

SHORT PAPER

Reorganizing Italy's Territorial Healthcare: the Ministerial Decree No. 77/2022 and its Comparative Significance

S.R. Vinceti¹

Key words: Public law, public health, comparative law, national health systems, NHS

Parole chiave: Diritto pubblico, sanità pubblica, diritto comparato, sistemi sanitari nazionali, NHS

Abstract

As approved by the European Commission in 2021, Italy's National Recovery and Resilience Plan encompasses a far-reaching reform in the governance and structure of the national health service (NHS) that should shift the focus of assistance from large, centralized hospitals to a tight network of numerous smaller health centers dislocated in the country. In this respect, the adoption of the Ministerial Decree no. 77 on May 23, 2022, represented a key step in the execution of the intended reform, to the extent that the Decree set forth the main terms of the primary care reorganization process. This review summarizes the key elements of the Decree, foreshadows its legal and public health implications, acknowledges the uncertainties about the economic feasibility of the reform, and highlights its possible comparative significance for health systems facing similar challenges, especially those — such as the UK NHS — that share a comparable type of funding system and organizational framework.

¹ Department of Law, University of Modena and Reggio Emilia, Modena, Italy

Introduction

Italy's National Recovery and Resilience Plan (NRRP) enacted several fundamental normative changes to the national health system (1). As defined in the Annex to the Council of the European Union's approving decision, the first healthcare milestone of the NRRP demanded the adoption of secondary legislation aimed at the "definition of a new organizational model of the territorial healthcare assistance network, through the definition of a regulatory framework which identifies structural, technological and organizational standards across regions" (2). To comply with the requirement and enact the framework, the Minister of Health adopted Decree no. 77 on May 23, 2022 (3), which contains detailed prescriptions on the implementation of the new territorial healthcare. Here some key aspects of the Decree will be summarized, which is to serve as blueprint for new territorial healthcare and that could be of interest to other comparative health systems, and especially to the very "archetype" of any Beveridge model: the UK's national health system.

Main parts of the decree

The Decree is made up of 4 articles and three annexes, of which the first contains a detailed explanatory description of the new framework, the second prescribes the normative rules, and the third is a glossary. The new territorial healthcare — as envisaged in the Decree — can be described as follows. The territory of each Local Health Authority shall be divided into *Districts* of 100,000 residents circa, with possible variations according to population density or peculiar orographic conditions. Within *Districts*, *Community Houses* for roughly 40-50,000 residents are to be established: as the fundamental "cell" of the territorial system, they are intended to serve as "front office" for the

general population, thus providing the first assistance for all non-urgent health needs. In *Community Houses* patients will be taken in charge by multi-professional teams of general practitioners (GPs), family pediatricians, ambulatory specialists, community nurses, members of the social services, and possibly even other health care professionals: the fact that psychologists are explicitly mentioned is of some interest, given that the national government challenged the constitutionality of the establishment of community psychology services in the past (4). *Community Houses* further divide between the hub and spoke units, with the "hub Houses" offering more wide and complex services on a 24/7 basis.

Every *District* will display one *Community Hospital* that is set to act as intermediate structure between the *Community House* and the classical hospital and is expected to serve patients in need of continuous professional monitoring for low-intensity diseases. The *District* will be globally supervised by the *Territorial Operative Room*, responsible for connecting the health services and the health professionals involved in the joint management of a patient, either at the *Community House* or the *Community Hospital* level. Additionally, other significant introductions can be also mentioned: the establishment of the *Nurse for family and community care*, a new professional figure to interact with all the health professionals involved in the management of the patient; *Mobile continuity care units*, which are expected to manage patients with challenging health issues and difficulties; the provision of *qualified health personnel devoted to home care of patients requiring systematic monitoring and assistance* (such as highly vulnerable or not self-sufficient individuals) or unsuitable for the hospital admission. It is also foreseen the establishment of *Palliative care networks*, acting in hospitals, at home, in hospices, or other ambulatory settings to provide appropriate palliative pharmacological and non-pharmacological treatments,

while also offering preventive care with reference to serious disability and disease worsening. Finally, there are two highly specific programs embedded in this NHS reform: *Healthcare services for specific and sensitive categories*, and *Telemedicine*. The first program entails the implementation of a broad range of integrated health care interventions (diagnostic, preventive, therapeutic, psychologic, psychiatric, and rehabilitative) for minors, women, couples, and families, whenever possible within the Community Houses. The second program aims at strengthening the development of information-communication technology (ICT) to manage health surveillance and monitoring, diagnosis, care, and prevention, by using digital devices and software within a network of health professionals and services.

