

Case Study Summary Italy

Summary

No official policy statements or regulatory guidelines on polypharmacy have been released to date by Italian Health Authorities. However, it should be acknowledged that the growing awareness of the problem has been documented by the release of observational studies on this issue by national study groups and scientific societies.

Medication reviews, conducted by application of appropriateness criteria and computerized decision support systems are approaches designed to improve the quality of prescribing for older people. In order to implement such strategies, more focused training courses on multimorbidity and polytherapy management are mandatory within healthcare curricula. Furthermore, the integration to a multidisciplinary team (physicians, pharmacists, and nurses) may positively impact on:

- Reducing the prescribers sense of fear to discontinue or substitute drugs prescribed by others;
- reducing the drug therapy fragmentation among different specialists;
- reducing costs; and,
- improving adverse drug reaction detection and reporting.

Lack of management programmes and/or working policies in Italy regarding polypharmacy prescription and adherence to drug therapy and management, particularly among older adults, stimulated the design of a pilot study aimed at providing an evidence-base of the current status of polypharmacy in Italy. Focusing on the Campania Region, and on Naples metropolitan area, data were obtained from a large tertiary care hospital (in particular from several Departments of Federico II University Hospital) representing the current protocol applied when prescribing for older patients with excessive polypharmacy. A multidisciplinary approach starting with identification of patients at risk of drug-related problems, followed by medication review over a period of time and the application of inappropriateness criteria, supported by computerized decision support and electronic prescribing systems, was embedded in the comprehensive geriatric assessment aiming to achieve the best-tailored pharmacotherapy for each patient.

Characteristics of the case study

Name of the programme

View on polypharmacy in Italy

Locality/region and country

Naples, Campania Region, Italy

Health care system overview

The global economic and financial crisis is having a strong impact on the Italian healthcare system. Therefore, in 2001 there was a devolution process from the central government to regions, setting “essential care levels” (Livelli Essenziali di Assistenza or LEAs), a package of benefits that are publicly funded and must be guaranteed to all citizens in all regions. Most essential drugs are

included in LEAs. This law (no. 405/2001) established the possibility for each region to adopt co-payment policies for citizens to contribute to the cost of pharmaceuticals by a fixed amount per prescription, ranging from 1 to 5 euros, depending on the region. Patients can benefit of an exemption from co-payment in case of low income or affection by specific chronic diseases. Also the exemption policies are decided on a regional basis. Therefore, the regionalization process established cross-regional variation. About one third of the regional governments, mainly in the central and southern part of the country, are facing substantial financial deficits. Today, Campania is one of the regions in payback plan. The Italian health care system is supported by the National Health Care fund and is determined on a yearly basis through the Balance Approval National Law. Then each region takes care of unifying the health care performance through regional laws, distributing their percentage assigned from the Health care fund among local health units. Moreover, in light of the global economic and financial crisis, tighter cost-containment measures on public health expenditure have been proposed and are being slowly implemented (e.g. caps on specific spending areas). At the same time, higher co-payments for outpatient/ambulatory care; diagnostics and drugs have been introduced, adding to private spending on health. The central issue with health service delivery is the heterogeneity of regional arrangements. In general, northern and central regions appear to keep pace with institutional, organizational and professional developments aligned with best international practices and in line with central government orientations, while southern regions appear to lag behind. The gaps between northern and southern regions mainly reflect socioeconomic and cultural factors that are far beyond the health-care system. However, it is also likely that decentralization policies introduced in the last two decades have not favoured the health equity of regional systems, as they provided opportunities for improvement to the best institutionally equipped regions while leaving southern regions with less central support to cope with more difficult social contexts, that cannot be addressed solely by policies aimed at economic balance. For example, support for preventive interventions and strategies of health promotion, when horizontal cuts are applied, lag behind and the focus switches to disease management rather than to approaches that demonstrate their sustainability in the medium-long term. Infrastructures aimed at exploiting evidence through tailored health information systems can help reduce the gaps in health equity to a more equitable social and health service provision, especially when paralleled by strong approaches to citizen empowerment and lifelong learning. In addition, important achievements in terms of waiting lists, continuity of care and patient centeredness, as well as integration between social and health care, are negatively affected by unprecedented horizontal resource cuts. These cuts are likely to cause a paradoxical effect on health outcomes, leading to a lack of or inadequate programmes for polypharmacy management and prescription adherence.

