

Impact of Ministerial Decree 77/2022 from different stakeholders' perspectives: clinicians, pharmacists, patients, and industry

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ABSTRACT

Introduction: Assess the implications of Ministerial Decree (MD) 77/2022 in Italy, which decentralizes healthcare through proximity-based models, from the perspective of key actors involved, and discuss its relevance to sustainability and value assessment.

Methods: A cross-sectional survey was conducted with four stakeholder groups: pharmaceutical companies, scientific societies, Health Economics and Outcomes Research (HEOR) experts, and patient advocacy organizations (N = 162). Structured questionnaires examined awareness/knowledge, perceived implementation, perceived impact, operational feasibility, and policy alignment.

Results: Over 60% of respondents recognized the strategic value of proximity care. Key barriers included administrative burden (47%), resource constraints (38%), and lack of Key Performance Indicator (KPI)-based frameworks (55%). Treatments in oncology, geriatrics, and metabolic diseases were considered most suitable for decentralized provision. Divergent perspectives emerged professional stakeholders emphasized methodological rigour and outcome monitoring, while patient organizations foregrounded equity of access, responsiveness, and patient-facing feasibility.

Conclusion: MD 77/2022 opens a policy window to align decentralized care pathways with sustainability and value assessment. However, the survey did not collect empirical pricing, reimbursement, or cost-effectiveness data; therefore, any implications for pricing governance should be interpreted as conceptual and hypothesis-generating rather than as demonstrated effects. Heterogeneous implementation and fragmented outcome measurement remain the primary barriers; a minimum viable KPI set and routine data infrastructure are prerequisites for translating perceived value into decision-relevant evidence.

Keywords: Key Performance Indicators, Ministerial Decree 77/2022, Outcome measurement, Pricing governance, Proximity care, Stakeholder survey

Introduction

Healthcare systems worldwide are undergoing structural reconfiguration to reconcile the principles of equity, efficiency, and sustainability (1). Within this landscape, the

Italian National Health Service (NHS) has introduced the Ministerial Decree (MD) 77/2022 as a strategic pillar of territorial healthcare reform. The decree envisions a shift from hospital-centric models to proximity-based service delivery, establishing community houses, community hospitals, and integrated home care as the new infrastructure for primary and chronic care (2). While the reform reflects international trends toward decentralized care (3,4), its implications for value assessment, governance, and sustainability, including conceptual links to pricing and reimbursement decision-making, remain underexplored (4,5).

MD 77/2022 does not merely relocate services; it redefines the *loci* of clinical decision-making, resource allocation,

Received: October 14, 2025

Accepted: May 19, 2026

Published online: June 19, 2026

This article includes supplementary material

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and therapeutic continuity (6). As such, it may reshape where and how value is generated and evidenced across care pathways, with potential downstream implications for reimbursement governance and evaluation requirements, particularly in contexts of heterogeneous infrastructure and workforce distribution (1,2). Treatments historically administered in high-intensity settings—such as intravenous or cyclic therapies in oncology, neurology, and rare diseases—are increasingly considered for decentralized administration supported by structured implementation strategies in home-based care models (6). However, the economic viability of such transitions hinges on the compatibility between service decentralization and reimbursement frameworks, a dimension insufficiently addressed in current policy design (5).

Survey data collected in this study converge on a shared awareness of the MD's potential but diverge sharply in their evaluation of its operational feasibility (7). While over 60% of respondents across datasets acknowledged the strategic relevance of proximity-based care, only a small minority reported the presence of structured evaluation mechanisms (e.g., formal monitoring frameworks, Key Performance Indicators (KPIs), or explicit modelling approaches) capable of supporting decision-relevant assessment (7). Administrative burden, misalignment with regional procurement systems, and lack of stakeholder coordination were identified as recurrent barriers to implementation (7).

From a Health Economics and Outcomes Research (HEOR) standpoint, the Italian case presents a critical opportunity to investigate how territorial reforms influence pricing governance and the distribution of value across clinical, organizational, and societal domains (4). Yet, without a formal framework to assess the incremental value generated by care decentralization, pricing negotiations risk relying on heuristics rather than evidence (5). Moreover, the absence of standardized KPIs to monitor the clinical and economic impact of decentralized services undermines the ability to quantify value for money and perpetuates asymmetries in service quality across Regions (4,8).

This study aims to address a critical knowledge gap by eliciting a multi-stakeholder perspective on MD 77/2022, focusing on awareness, perceived implementation, and perceived impact, and discussing implications for sustainability and value assessment as hypothesis-generating considerations.

In interpreting these findings, it is useful to distinguish between (i) empirically observed survey patterns (awareness, perceived implementation, perceived barriers) and (ii) normative implications proposed for policy and Health Technology Assessment (HTA) practice. The former are reported as descriptive or exploratory comparisons; the latter are presented as recommendations contingent on future outcome measurement and modelling.

Drawing on data from coordinated surveys conducted among scientific societies (ISPOR, SIMM, SIF, SIFO) and patient advocacy associations (UNIAMO), we examine how the abovementioned MD is perceived and implemented. Our objective is primarily descriptive and exploratory, and secondarily conceptual: to delineate the conditions under

which decentralized care models could be integrated with sustainability-oriented evaluation mechanisms that capture clinical, organizational, and financial value within the Italian health system.

Materials and methods

Study design and setting

This study used a two-stage, cross-sectional online survey design to capture a multi-stakeholder perspective on the perceived awareness, implementation, and expected impact of the Italian MD 77/2022 on proximity-based care models. Stage 1 consisted of an exploratory pilot survey administered to members of ISPOR, aimed at refining the instrument and testing feasibility. Stage 2 consisted of an expanded survey administered to members of selected Italian scientific societies and a national patient advocacy organization (SIMM, SIF, SIFO, and UNIAMO), focusing on clinical, organizational, and operational dimensions.

