

S.M.A.R.T. CARE

Soluzioni e Metodi Avanzati di Riorganizzazione Territoriale in Sanità

INTERNATIONAL

S.M.A.R.T. Care International:
 Advanced Solutions and
 Methods for the Reorganisation
 of Healthcare at Local Level –
 Relocation of hospital medicines
 to near-patient locations



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Contents

List of participants and their affiliations	2
Executive Summary	3
1. The international scenario	4
1.1 France	4
1.2 Germany	5
1.3 Spain	6
1.4 United Kingdom	7
2. Italy - Analysis of the domestic scenario	8
2.1 Italy - Home care	9
2.2 Italy - Intermediate care	11
2.3 Italy - Home delivery of medicines	12
2.4 Italy - Chronic medical conditions	12
2.4.1 The oncology setting	13
2.4.2 The neurology setting	14
3. International examples	15
3.1 The Near-Patient and Direct to Patient Case Study	15
3.2 The Home care - direct to patient case study	16
3.3 The intermediate care - near-patient case study	16
3.4 The telemedicine case study	17
4. Implementation guidelines	18
4.1 Adopting a rigorous methodology for developing the role of the community and home care	18
4.2 Developing the organisation of community care	19
4.3 Redesigning staff roles and skill sets	20
4.4 Digitising healthcare	21
4.5 Developing the role of the pharmacy	22
Conclusions	23
References	25



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Executive Summary

The purpose of SMART Care International is to identify actions to improve the care pathway of patients with complex chronic diseases, in the continuity of management between hospital and community care, by reviewing the international scenario. To this end, the working group carried out a preliminary supranational analysis of the main solutions adopted in some European countries for the management of intermediate (near-patient) care and home (direct to patient) care. More specifically, it reviewed the situations in the UK, Germany, France and Spain.

The SMART Care International working group analysed both the international scenario, where particular approaches are adopted to relocate care and medicines to the community setting, and the current Italian framework in which, although the COVID-19 pandemic has led to an acceleration in the home delivery of medicines and use of digital tools, intermediate and near-patient care is still limited and difficult to implement. Three lines of action for the evolution of Regional Health Services came to light during the comparison:

1. The "distributed" hospital in terms of intermediate and community care;
2. Digitisation and telemedicine;
3. The expansion of the range of home services provided to patient, such as the home delivery of medicines.

The SMART Care International working group considers that simultaneous implementation regarding all three lines of action is required, by taking action regarding healthcare professional flexibility, minimum requirements and regulatory simplification.

In this sense, a critical and key role is played by the projects associated with the National Recovery and Resilience Plan (PNRR) in the management of intermediate and community care, illustrated in Mission 6 Component 1: promotion of healthcare and the community healthcare network, for which 7 billion euros of investments are planned.

The SMART Care International working group then investigated the intervention required to implement the strategic lines of action, by reviewing international examples and the projects that are already under way in Italy in order to identify five "ingredients" of Italian healthcare in the PNRR era:

- The presence of a rigorous methodology even at supra-regional level, such as Value-based Healthcare, characterised by a rigorous system of process and outcome indicators;
- A sustainable reorganisation of community care settings based on regional pilot schemes in line with the proposed update of Ministerial Decree 70 and the imminent Ministerial Decree 71;
- Investments in the definition of new care roles and task-shifting and in professional development and skills;
- The identification of digitisation with a view to data sharing in order to improve and facilitate interaction between hospital and community, not least through the use of digital health and telemedicine tools;
- Development of the role of hospital and community pharmacies, in terms of management and services, in order to make the medicines pathway more efficient and identify appropriate ways of managing the home delivery of medicines, thereby guaranteeing patients quality standards and safe care.



1. The international scenario

At international level, pharmaceutical products are allocated to the hospital or retail channels depending on their classification and/or the location of the dispensing pharmacy; hospital medicines can be dispensed on either a “direct-to-patient” basis, when hospital medicines are delivered directly to the patient’s home, or on a “near-patient” basis, when hospital medicines are delivered to a location close to the patient’s home.

The size of the hospital market varies significantly from one country to another, depending on the type and volume of products that are dispensed at this level.

The rationales behind the decision on how to distribute the medicine are associated with a number of factors such as, for example, the reimbursability of the medicinal product and the possible safety and risk profiles associated with its use.

In most countries, a limit on the reimbursability of certain products in the hospital channel is established at regulatory level, in order to allow centralised purchasing and greater cost control measures. Further limitations are associated with the safety of prescribing and administering certain types of medicines, which necessarily require the presence of specialised doctors or specialist equipment, for example for the management of any adverse reactions, that cannot be used in a community or home setting. Furthermore, there may be logistical limitations associated with the limited number of patients and the product itself, such as in the case of medicinal products with special storage requirements.

Within the European scenario, there are four main countries that present examples of and best practices for the relocation of medicines: France, Germany, Spain and the United Kingdom¹.

	Italy	France	Germany	Spain	United Kingdom
Size of the hospital market (value)	€ 14.7 bln	€ 11.3 bln	€ 6.8 bln	€ 12.5 bln	€ 14.0 bln
Hospital share of total prescription medicines market (value)	55%	35%	14%	55%	57%
Number of hospitals	1,048	~2,000	~1,900	769	505
Hospital share of therapeutic area (value)	Oncology: 95% Neuroscience: 44%	Oncology: 60% Neuroscience: 33%	Oncology: 25% Neuroscience: 16%	Oncology: 95% Neuroscience: 31%	Oncology: 95% Neuroscience: 29%

Figure 1: Comparison between the hospital market in the European countries considered and Italy

1.1 France

In France, hospital medicines are classified through the following national hospital formulas: the hospital tariff system (groupe homogène de séjour, GHS), high-cost therapies through the liste en sus, and newly available therapies through temporary authorisation (autorisation temporaire d'utilisation, ATU). Medicines included in the "liste de rétrocession" are allocated to the retail channel.

The home delivery of hospital medicines, which was welcomed by French hospital users, is permitted under certain conditions by the French Public Health Code, Chapter VI: Pharmacies for internal use (Article L5126). This chapter authorises pharmacies, including hospital pharmacies, to dispense medicines for home delivery. It is, however, conditional to the prerequisite that the medicines are delivered in a sealed, opaque package bearing the patient’s contact details and under

¹ Sources regarding the international scenario: IQVIA MIDAS MTH, Nov'20; ; IQVIA Market Prognosis (2020)



the direct supervision of the pharmacist, in order to safeguard the condition of the medicine and ensure that the correct information is provided to the patient. As far as the financial aspects are concerned, the social security system is committed to fully reimbursing teleconsultations until 2023, unlike the home delivery service for the hospital channel, which is not reimbursed and therefore is entirely at the expense of the hospital. The obstacle to the introduction of the measures is associated with the risk of full absorption of community pharmacy sales.

In response to the COVID-19 pandemic, several French cities implemented social initiatives to facilitate the home delivery of medicines to particularly vulnerable patients, thereby limiting travel to minimise infection. Within the context of the exceptional situation associated with the pandemic and in order to fulfil its mission of providing care to vulnerable individuals, the French Red Cross set up a pro bono concierge service called "Red Cross at home", in concert with the FSPF (Fédération des Syndicats Pharmaceutiques de France) to serve all patients unable to leave their homes during the pandemic and guarantee them the necessary pharmaceutical treatments. Lastly, the French Oncological Pharmacy Society (SFPO) published guidelines for oncological pharmacy practices during the COVID-19 pandemic to ensure adequate pharmaceutical care. These measures are of a strictly emergency nature, as they do not provide for the continuation of services after the end of the COVID-19 emergency².

1.2 Germany

In Germany, the organisation of medicinal product distribution is based to a greater extent on the retail channel. This is facilitated by the presence of numerous outpatient clinics with an almost homogeneous distribution throughout the country, but particularly covering rural areas, which allow the distribution of medicines, including parenteral treatments, in near-patient locations. Medicinal products are distributed in various ways considered as belonging to the "retail channel", including: the outpatient clinic issues the prescription that the patient takes to a pharmacy to obtain the medicine; agreements between the specialised pharmacy and the outpatient clinic that supplies the medicine directly to the patient; agreements between the formulation laboratory and the outpatient clinic.

Very few medicinal products cannot be ordered from retail pharmacies, for example therapies such as Zolgensma and Kymriah. There is a class of products that can be purchased through the retail channel, for example Spinraza, but in clinical practice is limited to the hospital setting as they can only be administered by adequately trained staff. The availability of products through the retail channel reduces the need for direct-to-patient and near-patient solutions. German legislation on patient data protection, which came into force on 18 September 2020, makes the use of e-prescriptions mandatory from 1 January 2022. This should enable better use of telemedicine and home delivery services through the digitisation of processes.

In order to facilitate outpatient care during the COVID-19 pandemic, special regulations were implemented to prescribe home nursing care, and reimbursement was provided for the postal delivery of prescription medicines. Although defined as having an "emergency" nature, these services are currently still in place, presumably because of the added value they can offer to the current organisational model regarding pharmaceuticals in Germany.

As a contextual fact, from the perspective of a general reform of the level of care and, therefore, also of pharmaceutical care, it is worth noting that the percentage of telemedicine use has doubled compared to the pre-pandemic level, as it was facilitated by the introduction of incentives for telemedicine consultations by the National Association of Statutory Health Insurance Physicians³.

