro)
Northern regions									
Aosta Valley	82,477	48.1	0.65	89,146	51.9	0.70	171,623	0.35	1.35
Piedmont	1,541,284	35.9	0.35	2,746,959	64.1	0.62	4,288,243	8.66	0.97
Liguria	353,914	19.1	0.23	1,503,323	80.9	0.96	1,857,237	3.75	1.18
Lombardy	1,989,876	21.7	0.20	7,194,337	78.3	0.72	9,184,213	18.54	0.92
Trentino/South Tirol	389,003	48.5	0.37	413,762	51.5	0.39	802,765	1.62	0.76
Veneto	675,874	16.6	0.14	3,389,977	83.4	0.69	4,065,851	8.21	0.83
Friuli Venezia-Giulia	514,444	42.9	0.42	684,953	57.1	0.56	1,199,397	2.42	0.98
Emilia-Romagna	1,267,250	34.3	0.28	2,430,013	65.7	0.55	3,697,263	7.46	0.83
Center regions									
Tuscany	904,690	26.4	0.24	2,524,367	73.6	0.67	3,429,057	6.92	0.92
Umbria	375,705	44.8	0.42	463,027	55.2	0.52	838,732	1.69	0.94
Marches	420,386	26.6	0.27	1,158,198	73.4	0.75	1,578,584	3.19	1.02
Latium	792,127	20.8	0.13	3,010,692	79.2	0.51	3,802,819	7.68	0.65
Southern regions									
Abruzzo	314,659	29.8	0.24	742,538	70.2	0.56	1,057,197	2.13	0.80
Molise	20,209	14.4	0.06	119,807	85.6	0.38	140,016	0.28	0.45
Campania	2,819,859	66.6	0.48	1,411,609	33.4	0.24	4,231,468	8.54	0.72
Basilicata	96,344	31.9	0.17	205,501	68.1	0.36	301,845	0.61	0.53
Apulia	1,063,992	45.5	0.26	1,271,970	54.5	0.31	2,335,962	4.72	0.57
Calabria	405,093	30.7	0.21	912,495	69.3	0.46	1,317,588	2.66	0.67
Sicily	1,201,398	29.1	0.24	2,931,166	70.9	0.58	4,132,564	8.34	0.81
Sardinia	465,424	42	0.28	643,218	58	0.39	1,108,642	2.24	0.67
Italy	15,694,008	31.7	0.26	33,847,058	68.3	0.56	49,541,066	–	0.82
Northern regions	6,814,122	27	0.25	18,452,470	73	0.66	25,266,592	51	0.91
Center regions	2,492,908	25.8	0.21	7,156,284	74.2	0.59	9,649,192	19.5	0.80
Southern regions	6,386,978	43.7	0.31	8,238,304	56.3	0.40	14,625,282	29.5	0.70

LHA, local health authority; ONS, oral nutritional supplements.

Elaboration of market data provided by each single company marketing ONS in Italy.

- Health care organizations or specialists approved for prescribing publicly funded ONS;
- Activation of specific clinical pathways for malnutrition or for pathologies commonly associated with malnutrition or specifically approved for the prescription of publicly funded ONS;
- Specific norms regarding time frames for prescribing ONS;
- Distribution methods for ONS by regional bodies: Direct distribution through LHAs or distribution through retail pharmacies but publicly funded.

The analysis of the regional case studies was performed through a gray literature review of documents accessible via the internet or upon request from regional or LHA officers, and through interviews with officers responsible for clinical nutrition policies or programs at the regional or LHA level. Specifically, through scientific societies we identified and contacted 71 managers of clinical nutrition centers at LHAs in eight of the nine considered regions; 19 managers provided feedback. Moreover, we contacted 12 managers of Regional Health care Departments (RHDs) responsible for addressing clinical nutrition issues. Of the 12 RHD managers, 4 provided feedback. A semi-structured questionnaire was prepared for the interviews, designed to integrate and validate the information collected. The interviews lasted an average of 30 min and the notes taken during the interviews were compiled and sent back to the interviewees for validation.

To assess the British NHS case, we analyzed mainly gray literature available online, including guidelines from the National Institute for Health and Care Excellence (NICE), publications from the British Association for Parenteral and Enteral Nutrition, and documents from the Clinical Commissioning Group (CCG).