Conceptual domains and operational definitions

To avoid conceptual overlap between “awareness,” “implementation,” and “impact,” the questionnaire was structured around three predefined domains:

- (i) Awareness/knowledge: respondents' familiarity with MD 77/2022 and its core service components;
- (ii) Perceived implementation: respondents' reports of the presence/activation of territorial services and enabling infrastructure within their local district/organization;
- (iii) Perceived impact: respondents' expectations or perceptions regarding potential effects on care pathways (e.g., appropriateness, adherence, continuity of care, patient experience).

All analyses and figures were mapped to one of these domains. Importantly, “perceived impact” reflects reported perceptions and expectations rather than objectively measured outcomes.

Questionnaire development

Item generation followed a structured process. A targeted review of policy and background documents on MD 77/2022 and proximity-care implementation was used to define the core constructs and draft the initial item pool. A multidisciplinary expert review then assessed item relevance, clarity, redundancy, and domain coverage. Items were mapped to the three predefined conceptual domains, and response formats were harmonized where possible.

Items were either newly developed for the MD 77/2022 context or adapted from survey formats previously used by the study group. Adapted items were revised to reflect Italian organizational terminology and the service architecture of MD 77/2022. A final language review was performed to improve readability and consistency across stakeholder versions. The full questionnaires used in Stage 1 and Stage 2, together with response options and item coding, are provided as Supplementary Material (Appendix S1).

Pilot testing and instrument refinement (Stage 1)

The pilot phase was designed to test feasibility and improve measurement quality rather than to provide definitive estimates. It assessed item clarity, completion time, ambiguity or double-barrelled wording, adequacy of response options, use of “I do not know” categories where appropriate, and item-level missingness as a proxy for respondent burden and interpretability.

Based on pilot feedback and predefined refinement criteria, the questionnaire was revised before Stage 2. Revisions included rewording ambiguous items, splitting double-barreled items, standardizing “I do not know” options for questions requiring local implementation knowledge, and reordering sections to improve flow.

Sampling strategy, recruitment, and fieldwork

Participants were recruited using a convenience sampling approach through organizational channels. For each stakeholder group, the survey link was distributed by designated focal points within ISPOR and the participating organizations (SIMM, SIF, SIFO, and UNIAMO) using internal mailing lists and/or member communication channels. No incentives were offered. Because distribution occurred through organizational channels, the total number of individuals who received or viewed the invitation could not be determined; therefore, a formal response rate could not be calculated.

Participants and final sample

The final sample comprised 162 respondents: 71 ISPOR (43.8%), 44 SIF/SIFO (27.2%), 29 SIMM (17.9%), and 18 UNIAMO (11.1%). Respondents' regional distribution and organizational affiliations were collected to contextualize the perceived implementation of proximity-care services.

Data collection, anonymization, and management

Surveys were administered via Microsoft Forms. Participation was voluntary, and completion of the questionnaire was considered to imply informed consent for the use of anonymized responses for research purposes. No direct identifiers were collected. Data were exported to Microsoft Excel for cleaning and preparation. Data quality checks included duplicate screening, range checks for categorical variables, and consistency checks across related items.

Handling of missing data

Missing data were expected for items requiring local operational knowledge. Missingness was handled using available-case denominators at the item level. No imputation was performed. The proportion of “I do not know” responses was retained as an informative category for implementation-related questions.

Statistical analysis

Analyses were primarily descriptive, reflecting the study's exploratory and multi-stakeholder design. Categorical variables

were summarised as counts and percentages. For ordinal items, responses were summarised using median and Interquartile Range (IQR) and, where relevant, the distribution across response categories.

To enable cross-group comparisons of awareness/knowledge measured using different response formats across surveys, we constructed an ordinal harmonized knowledge score (1 = low, 2 = medium, 3 = high) by collapsing adjacent categories (e.g., very low/low = 1; medium = 2; high/very high = 3; ISPOR: none = 1, summary = 2, in-depth = 3). Between-group differences in the harmonized score were explored using the Kruskal–Wallis test. Where significant, pairwise Mann–Whitney tests were performed with Holm correction. All p-values are reported as exploratory, given convenience sampling and the lack of measurable denominators for a standardized response rate.

To further contextualize stakeholder heterogeneity without overextending statistical inference, selected cross-group comparisons were interpreted jointly with descriptive patterns across domains. No multivariable modelling was performed, given the exploratory design, the convenience sampling strategy, the limited and uneven subgroup sizes, and the absence of a measurable sampling denominator. Therefore, inferential tests and their findings were used only as exploratory tools to support the description of stakeholder-specific perception patterns, rather than to establish generalizable between-group differences or support confirmatory claims.

Results

Regarding regional distribution, the most represented Italian Regions by survey respondents are:

- in the North: Lombardy (11%) and Emilia-Romagna (15 %);
- in the Center: Lazio (14%);
- in the South: Campania (22%) and Puglia (11 %).

About the distribution of the organizations to which the survey respondents belong: 25% are part of territorial services such as specialist outpatient clinics, Department of Mental Health, and clinics; 18% are affiliated with a hospital or university hospital; 14% belong to a local health authority (*Azienda Sanitaria Locale* - ASL); 10% are categorized as “Other,” including High-Specialty National Hospital (HSNH), Department of Pharmacology and Toxicology, Pharmaceutical Department, Health Department; 7% are part of an *Istituto di Ricovero e Cura a Carattere Scientifico* (IRCCS) and Directly Managed Hospital Facility and 3% are associated with a Department of Prevention.

Knowledge of MD 77/2022 differed across stakeholder groups (Figure 1), indicating heterogeneity in self-reported awareness levels. All results below refer to respondents' reported awareness and perceptions of implementation and impact; they should not be interpreted as objectively measured service performance or clinical outcomes.

Using a harmonized ordinal knowledge score (1 = low, 2 = medium, 3 = high), median (IQR) scores were 2 (1-2) for ISPOR, 3 (2-3) for SIMM, and 2 (1-3) for SIF/SIFO. Differences across groups were observed (Kruskal–Wallis $H = 9.07$, $df = 2$, $p = 0.0107$). In pairwise exploratory comparisons with Holm

correction, SIMM showed higher knowledge than ISPOR ($p_{\text{Holm}} = 0.0084$) and SIF/SIFO ($p_{\text{Holm}} = 0.035$), whereas ISPOR and SIF/SIFO did not differ ($p_{\text{Holm}} = 0.953$).

