

Stewardship and cancer screening programs in Italy

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Abstract

As one of the four major functions of health systems, Stewardship is on the health agenda of several countries worldwide. There is, however, little empirical evidence to support or guide its implementation. To help bridge this gap, the paper aims to contribute to the empirical evidence for health system stewardship and, importantly, to offer implementers an explanatory example of what it could mean in practice. It achieves this by analyzing the experience of the Italian Cancer Screening Programs (from 2004-2009) within a comprehensive framework for health system stewardship. The analysis is largely based on primary and secondary qualitative data, using information collected from an in-depth interview, official documents, and scientific and grey literature. We describe the framework and sub-functions of stewardship, identify the stewardship activities that were carried out by the Programs, and reflect upon the operability of the framework as well as the activities that the Programs have not implemented but would benefit from doing so. The general experience and activities of the Italian Cancer Screening Programs fit well into the stewardship framework, despite not having followed it a priori. Overall, the Programs managed to implement most activities under each sub-function. As an empirical case study, they corroborated the theoretical framework and demonstrated how it could be translated into certain activities on an operational platform. Ultimately, the analysis showed that the framework of stewardship is useful for structuring and prioritizing the most important activities of a steward and, thus, provides a good benchmark for implementers.

Key words: stewardship, cancer screening, Italy, health systems

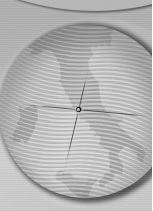
Introduction

Over a decade ago, the World Health Organization's seminal annual report introduced the concept of stewardship to the health sector, identifying it as one of the four major functions of health systems worldwide [1]. It distinguished stewardship from governance, defining it as the "careful and responsible management of the well-being of the population." Subsequently, a series of reports and articles further expanded upon the concept and defined its conceptual framework. Travis et al. framework for stewardship [2] is arguably the most referenced and comprehensive of these in the health system literature.

Following these efforts, stewardship has been on the health agenda of many countries worldwide. Most notably, in June of 2008, it was included in the Tallinn Charter, which was adopted at the WHO European Ministerial Conference on Health Systems and endorsed by all 53 Member States in

the WHO European Region [3,4]. As such, these States committed themselves to catalyzing the implementation of health system stewardship by pledging the following:

"While each Member State has its own way of governing its health system, ministries of health set the vision for health system development and have the mandate and responsibility for legislation, regulation and enforcement of health policies, as well as for gathering intelligence on health and its social, economic and environmental determinants. Health Ministries should promote inclusion of health considerations in all policies and advocate their effective implementation across sectors to maximize health gains. Monitoring and evaluation of health system performance and balanced cooperation with stakeholders at all levels of governance are essential to promote transparency and accountability."



- Tallinn Charter: Health Systems for Health and Wealth

Supported by a conceptual foundation and Charter, today, European countries have begun to understand the practical means of stewardship. However, they have little empirical evidence to support or guide its implementation. Moreover, they lack relevant data and information for its proper measurement. The reason for this is two-fold: (i) stewardship is a fairly new concept to health systems, and (ii) its theory has not reached an operational level. For example, take Travis et al. stewardship framework; when applied empirically, it leaves substantial room for interpretation by the author(s) [5]. This makes it less robust for cross-country analysis and more difficult to understand the effects of the implementation of stewardship [5].

To help bridge the gap between theory and practice, it is useful to compare the conceptual framework for health system stewardship to a detailed case already in motion. As such, this paper examines the experience of the Italian cancer-screening programs (or CSPs) within Travis et al. framework for health system stewardship. In particular, it attempts to verify the framework's operability in practice and to better understand how it might be strengthened for implementation. Its objectives are to contribute to the empirical evidence for health system stewardship and, importantly, to offer implementers an explanatory example of what health system stewardship could mean in practice.