² Sources regarding France: https://www.francetvinfo.fr/sante/medicament/la-livraison-a-domicile-de-medicaments-en-plein-essor_3995463.html; <https://www.vie-publique.fr/loi/276423-loi-14-decembre-2020-financement-securite-sociale-2021-plfss-budget-secu>; <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000042685681/2021-07-01/>; https://solidarites-sante.gouv.fr/IMG/pdf/liste_des_medicaments_retrocedes_20200421.pdf; <https://solidarites-sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/prescription-et-dispensation/article/medicaments-retrocedes-retrocession>; <https://www.croix-rouge.fr/Actualite/Coronavirus-COVID-19/COVID-19-Croix-Rouge-chez-vous-livraison-de-medicaments-sur-ordonnance-2360>
³ Sources regarding Germany: Rahmenvertrag Entlassmanagement nach Krankenhausbehandlung; Onkologie-Vereinbarung; <https://www.kbv.de/html/coronavirus.php#content45248>; Information on COVID-19 Entlassmanagement guidelines; <https://www.kbv.de/html/avv.php>; https://www.kbv.de/html/haeusliche_krankenpflege.php



1.3 Spain

In Spain, the hospital channel is predominant, as it constitutes more than half of the market value. Specialist products are dispensed through hospital pharmacies, and certain therapeutic areas are almost entirely confined to the hospital, most notably oncology, where 95% of products are distributed through the hospital channel. The Autonomous Communities, which are responsible for healthcare, have the power to establish their own systems for the delivery of medicines in hospitals. At national level, the home sale of prescription medicines is substantially prevented by the current legislation (Royal Legislative Decree 1/2015, approving the Law on the Guarantee and Rational Use of Medicines and Health Products). This restricts the possibility of establishing a formal evolution of home delivery systems.

Nevertheless, the COVID-19 pandemic prompted a substantial change in this approach. As a matter of fact, with the law of 29 March 2021 (Law 2/2021), the central government decided to authorise the dispensing of medicines at the patient's home under exceptional conditions, including the protection of public health or if the patient's clinical situation, vulnerability and risk do not allow for a different method of delivery of the medicinal product. The law provides that, in such circumstances, both the delivery and the pharmacological therapy plan of the product are the responsibility of the dispensing pharmacy. The latter is also responsible for the medicine's compliance with safety and quality standards.

This regulatory paradigm shift follows the emergency organisational changes imposed by the pandemic in 2020, when there was a strong demand for home delivery services for hospital medicines. At the same time, the Spanish Society of Clinical, Family and Community Pharmacy (SEFAC - Sociedad Española de Farmacia Clínica, Familiar y Comunitari) implemented a temporary action protocol in response to the state of emergency, in order to guarantee patients the medicines dispensed by hospitals, through: home delivery, delivery to a community pharmacy or delivery to a primary care facility (Centros de Atención Sanitaria). Subsequently, hospital pharmaceutical services improved their internal organisation and management procedures by extending the duration of prescriptions, telepharmacy services, home delivery and dedicated circuits for COVID-19 patients. Lastly, the General Council of Pharmacists' Associations (Consejo General de Colegios Farmacéuticos) and the Red Cross established a network of more than 22,000 pharmacies, with the support of 200,000 volunteers, to facilitate the home delivery of medicines to vulnerable patients⁴.

⁴ Sources regarding Spain: <https://www.diariofarma.com/2020/03/25/medicamentos-a-domicilio-cuando-la-urgencia-por-parar-la-pandemia-desborda-el-marco-legal>; <https://www.boe.es/buscar/doc.php?id=BOE-A-2015-8343>; <https://www.boe.es/buscar/doc.php?id=BOE-A-2002-915>; <https://www.boe.es/buscar/doc.php?id=BOE-A-2019-13517>; <https://www.boe.es/buscar/pdf/2008/BOE-A-2008-3179-consolidado.pdf>; <https://2opfle1yeg2f3zqyqbpfbx76-wpengine.netdna-ssl.com/wp-content/uploads/2020/07/Plan-de-acci%C3%B3n-para-la-transformaci%C3%B3n-del-Sistema-Nacional-de-Salud-e-n-la-era-post-COVID-19%E2%80%99-v5.pdf>



1.4 United Kingdom

In the United Kingdom, most medicines are distributed through the hospital channel in order to ensure centralised purchasing and greater cost control measures. For example, in the oncology setting 95% of products by value are distributed through the hospital channel.

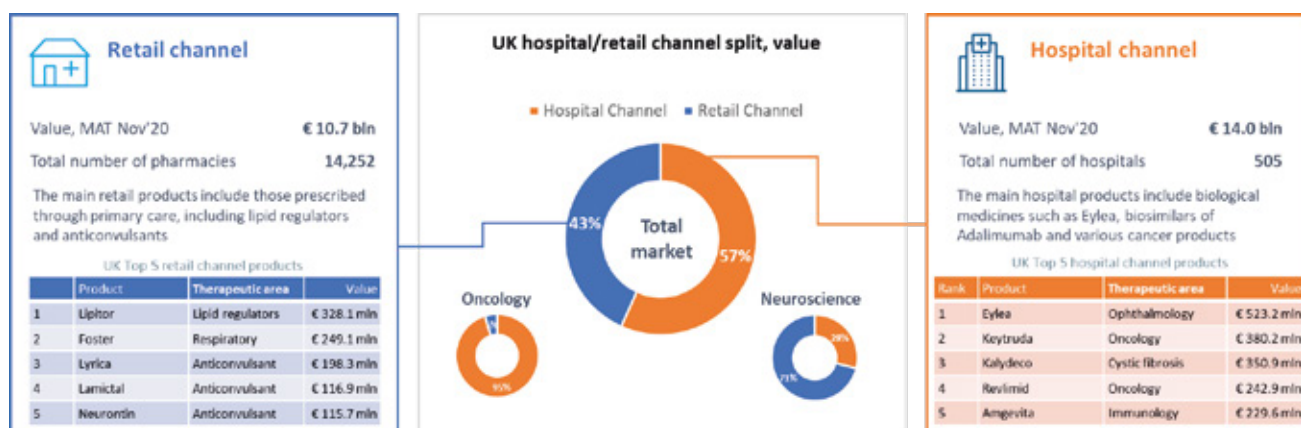


Figure 2: Hospital/ retail channel split in the UK

The home delivery of hospital products is permitted by law for all types of medicine. British legislation governing the dispensing of medicines is dictated by “The Human Medicines Regulations” (2012) and, in particular, Regulations 220 and 248. According to Regulation 220 prescription medicines may only be sold or supplied through a registered pharmacy. However, Regulation 248 permits the delivery of medicines, provided that they are not delivered to a public place. “Tariff-excluded” medicines (intravenous, chemotherapy and special high-cost drugs) are only available through the hospital channel and are therefore purchased centrally by the NHS (National Health Service) and reimbursed by the commissioning party. NHS-managed hospital pharmacies have to pay VAT on medicines, whereas third-party pharmacies are exempt. This is connected with the original guidelines issued following the establishment of the NHS (1948), when the management of medicines was geared towards reducing the costs to the NHS. As a result, hospitals can achieve a VAT saving of 20% by distributing a medicine through third parties, and this financial incentive is the key to the success of home care in the United Kingdom. In the Carter report (2016), home care is the formally recommended practice. Direct delivery of medicines to the patient is provided through home care and is generally provided in collaboration with private third-party providers. Currently, more than a quarter of the total amount of medicines in UK hospital pharmacies is supplied through home care. Specialised hospitals may also run satellite units in existing community facilities with the necessary skill sets. These units are generally founded by a specialised clinic within a larger hospital and common locations include community hospitals and local medical centres. Medicines are either supplied directly by the specialist trust (through its own pharmacy) or indirectly (billed by the host facility’s pharmacy). This service meets the need generated by the absence of local specialist clinics in the British healthcare system and provides highly specialised tertiary services closer to the patient. Alternatively, mobile units may be deployed to overcome the need for physical sites: these units are managed by a nursing team, in direct contact with doctors and pharmacists in the referring hospital. This solution has the added advantage of being able to move around the area, thus providing wider coverage. This solution is also managed by a specialised hospital trust, in the form of private entities, which provides different types of services: from single, adaptable units to high-capacity multi-unit solutions, in compliance with the Disability Discrimination Act and in accordance with NHS standards. A mobile unit dedicated to chemotherapy infusions may be, for example, 56 square metres in size, formed of 6 different spaces, and equipped with a



clinical preparation and storage area, clinical sinks and medical supplies for handling any unforeseen events and/or side effects, an on-board generator or, alternatively, direct mains power connection, a video surveillance system, burglar alarm and outdoor lighting.

In response to the COVID-19 pandemic, the NICE published guideline 161 to maximise the safety of cancer patients, minimise travel and infection, and optimise NHS resources, through recommendations for modifying usual medication, and procedures to minimise hospital admissions. The "digital-first" principle was also implemented for primary care and outpatient management. Lastly, the NHS, in collaboration with the Royal Voluntary Service and the GoodSAM5 app, set up a temporary group of volunteers to facilitate home deliveries. Given the peculiar nature of the UK system, it was considered interesting for the exportation of good practices⁵.

2. Italy - Analysis of the domestic scenario

Italian law governs the salient points regarding the relocation of hospital medicines at various levels: management of home care, implementation of intermediate care and home delivery of medicinal products. The pandemic situation has prompted experiments aimed at enabling the continuation of care, including on a remote basis: telemedicine (in the three forms provided by the Ministry of Health - "Telemedicine, National Guidelines"⁶), home visits and the relocation of medicines. However, these experiences must be maintained and improved even after the end of the emergency situation, in order to devise a new organisational model. To achieve this, it is necessary to resynchronise the legal/ administrative aspects and the health aspects, which often proceed at different speeds.

The examples of international best practices are undoubtedly useful as paradigms for organisational and management models to be implemented. In particular, the comparison with the management of care in the United Kingdom, as explained in Figure 3, can provide a stimulus for improving the state of the art in Italy, given the high level of organisation and diffusion of intermediate care, which includes the home delivery of medicines. In Italy, on the other hand, the intermediate care setting is under-developed and characterised by regional differences that prevent it from being exploited to the full; however, the recent dissemination of the PNRR represents a good opportunity for improving this area. This is not least true for the home delivery of medicines, implemented during the COVID-19 pandemic, which highlighted the benefits for patients.

