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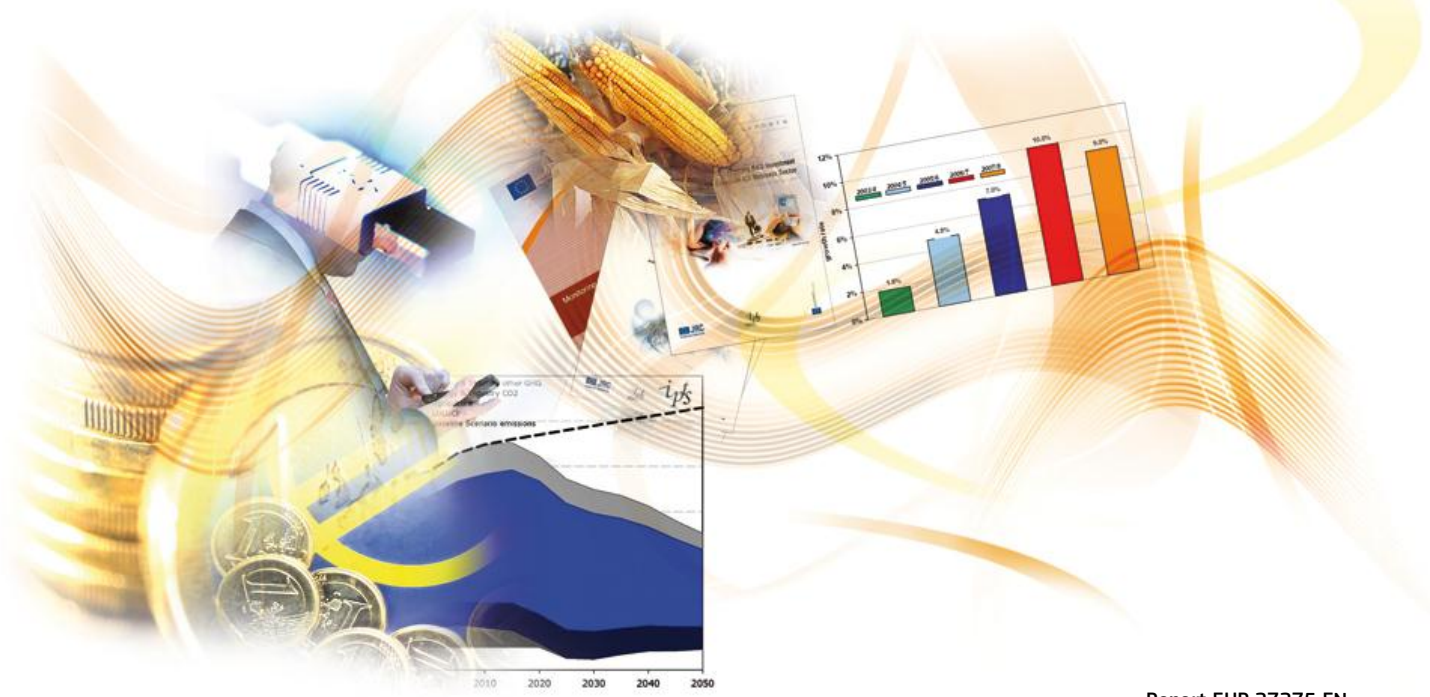
Strategic Intelligence Monitor on Personal Health Systems Phase 3 (SIMPHS3)

*SOLE/FSE (Italy)
Case Study Report*

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Abstract

SOLE ("Sanità On Line" – "Health Care On Line") is the integrated network of local health units, hospitals, general practitioners and paediatricians in the Emilia-Romagna region in Italy. Together, these entities constitute the physical and virtual infrastructure of all patient-centred integrated care services organised by the health actors in the region. The FSE ("Fascicolo Sanitario Elettronico" – Personal Health Record) is a software application which helps to organise, retrieve and manage the clinical history of every citizen in the region.

The SOLE/FSE started about 12 years ago as an initiative of Emilia-Romagna's regional government, with an investment of about €80 million. CUP 2000 S.p.A., an in-house company, was designated to be in charge of the design, development, maintenance and continuous improvement of the system and the Integrated Care services provided. The SOLE/FSE case addresses the population of the Emilia-Romagna in its entirety and is used by all 3,700 GPs/paediatricians practicing under the 11 local health units and in the 6 hospital districts of the region.

The case focuses on chronic disease management, home care management, and health and social care services integration.

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Preface

The Strategic Intelligence Monitor on Personal Health Systems (SIMPHS) research started in 2009 with the analysis of the market for Remote Patient Monitoring and Treatment (RMT) within Personal Health Systems (PHS). This approach was complemented in a second phase (SIMPHS2) with the analysis of the demand side, focusing on needs, demands and experiences made with PHS by healthcare producing units (e.g. hospitals, primary care centres), healthcare professionals, healthcare authorities and patients amongst others.

Building on the lessons learnt from SIMPHS2 as well as on the European Innovation Partnership on Active and Healthy Ageing initiative, SIMPHS3 aims to explore the factors that lead to successful deployment of integrated care and independent living, and define best operational practices and guidelines for further deployment in Europe. This case study report is one of a series of case studies developed to achieve these objectives.

The outcomes of SIMPHS2 are presented in a series of public reports discussing the role of governance, innovation and impact assessment in enabling integrated care deployment. In addition, through the qualitative analysis of 27 Telehealth, Telecare and Integrated Care projects implemented across 20 regions in eight European countries investigated in SIMPHS2, eight facilitators have been identified, based on Suter's ten key principles for successful health systems integration.

The eight main facilitators identified among these as necessary for successful deployment and adoption of telehealth, telecare and integrated care in European regions are:

- Reorganisation of services
- Patient focus
- Governance mechanisms
- Interoperable information systems
- Policy commitment,
- Engaged professionals
- National investments and funding programmes, and
- Incentives and financing.

These eight facilitators have guided the analysis of the cases studied in SIMPHS3 and a graphical representation with arrows whose length represents the relative importance of each facilitator is presented in each case study.

In addition to the above facilitators analysed in each case report, a specific section is dedicated to the analysis of care integration. It should be noted that the definition of vertical and horizontal integration used in this research is taken from the scientific literature in the field of integrated care¹ and differs from the one mentioned in the European Innovation Partnership on Active and Healthy Ageing Strategic Implementation Plan². We define horizontal integration as the situation where similar organisations/units at the same level join together (e.g. two hospitals) and vertical integration as the combination of different organizations/units at different level (e.g. hospital, primary care and social care).

¹ Kodner, D. (2009). All together now A conceptual Exploration of Integrated Care.

² http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/steering-group/operational_plan.pdf (page 27).

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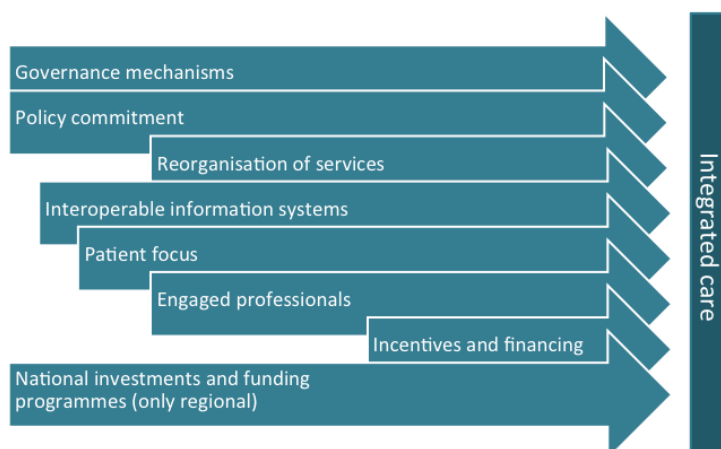
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Case outlook

SOLE (“Sanità On Line” – “Health Care On Line”) is the integrated network of local health Units, hospitals, general practitioners and paediatricians of the Emilia-Romagna region in Italy. Together, these entities constitute the physical and virtual infrastructure of all patient-centred Integrated Care services organised by the health actors of the Emilia-Romagna region. The FSE (“Fascicolo Sanitario Elettronico” – Personal Health Record) is a software application which helps to organise, retrieve and manage the clinical history of every citizen of the region.