In the following, we first describe the paper's analytical framework and methods. Next, we provide a brief history of the development of CSPs in Italy over the past decade. Then, we present the findings of the analysis, looking at the elements of the CSPs that both coincide with and deviate from the stewardship framework. Following this, we discuss the results of our analysis and offer some conclusions on the exercise and recommendations for future work.

Analytical framework and methods

The study analyzes the Italian experience managing and administering its national CSPs during the period 2004-2009 and compares it with Travis et al. stewardship framework² for health systems. Prior to 2009, the Italian CSPs were carried out according to *business as usual* and not with the stewardship framework or method in practice. As such, it provides an example for understanding how the programs' functions and activities are organized or not in terms of the framework.

We chose the Italian CSPs for several reasons: (i) they are part of the nationally-defined benefit package (called the *Livelli Essenziali di Assistenza* or LEA) [6], over which the Ministry of Health (MoH) has particular influence; (ii) combined, they involve almost half (47%) of the Italian population; and, (iii) despite devolution, they are based on the same organizational model for implementation and evidence across the 20 Italian Regions.

Travis et al. framework proposes six main sub-functions of health system stewardship:

(F1) Formulate a strategic policy framework;

(F2) Ensure a fit between policy objectives and organizational structure and culture;

(F3) Ensure tools for implementation: powers, incentives and sanctions;

(F4) Build coalitions and partnerships;

(F5) Generate intelligence; and,

(F6) Ensure accountability.

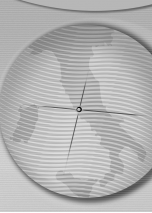
Although unconventional, we present the conceptual description of each function in the findings section under its corresponding heading, and preceding the actual findings. Although there may be multiple stewards of the health system, for our analysis we reflect mostly on the stewardship actions of the Italian MoH for CSPs. In devolved systems, the MoH is often referred to as the 'steward of stewards', with the latter being the regional ministries of health.

The analysis is based on primary and secondary qualitative data. We reviewed the literature on health system stewardship in theory and practice, using official documents, and scientific and grey literature. We also conducted an in-depth interview with the lead officer on CSPs at the MoH. Finally, we utilized secondary quantitative data on CSPs in Italy.

The analysis has two main limitations. First, since the programs were not previously implemented under a strategy or framework of stewardship, it does not measure how well the Italian CSPs adhered to the stewardship framework but rather how the programs already in place fit into the framework. Moreover, from the analysis, no causal relationships between the policy and practice of stewardship can be drawn. Second, because the analysis and use of stewardship framework were applied to specific health programs and not to the health system as a whole, some sub-functions of stewardship are not carried out by the stewards of the programs but rather by those of the health system as a whole.

Cancer screening programs in Italy

Italy has a National Health Service (NHS) that provides universal health care coverage to its



population. From the 1990s until 2001, the NHS decentralized health service management from the central to the regional level of government. As a result, today, the central government MoH is responsible for ensuring the general objectives and fundamental principles of the NHS; while the regional governments, through their regional health departments, are responsible for ensuring the delivery of a nationally-defined benefit package (or LEA) through a network of public and private service providers (clinics and hospitals). [7] The benefit package is financed primarily by earmarked central and regional taxes. The Regions may choose to provide additional health care services with their own resources as well.

In 1996, the MoH published clinical guidelines for breast, cervical and colorectal cancer, and began providing mass-population screening programs for them. These Programs (or CSPs) were designed to reduce cause-specific mortality rates in target populations, as defined by age-related risk to develop cancer (average-risk population). Since 2001, these CSPs have been included in the LEA for average-risk populations. [8] In 2001, breast and cervical CSPs were active in more than half of the Italian Regions, reaching almost 30% of their target populations nationwide (Table 1) [8-10]. Colorectal CSPs, however, were not yet active in any of the Regions.