One essential factor for promoting intermediate and home care is undoubtedly telemedicine and, as part of a broader outlook, digitisation. According to the national guidelines issued by the Ministry of Health, Telemedicine is defined as "a method of providing healthcare services, through the use of innovative technologies, in particular Information and Communication Technologies (ICT), in situations where the healthcare professional and the patient (or two healthcare professionals) are not in the same location"; services provided on a Telemedicine basis do not replace traditional healthcare services, rather they complement them in an attempt to improve their efficacy, efficiency and appropriateness. Although the emergency period has favoured its use, the diffusion of telemedicine in Italy is still fragmented and non-institutional. Once again, in this scenario, the UK provides large-scale experiences that can provide valuable examples for implementation in Italy.

One obstacle to be considered is the resistance to change by both medical professionals and patients, which calls for intervention on two fronts: on the one hand, creating a training model for future medical professions aimed at raising awareness and addressing organisational issues and problems, and, on the other hand, providing patients with a very clear message that the management of the care pathway remains the same and there is no loss of continuity or expertise, as the only thing that changes is the setting within which care is provided.

5 Sources regarding the United Kingdom: <https://www.legislation.gov.uk/uksi/2012/1916/introduction>;
<https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services>; <https://www.gov.uk/government/publications/productivity-in-nhs-hospitals>;
<https://www.nice.org.uk/guidance/ng161/chapter/7-Modifications-to-usual-service/>;
<https://www.bma.org.uk/advice-and-support/covid-19/adapting-to-covid/covid-19-video-consultations-and-homeworking>;
<https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-community-pharmacy/>;
<https://psnc.org.uk/our-news/covid-19-funding-update-ministers-agree-300-million-cash-injection/>; <https://nhsvolunteerresponders.org.uk/>; The Human Medicines Regulations (2012)
6 https://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf



The geographical breakdown of the country is undoubtedly a major limitation. The various regional health systems are very different and the management of community care is influenced, among other things, by the characteristics of the area covered. The same fragmentation can also be found within the same region, in the absence of a specific structuring of services. A great many experimental systems have yielded excellent results, with “enlightened” specialists and examples of best practices; however, these situations are not structured and disseminated, and they remain mere exemplary exceptions. In order to pursue the objectives set, it is therefore necessary to share a common organisational approach, based on interaction and integration, but with different models according to the specific needs of each region and geographical area.

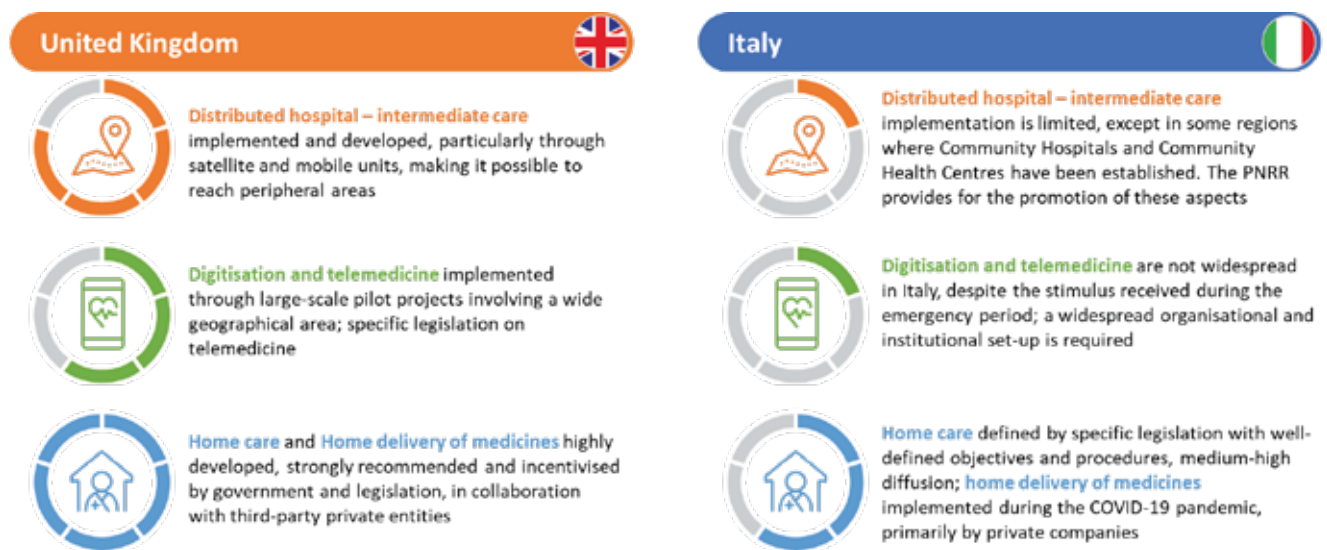


Figure 3: comparison of the national and UK scenarios

2.1 Italy - Home care

In accordance with the definition provided by the Ministry of Health "Home care consists of medical, nursing and rehabilitation treatments, provided by qualified personnel for the care and assistance of non-self-sufficient and frail individuals, with current medical conditions or outcomes of the previous conditions, to stabilise the clinical situation, limit functional deterioration and improve the quality of daily life" (Ministry of Health - General Directorate for health planning, levels of care and ethical principles of the system - New characterisation of home-based community care and home-based hospital interventions). This approach ensures continuity of care for patients discharged from healthcare facilities who require further treatment. The resulting improvement in the patient's quality of life, in addition to the physical and emotional support the patient's family can receive, is evident. In addition to defining the objectives of home care, the Prime Minister's Decree of 12 January 2017 ("Definition and updating of the Essential Levels of Care") also sets forth the requirements for enabling the service, the procedures for managing care and the corresponding charges. It is important to stress that care is based on a multidimensional approach and on a global assessment of the patient's functional status, placing him or her at the centre of the care pathway.

In this context, it should be emphasised that optimal home care must be suited to the health conditions and social and health needs of the patient for whom it is intended. As a matter of fact, there is a correlation between the level of service provided



and the complexity of care required, with the provision of medical, nursing and rehabilitation services, in addition to diagnostic tests and the provision of medicines. The current characterisation of home-based community care and home-based hospital interventions differentiates care according to increasing levels of care intensity (which in the Prime Minister’s Decree of 12 January 2017 are classified from "basic level" home care to high-intensity home care), which are then complemented by social interventions in accordance with the outcomes of multidimensional assessments. In short, depending on needs and local organisational approaches, the following are identified: non-continuous home care, characterised by occasional or cyclical healthcare services, for a specific medical, nursing and/or rehabilitation need that, even when it is repeated over time, does not involve the management of patient care; integrated home care, in which the need has a functional and social as well as clinical nature and it may be of a first or second level, if it involves medical-care services or rehabilitation-care services with management of patient care (IHC), or third level, if it involves Home-based Hospitalisation (HBH) and, depending on the level of complexity, it is characterised by the definition of an Individualised Care Plan (ICP) devised on the basis of a multidimensional assessment and provided through multidisciplinary and multiprofessional care management; home palliative care for terminally-ill patients, involving home-based community care for terminal patients and HBH, with a high-intensity response to highly-complex needs, defined by the individualised care plan and provided by a team possessing specific skill sets.

The current structure of home care varies considerably across the country, with different organisational and management models in different regions and, in some cases, even between health authorities within the same region. By contrast, the type of services provided appears to be more standardised. The national figure for integrated home care (Figure 4) is a median of 96 patients per 10,000 inhabitants. Emilia Romagna and Tuscany are the regions with the highest home care rates, with a value of more than 280 patients per 10,000 inhabitants. The region with the lowest rate is the Aosta Valley⁷.

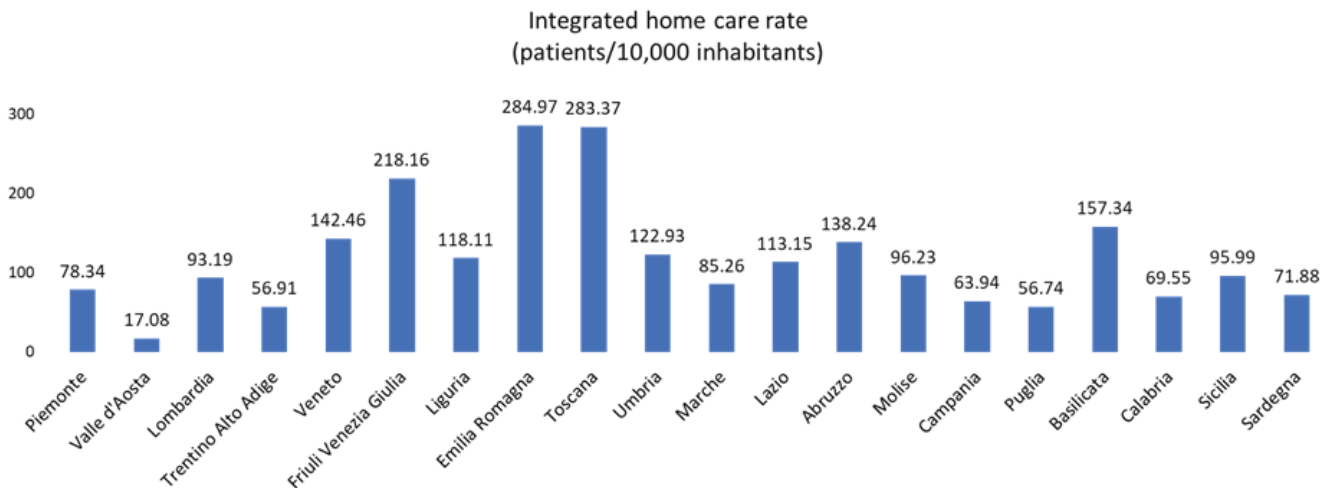


Figure 4: Integrated home care rate (patients/10,000 inhabitants)

⁷ interventi ospedalieri a domicilio 2006; DPCM 12/01/2017; Raccomandazione n.14 del Ministero della Salute per la prevenzione degli errori in terapia con farmaci antineoplastici, 2012



2.2 Italy - Intermediate care

Intermediate care, intended as the completion of the post-acute care process to achieve the best possible health status, forms the cornerstone of Transitional Care models, and has been the subject of continuous improvement and reorganisation in recent years. As early as 2007, the Italian Budget Law provided for substantial investments in experiments regarding the “Case della Salute” [Community Health Centre] care system. This issue was addressed in the Ministry of Health Decree of 10 July 2007, through the definition and identification of guidelines for access to co-payment and the requirements for their implementation. At the same time, the need to implement telemedicine and teleconsultation services is also defined, in order to facilitate real-time connections between the referring hospital and the community system. Subsequently, Ministerial Decree no. 70 of 2015, “Regulations defining the quality, structural, technological and quantitative standards for hospital care”, provided indications regarding intermediate facilities, such as Community Hospitals, organisational units with about 20/25 beds, managed by nursing staff, in concert with General Practitioners and Primary-Care Paediatricians. However, the Community Hospital was not formally defined until the State-Regions Agreement of 20 January 2020, which clarified its intermediate function between the patient’s home and hospitalisation, to provide low-intensity clinical intervention.