The SOLE/FSE case started about 12 years ago as an initiative of Emilia-Romagna's regional government, with an investment of about €80 million. The CUP 2000 S.p.A. was the *in-house* company in charge of the design, development, maintenance and continuous improvement of the system and the Integrated Care services provided. The SOLE/FSE case addresses the population of the Emilia-Romagna in its entirety and is used by all 3,700 GPs/paediatricians practicing under the 11 local health Units and in the 6 hospital districts of the region.

The case focuses on chronic disease management, home care management, and health and social care services integration. SOLE/FSE enables “horizontal integration” of all work undertaken by GPs and paediatricians. They have access to the FSEs if authorised by the patients concerned. SOLE/FSE also allows “vertical integration” among GPs/paediatricians and health Units/health care organisations in terms of management of administrative and clinical pathways. Moreover, it helps citizens and patients to manage their clinical history by means of a virtual portal, which enables each individual to upload, withdraw, view and share personal health-related information in accordance with existing security and privacy regulations. Key drivers of the case are the strong commitment and shared vision of all the actors involved, and the existence of a widely distributed information and communication network infrastructure which integrates all the health care actors of the region. Barriers to the diffusion of the SOLE/FSE case that could also hinder the transferability of the initiative are privacy and security constraints, slow adoption by citizens due to lack of awareness, resistance to organisational and technical changes in the health actors' premises and lack of evidence-based impact evaluation processes. The following figure sketches the main integrated care facilitators.



1 Background

1.1 Italian social and health care services

The Italian healthcare system is characterised by universal access to a uniform level of care throughout Italy, as established through the Servizio Sanitario Nazionale (Italian National Health Service, INHS) in 1978 (Figure 1). The central government controls the distribution of tax revenue for publicly-financed health care (INHS) and defines a national minimum statutory benefits package to be offered to all residents in every region - the “essential levels of care” (livelli essenziali di assistenza, or LEAs). Health care is financed primarily through a corporate tax pooled nationally and allocated back to the regions, typically to the source region (there are large interregional gaps in the corporate tax base, leading to financing inequalities), and a fixed proportion of national value-added tax (VAT) revenue collected by the central government and redistributed to regions unable to raise sufficient resources. Universal access to a uniform level of care is compromised by considerable variations in terms of coverage and service quality across regions in the north and south. The system provides for a full spectrum of services, ranging from visits to GPs, specialised in-patient treatments, post-operative rehabilitation to ambulatory care and outpatient treatment. Drugs and medicines are covered to a considerable extent by the INHS. A decisive change of the Health Care System took place when a major reform of the Constitution (Constitutional Law No. 3 of 18 October 2001) altered the roles and responsibilities of the state and the regions. It provides that national authorities are to ensure general principles and objectives of the healthcare are met, and that they retain the responsibility to define the basic benefits package to be uniformly provided throughout the country (LEA). The regional authorities, on the other hand, retain considerable powers to legislate on the regional basis and allocate funding. Both national and regional authorities enact major policy decisions in inter-institutional “State-Regions Conferences”, in which representatives from both authorities participate to deliberate on relevant issues.

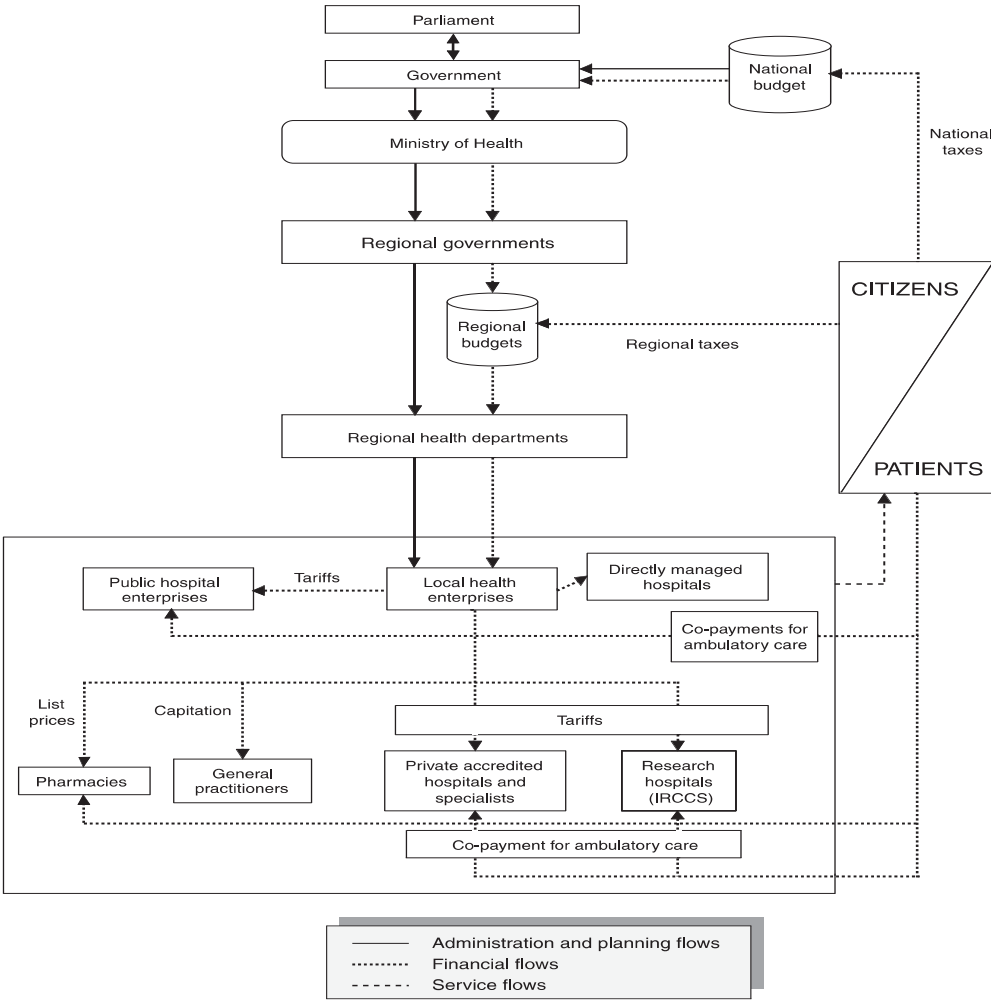
The INHS is organised at three levels: national, regional and local. At the national level, the Ministry of Health is the central body of the INHS in charge of coordination of the services covering human health, occupational health and safety, and food hygiene and safety. The Ministry has the authority to pass laws concurrently with the regions, and it has regulatory authority over the regions with regard to safeguarding health, occupational health and safety, regulation of the professions, nutrition and scientific research. Agreements between the state and the regions establish the financial resources for a three-year period and the essential levels of care.

At a regional level, according to national laws and general indications of the Ministry of Health, there are 19 regions and two autonomous provinces, which are responsible for the organisation and delivery of health services in its areas in terms of health education and promotion, and disease prevention and care.

At the local level, the health system is organised in local health units (Aziende Sanitarie Locali, ASL), which are bodies with public juridical status operating autonomously with regard to organisation, administration, management of assets, accounts, general management and technology. Medical care and services are provided in each area by public or accredited private hospitals and health centres. The ASL territorial facilities are organised in districts. The human health districts provide the following services: health education; information and advice to help residents make informed choices; primary health care; home health care; health certificates; prevention and control of infectious diseases;

hygiene in confined environments; food hygiene; protection of mothers' and childrens' health; and assessment of interventions for the disabled. In this regard, hospitals provide all clinical care within their settings, including day-care medicine, surgery and ambulatory services, while the ASL is responsible for the health status of the population living in the area. ASLs are responsible for investigating the population's health needs and assessing the most common risk factors for acute and chronic diseases in the area, planning the health services required to respond to the population's health demands, paying the hospitals and other local authorities for the services they provide, and evaluating the effectiveness, safety and cost-benefit ratios of the health services provided according to standards of quality.

Figure 1: Overview of the Italian health care system



Note: IRCCS: National Institutes for Scientific Research.

Source: Scalzo et al. (2009)

Social care is delivered at local level. Every municipality can opt for direct provision or can outsource services to an external market provider. The Italian social services have come under particular government pressure to improve their levels of efficiency and effectiveness. Under Law n8328/2000 and decree-law n8207/2001, new institutional settings for social care organisations were defined. These reforms also created a new

institutional actor, the ASP (Assistenza Servizi alla Persona), in order to improve the way social services were provided. The ASP was intended to be a more efficient and flexible type of organisation, where professionals could achieve their maximum potential by adopting private management styles. Most of the social care in several Italian regions is now provided through ASPs as autonomous entities usually owned by the municipalities themselves.