These comparisons should be interpreted as exploratory and descriptive of stakeholder-specific awareness patterns. They were not intended to establish representative or generalizable differences between professional communities, given the convenience sampling strategy, the absence of a measurable response denominator, and the heterogeneity of stakeholder-specific survey instruments.

Among the first services rolled out under the MD were community houses—physical hubs for community care intended to replace General Practitioners (GPs)-led primary care. In our survey, 66% of respondents reported the presence of a community house in their district; of this subgroup, 49% reported it is already operational. Median (IQR) harmonized knowledge scores and exploratory between-group comparisons are summarised in Table 1.

TABLE 1 - Harmonized knowledge score (ordinal 1-3) by stakeholder group and exploratory between-group comparisons

Stakeholder group	Harmonized knowledge score, median (IQR)	Between-group (overall)	Pairwise exploratory comparisons (Holm-corrected)
ISPOR	2 (1–2)	Kruskal–Wallis H = 9.07; df = 2; p = 0.0107	SIMM > ISPOR: $p_{\text{Holm}} = 0.0084$
SIMM	3 (2–3)	SIMM > SIF/SIFO: $p_{\text{Holm}} = 0.035$	
SIF/SIFO	2 (1–3)	ISPOR vs SIF/SIFO: $p_{\text{Holm}} = 0.953$	

Knowledge score derived by collapsing adjacent response categories into a three-point ordinal scale (1 = low, 2 = medium, 3 = high). Between-group p-values are exploratory, given convenience sampling and the absence of a measurable denominator for a standardized response rate.

Another service introduced by MD 77/2022 was community hospitals, which represent an intermediate care facility between home care and hospitalization. Their goal is to provide low-intensity clinical care and prevent hospital overcrowding. The survey reveals varied responses: 48% declare the presence of community hospitals in their district, while 33% are unsure and 19% declare their absence. Among those who respond positively, 37% of respondents state that community hospitals are not operational in their district; another 37% of respondents said they were unaware of this information, demonstrating that the implementation of community hospitals is still perceived as unnoticed.

MD 77/2022 also establishes the introduction of new specialized healthcare roles, like family nurses. These professionals operate within the community, focusing on proximity, continuity, and health education. Their goal is to monitor and support patients, promote prevention, collaborate with General Practitioners, and assist in care. Data show a lack of awareness and communication about the role of family and community nurses. Over a third (36%) of respondents are unaware of their existence, 33% state that they exist, and 32% state that they do not exist.

Next, survey participants were asked about the availability of Integrated Home Care (IHC) in their district. This public health and social care service offers home care for patients with chronic conditions or disabilities, those discharged after acute illness, terminally ill individuals, and elderly residents. It aims to provide continuous, appropriate care at home, alleviating the pressure on hospitals. The majority (86%) of respondents confirm local presence of IHCs, while 3% declare their absence and 11% are uncertain.

Confirming the above findings, the overall IHC rating also reveals a positive picture. The data indicate that 44% of respondents believe these services are efficient, with 9% rating them as very efficient. A small proportion view them negatively, with 9% describing them as inefficient and 2% as very inefficient.

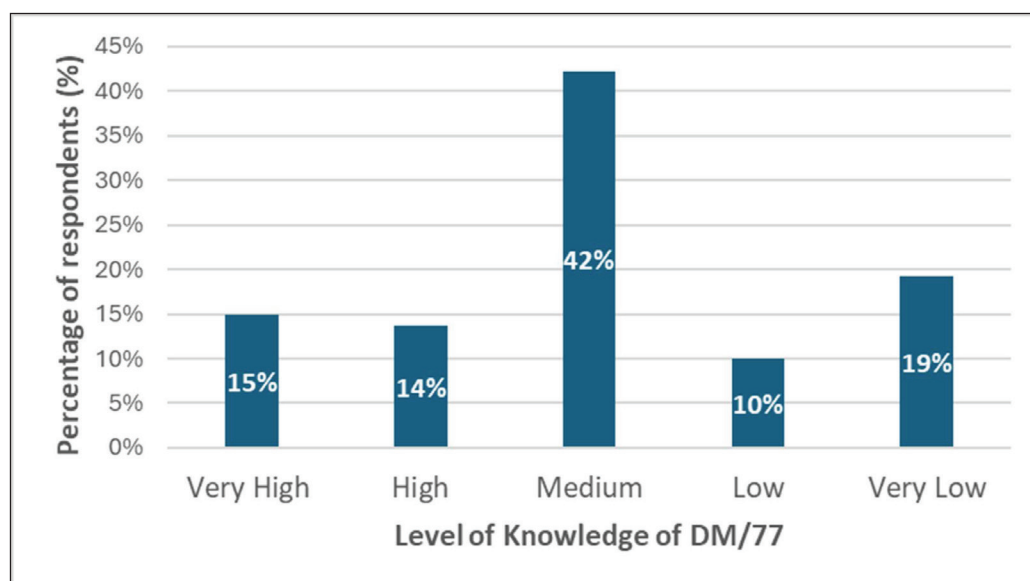


FIGURE 1 - Knowledge of MD 77/2022.

The data on the presence of palliative care in the respondents' district also show good awareness and dissemination: 68% of respondents confirm its availability; nonetheless, the 22% uncertainty highlights ongoing issues related to information and perceived accessibility. Overall, the palliative care service stands out as a key strength of the community healthcare system and is considered the most efficient among those analyzed so far (over 70% of respondents rate it as efficient or very efficient). Only 4% of respondents rated the service negatively, and 25% did not express a negative or positive preference in this regard.

Telemedicine is a service that is helping to modernize local healthcare services, with 47% of the respondents recognizing the presence of telemedicine in their district, while 32 % are uncertain and 22% answer negatively.