In response to the low screening coverage and following the Council of the European Union's [11] endorsement of CSP, the Italian

MoH designed its first national plan for cancer screening (Piano Nazionale dello Screening or PNS). The plan aimed at strengthening breast and cervical cancer-screening and initiating colorectal cancer-screening in the country. It was set for three years (2004-6) and had its own budget to motivate the Regions - especially those without active programs - to reach complete coverage of their target populations. By the end of 2004, breast and cervical CSPs were active in almost all Regions, whereas colorectal CSPs were active in only six Regions. Moreover, they had only reached 50% and 5% of their target population nationwide, respectively [9].

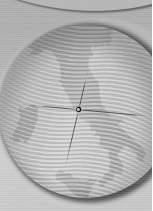
Thus, while the CSPs were improving their coverage, they still required further policy interventions. So, in 2005, the MoH and the Regions signed the first (five-year) National Prevention Plan (PNP), which was parallel to the PNS and included provision of CSPs to the population. The PNP established a level of results-based financing for prevention activities, modifying the way the Regions usually received funds. Following this, the second PNS (2007-2009) was created similar to the first but with new special funding directed to the lower performing southern Regions [7].

With this political and financial backing, CSPs in Italy came even closer to reaching their targets. By 2008, all Regions (20) had at least one active CSP. Moreover, a total of 51.4% of all three target populations (or 8.45 million people) had been invited to participate in CSPs

Table 1. Percentage of the target population invited to participate in CSPs and the number of Regions (n=20) with at least one active CSP.^[8-10]

CSPs	2001		2004		2008	
	% Target population	Regions (20)	% Target population	Regions (20)	% Target population	Regions (20)
Breast (Women age 50-69)	29.9	13	51.9	18	67.5	20
Cervical (Women age 25-64)	33.9	16	51.7	19	65.4	19
Colorectal (Men & women age 50-69)	0	0	4.7	6	41.6	18

Note: For the considered period, in southern Regions, there were persistent delays in implementation of CSPs.



nationwide, meeting the European Council's recommendation criteria [11]. In particular, breast CSPs had invited close to 67.5% of the target population, cervical CSPs 65.4% and colorectal CSPs 41.62% [10]. Considering such progress, the second PNP (2010) [12] was designed to absorb the objectives and functions of the PNS. Importantly, it explicitly mentioned stewardship as the governance framework that the MoH should adopt for implementing its objectives.

Findings

In this section, we present the findings of the analysis. Each of the six sub-sections is dedicated to a sub-function of Travis et al. framework for health system stewardship [2]. First, we give a brief description of each sub-function. Then, we compare it with the activities carried out by the Italian CSPs between 2004 and 2009, highlighting the activities coinciding in both, and those included in the framework but not carried out by the programs.

F1: Formulate strategic policy framework

Formulating a strategic policy framework is a key stewardship sub-function of the NHS and, in our case, CSPs. Under it, the steward should articulate a vision for the programs as well as goals and objectives for the short- to long-term. It should clearly define the roles of the public, private and voluntary health sectors for the programs. It should also outline feasible strategies, guide the prioritization of health expenditures, and monitor the performance of sub-centrally run health services.

The Italian CSPs follow two national strategic policy frameworks, one that is a policy guide for the whole system (the PNP) and another that sets the strategy for implementing the CSPs (the PNS). These plans are drawn up by the MoH and agreed on by the Regions at the highest platform for coordinating and making executive decisions on the health system, the *Intesa Stato-Regioni*. While both plans define the goals and objectives for CSPs in the relatively short-term (3-year plans, with activities by year), they do not explicitly set a vision or mission nor do they include a longer-term planning mechanism, which are both important for health systems.

While the PNP defines the roles of health sector actors in general, the PNS defines the stakeholder roles and program needs, and promotes planned research for the CSPs. Moreover, the PNS defines the objectives and interventions of the CSPs and whether or not the MoH needs to enter into third-

party agreements with external organizations to deliver such interventions. It also delineates the parameters and quality standards for the programs' intelligence, including how it should be collected, monitored and evaluated.