1.2 The Emilia-Romagna region

The Emilia-Romagna region is about 22,445 km² and has 4,500,000 inhabitants, with a density of about 200 inhabitants per km². It is located in the North of Italy, with the Lombardy and Veneto regions on its Northern borders and Tuscany and Marche on its Southern borders.

Emilia-Romagna has an annual GDP of more than €137 billion (representing about 10% of the total annual GDP of Italy), and an annual GDP per capita of €30,444. The average age of the population is about 43 years old and 22.8% of individuals are over 64. This percentage increases at a yearly rate of 0.5%, against less than 0.2% for other age groups. Therefore, in the Emilia-Romagna region, population ageing is an important and growing phenomenon, in line with the rest of Italy, which lies above the EU28 average (17.5% of the Italian population is over 64). The Emilia-Romagna region has 11 Health Care Units in charge of the programming, monitoring and evaluation of the health care-related activity in their territories. They are responsible for the operational activities and the provisioning of the services through local health districts. The following table summarises the main figures related to Emilia-Romagna and its regional health system.

Table 1: Emilia-Romagna region health care system characteristics

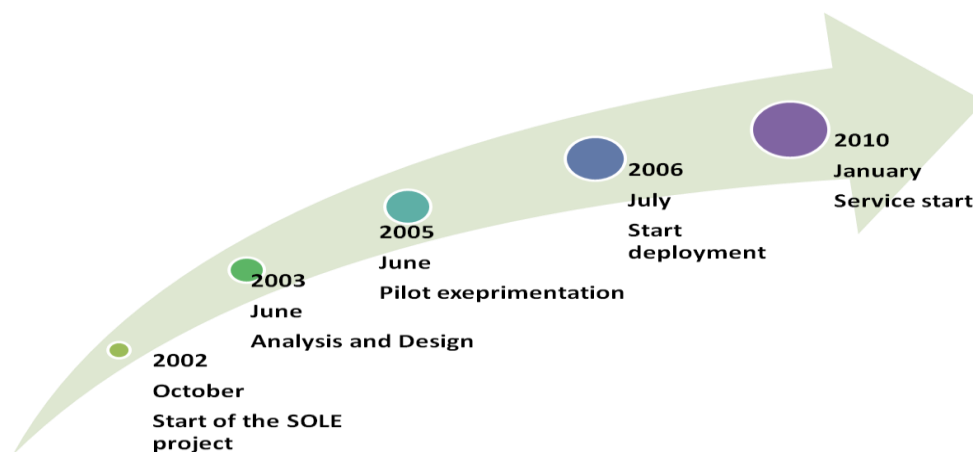
Geographical coverage km²	22,445
Inhabitants per km²	200
Number of inhabitants	4,500,000
Life expectancy at birth, years	76.8 males – 81.6 females
Regional GDP (2012), billion €	€137 billion
Regional GDP per inhabitant (2012), €/inhabitant	€30,444
General Practitioners /1.000 inhabitants (2010)	0.78
Specialists /1.000 inhabitants (2010)	3.67
Regional Budget for Health services management (2013), billion €	€8.5 billion
Health care professionals / 100.000 inhabitants	386
Regional health care budget € per inhabitant (2013)	€1,888
Hospital beds (2012)	20,493
Hospital beds/1.000 inhabitants (2012)	4.5

1.3 The SOLE/FSE case

SOLE (“Sanità On Line” – “Health Care OnLine”) is the integrated network of local health units, hospitals, GPs and paediatricians of the Emilia-Romagna region and FSE (“Fascicolo Sanitario Elettronico” – Personal Health Record) is the software application which organises, retrieves and manages the health record of every citizen of the region. Together they form the physical and virtual infrastructure of all health services provided by the regional health actors to the citizens of Emilia-Romagna.

SOLE/FSE started in 2002 (Figure 2), under the Information and Telecommunication Plan of the Emilia-Romagna region. This plan aimed to develop and sustain an integrated network amongst local health Units, GPs and paediatricians, allowing them to share clinical and administrative data and allowing citizens to access their clinical history by means of the FSE.

Figure 2: Technological development trajectory of the SOLE/FSE



Source: ASSR-ER (2013)

The SOLE/FSE project started in October 2002. From 2002 to 2004, the efforts were dedicated to analysis and design of the platform. The next year and a half was spent on piloting. The real deployment of the initiative started in July 2006 and it became fully operational in January 2010, when the SOLE infrastructure started delivering services to health care professionals, health organisations and citizens of the region. Jointly, SOLE and FSE constitute the logical and physical infrastructure enabling health and social care regional services development and provisioning. They also form the basis for the development of integrated health and social care services for the citizens of Emilia-Romagna.

The SOLE/FSE case study focuses on Integrated Care practices that combine the logical and physical infrastructure of SOLE and FSE with specific health and social care applications in various forms. It is worth mentioning that even though the examples of SOLE/FSE applications are limited to specific territorial ambits of the Emilia-Romagna region and some of them are just pilots tests, the wide diffusion of the SOLE/FSE network to the whole Emilia-Romagna region will enable the short and mid-term upscaling of the Integrated Care initiatives to serve the entire Emilia Romagna population and to integrate all health and social care services.

Currently, SOLE/FSE comprises the following initiatives.

Integrated Home Care Assistance (IHCA) where SOLE/FSE acts as enabler of independent living solutions in the region. This application started in 2011, plans to develop a specific action for interoperable independent living solutions in the regional health strategy. The aims are (1) to test and validate the implementations of interoperable platforms, solutions and applications based on SOLE network, and (2) to provide evidence on return on investment of these solutions and applications, based on experience involving at least 10 major suppliers, 100 SMEs and 10,000 users.

The **PROFITER project** which comprises the development of a frailty index and related frailty prevention and care protocols, based on the retrospective analysis of the information

continuously collected through the SOLE network and stored in the FSEs of citizens from the Emilia-Romagna region. The objective of the project, which started in 2013, is to develop a collaborative model at regional level involving all social and health care providers in at least 5 local health units within three years. The operational model is supported by a technological infrastructure integrated within the SOLE network and based on a mix of portable devices and home sensors to allow the monitoring of elderly people at their homes and outside, in order to prevent them from falling and give them faster access to assistance and care.

Home care management of diabetic patients comprises the development of a personalised integrated care pathway for patients with diabetes. This relies on clinical-metabolic monitoring of the patients by their GPs and subsequent provision of temporary or permanent assistance to the patient by the diabetes centre.

Integration of drug addiction treatment services to the SOLE/FSE consists of the development of an information-sharing protocol between the organisation in charge of the drug addiction treatment and the GPs.

Cardiovascular disease prevention. This project promotes the integrated use of the cardiovascular risk card. The SOLE/FSE can manage all the phases of the cardiovascular disease diagnosis process. Collected data on patients' cardiovascular risk are made available by the GPs in the SOLE/FSE, where patients can access their records online. Other health care professionals, to whom the patient has given written consent, can also access these records.

Hemophiliac regional portal. The regional health records for haemophilia are made available by the SOLE/FSE to citizens and to those health care professionals to whom the patients have given written consent.

Beyond these concrete applications, the SOLE/FSE network infrastructure is potentially available for all citizens and health providers in the region. As of today, the SOLE/FSE initiative involves all the GPs and paediatricians of the region (about 3,700 health providers) and all the citizens (about 4.5 million inhabitants) of the Emilia-Romagna region, who can directly access their FSE through a dedicated website (www.fascicolo-sanitario.it). By the end of 2013, more than three quarters of citizens had agreed to share their personal health records with health and social care professionals in the region³ through the SOLE/FSE infrastructure. All the regional Local Health Units and 6 health care organisations have adopted the SOLE/FSE.

³ This is an important issue that will be analysed when addressing barriers (see paragraph 3.3). According to privacy regulation in Italy, the citizens have to provide a written consent to each health care professional they wish to share their own personal data with. Therefore at the moment not all health care professionals can access the personal health information of each citizen.

2 Integrated care analysis

2.1 Dimensions of integration

The evolution of the ICT network underpinning the SOLE/FSE initiative is focused on the creation of care pathways. Integrated case services addressing chronic disease management, inbound and outbound health and social integration and home care are therefore based on these pathways.