The data show that 47% of respondents are aware of telemedicine prescribing; however, 32% are uncertain, and 21% deny being aware of it.

Focusing on the most common therapies provided by these local facilities, Figure 2 shows a system designed for long-term treatment. The data suggest that community services are particularly well-suited for managing simple, chronic, and cyclical treatments, such as oral therapies (51%), due to their ease of administration and high suitability for out-of-hospital settings, and low-impact infusion therapies (26%), followed by intramuscular (11%) and subcutaneous (6%) therapies. The "Other" category (7%) includes dressings, rehabilitation, psychological support, and wound care. Regarding the most appropriate pharmacological treatments to be provided through local community services, the results confirm that

the management of chronic conditions remains the main objective of community care: 60% of participants identified chronic treatment as the most appropriate for community settings; 28% identified cyclical treatments; 12% acute treatments, suggesting that hospitals or GPs are still considered the most appropriate points of contact for such issues.

Figure 3 shows a strong consensus among stakeholders that certain clinical specialties are particularly suited to local management. Geriatrics ranks first (66% SIMM; 57% SIF and SIFO), followed by Cardiology (62% SIMM; 34% SIF and SIFO), Oncology and Oncohaematology (59% SIMM; 59% SIF and SIFO; 28% UNIAMO), Metabolic Disorders (55% SIMM; 41% SIF and SIFO; 17% UNIAMO), Neurology (38% SIMM; 25% SIF and SIFO; 50% UNIAMO), Rare Diseases (14% SIMM; 25% SIF and SIFO; 50% UNIAMO), Psychiatry (48% SIMM; 25% SIF and SIFO) and Pulmonary Medicine (45% SIMM; 18% SIF and SIFO).

The "Other" category, which includes Otorhinolaryngology (ENT) and Ophthalmology, is minimally reported across all groups, with percentages below 15%, suggesting lower perceived systemic impact in those areas.

The areas most affected by the implementation of MD 77/2022 were found to be: monitoring of Adverse Events (45% for both SIMM and SIF/SIFO; 33% for UNIAMO); monitoring of drug interactions (45% for SIMM; 39% for SIF/SIFO; 11% for UNIAMO); prescription appropriateness (41% for SIMM; 34% for SIF/SIFO; 17% for UNIAMO) and therapeutic adherence, which is rated highly by SIF and SIFO (41%) and moderately by the other groups.

Figure 4 clearly highlights the effects of the MD implementation identified by stakeholders.

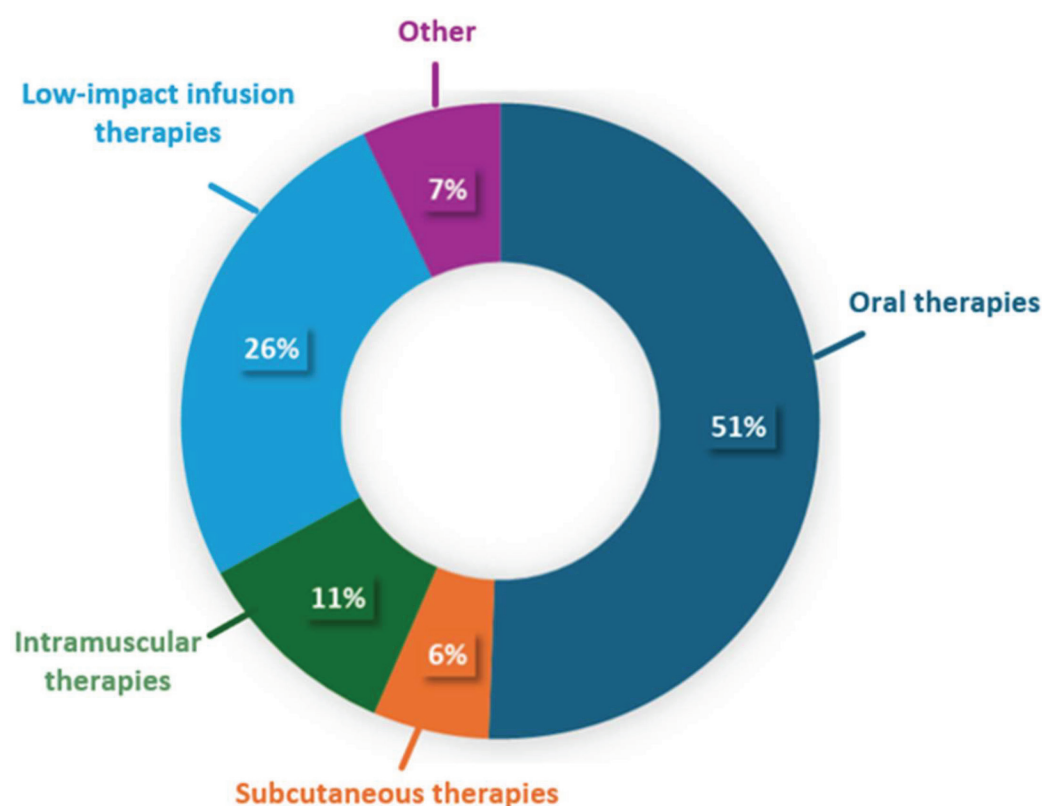


FIGURE 2 - Types of therapies provided through local services.