Overall, these organizational perspectives and goals appear to be both ambitious and challenging, not merely because of financial aspects (which are only partially provided for in the NRRP (1)) but also in light of the current complex legislation and organizational features of the Italian NHS. For instance, the relationship between the new territorial entities foreseen in the Decree no. 77/2022 and the role of traditional GPs, providing healthcare to all Italian residents, represents an emerging and heavily debated legal issue that will possibly lead to changes in the very employment status of the GPs (5). Other issues are the traditional approach of Italian citizens in seeking personalized healthcare, based on self-selected fiduciary physicians and other professionals and frequently leading to health mobility across the entire country (6), or the habits of health professionals — the majority of Italian physicians, it bears emphasizing, are over the age of 50 — who might not fully support the revolutionary changes embedded in the newly-designed NHS by the Decree no. 77/2022. An additional challenging issue is the transition from hospital-based

assistance to community services such as the newly established Community Hospitals, an effort that could be difficult and could be undermined by resistance due to traditional or professional reasons. Moreover, the current budget allocation will hardly meet the costs needed to implement the new model of territorial health: with the well-known shortage of GPs in Italy and the aging population of healthcare professionals in general, it is far from clear that there will be enough personnel to staff Community Houses and especially Community Hospitals; in this sense, the economic feasibility of territorial healthcare reform in absence of new budget expenditures is doubtful (7). These and many other issues may hamper the implementation of the new scenario envisaged by Decree 77/2022, and therefore an adequate legal, organizational, and informative effort must be implemented to counteract delays and failures that may arise underway.

A comparison with the UK NHS and its ongoing issues

The reorganization of Italian healthcare takes stock of the OECD's recommendation on the importance of strengthening primary care (8) and should be of interest to numerous other health systems, especially those sharing a traditional Beveridge system. A comparison with the UK health system is, in this regard, particularly relevant: not only the Italian system explicitly took UK NHS as its legislative model (9), but quite similar to Italy the UK NHS can be regarded as a cluster of different national health systems. Moreover, the UK system also underwent substantial reform in 2022, due to the adoption by the UK Parliament of the "Health and Care Act (HCA)" Government Bill (10).

The British NHS system can also be framed as facing some difficulties in its financial sustainability, with some community care services that have been found

to be not cost-effective (11), and this has also been proven true for some telehealth programs (12) — a circumstance that raises some concerns about similar programs under the Italian reform driven by the Decree 77/2022. This issue of cost-effectiveness also informs the 2022 HCA Bill, showing leads of reform that aim at reducing the burden of costs for the public sector (and the citizens) while keeping the effectiveness and quality of the health services. The HCA bill foresees that community healthcare is part of a shift from the so-called “Clinical Commissioning Groups” to the Integrated Care Boards (ICBs), whose structure and public control are far less clear and defined, may replace GPs’ responsibility in some cases, and generally allow private entities to play “an active and strong leadership role” as provider collaboratives will in the ICBs (13). Therefore, a fundamental goal of the ongoing NHS reform in the UK, in line with previous acts of legislation and policy reforming NHS 1990, 2003, and 2012, is to favor the development of the market and private provision of the different health services, including the community services, allowing a “marketized, two-tier, mixed-funding system with several similarities to the United States” (13). Such changes take place despite indications that devolution towards the private sector may not fully encompass an advancement in terms of healthcare quality and effectiveness (14), including the assistance of especially vulnerable subgroups (15). This is a markedly different approach compared with the Italian one, which is striving to keep almost entirely “public” in terms of healthcare providers and focuses instead on a progressive devolution of resources from the hospitals and the GPs themselves towards newly designed community services. In this respect, the NRRP perspective on the Italian NHS reform is still fully in line with the founding principles and pillars of the British NHS as foreseen by the NHS Act of 1946 (concerning England and Wales),

broadly based on secondary, primary, and community services (13).

Conclusions

Italy’s national health system is set to undergo sweeping changes within the context of the NRRP. While other health-related introductions will play an equally important role, there is hardly any doubt that the enhancement of territorial care represents the most crucial and momentous innovation to the health system, which aptly aligns with the OECD’s longstanding recommendations on the importance of strengthening primary care. To the extent that Italian healthcare is subjected to challenges many other European health systems face, researchers should not fail to keep track of the unfolding of the Italian reforms. In particular, the developments in the reorganization of Italian primary care could bear provide insights to researchers in the UK, given the common Beveridge model, the presence of multiple decentralized health systems, and the mounting debate on the expansion of private healthcare.

Conflict of interest statement: The author declares no conflict of interest.