Looking at the applications that are being tested or deployed with SOLE/FSE, functional integration is by far the most implemented of the various types of integration we have considered. The SOLE/FSE infrastructure integrates all health care actors operating in the region and manages all health-related information about citizens and the administrative data of the health care professionals in Emilia-Romagna.

SOLE/FSE facilitates the provision of integrated care services through back-office and support functions, which aim to:

- Manage the prescription-referral life cycle.
- Provide continuing assistance management processes to GPs, hospital units and local health Units.
- Keep GP/company administrative management flows.
- Supply integrated home care assistance in management processes.

SOLE/FSE further enables organisational, professional and service/clinical integration, as in the case of the IHCA on trial in the Modena and Cesena Health Units, and in the case of the PROFITER project which, thanks to SOLE/FSE, is trying out a new collaborative model at regional level.

In terms of breadth of integration, the SOLE/FSE enables both horizontal and vertical integration. Horizontal integration is guaranteed among all the GPs/paediatricians of the region, who, through the SOLE/FSE network, can share patient information, clinical histories, referrals and prescriptions with previous consent of the patients. Vertical integration is achieved mainly through administrative data-sharing between GPs/paediatricians and local health units, both in relation to prescriptions and to service provision where the local health units monitor the contracts with health care professionals. Whereas vertical integration is limited to administrative processes at the moment, the SOLE/FSE network is organised in such a way that it can also support vertical integration of health care processes (GPs and hospitals).

Based on the above, we can consider that the SOLE/FSE initiative facilitates communication, information-sharing and collaboration through coordination of care pathways, service responsibilities and inter-organisational mechanisms, including the administrative control of GPs' services provision. However, it is important to emphasise that though this could be considered as a medium degree of integration, SOLE/FSE could support full integration for the entire continuum of care.

2.2 Impact

The SOLE/FSE infrastructure currently supports a limited number of applications but it has the potential to support the full integration of the health care system at regional level. This scenario would enable a complete transformation of the health care system. A major

positive impact could be expected in terms of efficiency and efficacy, and therefore in the sustainability of the system. However, even though the number of implemented initiatives is still low, the SOLE/FSE case has already had the following positive impacts.

- Improved **knowledge of the clinical history of every patient/citizen** living in the Emilia-Romagna region. This holds for both the patients/citizens and the health care actors in the territory. From a short/mid-term perspective, every citizen of the region could have access to his FSE, monitor his clinical history, and share it with health care professionals involved in the care pathway, without the need to bring paper-based clinical and health-related information to each doctor. By 31 December 2011, about 4,000 electronic medical files had been activated in Emilia-Romagna and about 100,000 citizens were already using their FSE account, representing about 3%⁴ of the whole population of the Emilia-Romagna region.
- **Reduction of administrative burden** for citizens and health care professionals. The possibility to have patient-related information accessible through the SOLE/FSE infrastructure allows health care professionals to access (with the consent of the patient) a patient's health record and provide more personalised diagnoses, prescriptions and treatments. At the same time, they reduce the administrative burden of patients when visiting their GP or a health care specialist.
- **Improved quality of health care services.** Thanks to SOLE/FSE, health care professionals can access their patients' clinical information in real time to provide a better and faster service. This could also allow a reduction of clinical errors, and increase compliancy with both therapeutic and pharmacologic treatments.
- **Time and cost savings for patient care management.** SOLE/FSE improves data sharing among the different health care structures located in the region, and decreases the duplication of exams and visits.
- **More tailored health and social policies** and related services, based on statistical elaboration of the citizens' health and social data collected on a yearly basis by the Local Health Units

In addition, according to the responsible authorities of the Emilia-Romagna Region, the above impacts have proven positive as they have improved:

- **the health outcomes of the regional health care systems** by increasing the quality of care and efficiency in the care services provisioning, enabled through the sharing of patient information.
- **the sustainability of health care service** by reducing operating costs of clinical services, through improved horizontal and vertical integration of the health organisational units that constitute the regional health care system.
- **the quality of work of the health care professionals** by reducing their administrative costs and administrative burden.
- **the cost-effectiveness of entirely new modes of care** enabled by the SOLE/FSE physical and virtual infrastructure. In this context, we can consider examples such as the Integrated Home Care Assistance or the PROFITER projects,

⁴ This is clearly a low level of adoption of the system by the citizens who are the final beneficiaries of the SOLE/FSE service. According to the experts consulted, this is probably due to the lack of communication efforts and promotion campaigns to inform the citizens of the advantages of SOLE/FSE for their health care management. Moreover, it is also due to the Italian privacy regulation that requires informed written consent by citizens for every single doctor with whom they want to share their health care information.

which are experimenting with continuity of care and integrated care services, based on the SOLE/FSE network infrastructure.

Furthermore considering a mid/long-term perspective, SOLE/FSE will facilitate the **improvement of chronic disease management** particularly with regard to multi-morbidity. The authorities in charge of health care in the region are targeting the wide diffusion of the SOLE/FSE network to guarantee a rapid uptake of the integrated care initiatives currently on trial in a limited number of local health Units. At patient level, SOLE/FSE could **increase citizens' engagement** in the care process and **their empowerment in self-care management practices**. As already discussed above, the development of the FSE service is fully integrated with SOLE, and allows direct involvement of citizens/patients, enabling better communication with GPs and health care specialist.

As yet, there is no counterfactual evidence on the impacts of the SOLE/FSE initiative on the health care system of the Emilia-Romagna Region. The following table presents, however, some results provided by CUP 2000 S.p.A on the effects of the use of SOLE/FSE on the number of pharmacological prescriptions issued by GPs/paediatricians between 2012 and 2013.

Table 2: Evidence of SOLE/FSE impact

Impact Indicator	Year 2012	Year 2013
Number of pharmacological prescription	44,223,667	39,077,008
Number of pharmacological prescription per GP/Paediatrician (3.624 doctors have used SOLE/FSE in the two years)	12.203	10.506
Cost of pharmacological prescription (0,4€ per printing a prescription)	17.7 million €	15.3 million €

Source: Authors elaboration based on CUP 2000 S.p.A

As outlined in the table, comparing data from 2012 and 2013, there has been a significant reduction (about 12%) in the number of pharmaceutical prescriptions of GP/paediatricians operating within the SOLE/FSE network. This is also the case if we compare the first quarter of 2014 (12,091,250 pharmacological prescriptions) with the same quarter of 2012 (14,717,230 pharmacological prescriptions). In this case the prescriptions' reduction is even more significant and it is close to 18%. This significant reduction of pharmacological prescriptions between 2012 and 2013 represented an overall net saving of about €2.4 million for the regional health care system. CUP 2000 S.p.A. uses the printing cost of each prescription (about €0.4) as the indicator of cost saving. This is certainly an underestimation of the overall savings produced by the use of SOLE/FSE, nevertheless it gives a clear indication of the significant cost reduction the SOLE/FSE initiative can make for the regional health care system.

2.3 Drivers and barriers

All experts consulted agreed that the **key drivers** of the SOLE/FSE case have been:

- **Strong commitment of the regional government** to the SOLE/FSE initiative since its inception in early 2000 and the huge investment made. This commitment remained strong in the following years, and additional investment was made by the regional government of about €24 million for upgrading the SOLE network,

developing the FSE and digitalizing the citizen referral and other health documents (e.g. prescriptions, exams, etc.).

- The **existence of an information and communication network infrastructure** which integrates all the health care actors of the region and has been fully operational since 2008, underpinning the SOLE/FSE initiative. This should be beneficial for a faster take-up of actual and future integrated care initiatives that are/will be organised in the region.
- A **Common vision** among the regional health care actors as regards the importance of the SOLE/FSE initiative for their activity.