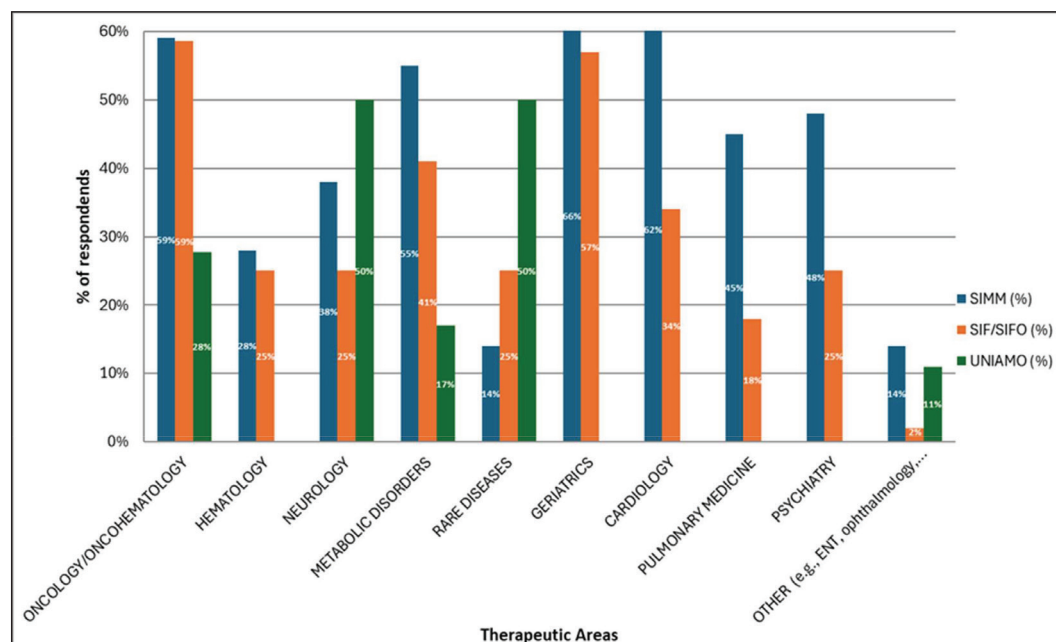


FIGURE 3 - Therapeutic areas most suited to community care services.

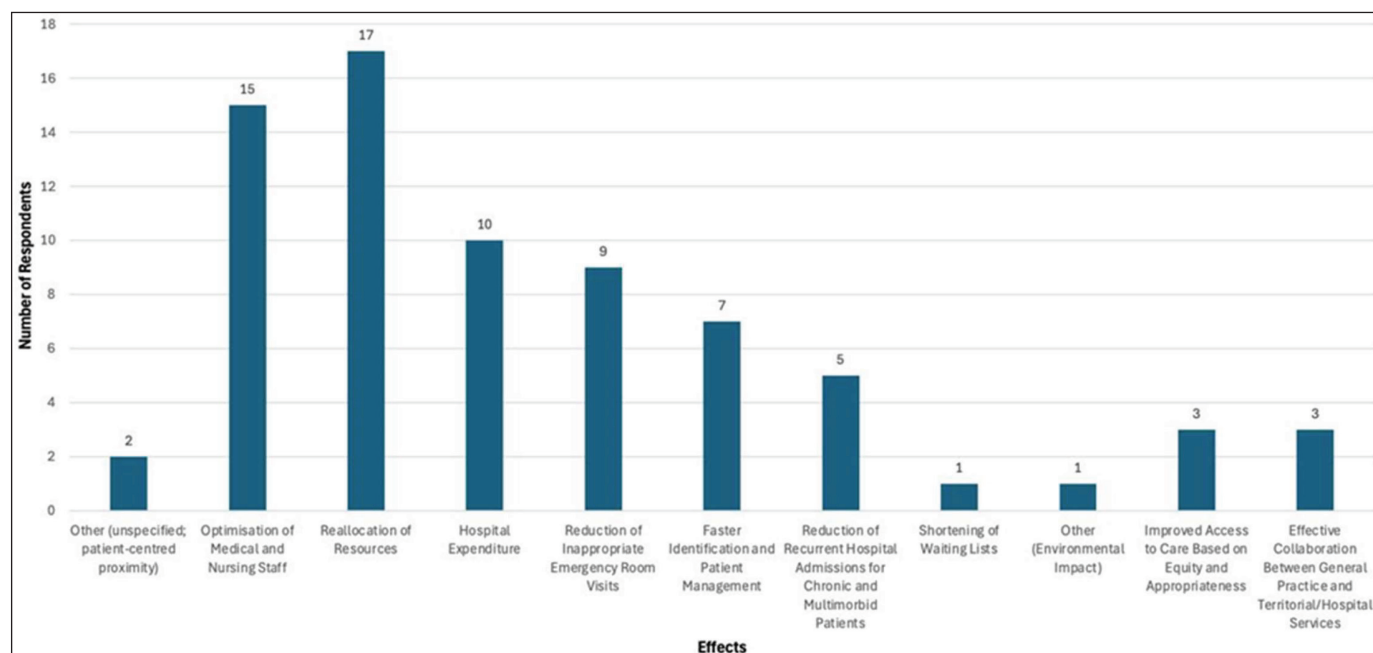


FIGURE 4 - The most significant effect of the territorial assistance provided by MD 77/2022.

Given the significant potential of MD 77/2022, it is important not to overlook the key issues it raises, which are necessary to understand the challenges in fully implementing the territorial model. The main concerns identified include infrastructure problems, noted by all, especially SIF/SIFO (36%) and SIMM (33%). Organizational processes are another shared concern, highlighted by 36% of SIF/SIFO, 33% of UNIAMO, and 31% of SIMM. Staff training is seen as a major issue, particularly by UNIAMO (39 %) and equally by

SIMM and SIF/SIFO (34%). Adverse Event management is particularly emphasized by SIMM (38%).

Figure 5 provides a descriptive visual synthesis by adding ISPOR responses and juxtaposing stakeholder perspectives. Radar charts are presented for descriptive purposes and do not imply statistical significance; inferential analyses are reported separately where applicable. The aggregate in the graph represents the combined perspective of SIMM, SIF, and SIFO. Overall patterns suggest that patients (UNIAMO)