Riassunto

La riforma dell’assistenza sanitaria territoriale in Italia: il Decreto Ministeriale n. 77/2022 e la sua rilevanza comparatistica

Per come deliberato dalla Commissione europea nel 2021, il Piano nazionale di ripresa e resilienza dell’Italia contiene una riforma sistemica nella gestione e nella struttura del sistema sanitario nazionale, che dovrebbe spostare il focus dell’assistenza dai grandi ospedali centralizzati ad un network di numerosi centri di cura più piccoli e dislocati sul territorio. Da questo punto di vista, l’adozione del Decreto ministeriale 23 maggio 2022, n. 77, ha rappresentato un momento cruciale ai fini dell’ese-

cuzione della pianificata riforma, dal momento che il Decreto dispone il tracciato fondamentale del processo di riorganizzazione territoriale dell'assistenza sanitaria primaria. Questa review sintetizza gli elementi centrali del Decreto, adombrando le sue implicazioni giuridiche e di sanità pubblica, evidenziando la problematica associata alla carenza di adeguate risorse finanziarie per tale riforma, e sottolineando il possibile rilievo comparato per quei sistemi sanitari che sono chiamati a fronteggiare sfide analoghe, e specialmente quelli — come l'NHS britannico — che condividono la stessa modalità di finanziamento e struttura organizzativa.

References

- Filippini T, Vinceti SR. Italian National Recovery and Resilience Plan: a Healthcare Renaissance after the COVID-19 crisis? *Acta Biomed.* 2021 Nov 17; **92**(S6): e2021463. doi: 10.23750/abm.v92iS6.12339.
- Council of the European Union. REVISED Annex to the COUNCIL IMPLEMENTING DECISION on the approval of the assessment of the recovery and resilience plan for Italy. 2021 Available on: <https://data.consilium.europa.eu/doc/document/ST-10160-2021-ADD-1-REV-1/en/pdf>. [Last accessed: 2023 January 25].
- Ministero della Salute. Decreto 23 maggio 2022 n.77. Regolamento recante la definizione di modelli e standard per lo sviluppo dell'assistenza territoriale nel Servizio sanitario nazionale. *Gazzetta Ufficiale - Serie Generale* 2022 n. 144 del 22 giugno 2022.
- Vinceti SR. La costituzionalità della psicologia di base: Una pronuncia “regionalista” con interessanti profili di diritto comparato. *Giurisprudenza costituzionale* 2021; **6**: 2688-97.
- Vinceti SR. The Legal Status of General Practitioners at the dawn of the New Primary Care in Italy. *Ann Ig.* 2022 Sep-Oct; **34**: 431-8. doi: 10.7416/ai.2021.2492. Epub 2021 Nov 30.
- Vinceti SR. La mobilità sanitaria interregionale in Italia alla luce della teoria federalista e delle esperienze comparate. *Corti Supreme Salute* 2022; **3**.
- CERGAS – Bocconi. Rapporto OASI 2022: Osservatorio sulle Aziende e sul Sistema sanitario Italiano. Egea Editore.; 2022.
- OECD Health Policy Studies. Realising the Potential of Primary Health Care. 2020. Available on: <https://www.oecd.org/health/realising-the-potential-of-primary-health-care-a92adee4-en.htm> [Last accessed: 2023 January 25].
- Toth F. La sanità in Italia. Bologna: Il Mulino; 2014.
- UK Parliament. Health and Care Act 2022 - Government Bill 2022. Available on: <https://bills.parliament.uk/bills/3022/publications> [Last accessed: 2022 January 25].
- Clarkson P, Brand C, Hughes J, Challis D, Tucker S, Abendstern M. Cost effectiveness of pilot self-assessment sites in community care services in England. *Aust Health Rev.* 2013 Nov; **37**(5): 666-74. doi: 10.1071/AH13056.
- Henderson C, Knapp M, Fernandez JL, et al. Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial. *BMJ.* 2013 Mar 20; **346**: f1035. doi: 10.1136/bmj.f1035.
- Roderick P, Pollock AM. Dismantling the National Health Service in England. *Int J Health Serv.* 2022 Oct; **52**(4): 470-9. doi: 10.1177/00207314221114540. Epub 2022 Jul 25.
- Street A. For-profit health care might be damaging population health. *Lancet Public Health.* 2022 Jul; **7**(7): e576-e7. doi: 10.1016/S2468-2667(22)00142-6.
- Bach-Mortensen AM, Goodair B, Barlow J. Outsourcing and children's social care: A longitudinal analysis of inspection outcomes among English children's homes and local authorities. *Soc Sci Med.* 2022 Nov; **313**: 115323. doi: 10.1016/j.socscimed.2022.115323. Epub 2022 Aug 30.

Corresponding author: Dr. Silvio Roberto Vinceti, Department of Law, University of Modena and Reggio Emilia, Via San Geminiano 3, Modena, 41121 Italy.
e-mail: silvioroberto.vinceti@unimore.it

ORCIDs: Silvio Roberto Vinceti: 0000-0002-1536-5745