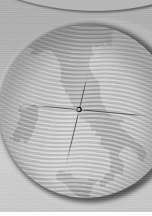
F2: Ensure a fit between policy objectives and organizational structure and culture

Important for the successful implementation of the health system, the steward is responsible for guaranteeing the overall architecture of the health system and its coherence with the social and cultural values of the country. As such, it should work to minimize overlapping roles, undesirable duplication of services and fragmentation within the system.

The general architecture of the health system, which encompasses CSPs, is embedded in the laws and norms of the country. Its foundation is the 1947 Italian Constitution, which stipulates the right to health and health care (including preventive care) for all citizens. To guarantee this right, the 1978 general health law mandates the establishment of an NHS. The health system architecture also articulates different plans and strategies for implementation of CSPs. The NHS's structure is generally aligned with the cultural and societal values of the country as well as its policy objectives. This is reflected by the population's satisfaction with the regional health services. In 2005, 43.4% were satisfied and 34.0% were highly satisfied. [13] Moreover, worldwide, Italy ranks second only to France in overall health system performance [1].

The specific architecture of the CSPs was laid out in the PNP and PNS combined. On the one hand, through these plans, the MoH has shown agility by changing their policies in response to evolving needs overtime. Created as a temporary source of additional funds, the PNS incentivized the implementation of CSPs until their goals were attained. The PNS was, then, discontinued but its objectives were incorporated into the PNP.

On the other hand, the MoH has faced challenges to consolidate the organizational structure of its CSPs. It originally arranged the CSPs according to a disease management model. In parallel, however, primary health care providers at the Local Health Unit-level (*Agenzia Sanitaria Locale* or ASL) are also delivering CSP interventions upon request. This has generated an overlap in service delivery. So, the MoH conducted some studies (using process and early outcome indicators) to understand which of the two models is more effective. The results showed that the disease management model (as



opposed to the spontaneous, individual use of preventive tests) was more effective in reducing mortality. [14,15] Consequently, the 2010 PNP argues that the ASL-level needs to 're-engineer' its model of delivering preventive care to one that redirects patients to CSP services.

F3: Ensure (formal) tools for implementation: powers, incentives and sanctions (also exerting influence – soft tools)

The third sub-function of stewardship regards making sure that the appropriate tools and rules are employed for all actors of the system. As such, it is the steward's duty to ensure that its powers are coherent with their responsibilities. It must also do this for the other health system stakeholders, making certain that, while aligned for each stakeholder, the powers and responsibilities should be minimally overlapping among stakeholders. In addition to aligned powers, the steward should ensure that the system's stakeholders have at least access to the tools they need for implementation. It must also make certain that it has the right tools for monitoring and exerting influence on the other stakeholders. Furthermore, the steward must take action to set and enforce appropriate rules, incentives and sanctions for the system's stakeholders – most importantly, the sub-central levels of government in a decentralized NHS [2].

To ensure the implementation of CSPs, the Italian health system has several tools, which include the utilization of incentives and, to a certain degree, sanctions. As mentioned above, the CSPs are incorporated into the different prevention (PNP) and cancer specific (PNS) plans, which are agreed upon by both the Ministry of Health and the Regions. The PNP and PNS each have their own system of rules, incentives and sanctions. The broader PNP offers each region incentives to reach the targets set out under each intervention. It introduces and defines results-based financing, allocating approximately 0.5% of the total annual health budget to regions that have reached specific targets with regard to prevention activities. While the PNP does not involve formal sanctions (as all funds are given eventually to the Regions and cannot be re-allocated for other uses), the Regions are penalized by a delay of these funds at times. Additionally, if a Region has trouble reaching their targets, there is no mechanism for technical assistance or support to help them 'catch-up'. For some Regions, this has led to a perpetual and vicious cycle. As mentioned previously, the PNS tied additional funds (or financial incentives) to the implementation of

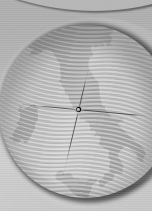
CSPs. It also included 'soft' incentives to the Regions in the form of technical assistance (worth approximately €180,000 per year) provided by the National Centre for Screening Monitoring (Osservatorio Nazionale Screening or ONS) with funds from the MoH. In addition to the PNP and PNS, implementation of the CSPs is guided also by national guidelines and protocols.