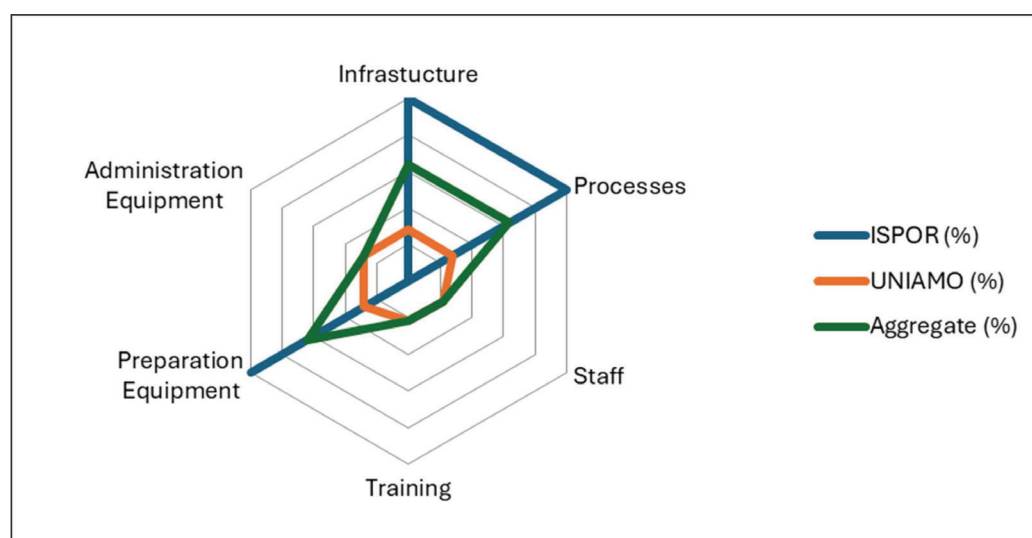


FIGURE 5 - Radar chart of perceived critical issues related to proximity care services. Axes represent Likert-type items; values plotted correspond to the median score (1-5) for each stakeholder group.

may assign different salience to critical issues compared with professional stakeholders. This finding should be interpreted cautiously, given the numerical underrepresentation of patient-organization respondents and the possibility of differential access to implementation-level information (e.g., local monitoring outputs and KPI dashboards), rather than genuine disagreement on priorities.

For Likert-type items, central tendency is summarized as the median; the radar plot displays stakeholder-specific medians to allow for an immediate comparison between the various domains.

Across domains, the comparative reading was therefore based on convergence and divergence of descriptive patterns rather than on formal hypothesis testing for each item. This approach was considered more appropriate than multiple item-level testing, which would have increased the risk of spurious findings in the context of small and uneven stakeholder subgroups.

It is also significant to analyze the level of awareness regarding the measurement of concrete benefits in the different roles of pharmacist, clinician, and patient because these are key elements for evaluating the effectiveness in the implementation of MD 77/2022. The data show widespread uncertainty or lack of concrete evidence. Only 4% of respondents reported that the benefits had been measured, while 27% believed they had not been measured. The majority, 68%, answered that they did not know whether these benefits were detected. The rollout of community reforms was seen as poorly traceable in terms of impact, indicating a significant absence of a publicly accessible or officially recognized monitoring and reporting system. This gap provides the empirical rationale for the minimum viable KPI taxonomy proposed in the Discussion Section (Table 2). The taxonomy should be understood as a conceptually informed framework, prompted by the monitoring deficits identified in the survey and structured according to established quality-assessment and health-system performance principles, rather than as a measurement tool directly derived or validated from the survey data.

At the same time, 86% of respondents (Fig. 6) believe that clinicians will experience a role change, likely involving expanded responsibilities and/or greater involvement in community care management, and 82% see a shift in pharmacists' roles, reflecting an enhancement of their skills aimed at an integrated care approach, with more focus on medication management, adherence, and interactions. In contrast, among patients, only 44% see themselves as having a change in their role, while 56% do not notice any change. This suggests that, despite organizational and professional innovations, the reform may not yet be visible to patients as a tangible change in roles and care pathways, and that patient-facing engagement, communication, and shared decision-making mechanisms may be lagging behind organizational redesign. This should not be interpreted as a lesser relevance of patient-reported perspectives, but as a signal that information and involvement mechanisms may be unevenly distributed.

Discussion

The findings of this exploratory study provide a perception-based lens through which to examine implementation signals and stakeholder expectations surrounding Italian MD 77/2022. Across stakeholder groups, proximity-based care was recognized as conceptually valuable, but its operational translation appeared constrained by gaps in infrastructure, outcome monitoring, evaluative frameworks, and stakeholder coordination. Importantly, the survey was designed to capture stakeholder perceptions and implementation signals, not to measure economic outcomes. No empirical pricing, reimbursement, utilization, budget impact, or cost-effectiveness data were collected. Accordingly, references to pricing governance, value-based arrangements, or potential threshold implications should be read as conceptual inferences motivated by perceived governance misalignment, not as demonstrated economic effects.

The analytical contribution of the study should therefore be understood as exploratory rather than confirmatory. The statistical comparisons were deliberately limited to selected harmonized variables, where cross-group interpretation was

TABLE 2 - Pragmatic KPI taxonomy for MD 77/2022 implementation (minimum viable framework)

