

Digital health and clinical decision support: the HealthSOAF project and the Calabria Headache Network

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Abstract. Good clinical governance of headache implies efficient and accessible diagnostic and therapeutic pathways involving different levels of health care. Headache syndromes are often diagnosed and treated inadequately. Information and communication technology (ICT) can play a key role in improving access to treatment and, from the clinical management perspective, in increasing the levels of quality, efficiency and prevention. The HealthSOAF (Service-Oriented Architecture Framework) is a networking and interoperability technological platform, designed to assist healthcare decision making and improve access to care at appropriate levels. The Headache Network operating in the Italian region of Calabria provided the HealthSOAF platform with its first real test bed in Europe, with the aim of helping clinicians working at different levels of health care to correctly diagnose, manage and refer headache patients. Use of the HealthSOAF platform in this experimental pilot study was found to be associated with enhanced diagnostic accuracy and appropriateness of referrals to specialist headache services within the area considered, suggesting that ICT-based clinical decision support based on a network of information tools can improve the clinical management of headache.

Key words: interoperability, SOA, HSSP, model-driven architecture, e-Health, headache network

LA SANITÀ DIGITALE A SUPPORTO DELLE DECISIONI CLINICHE: IL PROGETTO HEALTHSOAF - RETE CEFALEE CALABRIA

Riassunto. La buona pratica clinica della cura delle cefalee implica percorsi diagnostici e terapeutici efficaci e accessibili coinvolgenti differenti livelli di cura. Le sindromi cefalalgiche sono spesso diagnosticate e trattate non adeguatamente. Le tecnologie dell'informazione e della comunicazione possono svolgere un ruolo fondamentale nel migliorare l'accesso alle cure, la qualità, l'efficienza e la prevenzione nella gestione clinica. Health SOAF (Service-Oriented Architecture Framework) è una piattaforma tecnologica di networking e interoperabilità finalizzata ad assistere i processi decisionali sanitari per migliorare l'accesso alle cure ai livelli appropriati. La Rete Cefalee nella Regione Calabria ha costituito il primo reale scenario di test in Europa della piattaforma Health SOAF, con l'obiettivo di aiutare i clinici ai differenti livelli di assistenza sanitaria a correttamente diagnosticare, gestire e indirizzare i pazienti cefalalgici. L'utilizzo della piattaforma Health SOAF in questo progetto pilota sperimentale è associato con una maggiore correttezza diagnostica e appropriatezza dell'accesso ai servizi specialistici per la cefalee nella zona considerata, suggerendo che il supporto alla decisione clinica basato sulla rete di strumenti informativi sia in grado di migliorare il governo clinico della cefalea. Inoltre, verrà presentato il contesto clinico su cui sarà eseguita l'attività di sperimentazione e validazione del framework HealthSOAF, ossia il dominio neurologico, con specifico riferimento alla nascente rete regionale calabrese per la gestione clinica integrata dei pazienti di cefalea ed emicrania (Rete Cefalee Calabria).

Parole chiave: Interoperabilità, SOA, HSSP, model driven architecture, e-Health, network headache

SALUD DIGITAL EN EL APOYO DE DECISIONES CLÍNICAS: EL PROYECTO HEALTHSOAF - RED CEFALÉE CALABRIA

Resumen. La buena práctica clínica del tratamiento de las cefaleas implica vías diagnósticas y terapéuticas eficaces y accesibles que implican diferentes niveles de atención. Los síndromes de cefalea se suelen diagnosticar y tratar de forma inadecuada. Las tecnologías de la información y la comunicación pueden desempeñar un papel fundamental en la mejora del acceso a la atención, la calidad, la eficiencia y la prevención en la gestión clínica. Health SOAF (Service-Oriented Architecture Framework) es una plataforma tecnológica para la creación de redes y la interoperabilidad diseñado para ayudar a la toma de decisiones para mejorar el acceso a la atención en los niveles adecuados. La Rete Cefalee en la región de Calabria fue el primer escenario de prueba real en Europa de la plataforma Health SOAF, con el objetivo de ayudar a los médicos a diferentes niveles de atención para diagnosticar, gestionar y dirigir los pacientes con cefalea. El uso de la plataforma Health SOAF en este proyecto piloto experimental se asocia con una mayor precisión diagnóstica y la adecuación del acceso a los servicios especializados para los dolores de cabeza en la zona en cuestión, lo que sugiere que el apoyo de decisiones clínicas basadas en la red de herramientas de información puede mejorar el manejo clínico de dolor de cabeza. Además, se introducirá el contexto clínico en el que se realizará la prueba y validación de marco de trabajo Health SOAF, es decir, el dominio neurológico, con referencia específica a la red regional naciente de Calabria para la gestión clínica integrada de pacientes con dolor de cabeza y migraña (Rete Cefalee Calabria).