Strategically, the Ministry of Health formed a partnership with the ONS to further guarantee the implementation of its CSPs (see F4 for more detail). The ONS is the main interlocutor between the Ministry and the Regions for putting the CSPs into operation. It has strengthened the coordination of the CSPs between the Ministry and the Regions, and within and among the Regions. This type of collaboration has resulted in a series of audit and training programs directed towards the continuous improvement of quality of CSPs at the regional level. It has also led the MoH to develop a position paper on how to manage interval breast cancers and a national re-training program for endoscopy technicians (for colon cancer screening programs), as well as to promote a clinical risk management plan specifically for CSPs.

F4: Build coalitions and partnerships

Factors outside the main steward's realm impact on health and, so, it is prudent to build and maintain effective coalitions and partnerships, especially in a decentralized system. Compacts with health system stakeholders will help the steward promote changes in the system. Such partnerships or coalitions may vary on a relationship continuum that stretches from loose affiliations to legally binding relationships.^[16] They can be established for ongoing activities or one-off issues or events, or to develop a new policy or a media campaign. Partnerships can be formed with professional associations, patient or consumer groups, other ministries, private enterprises, medical schools, the pharmaceutical industry, research foundations, politicians at all government levels, NGOs, etc.^[2] In a decentralized system, partnerships with sub-central levels of government are essential for a fully functioning system.

While the Italian Ministry of Health has not performed a formal stakeholder analysis for its CSPs (as according to the stewardship framework), it has taken specific actions to build partnerships with main actors involved with the programs. The Ministry has formed two main types of partnerships: (i) those that we consider formal and can be defined as agreements with



other public entities that include a contract with financing; and (ii) those that are less formal, which usually involve shared objectives and obligations but no financing (Table 2).

Besides the abovementioned joint strategies and plans with the Regional Governments for CSPs (e.g. PNP, PNS), the foremost formal partnership that the MoH has created is with the National Cancer Screening Observatory (ONS). This is a strong relationship. The ONS has even helped the MoH's to achieve partnerships or coalitions with other stakeholders. Additionally, the MoH's work with the ONS has promoted partnerships between professional associations, such as the various health professional societies involved in CSPs. It has finally entrusted the ONS with the organization of events, seminars and conferences (rather than a general events coordinator), which has proven to further promote cohesion among stakeholders. Other formal partnerships include those with the Lega Tumori to enhance the adherence of the target populations to CSPs and the Abruzzo Regional Health Services to coordinate scientific research programs in the field. The MoH, for example, works with the Lega Tumori, who works with the Regions to provide a promotional media campaign to sensitize the population on the importance of their participation (compliance and adherence) in CSPs.

Examples of less formal partnerships include the signing of Partnership Agreements (Carta dei Rapporti) that state the shared objectives and obligations between the Ministry of Health and patient associations (voluntary organizations or NGOs). Moreover, the MoH has promoted partnerships between other stakeholders, using agreements with stated common objectives (Documenti di Obiettivi Comuni). For example, the Lega Tumori has partnered spontaneously with women patient associations. Collaboration at the regional level and with regional politicians, however, has been patchy. Furthermore, the MoH has not yet built relationships around CSPs with other Ministries, the pharmaceutical industry or government politicians at the regional level.