Programme aims and objectives

Polypharmacy and medication non-adherence in the older population are growing public health issues throughout the European Union (EU), and are critical issues in integrated care. Older persons who are affected by multimorbidity are prescribed polypharmacy and they are at high risk of over-prescription, inappropriate use of medications and drug-related problems.

In Italy, healthcare professionals have acknowledged the absence of key policies and procedures focusing on polypharmacy management in older adults. Some regions developed polypharmacy consensus papers or local policies (Toscana, Lombardia, Emilia Romagna). These documents also suggest some warnings on potential inappropriateness prescription in the elderly. Although the stakeholders have an awareness of the need to develop strategies for polypharmacy management,

there is a lack of policies at a national level and a clear need for development of a comprehensive practical guideline.

This case study aims to provide insight into a) why policies regarding polypharmacy and adherence in Italy have not been implemented; b) how relevant programmes could be developed, implemented and evaluated including possible barriers and facilitators of change.

Institutions included in case study

Federico II University Hospital, the largest tertiary care hospital of Campania Region. It is a facility for the entire region (>5 800 000 residents) and neighbouring areas. Its mission is integrating research, training and health service provision, for which its involvement can ensure a multidimensional approach to innovations. Furthermore, it provides expertise in the field of Internal Medicine, Geriatrics, Clinical Pharmacology, Multimorbidity and management of complex prescription regimens. Its integration with Federico II University ensured multidisciplinary expertise, such as with its Centre of Regional Relevance for Drug Prescription and Appropriateness Analysis (CIRFF). CIRFF has been contributing to the involvement of pharmacists to the implementation of the pilot study.

Managerial and policy highlights of the programme

Moving from importance to urgency

The absence of key policies and procedures in Italy focusing on polypharmacy management in older adults emerged from our case study. This could be ascribed to the heterogeneity in health policies among different Italian regions. In fact, Italy is characterized by a National Health System, which is differently planned, administered and organized at the regional level. Hence, local results on inequalities in health services utilization can be interpretable with specific reference to the regional context; therefore, scaling up data at national level is desirable. Moreover, it should be highlighted that, in Italy, the role of clinical pharmacist is still being defined. Community pharmacies are developing more comprehensive approaches to pharmaceutical care, but process is still at an early stage. Although, in 2009, it was approved by National Law (no. 69/2009) that the role of community pharmacy which was intended as a multipurpose centre of services. This Law is still far from being fully implemented. This is due to a number of factors:

- Slow increase in political interest in promoting the role of pharmacists as caregivers.
- Absence of financial investments to support this kind of service.
- Poor organization and communication between stakeholders both at local and national level.

Overall, therapeutic review and reconciliation are two mandatory steps in both the prescribing process and the de-prescribing process (the process of tapering off or stopping drugs). In fact, the same good practices and principles should be applied when a drug therapy is initiated and when it is discontinued. However, tools to assess quality of prescribing and avoid inappropriate drug prescriptions should be implemented. During the last few decades, much effort has been directed towards improving the quality of drug prescription in older adults, and several criteria have been developed. However, the lack of data integration and interoperability of ICT solutions in healthcare is a national issue in Italy. In 2016, Italy is still lacking a nationwide e-health record. In addition, pilot studies do not translate well in regulatory actions of the National Health System. Several pilot

studies have been conducted in Italy; however, data obtained were not well received at Ministerial level and not translated into formal guidelines or policies.

In our case study, an increase in awareness on polypharmacy and its logistical effects on economics, ethics and health-related issues has been detected. A multidisciplinary team approach including general practitioners (GPs), consultants, pharmacists, nurses and pharmacologists has been proposed to optimize therapeutic strategies in patients prescribed polypharmacy. The teamwork practices are to be supported by ICT.