Although there is specific legislation on intermediate care, it is neither widespread nor structured, especially in certain regions of Italy. By analysing, for example, the models adopted in Veneto, Tuscany and Puglia, it is possible to observe different degrees of implementation, despite the fact that specific regulations exist in all three regions. Once again in this case, intermediate care has been seen to play an important role following the impact the COVID-19 pandemic has had on regional health services. As a matter of fact, the emergency prompted a considerable increase in the settings associated with this level of care, which now represents a wealth of investment and resources that must be maintained and promoted through implementation and financial interventions. In this regard, it is worth emphasising that Mission 6 of the PNRR provides for investments of € 15.6 billion for outreach networks, intermediate facilities, telemedicine, technological and digital upgrades, and training and scientific research in the health field. More specifically, Mission 6 formally defines the so-called Outreach Networks, identifying the patient’s home as the first place of care and the promotion of the community and intermediate networks. It also adapted the definition of “Community Health Centres” and “Community Hospitals” and clarified the role of the Community Help Desk (COT), as a place of coordination and liaison between healthcare professionals and therefore the different levels of care. An equally important role is played by telemedicine, to which 23% of the investments indicated in Mission 6 are allocated, as a key element for fostering proximity and access to health services and for bridging geographical gaps⁸.

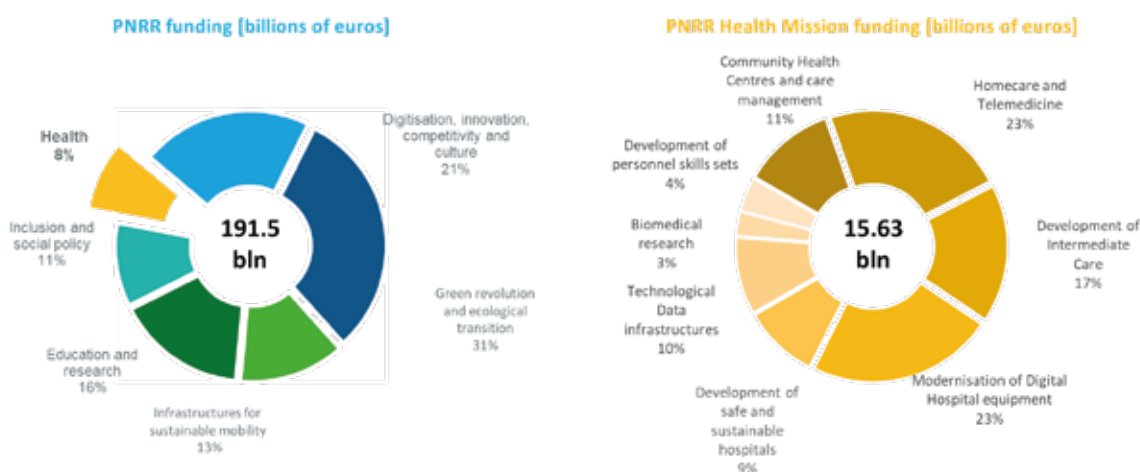


Figure 5: National Recovery and Resilience Plan – Mission 6 Health

⁸ Sources regarding intermediate care: <https://www.quotidianosanita.it/allegati/allegato9118664.pdf>; Legge Finanziaria 2007 (Legge n. 296 del 2006); Decreto del Ministero della Salute del 10 luglio 2007; Decreto Ministeriale 2 aprile 2015 n. 70; Intesa Stato-Regioni 20 Gennaio 2020; PNRR al 27/04/2021;



2.3 Italy - Home delivery of medicines

Epidemiological and social changes and the need to optimise health services and resource management, in the light of the dramatic impact of the COVID-19 pandemic, emphasised the need to provide for the home delivery of medicines to frail individuals who, especially during the darkest moments of the pandemic, were unable to collect their therapies from community and/or hospital pharmacies. Despite of the absence of specific legislation, many pharmaceutical companies have played an active role, since the early stages of the pandemic, in supporting home delivery services, especially with regard to medicinal products distributed by hospitals or local health authorities. Similarly, many pharmacies, in some cases in collaboration with voluntary associations, have also set up home delivery services. Given the undeniable benefit and importance of these services, the home delivery of hospital medicines must not be relegated to the pandemic situation alone and must be further explored and implemented even once the emergency period has ended.

At the same time, increased attention has been dedicated to Patient Support Programmes (PSPs) funded by private institutions and companies. There are currently no regulatory provisions on this subject, as the only source that defines these programmes and their main indications is the Farmindustria Code of Professional Conduct, which is binding only for its member pharmaceutical companies.

Despite the fact that there are many obstacles to their implementation, it is essential for the home delivery of medicines to be disciplined from a regulatory perspective. The first obstacle to be tackled is the current inclusion of medicines and medical devices in public tender procedures, which differs greatly to the management of medicinal products, which is dynamic and complex. It is imperative to propose a simplification of the tender code for exclusive and non-competitive pharmaceutical products, i.e. medicines with a valid patent. Moreover, the classification of medicinal products according to reimbursability, which allocates them to different distribution channels, must not be overlooked, since a single patient may use medicinal products distributed by different channels. Article 92(1) of Legislative Decree 219/2006 - Medicinal products for use only in hospital or hospital-like settings - provides that: "Medicinal products for use only in hospital environments are medicinal products that, due to their pharmacological characteristics, innovative nature, or method of administration, or other reasons associated with the protection of public health, cannot be used sufficiently safely outside hospital facilities". Hospital-like settings must guarantee measures for safe administration, in accordance with the instructions provided by the doctor and in close collaboration between the prescribing hospital specialist and the GP in charge of managing the treatment plan. This highlights the need to devise different distribution models for medicinal products provided through different channels. It is also necessary to revise the specific legislation on prescribing, to incorporate the possibility of excluding certain types of medicinal product - on the basis of specific requirements, such as the route of administration, safety profile, medical condition, etc. - and to broaden the range of prescribers to include community specialists and GPs. Lastly, further aspects that should not be underestimated are the management of treatment compliance and medicinal product reconciliation, for which adequate community-level management is currently lacking⁹.

2.4 Italy - Chronic medical conditions

The points raised so far are all the more relevant and call for the rapid implementation of the proposals outlined above, if we consider the current epidemiological situation in Italy. The data on chronic disease and multiple chronic diseases show that a great many people suffer from one or more chronic diseases, and this figure is gradually increasing as the population ages. Chronic illness is therefore a huge chapter, requiring considerable commitment of resources and close interaction between health and social services. The National Chronic Diseases Plan (PNC) was devised as a policy and governance tool, in order to outline a homogeneous national system for the management of chronic diseases with residential and community services, which are yet to be sufficiently implemented. In addition to continuity of care and comprehensive patient care, the main

⁹ Sources regarding home delivery: http://www.agenziafarmaco.gov.it/sites/default/files/DL_2006_219_0.pdf; Decreto Legislativo 24 aprile 2006, n. 219 «Attuazione della direttiva 2001/83/CE (e successive direttive di modifica) relativa ad un codice comunitario concernente i medicinali per uso umano, nonché della direttiva 2003/94/CE»; Legge 16 novembre 2001, n. 405



objectives of the PNC include the operation of care networks, with the integration and interaction of the various players involved in the process, placing particular emphasis on home care. Five years after the approval of the PNC, these goals have still not been achieved.

The shared data of the PASSI (dedicated to the population aged 18-69) and PASSI d'Argento (dedicated to the population aged 65 years and over) national surveillance systems, coordinated by the Istituto Superiore di Sanità [Italian Institute for Health] (ISS), in concert with the Regional Authorities, provide details on the number of individuals with one or more chronic diseases. The data show that more than half the population over the age of 65 lives with one or more chronic diseases, and this proportion increases with age: among individuals over 85 years of age, more than half have two or more chronic diseases¹⁰.