The effect of the policies on access to ONS was estimated by comparing the implementation methods outlined in the policies with the average values of per-capita public expenditure for ONS and on the level of public coverage of the market for ONS.

Results

On average, 32% (€0.26 per capita) of the €49.5 million total market (€0.82 per capita) for ONS in Italy in 2015 was covered by the SSN, with large regional variation in the proportion covered by public funds. These figures include total outlays by hospitals and LHAs to ONS producers, paid through a tender system, to cover distribution of ONS to inpatients and, in some regions, outpatients, where LHAs have authorized direct, discretionary funding. Private spending, that is, purchases by individual Italian residents in retail pharmacies, for ONS equaled roughly \$0.56 per capita in 2015. A small portion of this out-of-pocket spending may be reimbursed by private insurance or integrated funds, which account for a limited portion of total health expenditure in Italy (~2%) [13].

Regional policies are illustrated in Figure 1, whereas an appendix in the Supplementary material provides a detailed summary of the regional comparison. Table 2 provides a summary table linking per-capita public spending and the split between the public and private markets for ONS (Table 1), with regional policies.

Between the end of the 1990s and the beginning of the 2000s, all nine Italian regions released specific policies aimed at developing and implementing hospital-territorial networks for EN and PN, and for managing patients with malnutrition at home, therefore demonstrating a formal interest in the theme of malnutrition treatment. Nonetheless, in four regions (Piedmont, Lombardy, Campania, and Apulia), the associated normative provisions never directly cite ONS (Fig. 1B). The explicit mention of ONS does not necessarily predict either coherent regional policies or public expenditure for these products (Table 2). For example, Piedmont, which lacks a specific regional law covering ONS, formally guarantees the most comprehensive network of access to ONS, as well as to nutrition home-based services. There is no specific mention of ONS in regional directives in Apulia and Campania, but this has not prevented these regions from providing more patient access to ONS (Table 1).

Regions have identified different type of patients prioritized for access to ONS at regional expense. Some regions (Piedmont, Veneto, and Tuscany) provide for wide coverage based on potential patient needs. Other regions have designated coverage for patients with specific pathologies (Lombardy, Latium, Campania, and Sicily). Still

others have deferred decisions to single LHAs (Emilia-Romagna and Apulia), usually contingent on enrollment in clinical pathways and/or integrated care programs at the LHA level (Fig. 1C). Still, wider formal coverage does not predict a larger level of access (Table 2).

An important regional policy is represented by the formal predisposition of territorial health centers/operational units/teams charged with managing nutrition, including ONS prescriptions. Centers and units, variously named, have been developed in Piedmont, Veneto, Tuscany, Latium, and Campania. In Emilia-Romagna, a regional directive requires LHAs to establish multidisciplinary nutritional teams, like in United Kingdom, whereas in other regions no policy has been implemented (Fig. 1).

The formal predisposition of dedicated centers/units does not seem to have greatly improved access to ONS funded by the SSN (Table 2). Possible explanations for this phenomenon are as follows:

- The implementation of the regional directives has been quite uneven at the local level, depending on the initiative of a few highly motivated, clinical nutrition specialists who establish exemplar centers in some areas, whereas other areas have no such centers (Veneto and Tuscany);
- GPs, disregarded by these policies, may not be prepared to manage the referral process in a timely manner.

Only in very rare cases has the definition of a formal regional or local clinical pathway been established for the diagnosis and treatment of malnutrition or pathologies correlated with malnutrition (Fig. 1A and Fig. 1D). The presence of formal pathways does not seem particularly tied to the level of public spending on ONS (Table 2), although the limited observation of pathways does not allow for drawing definitive conclusions.

Even the explicit and specific definition of the time frames for prescribing ONS, and providing for ongoing monitoring of patients (Piedmont, Lombardy and Sicily), does not seem to particularly affect the level of public spending or the proportion of the market covered by public funding for ONS (Table 2).

In the majority of the regions surveyed, the health care organizations directly distribute the ONS, even to patients' homes. In three regions (Latium, Campania, and Sicily), retail pharmacies are also used for distribution (Fig. 1E). On average, patient access to ONS is generally higher in these three regions, a sign that a willingness to employ differing means of distribution can lead to an increase in the reference market (Table 2).