Domain	KPI (example)	Operational definition (numerator/denominator)	Data source	Suggested frequency	Decision use
Clinical outcomes	Unplanned hospital admissions	Unplanned admissions among eligible chronic patients / eligible chronic patients	Hospital discharge data + primary care registry	Quarterly	Detect failure of territorial continuity
Clinical outcomes	ED visits for ambulatory care-sensitive conditions (ACSC)	ED visits for ACSC/population	ED flows + ICD coding	Quarterly	Signal substitutability of proximity care
Clinical outcomes	Medication adherence (PDC/MPR)	Mean PDC (or % with PDC $\geq$ 80%) for chronic therapies/eligible treated patients	Pharmacy dispensing data	Quarterly	Target adherence support and medication review
Clinical outcomes	30-day avoidable readmissions	Readmissions within 30 days/ discharges	Hospital discharge data	Quarterly	Monitor transition-of-care quality
Organizational/ process	Service activation rate	Districts with operational Community House/Community Hospital/IHC/districts	Regional implementation plans + local reporting	Semi-annual	Track implementation fidelity
Organizational/ process	Referral-to-first-visit time	Median days from referral to first community visit	Booking systems/ EHR scheduling	Monthly–Quarterly	Identify access bottlenecks
Organizational/ process	Workforce coverage	FTE family/community nurses (or equivalent)/planned target FTE	HR rosters + regional staffing plans	Semi-annual	Align capacity with planned service volume
Organizational/ process	Care-plan documentation	Patients with a documented care plan/eligible chronic patients	EHR	Quarterly	Governance of continuity and accountability
Economic	Implementation cost per district	(One-off + recurring) implementation costs/district	Regional/local budgets	Annual	Feasibility and investment case
Economic	Cost per managed patient-month	Total territorial pathway costs / patient-months in the community pathway	Claims/admin data + local accounting	Quarterly–Annual	Efficiency monitoring and scalability
Economic	Hospital cost offset	Δ inpatient cost versus baseline period/population	Claims + DRG tariffs/cost weights	Annual	Value-for-money narrative and budget planning
Economic	Avoided transport and productivity costs (proxy)	Visits shifted to community/home $\times$ unit cost difference	Claims/admin data + tariff tables	Annual	Budget impact hypotheses and prioritization
Patient-reported (PROM/PREM)	Experience of care coordination (PREM)	% reporting high coordination score (standardized PREM)	Standardized PREM survey	Semi-annual	Patient-facing redesign and accountability
Patient-reported (PROM/PREM)	Treatment burden (PROM)	Mean treatment-burden score (or % above threshold)	Standardized PROM	Semi-annual	Detect unintended burden shifts to households
Patient-reported (PROM/PREM)	Access and responsiveness (PREM)	% reporting timely access and problem resolution	Standardized PREM survey	Semi-annual	Equity and responsiveness monitoring
Patient-reported (PROM/PREM)	Confidence in self-management (PROM)	Mean self-efficacy/self-management score	Standardized PROM	Semi-annual	Target education and community support

Domain	KPI (example)	Operational definition (numerator/denominator)	Data source	Suggested frequency	Decision use
Equity and geographic comparability	Coverage gap by deprivation	Δ coverage (or activation) between most and least deprived districts for key services (e.g., Community House/IHC)	Regional implementation plans + population deprivation index	Annual	Detect inequitable rollout and prioritize corrective investment
Equity and geographic comparability	Rural/remote access proxy (time-to-first-visit gap)	Median referral-to-first-visit time in rural/remote districts versus urban districts	Booking systems / EHR scheduling	Quarterly	Monitor geographic inequities in access and responsiveness

Note: Candidate KPIs are proposed as a conceptually informed minimum viable evaluative framework, prompted by the survey findings and supported by established quality-assessment and health-system performance principles. They should not be interpreted as empirically derived or validated indicators from this survey. Operationalization requires standardized definitions, prospective testing, and harmonized data flows across Regions.

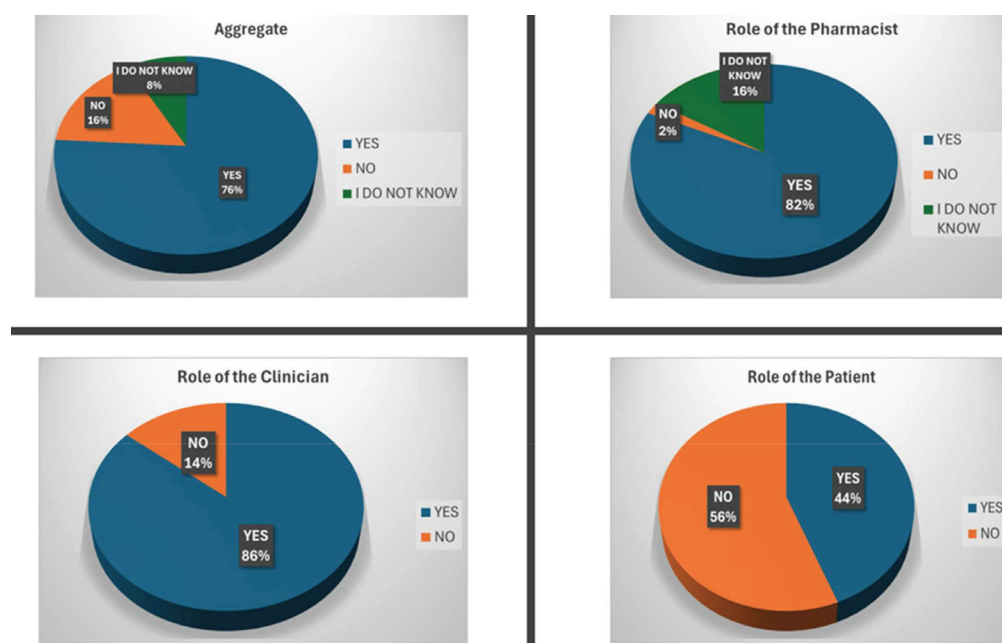


FIGURE 6 - Changing the role of pharmacist, clinician, and patient with the optimization of proximity care services.

methodologically defensible. For the remaining domains, the analysis privileges descriptive triangulation across stakeholder groups, identifying areas of convergence, divergence, and uncertainty. This approach reflects the structure of the available data and avoids attributing undue precision to perception-based responses collected through non-probabilistic sampling.

First, respondents' perceptions suggest a misalignment between decentralized delivery and existing governance and evaluation arrangements. In the absence of consistently implemented outcome monitoring and decision-analytic frameworks, decentralized reforms may struggle to translate perceived value into decision-relevant evidence for resource allocation and reimbursement governance (9, 10). The persistence of administrative burden as a primary barrier is consistent with previous decentralization literature, particularly in contexts where regional implementation outpaces national oversight (10). Second, respondents reported limited visibility of formal economic evaluation within local implementation processes, despite identifying chronic and cyclic therapies as