F5: Generate intelligence

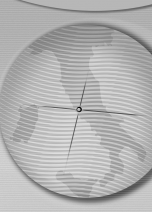
Generating intelligence for a health system is essential for creating an evidence base for decision-making. When put to effective and good use, intelligence can even improve health outcomes. Intelligence is much more than just information. It is reliable, up-to-date information on (i) important contextual factors, (ii) the actors that influence the system and/or programs, (iii) current and future health and health system performance trends (the current information system and future applied research), and (iv) possible policy options, based on national and international evidence and experience [2-17]. Information on important contextual factors in OECD countries is generally readily available and widely accessible; Italy is no exception. Intelligence regarding actors is particularly important for setting the agenda and designing political strategies to improve the probability of policy adoption [18]. In general, this type of intelligence is difficult to analyze, as it is most often confidential or undocumented. Thus, we focus our analysis on the last two types of information generation for CSPs.

The generation of intelligence is an important sub-function of stewardship for CSPs because they have been built almost entirely on the evidence and effectiveness of their interventions and programs. The health and general political systems in Italy provide intelligence on the contextual factor that surround CSPs and, as above-mentioned, the MoH would benefit from performing a formal analysis of CSP stakeholders. In particular, a stakeholder analysis would help the MoH to understand the organization of actors at the regional level and their needs. The third and fourth types of intelligence, in particular, are directly related to the role of the MoH to ensure the production and dissemination of data and to outline possible policy options for the health system, including CSPs.

Information on the current and future health and health system trends can be separated into two categories: information that is currently

Table 2. Types of partnerships.

Formal	Less Formal
<ul style="list-style-type: none"> ONS (National Center for Screening Monitoring) 	<ul style="list-style-type: none"> Lega Tumori
<ul style="list-style-type: none"> Abruzzo Regional Health Services 	<ul style="list-style-type: none"> NGOs and voluntary organizations
<ul style="list-style-type: none"> Lega Tumori (Italian League for the Fight against the Cancer) 	<ul style="list-style-type: none"> Scientific societies (clinicians and primary care physicians)



gathered and that which can be utilized in applied research for the future. Currently, the health system gathers health and health system, including CSP, data and information annually. The information system for CSPs is built on a platform of disease management for cancer screening. So, it not only collects data on the number of screenings but also on patient treatment and follow-up. As such, the information system, importantly, collects data for process and early outcome indicators in addition to health outcome indicators, as the latter take a longer time to produce. The ASLs collect the data for their territorial area and send it to their Regional Reference Center (Centro Regionale di Riferimento), which validates the quality of the data and sends it to the ONS. The ONS, then, verifies the epidemiological quality of the data, analyzes it and publishes the results each year. For the quality evaluation, the ONS uses standard quality assurance indicators for CSPs, defined by the European Union. The information included in the annual reports is shared with all partners. The MoH is currently updating the health information system, by constructing a national data warehouse. Besides the health information system of the MoH, the Tumor Registry (Registri Tumori) is the best account of cancer-screening data provided geographically.

The Ministry of Health has created a program for applied research for the NHS. The MoH defines the technical areas and conducts a bid for studies in those areas. It, then, selects the most qualified studies and finances them. Generally, research centers as well as ASLs perform the studies. The latter allows for a good sample size. It also helps to ensure that the scientist that conducts the research would be in close contact with the CSPs, which is important for the coherency and robustness of the studies' results. Through this applied research program, it has financed epidemiological and qualitative studies on the strengthening of CSPs as well as studies that evaluate alternative programs to cancer screening. Through this applied research, the MoH has been able to incrementally change the organizational model of the CSPs. For example, the possible substitute of the PAP-smear test for the HPV test in certain cases. This program of applied research has also led to better effectiveness for the CSPs; for example, improved detection of breast tumors. Furthermore, the MoH is currently working on the creation of pilot studies to evaluate the cost-effectiveness of CSPs.