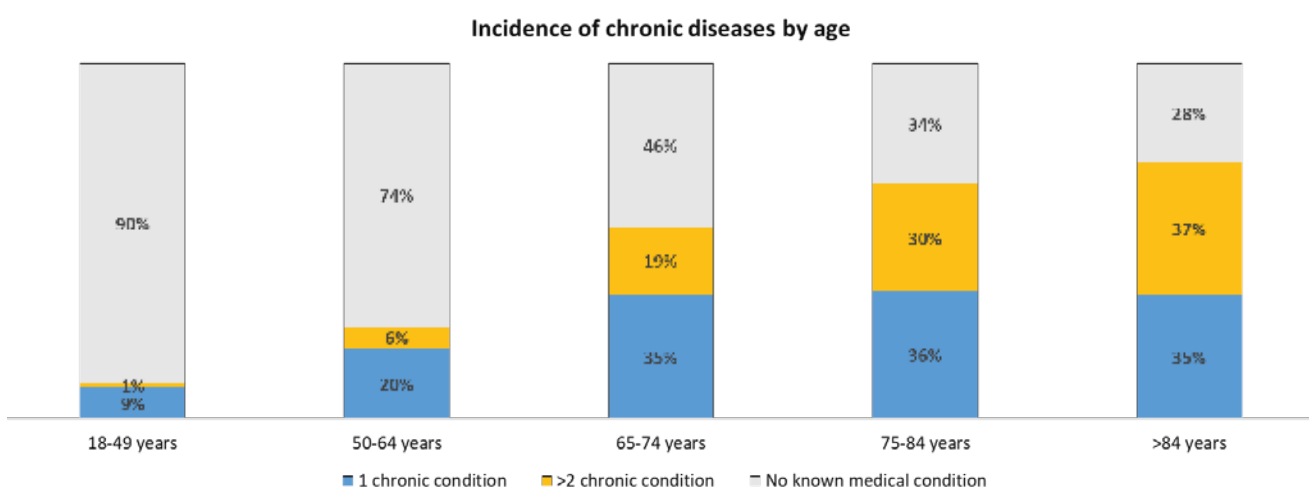


Figure 6: incidence of chronic diseases in Italy

2.4.1 The oncology setting

The eleventh edition of “I Numeri del Cancro in Italia” (“The Figures regarding Cancer in Italy”) published by the Italian Medical Oncology Association (AIOM 2021) states that there are 3.6 million people diagnosed with cancer (about 6% of the population) and 1,000 new cases every day. These numbers are indicative of the progressive ageing of the population, with a greater number of people potentially affected by cancer, and of therapeutic developments that have led to the chronicisation of the clinical course of cancer patients.

In oncology, the clinical course is currently predominantly managed by hospitals, resulting in facility overload and, all too often, a delay in the provision of services. COVID-19 and the resulting emergency reorganisation of healthcare facilities and reconverted hospitals, has had a great impact on the management of cancer patients in terms of organisation and, above all, care. The AIOM and AIRTUM annual report indicates, for example, a decrease in the number of cancer surgeries in 2020.

At the same time, however, it also highlights the need to integrate community and hospital services, that has come to be essential for the management of cancer patients. In order to achieve a better connection between care settings, it is essential to share data and electronic medical records. The hospital must become a place for acute cases, supported by organised and experienced out-of-hospital phases to manage follow-up and both immediate and delayed toxicity. It is therefore

¹⁰ Sources regarding chronic diseases: <https://www.epicentro.iss.it/coronavirus/sars-cov-2-flussi-dati-confronto-passi-pda-cronicita>



necessary to redesign the oncology pathway in the light of additional care settings: intermediate care, chronic care model and home care. The spread of oncology networks, as also defined by Ministerial Decree no. 70 of 2 April 2015, is based, among other fundamental aspects, on the structuring and strengthening of inter-institutional collaborations, in order to perform efficacious interventions.

One example of a best practice is the Region of Tuscany, which, as established by Regional Resolution no. 735 of 2020 "Regional oncology network - approval of guidelines for the development of integrated care pathways", has entrusted ISPRO (Institute for Cancer Research and Prevention and Oncology Network) with the overall coordination of local health authority projects for the definition of a one-year trial on the management of oncology patients. For this project, three Functional Community Clusters (AFT) have been identified, one for each Area Vasta [Macro-area], covering 30/35,000 patients, with a dedicated team of professionals, who liaise with GPs and hospital oncology units. ISPRO, in concert with Scuola Sant'Anna, is also in charge of monitoring and evaluating the projects and will define, at the end of the process, the organisational requirements of the model and the corresponding indicators. A subsequent resolution, no. 161 of 2021 "Approval of the ISPRO project "Community oncology: organisational model and trial start-up" also allocated € 290,000 of the budget to the implementation of the project. At the end of the trial, the organisational requirements of the model will be defined and the procedures for its possible extension to regional level will be identified, depending on the outcome of the trial¹¹.

2.4.2 The neurology setting

Neurological diseases represent a large group consisting of different medical conditions, including 940,000 patients with stroke sequelae, 400,000 patients with Parkinson's disease, 120,000 patients with Multiple Sclerosis and up to 1 million people with mental impairment. In Italy, stroke is the second most common cause of death after ischaemic heart disease, accounts for 9-10% of all deaths and is the leading cause of disability. Seventy-five per cent of people with stroke sequelae survive with some form of disability, and of these, half have such a severe deficit that they are no longer self-sufficient, making it a chronic condition to all intents and purposes. The WHO has predicted that, within twenty years, neurological disorders will be the leading cause of death and disability. For these reasons, the management of chronic neurological conditions and related pathways is one of the upcoming challenges for the National Health Service.

The neurology setting is highly fragmented and heterogeneous, with sectoral aspects and limited initiatives. It is necessary to do away with this fragmentation and create a common approach, by establishing neurology networks that put the patient's needs at the centre of the service, regardless of the medical condition in question, and develop the training of healthcare professionals. The regional health services need to adapt the resources and services dedicated to care for neurological diseases, taking the Chronic Care Model as a benchmark. Integration between neurology facilities and community medicine is essential, not least by making use of the new intermediate care settings. The pandemic scenario has made it clear that the use of telemedicine, and in particular teleconsultations, can help reduce the number of visits to neurology facilities and facilitate the consequent community/home management of the patient. However, telemedicine can only take off where there is already a structured network connecting hospital and community care. Therefore, the need for structured and organised neurology networks remains. Specific indications to this effect are given in the proposed update to Ministerial Decree no. 70, which provides for the establishment of neurology networks¹².

11 Sources regarding the oncology setting: Decreto Ministeriale 2 Aprile 2015, n70; Atto n. 59/CSR del 17 aprile 2019 «Revisione delle Linee Guida organizzative e delle raccomandazioni per la Rete Oncologica che integra l'attività ospedaliera per acuti e post acuti con l'attività territoriale»; Rapporto reti oncologiche regionali; <https://www.aiom.it/i-numeri-del-cancro-in-italia/>

12 Sources regarding the neurology setting: <https://www.iss.it/malattie-neurologiche>; <http://www.rssp.salute.gov.it/rssp/paginaParagrafoRssp.jsp?sezione=situazione&capitolo=malattie&id=2655>; Barometro della Sclerosi Multipla 2020-2021



3. International examples

The SMART Care International working group analysed several international case studies related to the "distributed" hospital setting, the digitisation of healthcare and the expansion of home care services, in order to identify concrete and effective examples to complement national good practices, to build a universal healthcare system that is increasing close to patients.

3.1 The Near-Patient and Direct to Patient Case Study

One case study that incorporates a great deal of information is that published by the Isle of Wight NHS Trust, which provides health services for the Isle of Wight, a small island in the English Channel, and therefore completely cut off from the mainland, with a total population of over 140,000 people. The most important community service is the Out-Patient and Home Parenteral Infusion Therapy service, which provides intravenous therapy to patients referred by a hospital or a general practitioner in the community. Patients are managed through an outpatient infusion clinic or, in special conditions, they may request caregiver training in order to manage medicinal product administration themselves, scheduling follow-up visits with trust staff to ensure proper and safe care. If the latter option is chosen, the trust guarantees weekly visits from a member of the team to manage any issues and complications. The benefits observed are a reduction in hospital admissions, with a consequent decrease in facility overloading, a reduction in the risk of treatment-related infections and an improvement in the patient's quality of life¹³.

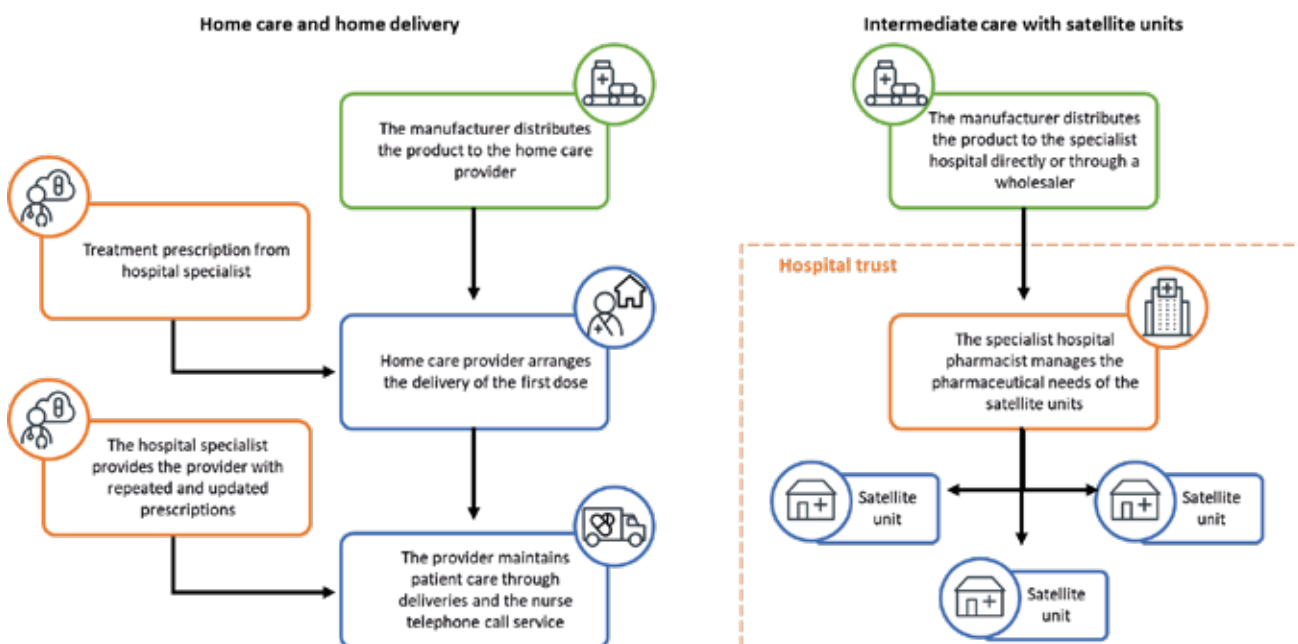


Figure 7: Graphical representation of home care and intermediate care in the United Kingdom