particularly suitable for decentralized provision. This suggests a potential opportunity to embed real-world cost-effectiveness and budget-impact assessment into future planning, while recognizing that the present study did not collect economic outcome data (11). In contrast to international models where decentralized care may be linked to adaptive payment or contracting mechanisms, the Italian framework appears, from respondents' perspectives, less explicitly connected to evaluative and reimbursement tools (12). Third, the reform's shared evaluative architecture remains under-specified, thereby limiting comparability across districts and Regions to prevent "proximity" from becoming a purely infrastructural label. MD 77/2022 requires an explicit, multi-domain KPI set that links structure, process, and outcomes and that is feasible within routine data flows. The proposed KPI taxonomy is therefore not intended as an empirically derived scale or as a validated performance instrument. Rather, it is a conceptually informed framework, motivated by the survey findings and anchored in established quality-assessment, primary-care performance, and health-system evaluation literature. It

aims to provide a pragmatic starting point for future prospective monitoring, benchmarking, and decision-analytic work. Building on established quality assessment logic and on international primary care indicator initiatives, a pragmatic KPI taxonomy can be organized into five domains: (i) clinical safety and effectiveness, (ii) resource use and efficiency, (iii) organizational performance and continuity, (iv) patient-reported experience/outcomes, and (v) equity and geographic comparability (13-16). Such a taxonomy enables Regions to benchmark implementation while preserving local flexibility, and it creates the minimum evidentiary substrate needed for credible value-for-money discussions in decentralized pathways.

Operationally, the KPI set should prioritize indicators that are (a) sensitive to decentralization, (b) attributable to the new territorial care pathways, and (c) measurable without bespoke data collection at scale. Table 2 provides a minimum viable “starter set” that can be populated using routine administrative flows, standard Electronic Health Record (EHR) extracts, and short Patient-Reported Outcome Measures/Patient-Reported Experience Measures (PROM/PREM) modules, enabling periodic dashboards and benchmarking.

Moreover, the heterogeneity of stakeholder perspectives reflects a structural asymmetry in expectations. While HEOR professionals emphasized methodological rigour and outcome monitoring, patient groups prioritized equity of access, psychosocial support, and local responsiveness. Bridging this divergence requires governance mechanisms capable of integrating both clinical-economic evidence and social legitimacy into reimbursement processes (17).

Notably, the apparent attenuation of perceived criticalities among patient-organization respondents should not be treated as a neutral counterpoint to professional concerns. In reforms mediated through organizational layers, such patterns may reflect an epistemic asymmetry: professionals are closer to operational constraints and measurement deficits, whereas patient organizations may have limited access to implementation reporting, monitoring outputs, and locally available KPI dashboards. Addressing this asymmetry is itself a governance task and requires transparent dissemination of implementation metrics, co-designed indicators, and structured mechanisms for patient involvement beyond consultation.

Strengths and limitations

This study has several strengths and limitations. Its main strength lies in the multi-stakeholder design, which allowed MD 77/2022 implementation to be examined from professional, patient-advocacy, and health-economics perspectives. The use of predefined conceptual domains also helped distinguish awareness, perceived implementation, and perceived impact. However, the findings should be interpreted in light of several limitations. Participants were recruited through convenience sampling via organizational channels; therefore, the sample should not be considered statistically representative of all Italian professionals, patients, organizations, or institutions involved in MD 77/2022 implementation. In addition, because the survey was disseminated through mailing lists and internal communication channels, a measurable

denominator was unavailable, and a formal response rate could not be calculated. Selection bias and information bias are also possible, as respondents with a greater interest in territorial healthcare reform may have been more likely to participate, and several items relied on self-reported awareness rather than independently verified implementation or performance data. Finally, stakeholder-specific survey instruments were used to preserve contextual relevance; although selected analyses were harmonized, residual measurement heterogeneity and uneven subgroup sizes may have limited between-group comparability. The study did not collect objective clinical, utilization, budget-impact, pricing, or cost-effectiveness data; therefore, implications for value assessment, reimbursement governance, and pricing should be interpreted as conceptual and hypothesis-generating.

Conclusions

The implementation of MD 77/2022 in Italy marks a decisive step toward reconfiguring healthcare delivery around principles of territorial proximity and continuity of care. These findings are perception-based and should be interpreted as hypothesis-generating with respect to pricing and value assessment, pending empirical evaluation using routine administrative and economic data.

However, our findings suggest that without an integrated framework linking service decentralization to performance indicators and decision-relevant evaluation approaches, implementation risks remain administratively fragmented and difficult to appraise in terms of efficiency and equity.

While stakeholders broadly support the conceptual goals of the reform, their perspectives diverge on feasibility and sustainability. The limited availability of outcome monitoring and consistent KPI utilization across Regions constrains the system’s ability to generate comparable evidence on the value of proximity-based interventions. Furthermore, respondents reported limited visibility of embedded health-economic methodologies within local pilot initiatives; accordingly, implications for pricing governance should be interpreted as policy hypotheses rather than as evidence of observed cost-effectiveness shifts.

To unlock the full potential of decentralized healthcare, policymakers should pair infrastructure deployment with an explicit KPI-based evaluative framework, allowing Regions to monitor safety, outcomes, costs, and equity in a comparable way, and to iteratively recalibrate territorial pathways based on evidence rather than assumptions (13-16). MD 77/2022 could serve as a model of adaptive transformation, but only if coupled with evaluative governance: transparent outcome monitoring, stakeholder-aligned metrics, and decision-analytic approaches capable of informing future reimbursement and sustainability choices.

Acknowledgments

The Authors wish to express their sincere appreciation to the scientific societies ISPOR, SIF, SIFO, and SIMM, as well as the patient organization UNIAMO, for their participation in the survey and for providing invaluable insights that significantly informed this study.

The Authors also gratefully acknowledge the GIRF group for their ongoing support, collaboration, and dedication, which were instrumental in the successful completion of the research.

Disclosures

Conflict of interest: The Authors declare no conflicts of interest.

Financial support: This research was conducted independently and did not receive any funding from public, commercial, or non-profit organizations.

Author contributions: GAC: Conceptualization, Writing – original draft; LP: Project administration; DB: Validation, Writing – review & editing; MP: Writing – original draft; AM: Supervision.

Data availability statement: Data available on request: The data presented in this study are available on request from the corresponding author. The data are not publicly available to protect the confidentiality of survey participants.

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