The main **barriers** appear to be related to:

- **Privacy and security** of the data and information managed by the system. For the experts consulted, this constitutes by far the most important barrier to the diffusion of the SOLE/FSE use by the citizens. The current privacy law requires that citizens have to provide their written consent before sharing data with health care professionals⁵. This is required for all the health care professionals with whom citizens want to share their health histories. This certainly limits the adoption of the system and reaping the promised benefits. However, the health care operators recognise that digitalised patient histories are an important way of reducing the administrative burden for both citizens and health care professionals, and of reducing duplication of efforts and costs, while at the same time increasing accuracy in the therapeutic and pharmacological pathways. According to CUP 2000 SpA, a possible way to overcome this barrier is the use of the SPID (Single Point of IDentity). Thanks to the SPID, every citizen will have the possibility to register his identity with all health care professionals.
- **Internet access**. Time spent by citizens and health care professionals (mainly GPs/paediatricians) connecting and using internet access for their own purposes is still a limiting factor for the adoption of the SOLE network. According to the experts consulted, this is mainly due to the **non-homogeneous internet service provision at regional level**, due to the lack of homogeneous coverage of ICT networks, particularly in the mountainous areas of the region and the areas with lower population density.
- **Low number of patients using FSE**. Currently, adoption of the FSE is quite limited - no more 3% of citizens. This figure is in line with the actual level of adoption of eGovernment services in the Emilia-Romagna region, although it is higher than in the rest of Italy.
- **Data standardization**. This is one of the first activities started in the initial period of the SOLE network development. It is fundamental for promoting and implementing the interoperability of the systems and services integrated by the SOLE network. However, according to the experts consulted, it is still not completed and its realisation is presenting technical and organisational challenges.
- **Fragmented ICT health-related solutions** available on the Emilia-Romagna territory, not entirely interoperable with the SOLE network. A clear example of this

⁵ At the end of 2011 only 60% of the citizens (75% of the population at the end of 2013 as specified in ASSR-ER (2013)) agreed to use the system by providing formal consent to the information sharing of their FSE.

barrier is provided by the numbers of GPs/paediatricians and health Units/health care organisations compared with the number of ICT solutions selected. In fact, the regional health care system has around 3,700 GP/paediatricians who use 16 different solutions integrated with the FSE software. Moreover, the 17 health Units/health care organisations currently operate 172 different Information systems, belonging to 55 different providers. The Emilia-Romagna region is trying to overcome this barrier with the development of an ICT “backbone” based on the SOLE network, which would make any solution adopted by health care operators interoperable.

- **Procurement process of ICT equipment.** The availability of ICT equipment at the right time and with the proper quality of delivery is one of the main factors enabling health care process management changes. However, the lack of timely availability of ICT with adequate quality could constitute one of the major barriers.
- **Lack of extensive clinical trials and evidence-based impact evaluation** to show cost-effectiveness of the proposed solutions and to quantify the benefits produced by the solution for the final beneficiaries and for the health care system as a whole.
- **Lack of legal and juridical basis for m-health applications** (see also Darchini, 2014). The experts consulted agree that the practical use of m-health solutions is purely hypothetical at the moment, since there is no juridical framework that supports m-Health-based diagnoses and prescriptions. This certainly hinders the diffusion of the SOLE/FSE solution in a context where the penetration of smartphones is very high and still growing.

2.4 Organisation, health professionals and patients

The SOLE/FSE infrastructure covers all the stakeholders of the Emilia-Romagna health system, including all eleven Local Health Units. According to CUP 2000, 99% of physicians and paediatricians are already connected to the system (there are 3,698 GPs and paediatricians in single practices or joint groups), which facilitates communication among them and with health care providers. Specialists, and the hospitals where they practice, are also connected to the infrastructure. This includes the organisations in charge of chronic disease management and/or specific health care services provision such as the drug addiction treatment service mentioned before. SOLE/FSE also incorporates cooperatives, groups of practices, private organisations, NGOs etc. delivering home care services. Therefore, the beneficiaries of the SOLE/FSE initiative are:

- **Citizens.** They are the primary beneficiaries of the health care services offered by the system and directly access their health care information and/or follow their own care pathway.
- **Local health units and local and regional hospitals.** They promote the integration of the communications’ interfaces, protocols and procedures among the caring organisations and the GP/paediatricians.
- **GPs, paediatricians and health care specialists.** They are, together with the citizens, the main beneficiaries of the initiative and generate the data managed by the system (e.g. referrals, prescriptions, administrative documents related to the patients, etc.).

- **Health care and ICT providers.** They provide the infrastructural services for the local health Units and the local and regional hospital departments. They also provide the GPs' and paediatricians' FSE electronic toolkits and integrate their software solutions within the SOLE network.

The SOLE/FSE initiative enables better cooperation between all these actors through continuous information-sharing, thus ensuring cooperation between tiers of care. The SOLE/FSE infrastructure is organised in a way that all patient-related information is accessible to all GPs/paediatricians. Hence, GPs act as gateways to integrating the health care delivery and are able to provide diagnoses and treatments based on a complete and uniform set of information. This technological innovation has been deployed in parallel with a reorganisation of the services to ensure cooperation between tiers of care, facilitating patients' access to the continuum of care through multiple points. As a result, a patient-centred approach has been fostered, supported by the possibility for patients to access their medical records, which engages and empowers them in the care process.

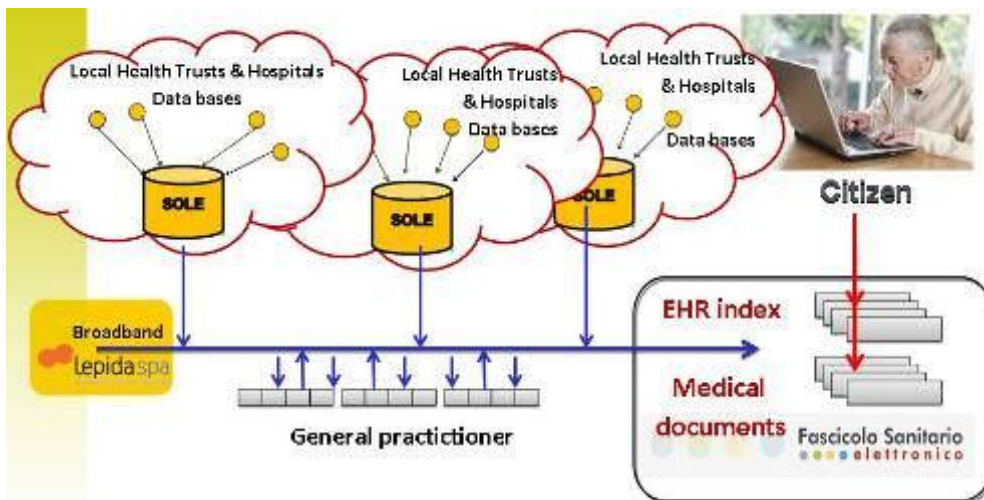
The e-Health services that are managed within the SOLE network comprise:

- **Management of the prescription-referral life cycle** of a patient's care.
- **Continuity of care management process** in terms of complete and on-time communication management between GPs/paediatricians and health care professionals operating in the hospitals for the management of in- and out-patients.
- **Administrative management flow for GPs/paediatricians and health Units** as regards complete and on-time communication between GPs/paediatricians and health Units about administrative data related to citizens' choices of reference doctor, GPs' activities outside their normal practices, and activities related to the integrated home care services performed.
- **Integrated home care management process** to help GPs/paediatricians provide home care services to their patients.
- **Clinical events indexing at regional level (IREC)** is a new way of accessing the health and clinical data of each patient/citizen. This forms the basis of patients' health-care histories.

2.5 Information and Communication Technologies

The core functionality of the SOLE solution is the indexing of clinical events for each citizen. In this way, an individual's health record can be tracked by the citizen himself, his GP/paediatrician, and health and social care specialists. The local SOLE infrastructures are connected through the regional broadband managed by LEPIDA, the technological in-house company of the Emilia-Romagna Region in charge of the development and maintenance of the regional ICT infrastructure on the basis of which all the eGovernment services of the region, including health care ones, are provided. Through LEPIDA's regional network telecommunication infrastructure, health and social care operators and citizens can access patients' health care records ("*Fascicolo Sanitario Elettronico*"). The same logical infrastructure guarantees the continuous update of patient-related information contained in the SOLE databases and in the FSE.