13 <https://www.iow.nhs.uk/our-services/acute-care-services/hospital-at-home/OHPIT.htm>; Gary Whitwam. Out-Patient and Home Parenteral Infusion Therapy: Economic Assessment Case Study. https://www.iow.nhs.uk/Downloads/Patient%20Information%20Leaflets/OHPIT_v1.pdf



3.2 The Home care - direct to patient case study

The SMART Care International working group also considered the case study published by York Hospital in England to be interesting. Like most hospital departments in the UK National Health Service (NHS), York Hospital runs a comprehensive range of home care services, known as MES (Homecare Medicines Services). In some cases, other types of nursing or educational support may be included in addition to the delivery of the medicinal product. To ensure the success of the home delivery service, the hospital has contracts in place with private companies. The home care provider is bound by the same confidentiality obligations as the NHS (the 1998 Data Protection Act) and the service is provided with the consent of the Patient using it. Each provider makes pharmacists available to dispense the medicines for home delivery, which is carried out by courier directly to the patient's home or to another safe and convenient location chosen by the patient. The proof of actual delivery of the medicinal product is constituted by the signature of the recipient or a designated person whose identity was made known to the provider in advance. If nursing intervention is involved, the provider ensures that the visit is carried out in the way that is most appropriate for the patient. Nursing intervention may consist in the administration of the medicinal product or the health education required to allow the patient to self-administer the medicinal product.

There is close collaboration between providers and the Hospital Homecare Team, a dedicated team of experienced NHS pharmacy staff who coordinate the management of home care and the medicines. This team, consisting of a pharmacist, a home care technician, a senior home pharmacy technician and financial/administrative staff, is based in the pharmacy departments of York and Scarborough hospitals¹⁴.

3.3 The intermediate care - near-patient case study

Christie Hospital in Manchester, in the north-west of England, the largest oncology facility in Europe and the first facility in the UK to be accredited as a cancer centre, manages a caseload of over 60,000 patients each year. In addition to a home care service that in 2020 provided care for 6,000 people, the Christie NHS Foundation Trust runs a mobile chemotherapy unit and two satellite radiotherapy clinics providing patients with chemotherapy, radiotherapy and other systemic cancer treatments.

The mobile chemotherapy unit was set up in 2013 to allow treatments to be administered in different locations throughout the week and is run by a team of nurses who administer the therapies. The unit is capable of delivering 1,700 treatments per year. The pharmacy of the referring hospital is responsible for preparing and dispensing the medicinal products.

The Christie at Oldham, opened in 2010, was the first satellite centre in the radiotherapy network, and provides patients with access to first-class radiotherapy closer to home. The treatment of different types of cancer is guaranteed by the presence of a team of radiographers and doctors and provides complex radiotherapy treatment to between 80 and 120 patients every day.

The Salford satellite unit is the second radiotherapy network and treats mainly common cancers, but is also one of the few centres in the UK to provide stereotactic radiosurgery for brain tumours¹⁵.

14 <https://www.yorkhospitals.nhs.uk/our-services/a-z-of-services/inflammatory-bowel-disease/homecare-medicine-services/>;
<https://thechristie.cld.bz/Highlights-of-the-Year-2020-21/20-21/>

15 <https://www.christie.nhs.uk/patients-and-visitors/visiting-the-christie/our-treatment-centres>



Figure 8: Christie Hospital Mobile Chemotherapy Unit

3.4 The telemedicine case study

The SMART Care International working group then looked at the case of the Department of Health, which in 2008 funded a large telecare and telehealth programme, the Whole System Demonstrator (WSD) Programme, which involved more than 6,000 frail and chronic patients and 200 doctors over two years. The results of the study were so encouraging that the Department of Health launched a new programme (the "Three Million Lives" campaign), targeting the potential 3 million patients eligible for telecare and telehealth services. Having recognised the benefit of using technology in healthcare, the NHS therefore developed the Technology Enabled Care Services (TECS) Resource for Commissioners in January 2015¹⁶. The aim of this document was to raise awareness among the various stakeholders of how the wide range of TECS resources can benefit patients, families, and health and social care professionals. The United Kingdom is now the most active country in the e-Health sector, offering telemedicine services in several domains: general medicine, through video and telephone consultations; medication, through e-prescriptions and applications; dentistry, through remote dental care services; and psychology, through telephone and video counselling.

The TECS archive contains several case studies on the application of telemedicine: the one the SMART Care International team found to be most interesting was that published by the Airedale NHS Foundation Trust (ANHSFT), which implemented telemedicine in a range of settings, including prisons, nursing homes and patients' homes. Home use was originally established for patients with diabetes and later extended to those with COPD, heart failure and complex diabetes and for end-of-life palliative care management. The system provides a secure two-way video link between patients and nurses and doctors, based in a Telehealth Hub at Airedale Hospital. The project involves the installation of a customised set top box on the patients' televisions and a software package, Cisco Jabber, for mobile devices. The results of the project are significant, as they show a 45% reduction in hospital admissions, a 60% reduction in emergency and urgent services, and a 50% reduction in the total number of days spent in hospital. Despite the pilot nature of the project described above, Airedale NHS Foundation Trust continuously provides a digital service, the Digital Care Hub. This service provides digital health and care support to people across the Bradford and Craven district to reduce the number of hospital admissions. The various health and care professionals involved provide telemedicine services, focusing particular attention on telemonitoring. The Digital Care Hub is a key aspect of the Act as One health and care partnership for the Bradford and Craven district. The Digital Care Hub fulfilled its purpose during the COVID-19 pandemic by providing 24/7 remote monitoring support and developing services to help people feel confident in caring for their health without the need for support from any service¹⁷.

¹⁶ <https://www.england.nhs.uk/tecs/>

¹⁷ <http://www.airedale-trust.nhs.uk/blog/digital-care-hub-shortlisted-for-national-awards/>; TECS CASE STUDY 002: Using telemedicine to reduce hospital admissions



4. Implementation guidelines

In the light of the scenario in Italy, the international case studies, the PNRR and the corresponding investments in healthcare, the SMART Care International working group identified five actions to achieve effective intermediate and community care, proper digitisation of care processes and the expansion of home care services. These actions are shown in Figure 9.



Figure 9: Implementation guidelines

4.1 Adopting a rigorous methodology for developing the role of the community and home care

In order to improve the efficacy of intermediate and community care, digitise healthcare processes and expand the range of home care services, the SMART Care International working group believes it is essential to choose and adopt a solid, structured method to guide the reorganisation of care processes. The SMART Care International working group considers the Value-Based Healthcare (VBHC - Figure 10) methodology to be the benchmark. The Value-Based Healthcare methodology improves the care pathway by focusing on health outcomes rather than on efficiency alone, and uses outcome, output and cost indicators to assess the achievement of results. To adopt the VBHC, it is necessary to carry out feasibility studies to measure the value of services, involving not only doctors but all health service stakeholders, and attributing private citizens an active role.

This can be seen, for example, in the Liguria Region, which implemented a pilot project within Local Health Authority 4, with a view to extending it to the rest of the region. The aim of this project is to implement the issues addressed in the PNRR, in terms of organisation and management, using tools such as Lean learning and telemedicine, in order to form interprofessional groups within the various health authorities and districts, to design processes with a common approach. Similarly, in the Narni district of the Puglia Region, attempts to relocate medicinal products are being implemented through pilot projects.

The Value-Based Healthcare methodology could then support the introduction of the concept of organisational essential levels of care, thus assuring patients not only outcomes, but also healthcare organisation that is always directed towards their achievement.

Lastly, the VBHC methodology could provide support in the systematic efficacy, accuracy and dissemination of the minimum requirements of the healthcare facilities in the community, as is evident from the first drafts of the soon to be issued Ministerial Decree no. 71. In this scenario, which needs to be deepened and widened, the VBHC methodology could provide



support for devising minimum Functional Unit accreditation standards, in order to identify “hospital-like settings”. More specifically, the draft version of Ministerial Decree no. 71 provides for the definition of standards for the following identified community locations:

- District: 1 per 100,000 inhabitants, including 1 or 2 Community Hospitals, 2 Hub and 2 Spoke Community Health Centres, 1 Hospice and 1 nursing home;
- Community Health Centre: 1 per 40-50,000 inhabitants, including a hub and spoke network with peripheral local outpatient clinics with a multidisciplinary team providing 24-hour care;
- Community Hospital: 1 per 50-100,000 inhabitants, including 20-40 beds for low-intensity and short-term interventions.

The Value-Based Healthcare methodology is already being used in some pilot cases, which constitute good practices to be promoted, disseminated and made systematic. The goal pursued by the SMART Care International working group is to employ the VBHC methodology to progress from limited trials to structured, systemic, region-wide programmes.

The Value-Based Healthcare methodology

In 2006, Michael Porter, an economist at Harvard Business School, published the book “Redefining Health Care: Creating Value-Based Competition on Results”, initiated the transition towards a Value-Based Healthcare (VBHC) system. According to Porter's definition, value-based healthcare focuses on maximising the “value” of care for patients and reducing the costs of healthcare. The management of a healthcare organisation must be able to cope with bureaucratic and administrative duties, while keeping the patient's Value at the centre of its work.