Creating teams and strategic vision

The optimization of prescribing processes in the elderly is emerging as a mandatory element for healthcare systems. However, in polytherapy management, the problem is not just the drug therapy in itself, but also the appropriateness of diagnostic pathways in order to rationalize resources for each patient. A multidisciplinary team (physicians, pharmacists and nurses) should work together in order to define the best strategy for polytherapy management, appropriateness and de-prescribing. Stakeholders should be encouraged to allocate resources to this healthcare area.

Creating practice models

In Italy, the absence of key policies and procedures on polypharmacy management strongly impact on current clinical practice. Fragmentation of therapy among and between different specialists and GPs is relevant, highlighting the lack of coordination among healthcare professionals. The lack of resources due to cutbacks, together with the healthcare system regional devolution, negatively impacts development of polypharmacy management policies. This case study revealed that a multidisciplinary approach represents the best strategy for polypharmacy management. At least at the initial step, case study participants suggested enrolling only healthcare professionals who are already motivated and accepting a multidisciplinary approaches at work. Resistance to change (cultural barriers) is a major issue for polypharmacy management: communication between different healthcare professionals should be implemented in order to build solid multidisciplinary teamwork. University training courses and curricula specifically focused on polypharmacy and adherence programme should further support polypharmacy programmes. These programmes should be delivered to medical, pharmacy and nursing students. Healthcare Professional Councils should be engaged to support the initiatives related to polypharmacy and adherence review programmes; as well as pharmaceutical industries which should be involved in the initiatives related to polypharmacy and adherence review programmes. GPs should be consulted and encouraged to reduce their workload by delegating agreed tasks to other healthcare professionals (pharmacists and nurses) to make the most of the skills of each healthcare profession. In line with other countries, community pharmacies should be integrated to GP practices for polypharmacy and adherence review programmes; and clinical pharmacist (working on hospital medical wards) should be fully adopted and engaged as health care professionals in Italy. Finally, health ICT infrastructure may help to suprogrammesupport implementation, communication and monitoring of a programme.

Building sustainability

A pilot study specifically focused on a polypharmacy and adherence management programme ("FRIENDD", Farmaci Rivisti Insieme: Empowerment nelle Diverse Discipline) has been proposed. This pilot study aims to involve patients with chronic diseases from different hospital wards (Internal Medicine, Geriatrics, Rheumatology, Endocrinology) to set-up, test and implement a

procedure to revise their prescription regimens in collaboration with the Pharmacosurveillance Unit of the hospital. The primary objective of this pilot study is to evaluate the polypharmacy regimen in elderly patients aiming to improve the appropriateness of the prescribing. A multidisciplinary team (clinical specialists, clinical pharmacologists; clinical pharmacists) will systematically review the drug regimens in patients with at least two chronic diseases and taking more than six drugs.

The findings of this project will be illustrated to Campania Region decision makers and to the ProMIS network of Italian Regions, in order to elaborate specific pathways for polypharmacy management at local, regional and national levels.

Conclusions

This case study provided insights into a) why policies regarding polypharmacy and adherence in Italy have not yet been implemented; b) how relevant programmes could be developed, implemented and evaluated highlighting any possible barriers and facilitators of change.

The main findings of this case study are that:

- Pilot studies should be designed to create evidence on outcomes of polypharmacy in elderly comorbid patients;
- stakeholders should be actively involved in designing and implementing polypharmacy management programmes;
- stakeholders should be sensitized to allocating resources to polypharmacy management programs;
- specifically focused educational programmes are the foundation for success in polypharmacy programme development;
- healthcare Professional Councils and Universities delivering healthcare professional education programmes should actively support and promote polypharmacy programmes;
- a multidisciplinary approach, starting with identification of patients at risk of drug-related problems, followed by medication reviews over a period of time, and the application of inappropriateness criteria, supported by computerized decision support and electronic prescribing systems need to be embedded in the comprehensive geriatric assessment. This should be adopted with the aim of achieving the best-tailored pharmacotherapy for each patient.