Figure 3: Logical interaction between SOLE and FSE

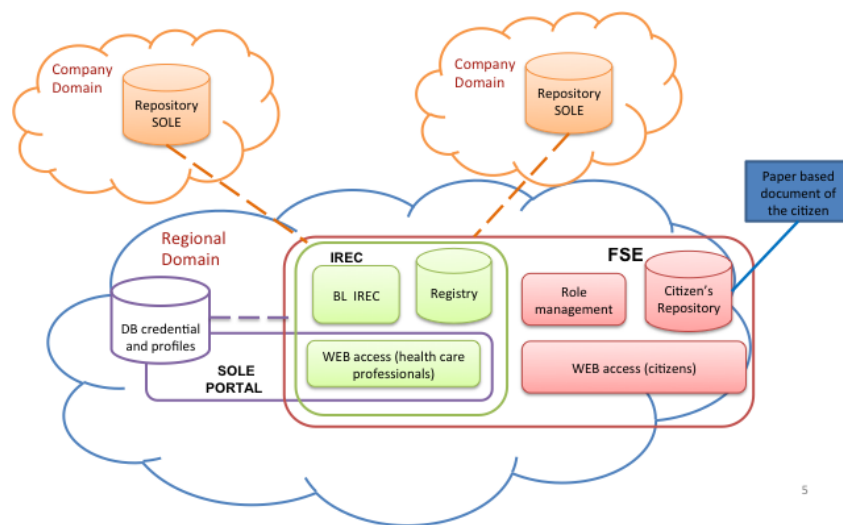


Source: ASSR-ER, 2013

The logical structure of the SOLE network model is described in

Figure 4. It was set up by the SOLE Repositories, which contain documents and health data from the different providers managed by the SOLE network. The SOLE network's document and data access is regulated by the level of citizen consent and the SOLE business logic, which manages the operational services, enabling process support and the communication protocol among SOLE's network of nodes.

Figure 4: SOLE/FSE logical architecture



Source: CUP 2000 S.p.A.

When developing its interoperability framework, the region benefitted from the interoperability specifications of the EC project epSOS in defining both the semantic and technological components of the infrastructure and related services. The evolution of the SOLE network forms should⁶: facilitate the connection of new nodes to the network inside the local health Unit itself and among other local health Units; split the tier of data

⁶ This effort goes towards increasing the interoperability of the fragmented ICT solutions used at the moment by the different providers of the regional health care system, which is one of the main problems hindering the release of the full potential of the SOLE/FSE initiative.

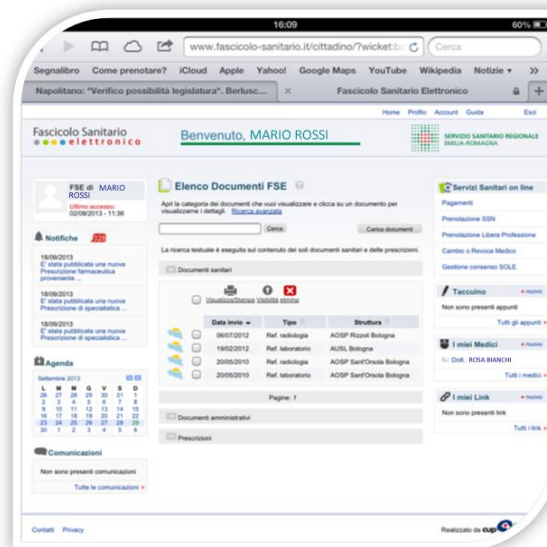
transport into those related to service provisioning and those related to data storage. It should also facilitate and enable full data access.

It is important to emphasise that the SOLE network allowed CUP 2000 to develop a Personal Health Record (“Fascicolo Sanitario Elettronico – FSE) that can be accessed, with the informed consent of the citizen, by all social and health care professionals operating in the region. Therefore, SOLE is the enabling infrastructure for the development of FSE *as*:

- In every health company, a SOLE node allows the uploading of documents to the SOLE repository. These documents are available to the rest of the providers following specific privacy and security policies.
- The information available in SOLE is codified syntactically and semantically on the basis of agreed standards (e.g. HL7 and CDA).
- The SOLE architecture integrates software solutions on the basis of operational applications across the various health care organisations.
- On the regional level, the SOLE network has an indexing system (IREC) which allows the system to be interoperable.

The following figure shows FSE citizen data after login with credentials. Each citizens' FSE can be accessed through the portal www.fascicolo-sanitario.it.

Figure 5: “My Page”: personalised access to citizens' personal FSE



Source: CUP 2000 S.p.A.

2.6 Governance

SOLE/FSE stakeholders are:

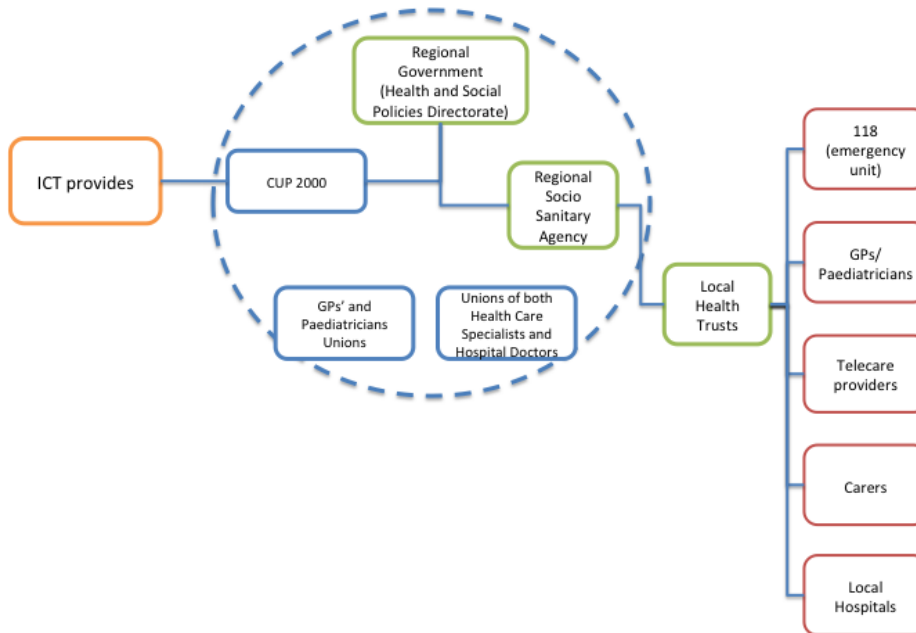
- The Emilia-Romagna Region, including the Organisation, Information System and Telematics General Directorate and the Health and Social Policies General Directorate. (<http://www.regione.emilia-romagna.it/entra-in-regione>). The region is the promoter and the founder of the initiative. Its responsibilities include the definition of the initiative's strategic guidelines and the monitoring and validation of the results.

- CUP 2000 S.p.A. (<http://www.cup2000.it/en>). This is the “in-house” company of the region and the initiative's general contractor. It provides the professional services needed for the development of the initiative and coaching and training activities. More particularly, it provides the professional services to develop, maintain and improve the system, and also to develop, in collaboration with the regional health actors, eHealth services and applications⁷. It also manages the purchase of technological products from external suppliers.
- Regional Socio-Sanitary Agency (<http://assr.regione.emilia-romagna.it/it/>) is responsible for the coordination of the 11 local health units of the Emilia Romagna region. It manages the relationships with the Regional Directorate of Health and Social Policies as regards regional investment in health that apply to all the local units. It is also responsible for the health care initiatives' joint communication strategies and for the development of joint actions by the local units at European level. Budget and administrative processes remain the responsibility of each local unit.
- Unions for GPs and paediatricians. These professional benefit from the system and are the promoters of eHealth services that are available through SOLE/FSE.
- Unions for hospital doctors and health care specialists. These professional also benefit from the system, and, like the GPs/paediatricians, they are promoters of eHealth services enabled by the logical and physical SOLE/FSE infrastructure.

In some specific services enabled by the SOLE/FSE 's infrastructure, such as the integrated home care service, the Regional General Directorate of Social Policies is part of the governance of the initiative. At the moment, the level of integration between health and social care is still weak from a political and organisational point of view. However, under specific circumstances, such as the services for the IHCA, both Health and Social Policies General Directorates have made a significant joint effort to achieve ICT integration of their services. Figure 6 provides a graphic representation of the governance of the SOLE/FSE initiative. The Regional Directorate of Health and Social Policy, as the promoter and the funder of the whole initiative, plays a central role.

⁷ See examples in paragraph 2.2.