Figure 10 illustrates Porter's Patient Value formula.

$$\text{Value} = \frac{\text{Patient-relevant results (in terms of outcomes)}}{\text{Costs per patient in order to achieve these results}}$$

Figure 10: Porter's Value formula

4.2 Developing the organisation of community care

Integration between hospitals and the community is one of the most critical aspects of healthcare. During the COVID-19 pandemic, a number of virtuous cases of interdisciplinary integration were developed; however, in the light of the improved pandemic situation and the recent development of the community setting, we now need to leave behind the emergency scenario and design a new permanent management model. The community must become an area with a solid and defined organisation that has the credibility of a hospital setting.

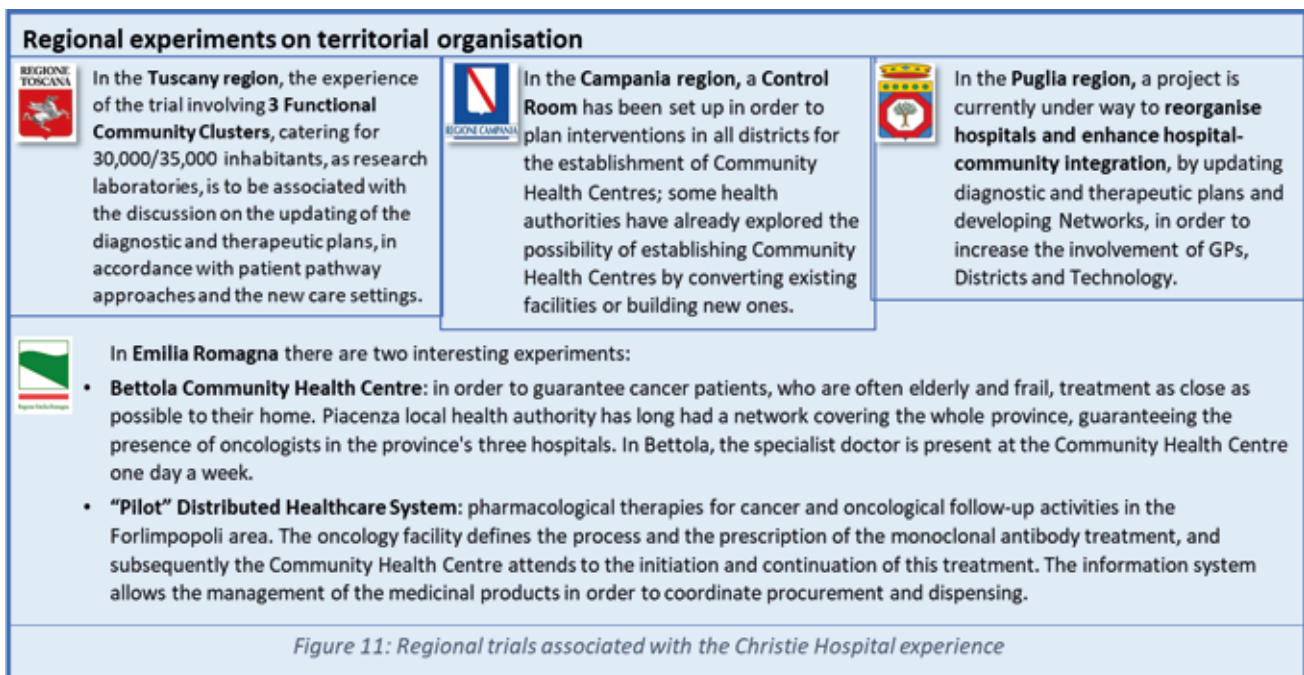
It is therefore necessary, in action and legislative documents, to overcome the silo approach, which prevents the patient pathway being followed in its entirety, and to define the organisational aspect of the Districts, which must be sturdy and structured. A key role is played by the Community Help Desk, which coordinates the activities of the various Districts.

Another, equally fundamental, element is the updating of diagnostic and therapeutic plans, within which it would be



appropriate to outline the most ergonomic care settings, calibrated to cater for the diverse needs of the natural history of each medical condition.

As far as territorial organisation is concerned, several experiments are known to be underway in Campania, Tuscany, Puglia and Emilia Romagna, as shown in Figure 11. The experiences described can be associated with the Christie Hospital (Section 3.2), which provides cancer treatment in near-patient environments, through satellite clinics and mobile units in order to reach a larger number of patients¹⁸.



4.3 Redesigning staff roles and skill sets

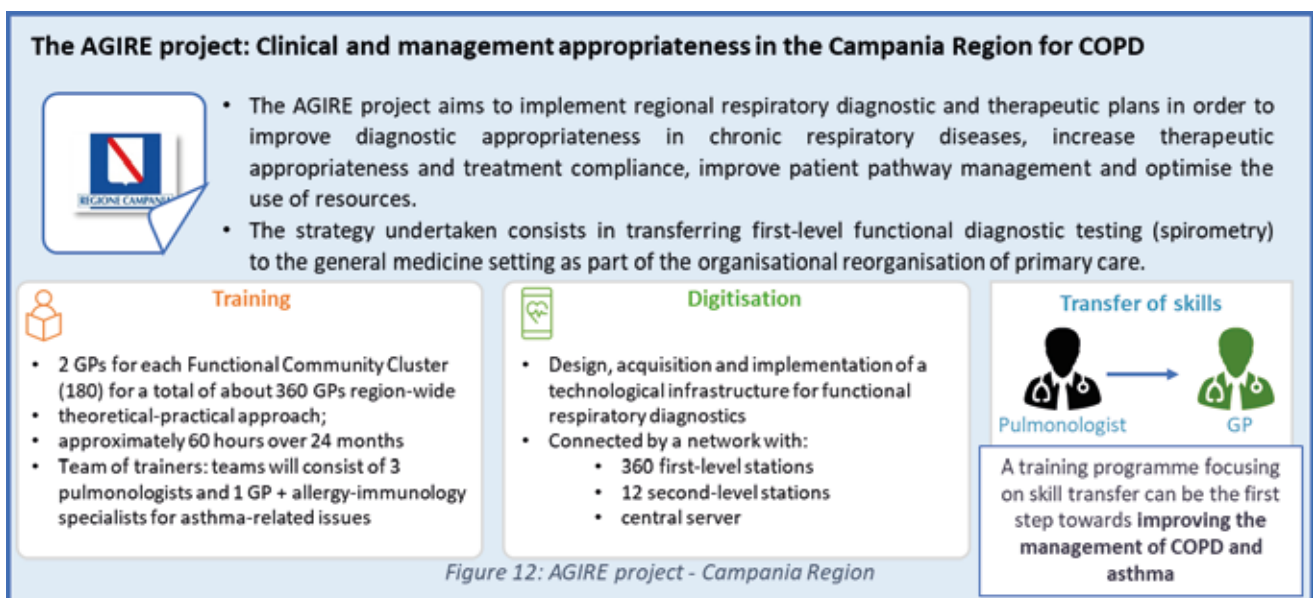
In order to make the desired change in the territorial organisation efficacious, there needs to be a simultaneous redefinition of the roles and skill sets of healthcare professionals. The patient pathway must necessarily involve all specialists and activities that may be involved in the management of the illness. Specialists must therefore feel part of the pathway and work in multiprofessional teams, ensuring a continuity of approach between the various settings involved.

The main limitation in the management of staff roles is the shortage of human resources, which is widespread across the country. This is a major concern, which has been partially overlooked by planned activities and investments (PNRR, Ministerial Decree no. 71). As things stand at present, it is not possible to guarantee the stabilisation of the healthcare professionals recruited during the COVID-19 pandemic and, at the same time, further staff reductions are expected in view of the forthcoming retirements.

¹⁸ <http://www.ausl.pc.it/news/newsDettaglio.asp?idnews=2704>; Distributed Healthcare System Digital health assistance: distretto, cronicità oncologica e assistenza primaria, una sfida di complessità clinica e organizzativa



A different approach to the management of the healthcare professionals present should therefore be considered, with reallocation designed to cover the areas with the greatest shortages and that are most relevant to the needs of the population. In this sense, it is necessary to redesign the roles of specialists and their degree of involvement in the pathway, as well as systematically forecasting the need for human and structural resources to be allocated to the community setting. Within this context, the District Director plays a key role in the management of community care and therefore requires specific training, with a corresponding certificate and the establishment of a national register to be consulted. At the same time, general practitioners should become, following appropriate training, the coordinators of the entire patient pathway for certain chronic conditions, through direct interaction with the specialists involved in the care pathway. In this regard, the AGIRE project carried out by the Campania Region is exemplary (Figure 12) with regard to the transfer of skills from specialists to GPs in the management of COPD.