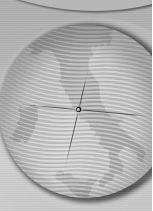
The health information system also produces potential policy options for CSPs at the national

and international level. Through the general information system, the ONS creates an annual report of the intelligence generated for CSPs in Italy, with detail of every Region and ASL. In addition, it presents the data at an annual National Conference of Cancer-Screening Programs. This intelligence informs the CSP agenda and helps to improve the program when and where there is need (mostly, due to poor performance). The MoH also holds various, ad-hoc workshops and meetings to go deeper into the research. It also exchanges this intelligence with other countries, in particular, France and the United Kingdom, while the ONS publishes it in English on the web and in hard-copy for dissemination to all countries in the EU.

F6: Ensure accountability

Ensuring that system actors can be held accountable for their actions is the last of the six sub-functions of stewardship. In a decentralized health system, like that of the Italian NHS, this generally means making certain that the central government is accountable to the sub-central governments as well as the entire country's population for performing its role and responsibilities to their fullest. At the same time, the sub-central governments should also be held accountable to both the central government and their constituents (the populations of their territories). Moreover, physicians and other health personnel are also accountable to their sub-central governments as well as their population catchments. In the health sector, direct accountability - that is, the short-route of accountability, from the central government to the population - is difficult to implement. [19,20] More often, there is a more indirect or longer chain of accountability that generally flows from the central government to the sub-central governments to the health professional and, finally, to the population. In addition, Travis et al. [2] recommend seven commonly cited markers for accountability, including the existence and operation of interest groups, publishing rules and independent watchdog committees as well as the level of access to political representatives.

One of their major elements of accountability, the Italian CSPs have an Editorial Plan (Piano Editoriale or EP) at the MoH-level with publishing and dissemination rules. The EP incorporates different types of deliverables, which are produced in Italian and/or English depending on their audience (e.g. politicians, researchers, the public, implementation officers). Besides publications on the results of the CSPs, the



EP includes publications for carrying out the CSPs; for example, manuals for quality assurance or the effective communication of information related to CSPs (e.g. the publication “Centom Domande” or One Hundred Questions on CSPs). Specifically for politicians, the EP includes short briefs with information on CSPs that can be used for policymaking. Its board looks specifically at how CSPs may be effectively communicated and diffused through society and has an annual communication campaign. In the name of accountability, the MoH also takes measures to prevent and manage negative and undesired effects of the CSPs; often, using a communication campaign to do this. Furthermore, the MoH also dedicated part of its applied research program to creating methods for the social reporting of CSPs at the regional level; they are currently implementing such studies [21].

The Italian CSPs, however, generally lack mechanisms to ensure accountability such as patient safety organizations and a complaint system. Patient safety organizations are useful accountability mechanisms for the health system and CSPs in particular. These types of organizations help the public to understand that mistakes are also possible in medicine. They also help to provide feedback to practitioners so that they may correct their mistakes. They help make the appropriate people or level of government responsible for both their success and their failures. The MoH has recently published a position paper on the need for a patient safety mechanism that could feed into its program of clinical risk management. There are no CSP-specific complaint systems but the population may use the NHS's general complaint system or consumer services. However, these systems vary from ASL to ASL. Despite this, complaints generally flow from the ASL to the MoH and, then, if deemed necessary, to court.

Discussion

Although the MoH did not follow a planned strategy of stewardship for CSPs, the overall experience and activities of the Italian CSPs during the period 2004-9 fit well into the framework of stewardship. In essence, the Italian CSPs - including all of the involved stakeholders (e.g. government officials, health professionals, scientific societies, etc.) - managed to carry out almost all activities under each of the stewardship sub-functions. To a certain extent, it is believed that devolution of the health system induced the MoH to face the new challenges of its role and to find new tools and policies to address

them. Most importantly, the MoH recognized the importance of developing a relationship with the many stakeholders involved in the CSPs (F4). It also realized the need for better direction and guidance of CSPs, putting in place a two-fold strategy (i.e. the PNP and PNS) to tackle that need (F1). Furthermore, it realized early-on the significance of a solid information system built for CSPs, putting the generation of intelligence at the center of its activities (F5).