Figure 6: Governance structure of SOLE/FSE



Source: Authors elaboration

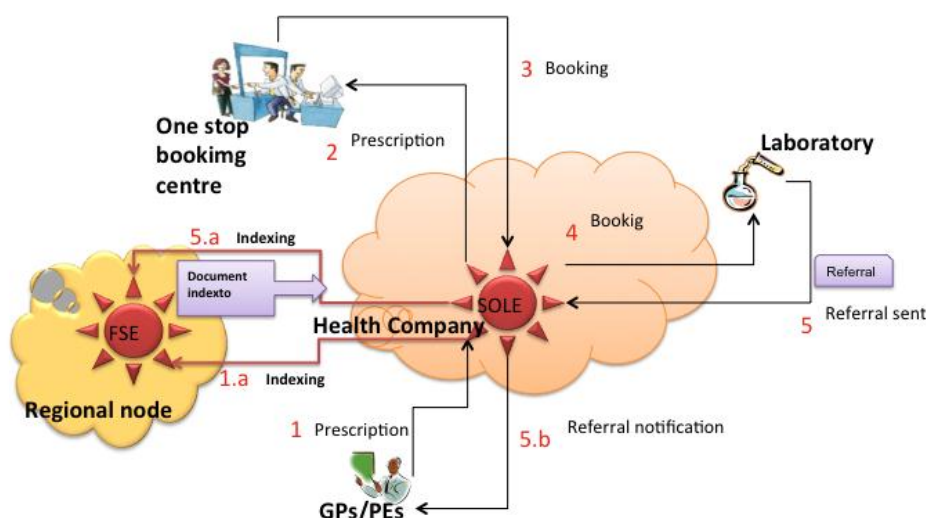
CUP 2000 is the technical arm of the initiative and responsible for the development of the ICT infrastructure underpinning SOLE/FSE services. It is also in charge of the definition of the projects, the bidding process for ICT providers' selection, and the management and monitoring of the funded projects. The Regional Government acts as promoter and catalyst of the initiatives of the Local Health Units. Furthermore, it provides an investment plan for the development of the SOLE/FSE infrastructure itself, the deployment of Integrated Care services that use SOLE/FSE infrastructure and the budget needed to deploy the projects. This plan (the Informatics and Telecommunication Plan of Emilia-Romagna Region - PITER) is periodically updated. According to the strategic guidelines of the plan, CUP 2000, the Local Health Units, and representatives of local hospitals and municipalities present project ideas to be funded by the regional government. A yearly plan of funded projects is agreed by the actors involved in the SOLE/FSE governance.

2.7 Organisational processes

As discussed in the previous paragraphs, the SOLE/FSE initiative aims to integrate all the administrative and clinical information of the patients/citizens living in the Emilia-Romagna region. Figure 7 provides an overview of the information that is being collected and of the processes, which are enabled by the SOLE/FSE networked infrastructure.

Figure 7: Organisational processes and ICT integration

SOLE: prescription-booking-referral preparation cycle



Source: CUP 2000 S.p.A.

In the case of the prescription-booking-referral cycle, the organisational and ICT integration processes consist of:

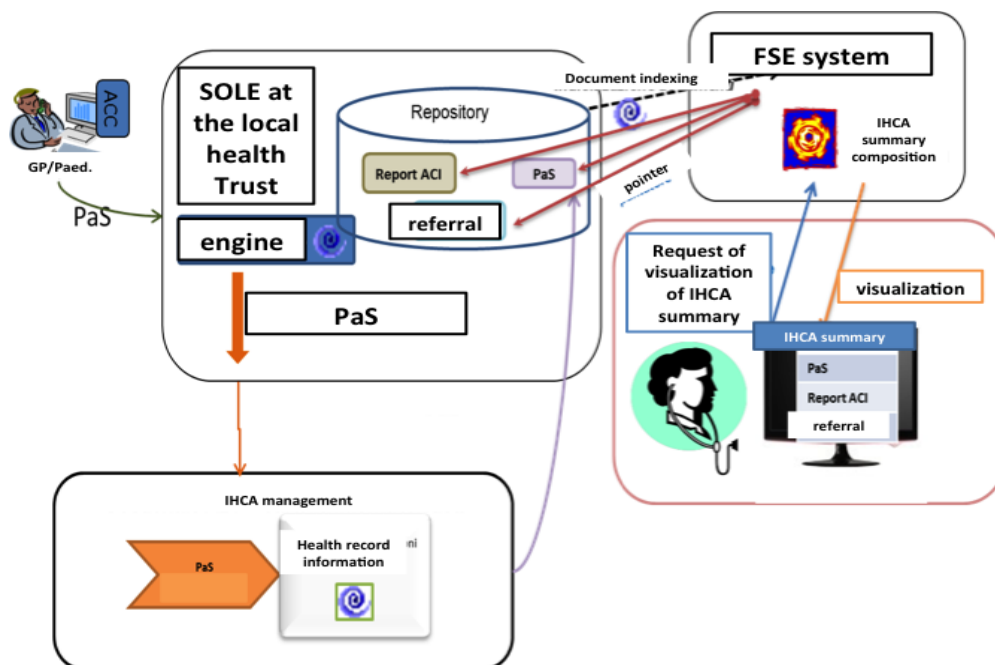
- Management of GPs' and paediatricians' electronic prescriptions and electronic referrals, which are automatically registered in the patients' FSE (<http://www.fascicolo-sanitario.it>) (arrow 1 in Figure 7).
- Automatic identification of the profile of the citizen requesting health services and the GP/paediatrician supplying the services, so as to monitor primary care services demand and supply (arrows 1.a and 5).
- Automatic acquisition, through the SOLE information system, of all data related to the electronic prescriptions and the booking data for visits or examinations with significant reduction of booking errors and delays (<http://www.cupweb.it>); (<http://www.pagonlinesanita.it>) (arrows 2, 3 and 4 in Figure 7).
- Management of the referral communication to citizens through their FSE and referral notification to the GP/paediatrician (arrows 5 and 5b of the Figure 7).
- Management of all patient discharges and admissions for GPs/paediatricians.

Other organisational processes supported by SOLE/FSE infrastructure are:

- Management of emergency referrals.
- Vaccination reports and statistics management.
- Payroll data management for GPs and paediatricians.
- Automatic management of the request for clinical examinations
- Management of integrated home assistance administrative pathways.
- Management of citizens' FSEs.
- Management of the administrative processes between GPs/paediatricians and the local health units.

Therefore, the SOLE/FSE networked infrastructure constitutes the technological layer of every integrated care service that has already been developed or that will be implemented in the coming years in the Emilia-Romagna region. From an organisational perspective, SOLE/FSE represents a very flexible solution that can be adapted to every organisational process underpinning integrated health care services. For example, if we consider the Integrated Home Care Service described in §1.3, the integration of the services within the SOLE/FSE infrastructure allows any authorised health professional (specialist, general practitioner, paediatrician, out-of-hours service doctor, nurse) involved in the home care service to access and update the medical file of the patient, to take decisions and to immediately inform the patient and other professionals involved in the care pathway. The following figure provides an example of the functioning of the **IHCA online**, and the protocol for the management of integrated home care, including the use of the IHCA summary which is shared among the health care professionals (professional carriers, rehabilitation personnel and GPs).

Figure 8: Use of the SOLE/FSE solution in the case of home care



Source: CUP 2000 S.p.A.

From an organisational perspective, the strategy adopted by the regional government of Emilia Romagna consisted of developing the technological infrastructure to support the health services, which now covers the whole region. It then promoted the deployment of health services, including integrated care services. This strategy presents several advantages:

- It provides a common information management system for all the regional health care operators and citizens/patients.
- It offers standard basic services (e.g. booking services for the citizens, payroll services for GPs and paediatricians) common to all the region;
- It facilitates the continuity of care services across different health organisations.

- It promotes the exchange of information between primary and secondary care professionals and between health care professionals belonging to the same tier of care;
- It allows the establishment of multiple point of access to health care services, fully integrated with one another and with the health care organisations located in the region.

These organisational advantages are certainly beneficial for the quality of care and assistance to the citizens/patients at lower costs. However, the level of deployment of the care services, including integrated care, with SOLE/FSE is still limited and only organised as medium-large pilots that do not address the entire population of Emilia-Romagna.

2.8 Reimbursement model and economic flow

Reimbursement for GPs and the other health care providers in the Emilia-Romagna region is based on a capitation model. Health care professionals receive a fixed amount of money based on standard performance parameters agreed at national level and partially adjusted by the Local Health Unit.