In general terms, no clear relation between single policies, mostly focused on patients and prescribing patterns, and patient access to ONS has emerged, apart from distribution. It may be inferred that either these policies did not focus on the right targets (e.g., referral by GPs has been mostly disregarded) or that each single policy is not sufficient to explain cross-regional variation in patient access to ONS.

As a counter-factual example, the British NHS has implemented a policy with two main features:

- NICE guidelines and other official documents [14–16] address the whole range of treatment options for malnutrition risk or malnourishment, including ONS.
- interventions are defined at the national level, providing common criteria and targets, organizational solutions and standardized tools to be used in secondary and primary care according to human resource availability.

The achievement of key clinical and organizational priorities set by NICE requires the involvement of not only patients and nutritionists, but also all professionals providing care to patients

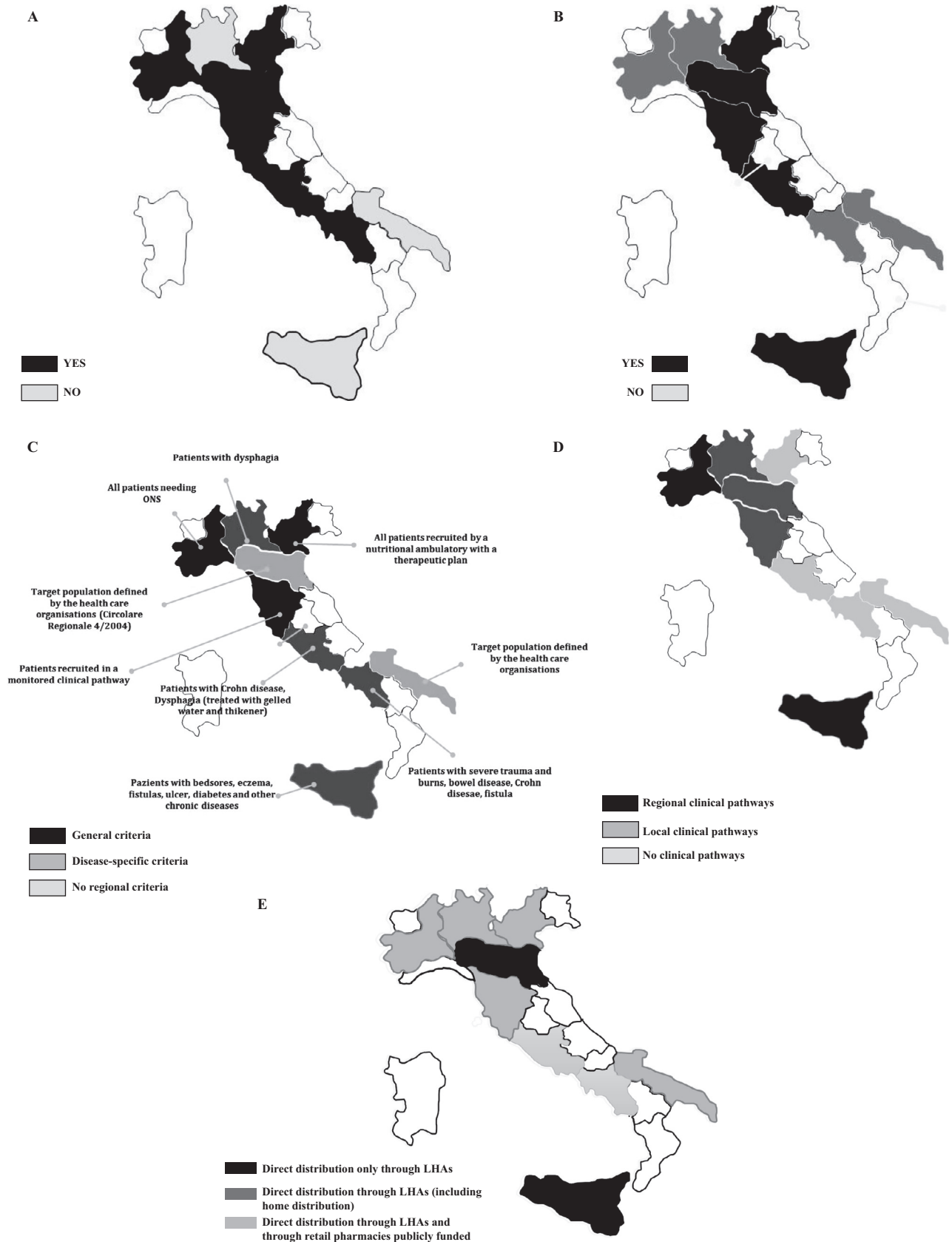


Fig. 1. ONS policies implemented by the largest regions in Italy. (A) Regional directive regarding facilities/specialists approved for prescribing reimbursed ONS. (B) ONS explicitly mentioned in regional directives, laws, and official policies. (C) Criteria for patients accessing reimbursed ONS. (D) Clinical pathways (specific for malnutrition or for malnutrition associated with a disease). (E) Reimbursed ONS distribution channels. LHA, local health authority; ONS, oral nutritional supplement.

Table 2
Regional policies on ONS and patient access to ONS

Implemented policies		Regions	Market for reimbursed ONS over total market (mean %)	Mean per capita spending for reimbursed ONS (€)
Reimbursed ONS distribution channels	Direct distribution through LHAs	Emilia-Romagna, Sicily	34.3	0.28
	Direct and home distribution through LHAs	Piedmont, Lombardy, Veneto, Tuscany, Apulia	29.2	0.24
Authorized purchasers for reimbursed ONS specified	Direct distribution through LHAs and distribution through retail pharmacies	Latium, Campania	43.2	0.30
	Region/Subregion	Veneto, Tuscany, Sicily	28.3	0.22
	Health care organization network	Piedmont, Emilia-Romagna	23.4	0.21
ONS explicitly mentioned in regional directives, laws, and official policies	Single LHAs	Lombardy, Campania, Apulia*	30.1	0.22
	Yes	Veneto, Emilia-Romagna, Tuscany, Latium, Sicily	24.7	0.20