Of the few activities in the framework that it did not perform, the MoH would benefit from carrying out the following activities for its CSPs:

(F1) Defining a vision; planning for the longer-term (>10 years)

(F2) None

(F3) Provision of more serious sanctions for the implementation of the CSPs at the regional level

(F4) Conducting a systematic stakeholder analysis; building stronger partnerships within the health sector (e.g. with the regional health authorities); reaching out to new stakeholders, including those outside of the health sector

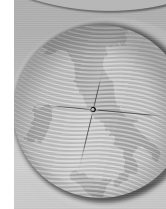
(F5) None

(F6) Introducing a CSP-specific patient safety watchdog into the system

In particular, implementing the activities under F4 would do much to strengthen the MoH's stewardship role. It could do so by conducting a systematic stakeholder analysis for its CSPs. From this, it could improve its performance by building stronger partnerships within the health sector - in particular with the regional health authorities - and, depending on the CSP, the pharmaceutical or medical equipment industries. In addition, it could broaden its knowledge of other stakeholders and outreach to them, including Ministries outside the health sector. For example, the MoH could collaborate with the Ministry of Education to provide a first introduction to cancer prevention and health promotion activities in high schools. Related to F4 but under F6, creating and maintaining a partnership with a patient safety watchdog organization would facilitate accountability in the CSPs. Furthermore, the activities needed under F1 should be implemented in conjunction with its partners - in particular, the regional governments - as the MoH has done with its other activities under this sub-function.

Conclusions and recommendations

The analysis presented the case of the CSPs in Italy as compared to Travis et al.'s framework for stewardship of the health system [2]. The



practical case mostly corroborated the theoretical framework for stewardship of the health system. It showed that Travis et al. sub-functions could be clarified into certain activities on an operational platform. It illustrated what the theory could mean in terms of everyday tools and practices at the level of the MoH. The analysis demonstrated that the framework for stewardship is not a completely new and superfluous change in an already well-managed program or system but that it is a reorientation of the best activities of a steward that provides a point of reference (or benchmark) for implementers.

From the case study analysis, we have a few recommendations for the clarification of the stewardship framework as well as for future research. With regard to the framework, Travis et al. [2] mention that the terms 'sub-function' and 'domain' are interchangeable. We point out that the former emphasizes the operational meaning, while the latter stresses the cognitive one and, for this reason, we believe the more appropriate term for the stewardship framework would be the former.

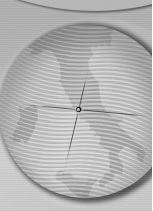
The overlap between sub-functions is another area that needs clarification but that is beyond the scope of this article. Travis et al. and others point out that several activities can be classified under different sub-functions, causing an overlap that adds confusion to the framework. Indeed, when analyzing our case study, we had to determine where some activities fit better in the framework. Often, this ended up being a very subjective process - depending on either the author's view

or the particular case study. For example, we discussed where clinical guidelines might go. Although they can be a type of intelligence produced generally by the government (F5); at the same time, they can be equally considered a tool for implementation or influence (F3). We chose to put them under F3. To resolve this conflict in general, two things may be done. On the one hand, as more and more empirical and case-study evidence on stewardship is collected and defined, a comprehensive list of activities could be indicated for each of the six sub-functions. On the other hand, the overlap between sub-functions may better represent the real complexity of stewardship and, perhaps, lead us to a deeper understanding it.

Regarding future investigations, we believe that there is a need for more practical research on health system stewardship and that the theoretical research could benefit from this. In particular, there is a need to create more country-, sector- and program-specific evidence in order to build a more profound understanding of stewardship. It would also be interesting to evaluate the impact of the stewardship model on other stakeholders of the system - especially the Regional Governments -, as well as on the organization behaviour of local governments. Moreover, there is a great opportunity for creating a culture of stewardship among health system stakeholders. Communicating an understanding of the concept and practice of stewardship to all stakeholders would be a first step, and building their implementation capacity a close second.

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