The GPs/paediatricians also receive a small amount as a “coordination fee” for using the SOLE/FSE solution to register all their patients' health care documents⁸ (e.g. treatments and pharmacological prescriptions, clinical examinations, etc.). Since the GPs/paediatricians are obliged by regional rules to use the SOLE/FSE solution, the “coordination fee” has to be considered a fixed component of their income. However, all the experts consulted agreed that there is a lack of innovation in reimbursement models applied that is mainly due to a lack of common outcome-oriented incentive schemes for the care managers and health care professionals involved.

The SOLE/FSE initiative does not affect the economic flow of the health care services provided to citizens and patients. It only makes an automatic registration of the service given by the health care provider and enables the reimbursement process.

The economic flow depends on the Integrated Care services deployed using the SOLE/FSE infrastructure. For example, in the case of the Integrated Home Care Assistance, nurse services are included in the tariff that the patients and their families have to pay according to the severity of the disease and their level of income, while the services of the GPs and the hospital doctors are reimbursed by the Local Health Units, as are the costs for drugs and specialist care.

3 Transferability

From a technological perspective, the SOLE/FSE infrastructure was built up in accordance with the interoperability specifications agreed among the regional and national organisations of a majority of the EU28 member states during the development of the EU CIP project EPSOS. In Italy, there was a twin project called SOS (Smart Open Services for European Patients), where all the regions were involved. Therefore, the software code could be easily transferred to local contexts in Italy and in Europe.

⁸ Note: referrals belong to the citizens/patients and are therefore only available on the EHR system of the health care professional (GP, paediatrician, specialist or hospital doctor). With “my space” in the FSE solution, the citizen/patient can choose to share his/her health information with every single health care professional he/she decides to involve in his/her care process.

From an economic and financial perspective, the cost of transfer to a local context using the same infrastructure would be significant, but not excessive, due to the fact that the interoperability standards used by SOLE/FSE are common in the majority of the EU countries. The investment that could hinder the transferability of the SOLE/FSE initiative is related to ICT infrastructure. Where ICT infrastructure is lacking, the SOLE/FSE initiative could only be transferred in areas where there is broadband.

However, according to the experts consulted, technical issues aside, the most critical success factors for transferability to other regions/countries are favourable institutional and cultural contexts and the local presence of a common strategic and operational management of the local health and socio-sanitary systems to guarantee:

- Strong commitment by the local government.
- The adoption of FSE services by citizens/patients.
- The deployment of integrated care initiatives that make use of the SOEL/FSE infrastructure.
- The cultural and organisational changes that allow information sharing across different tiers of care and between health care professionals in the same tier.

4 Conclusions

The SOLE/FSE ICT infrastructure is used to facilitate patient-centred integrated care services potentially for the entire population of the Emilia-Romagna Region. The initiative has been developed over the last 12 years as a physical and virtual infrastructure which allows health care professionals to organise, retrieve and manage the clinical history of every citizen in the region, and also the regional health care actors' administrative data. The regional government had the financial capability and the vision to start the initiative at the very beginning of 2000 and has been its main promoter ever since. CUP 2000 S.p.A., the regional government's "in-house" company, pushed the initiative forward and developed it from a technical and organisational point of view. This company has been the organisation in charge of the maintenance and the continuous improvement of the initiative over the time.

The project has allowed the development of several integrated care initiatives in recent years, among which:

- Integrated Home Care Assistance on trial in Cesena and Modena province Health Units;
- a programme for frail people in 5 out of 11 local health units within the Emilia-Romagna region;
- home care management services for diabetic patients;
- cardio-vascular disease prevention and therapeutic and pharmacological pathways for drug addicted individuals.

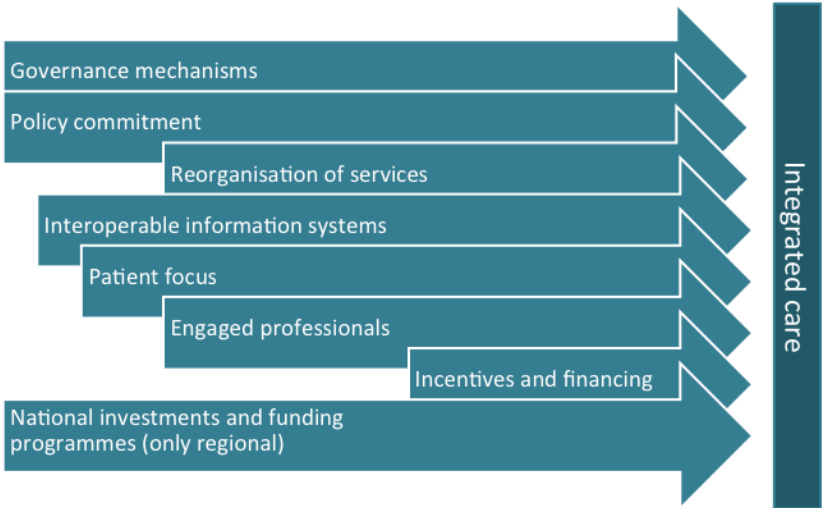
The 3,600 GPs/paediatricians act as gateways to the SOLE/FSE services. They are in charge of the primary care of 4.5 million people living in the Emilia-Romagna region. Up until the end of 2013, about 3.4 million inhabitants had agreed to share their medical records with health and social care professionals working in the region through the SOLE/FSE infrastructure. Furthermore, the SOLE/FSE solution has been adopted by all 11 local health Units and all 6 health care organisations of the region.

Despite the lack of counterfactual evidence on the impacts of the SOLE/FSE initiative on the regional health system, quite significant impact measures show the benefits of the system in an integrated care context. For example, a recent evaluation of the trend in GPs' and paediatricians' pharmaceutical prescriptions conducted by CUP 2000 between 2012 and 2013 confirms that there was an important reduction in prescriptions (equivalent to about 1,700 prescriptions per doctor during that year), with an overall net saving of about €2.4 million for the regional health care system. Other key results recognised by the experts interviewed are a reduction of the administrative burden for citizens and health care professionals and the improvement of the quality of health care services. Nevertheless, in order to exploit the full potential of SOLE/FSE initiative, the following barriers should be tackled:

- The most important barriers are related to privacy and security of the data and information managed by the SOLE/FSE system. The current privacy law requires that citizens provide their written consent before sharing data with a given health care professional.
- Lack of homogeneity of internet access at regional level due to the lack of homogeneous coverage of the ICT network.
- Lack of data standardization that is fundamental for promoting and implementing the interoperability of the systems and services integrated by the SOLE network.
- The highly fragmented nature of the ICT health-related solutions available in Emilia-Romagna, which are not all interoperable with the SOLE network.
- Lack of evidence-based impact evaluation, which means there is no clear and quantified evidence of the benefits produced by the solution for the final beneficiaries and for the health care system.

These barriers have been partially addressed by the SOLE/FSE facilitators which have pushed the development of integrated care services in the SOLE/FSE case. The following figure shows the comparative importance of these facilitators.

Figure 9: SOLE/FSE integrated care facilitators



Source: Authors elaboration

Policy commitment, national investment and funding programmes, and governance mechanism have been the main facilitators of this case at a regional level. Emilia-Romagna Health authorities have been pushing the SOLE/FSE infrastructure across the health system,

facilitating the governance mechanism in order to involve all the stakeholders (local health units; patients; providers and professionals) in the platform, which allows information and communication flows across the continuum of care. These flows are supported by the SOLE/FSE that acts as an interoperable information system for the different tiers of care and providers. Thus, interoperability could be considered as another key facilitator of integrated care services.

It is important to emphasise that SOLE/FSE gives Emilia-Romagna's citizens access to their personal health records. Even though the use of such applications still remains low, it is a clear example of a patient-centred approach that fosters patient engagement and participation in their own health.

Reorganisation of services and participation by professionals could also be considered as facilitators. SOLE/FSE has facilitated the cooperation between tiers of care, including patients' access to the care continuum through multiple points of access. This reorganisation would not have been possible without the implication of health professionals, especially GPs and paediatricians who have become the gatekeepers of the system. Thus, SOLE/FSE has given professionals a leading role. Finally, incentives and financing issues have not been the main driving force of integrated care. However, it is worth mentioning that the Regional Government is fully committed to financially supporting the infrastructure and to guaranteeing its long-term sustainability. SOLE/FSE is considered to be an enabling infrastructure, which is driving the reorganisation of the regional health care system in order to bring down costs and improve quality for citizens and the health and social care operators.

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