Criteria for patients accessing reimbursed ONS	No	Piedmont, Lombardy, Campania, Apulia	36.1	0.26
	General criteria	Piedmont, Veneto, Tuscany	26.3	0.24
	Disease-specific	Lombardy, Latium, Campania, Sicily	37.8	0.27
Regional directive regarding facilities/specialists approved for prescribing reimbursed ONS	No criteria	Emilia R, Apulia	39.9	0.27
	Yes	Piedmont, Veneto, Tuscany, Emilia R., Latium, Campania	36.8	0.30
Clinical pathways (specific for malnutrition or for malnutrition associated with a disease)	No	Lombardy, Apulia, Sicily	36.4	0.25
	Regional clinical pathways	Piedmont, Sicily	39.0	0.32
Regional directives that specify limits on the length of the prescriptions for ONS	Local clinical pathways	Lombardy, Emilia-Romagna, Tuscany	27.4	0.24
	No clinical pathways	Veneto, Latium, Campania, Apulia	37.4	0.25
	Yes	Piedmont, Lombardy., Sicily	33.2	0.28
	No	Veneto, Emilia-Romagna, Tuscany, Latium, Campania, Apulia	30.0	0.22

LHA, local health authority; ONS, oral nutritional supplement.

*Excluding Latium region (data unavailable).

enhancing the referral process. The identified tools are training interventions for all professionals, and establishment, in the acute hospital trusts, of “bridge” bodies and professionals such as multi-disciplinary Nutrition Support Teams (NSTs) [17,18], specialist nutrition nurses, and nutrition steering committees working within the clinical governance framework. Concerning primary care, specialist nurses and NSTs are charged with interfacing between secondary and primary care. In the primary care setting, the intervention strategy assigns Local Health Economies (LHEs) - including NHS commissioners, CCGs and providers at the local level [19] - to connect and match different competences and roles to enhance the referral process. This approach requires that LHEs address ONS use from a wide perspective [20], ranging from consumption measures and prescription monitoring to procurement and training for developing basic skills in nutrition screening and treatment for all community health care professionals.

Discussion

The present study analyzed public policies that are assumed to affect patient access to ONS, using the Italian SSN as a case study and the British NHS as a counter-factual example. To the best of our knowledge, there is no other study that has addressed this theme. Despite the need for extreme caution in generalizing the results of this study, the analysis provides certain important reflections on policy that can inform other countries.