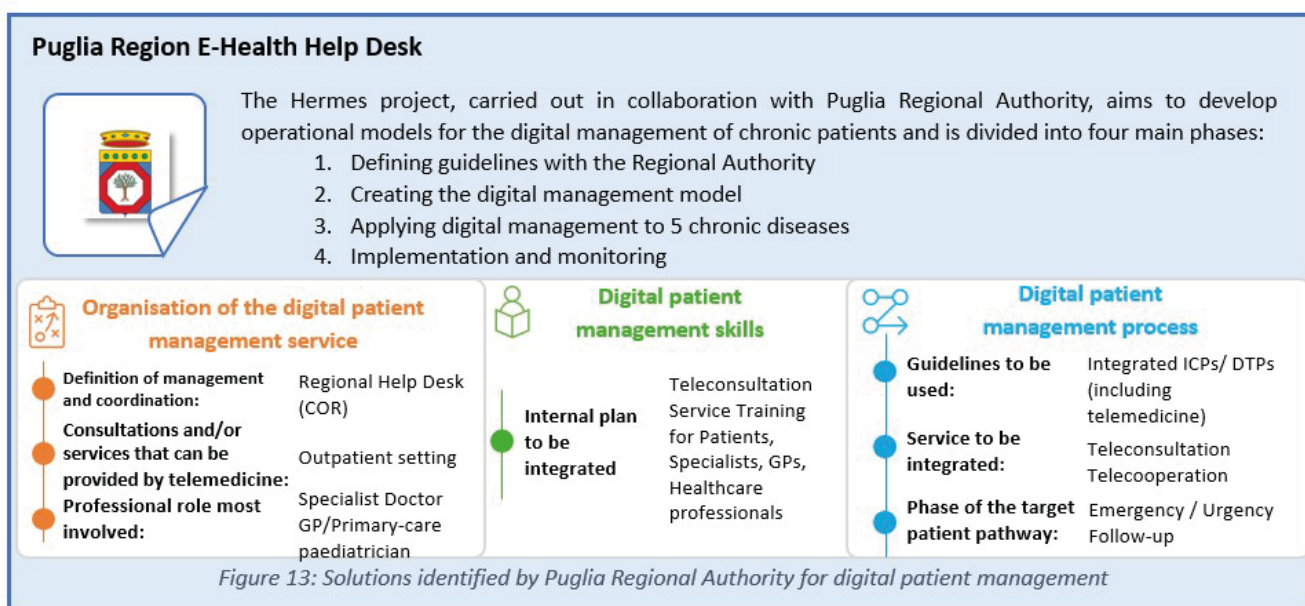
4.4 Digitising healthcare

Digitisation is a key functional factor of hospital-community connections, as it can ensure the sharing of medical records, direct communication and, ultimately, better overall patient management. The current situation of the telematics infrastructure is burdened by an organisational delay, which hampers communication and data transmission. To overcome this limitation, telemedicine needs to be structured and supported in terms of training and management, in order to avoid fragmentation of the pathway. Although the Italian Electronic Health Record is an extremely valuable tool, it is one in which further resources need to be invested, as it is currently merely a repository of more or less structured documents, which cannot be equiparated with the EHR (Electronic Health Record) concept. Last but not least, data protection is an important issue, as the transmission of sensitive and health-related data necessarily involves the management of data protection, which is often an obstacle to sharing. Although this aspect is of nationwide importance, there is currently no evidence of applicable solutions. The COVID-19 pandemic has brought to light a worrying fragmentation of IT systems and platforms, with COVID patients



being managed through independent and non-communicating platforms, each with its own access credentials, leading to a lack of data sharing.

Telemedicine, and remote consultation and teleconsultation platforms in particular, can help reduce problems associated with understaffing. The Hermes project carried out in the Puglia Region (Figure 13) and the establishment of the eHealth Help Desk (COR eHealth), which can be associated with the Airedale Hospital experience (section 3.3), are exemplary in this sense.



4.5 Developing the role of the pharmacy

The role of the pharmacy, be it a hospital or a community pharmacy, is crucial to the management of the patient pathway. As far as Community Pharmacies are concerned, investments in rural pharmacies are provided for in the Cohesion Mission of the PNRR, in order to strengthen the service of municipalities with fewer than 3,000 inhabitants. The SMART Care International working group believes that action must be taken to invest in pharmacist training and upgrade facilities, in terms of services and technology, in order to improve and support the patient pathway.

As far as Hospital Pharmacies are concerned, it is worth considering the role of the Hospital Pharmacist, who is dedicated mainly to clinical activities. In this sense, the management of home delivery of the medicine, which should be coordinated by the pharmacist, must first be dealt with in order to allow the cohesion of the two activities.

The issue of the relocation of hospital medicines hinges around two main aspects: dispensing and administration. Dispensing and home delivery require the establishment of an appropriate system based on precise and standardised logistics. Administration, on the other hand, presents a greater challenge, particularly in terms of verification and monitoring. In this regard, investments are required, first and foremost, in the healthcare professionals to be designated to this aspect; secondly, the involvement of non-healthcare professionals could be contemplated to facilitate home-based administration. For example, caregivers, if properly trained and educated and in direct contact with health professionals, through the use of

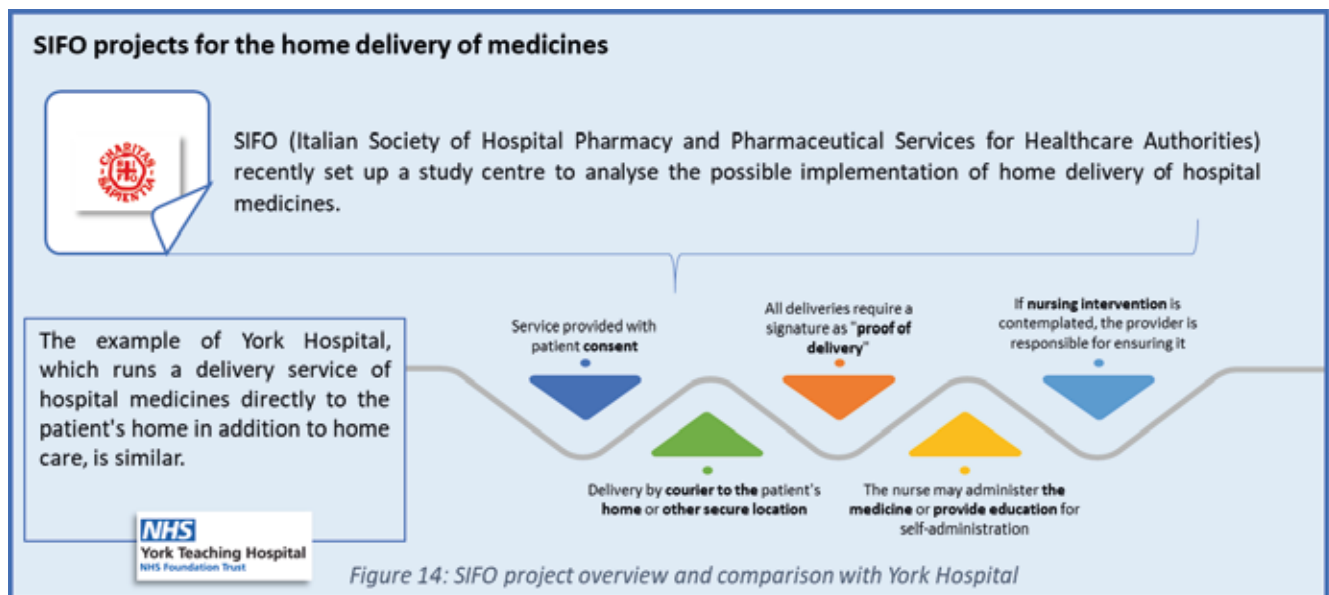


telemedicine platforms, could significantly improve this service.

The development of intermediate care and, in particular, of Community Hospitals represents a further opportunity to stabilize certain experiments carried out during the emergency period: in the Puglia region, Community Hospitals are currently being used to administer monoclonal antibodies to “pre-COVID” patients, who do not require hospitalisation for acute care. This example illustrates the potential of intermediate facilities as locations in which hospitals and community care meet.

Another aspect that the SMART Care International working group believes must not be neglected, is the management of drug-drug interactions, which are often overlooked at the prescription stage. It would therefore be appropriate to define the dispensing phase with specific criteria in order to protect patient safety. This can be facilitated by the use of supporting technological tools.

Figure 14 illustrates the SIFO experience regarding the research project on the home delivery of hospital medicines, which is similar to the international example of York Hospital.





Conclusions

In the light of the international experiences, the PNRR and the imminent Ministerial Decree no. 71, the reorganisation of community care is a key factor of future healthcare models, in which medicines constitute an important element.

The analysis and discussions carried out by the SMART Care International working group highlighted the relevant aspects of some European countries regarding the relocation of medicines and identified areas of concern.

In order to achieve this objective, action must be taken to give physicality and content to community care, by relocating services typically managed in hospitals, which can instead be transferred to more appropriate treatment settings, thereby making them accessible at community level. It is equally important to think in terms of minimum requirements, tools and concrete elements, to accelerate the national regulatory framework and the subsequent Region-specific adaptation.

The SMART Care International working group believes it is important not to overlook the management of the emerging care areas and the aspect of role distinction: it is necessary to define the management of patient care, which should ideally be entrusted to a multidisciplinary team. The investments contemplated by the PNRR and Ministerial Decree no. 71 provide a unique opportunity to redefine the role of community and intermediate care, focusing primarily on the Community Hospital within the District and the Intermediate Care setting.

According to the recent suggestions made by AGENAS with regard to Ministerial Decree no. 71, the future configuration of care should favour and support - in terms of planning and investment - the community setting, providing for organisational levels of a lower complexity than those of hospitals, supported by disease networks and the implementation of telemedicine and teleconsultation, especially for complex chronic conditions, and identifying the characteristics and requirements for "hospital-like settings" in order to guarantee efficacious, safe and high-quality services. In this perspective, the development of Community Hospitals, Community Help Desks and Community Health Centres will play a pivotal role, if they classify as "hospital-like settings".

Community Hospitals are intended for patients who require low-intensity, short-term clinical interventions; within these structures, nurses will play a key role, as they will be responsible for the majority of management tasks.

Community Help Desks will play a fundamental coordinating role in overall patient management and interconnection by means of an information system shared with the Regional Help Desk (toll-free number 116117). Subsequently, it will be possible to consider the development of Community Health Centres, to provide an organisation covering the whole of the local area and providing a continuous reference point for the population. Unlike Community Hospitals, Community Health Centres will offer multidisciplinary services and basic diagnostic technologies. However, the synergistic development of intermediate care will be necessary to achieve this transition.

The PNRR, as described above, and Ministerial Decree no. 71 must unambiguously clarify the standards and requirements for the new care settings.

Lastly, in order to put the projects into practice and use the available resources, the SMART Care International working group considers it essential to focus on structuring pilot projects, on a regional scale, in close collaboration with Agenas and the Ministry of Health. Subsequently, the main objective must be to rebalance the management of complex chronic diseases, between hospital and community care, in which a fundamental role will be played by Community Health Centres, Community Hospitals and home care, integrating the relocation of hospital medicines as a key element of the continuity of care.



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