Citing evidence that an approach to preventing and managing malnutrition includes ONS as an efficacious and cost-effective part of nutrition therapy [4,6–8], the analysis has shown that it is not sufficient to simply adopt regional policies to promote patient access to ONS. These policies should be accompanied by national and systematic actions aimed at enhancing awareness of malnutrition prevention and management among specialists of varying therapeutic areas, actions that have been advocated by the literature so far and implemented by the British NHS. For example, a push to create

dedicated centers/units for clinical nutrition will not translate to increased patient access to ONS if there is no structured, rapid process for referring these patients to such units by GPs and specialists of other disciplines.

Improving referral may be supported by educational programs aimed at enhancing awareness of malnutrition among GPs and specialists in hospitals and other health care settings. The survey with oncologists demonstrated that there is room for improving awareness of malnutrition among hospital specialists in Italy [12].

There is no cutting-edge evidence that British policies produced a broader diffusion of ONS, but they have provided a means to standardize their use within a more homogenous environment. The NICE guidelines also present the evidence supporting ONS as a treatment option for malnourished patients, along with dietary advice, PN and EN, and provide indications of cost-effectiveness for some conditions [14]. However, at least one CCG, while acknowledging the expected cost savings of using ONS to treat malnutrition, has addressed the potential risks for inappropriate prescribing; they provide recommendations related to adequate screening and assessment (where possible, using physical indicators such as body mass index and weight loss), prescribing guidelines and monitoring to avoid questionable practices [21].

The present study has several limitations. First, there were not enough observations of market data to conduct more refined analyses of the effect of the policies on access to ONS (e.g., regression analysis using panel data). The ONS market data reflect only one year and the unit of observation was only at the regional level, as an analysis at the single LHA level was beyond the scope of the research and would have greatly increased the level of missing data. A second limitation related to the region as the unit of measurement, which failed to adequately capture important differences at the intraregional level. The differences among various LHAs in a single region were often cited by the officials interviewed for the study, but they were not systematically mapped, making it difficult to make generalized statements about the region as a whole. Third, indicators of access were constructed using public

expenditure data for ONS, which depend on the acquisition price of these products. Consumption levels would have been more appropriate, but consumption data was available in terms of numbers of packages for private consumption only, making conversion to volumes impossible. The market refers to spending levels but it does not capture whether the ONS were used appropriately and for which patients. Finally, we lacked robust evidence on the effects of British NHS on patient access to ONS. Notwithstanding, these policies were used as counter-example of a health care system that relied on centralized actions focused on organizational issues, referral, and education.

Despite these limitations, our evidence suggested that patient access to ONS could be enhanced by integrating heterogeneous regional policies with national measures aimed at increasing awareness of the role of health care providers in the prevention and management of malnutrition through a systematic and coordinated action covering at least five areas.

Several studies provide positive indications regarding improved clinical outcomes and cost and resource savings following the administration of ONS [4,6–8,22]. First, the diffusion of this evidence, along with a critical evaluation of methods, may reinforce a “rational” approach to the choice of treatment (EN, PN, or ONS) for patients at risk for or suffering from malnutrition.

Second, prioritization of patients in gaining access to ONS should be rational and explicit, that is, in specific reference to the variables normally used for determining priority in a health care setting, considering the specifics of the underlying pathology, the urgency of clinical needs, and the highest clinical benefit from the most cost-effective of the available treatment alternatives. We have found, on the contrary, different regional models that may indicate inequity, despite their modest effect on patient access to ONS.

Third, it would be important to entrust the management of patients suffering from malnutrition to health care professionals specialized in clinical nutrition, ideally (but not necessarily) in dedicated operational centers/units in health care organizations. This requires not only considerable organizational effort (both in terms of facilities and management of the network of services), but also overcoming any cultural or professional barriers from other clinical specialists.

The central role played by specialists in clinical nutrition is not sufficient if the collaboration of primary care physicians and other specialists in identifying potential patient needs and referring patients to the appropriate clinical nutrition specialists or dedicated centers/units is not secured. Difficulties in this area have been widely observed in Europe [4].

The last element requires ensuring that malnutrition is addressed in clinical pathways for pathologies correlated with malnutrition or the implementation of ad hoc pathways for malnutrition. These strategies must in turn be coherent with any national policies, as in the recent example of government recommendations for addressing nutrition for oncology patients sponsored by the Italian Ministry of Health, which represent an important first step but fall short of a requirement and fail to introduce mandatory training in public physician education programs [23].

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.nut.2019.110560](https://doi.org/10.1016/j.nut.2019.110560).

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