Palabras clave: interoperabilidad, SOA, HSSP, model-driven architecture, e-Health, red headache

Background

Application of information and communication technology (ICT) within the socio-clinical-healthcare sector is seen as the key to making significant improvements in the provision of healthcare services, in order to better respond to the needs of citizens, while at the same time increasing the quality of services, cutting costs and reducing waste and inefficiency. The European Commission has long made healthcare the focus of action plans implemented (starting in 2004) with the aim of sharing, with member states, the steps necessary to define common languages and services to be adopted (Action Plan e-Health 2004 (1), Programma e-Europe (2), Iniziativa i2010 (3), Digital Agenda (4), Horizon 2020 (5)), and healthcare has also been the focus of numerous actions, aligned with European objectives, undertaken at national, regional and local level in Italy. Similar initiatives are under way in the USA, Canada and Australia. The new generation of distributed architectures for e-health — e-health being understood as the use of ICT tools to support and promote prevention and continuity of care, in terms of diagnostic, treatment and care pathways and the adoption and maintenance of appropriate lifestyles, at both individual and population level — constitutes

one of the most important areas of modernisation of ICT infrastructures in the healthcare setting. The key concepts underlying these new infrastructures include application cooperation and semantic interoperability between the different characteristic modules of health information systems, which are evolving towards increasingly distributed architectures that aim to ensure interoperability not only within hospital information systems, but also between different care environments (hospital, local care settings, home). Certainly, service orientation, which is based on the paradigm of the service-oriented architecture (SOA) meta-model of cooperation between organisationally heterogeneous and autonomous entities, can ensure complex collaboration among a large number of heterogeneous entities (organisations, applications, users, devices), a situation typical of the healthcare world, producing standardisation and interoperability of application services. It would be wrong, however, to think that technologies following an SOA approach are, by themselves, enough to meet the abovementioned needs. A real reduction in costs can be achieved:

- only by adopting a rigorous approach in the definition of interfaces between the various systems, so as to reduce implementation interpretations to a minimum;

- only by guaranteeing generic interfaces that can be effectively re-used through specialisation (and not replication) techniques;
- and only if the effective testability of these interfaces can be guaranteed.

From this perspective, the general problem of interoperability in the social and healthcare sector is addressed in an innovative way by the international Healthcare Service Specification Project (HSSP) (1), whose general objective is standardisation, on both a functional and a technical level, of the “generic” services that are involved in virtually all social and healthcare processes, and play a key role in these processes. The general approach of the HSSP is therefore to achieve interoperability of socio-healthcare processes at local, trans-regional and trans-national levels, through their “immersion” in a service-oriented architecture, and the use of common, standard “generic” services. This is the background to the HealthSOAF research project (2), co-funded by the Italian Universities and Research Ministry (MIUR) under a programme entitled “*Programma Operativo Nazionale (PON) Ricerca e Competitività 2007-2013*”. This project is aimed at designing and developing a framework of plug-and-play services, based on the SOA paradigm and meeting the HSSP international standards, for the new generation of e-health distributed architectures; the specific objectives of the research are to address the three requirements indicated above. In particular, the HealthSOAF project is aimed at acquiring, testing and validating new knowledge, in order to introduce, into the application modules of clinical-health information systems, an SOA approach that complies with the HSSP standards and is able to:

- guarantee a functional and technological definition of service interfaces according to a model-driven and contract-based approach, able to reduce implementation interpretations to a minimum;
- exploit the logic of semantic signifiers to ensure maximum re-use of interfaces, through effective specialisation and configuration techniques, rather than costly replication policies;
- define an effective (semi-automatic) process for the delineation and implementation of testing campaigns for these interfaces, in order to make testing activities in the software development cycle more effective and less costly.

In detail, the HSSP generic services deployed in the HealthSOAF framework implement the following functions:

- creation, search and retrieval of clinical and health data, in accordance with the HSSP RLUS standard;
- univocal identification and management of patient identity information and of identification information of other subjects and objects that are part of the socio-health ecosystem, such as equipment that has to be identified in order to ensure traceability of analyses and clinical examinations, in accordance with the HSSP IXS standard;
- management of terminologies and coding of records, drugs, laboratory analyses, etc., and of interactions between these terminologies and coding systems, in accordance with the HSSP CTS2 standard;
- multi-criteria searching of clinical/healthcare operators (specialists, laboratories, hospitals etc.) able to provide specific services in a specific geographical area, and within a specific time frame, in accordance with the HSSP HSCPD standard;
- control of access to clinical and health information, guaranteeing the privacy and integrity of this information and auditing of these security requirements, in accordance with the HSSP PASS standard;
- access to clinical and healthcare knowledge embedded in a multitude of executable models, “intelligent” systems, expert systems, decision support systems, knowledge-based systems, and applied guidelines, in accordance with the HSSP DSS standard.

The HealthSOAF framework has been validated through testing of a pilot diagnostic-therapeutic pathway. The aim was to explore, in a real healthcare setting (in Calabria), how standard interoperable services promote cooperation between the different subjects (general practitioners, hospitals, laboratories, specialist centres, local health authorities, etc.) involved in the process of integrated management of patients within the said diagnostic-therapeutic pathway.

The HealthSOAF project

As explained above, the general problem of interoperability in the social and healthcare sector is addressed in an innovative way by the HSSP, promoted

jointly by HL7 and the Object Management Group (OMG). The HSSP's general objective is standardisation, on both a functional and a technical level, of the “generic” services that are involved, and play a key role, in virtually all social and healthcare processes. HealthSOAF (Health Service-Oriented Architecture Framework) is an experimental industrial research and development project co-funded by MIUR under a programme (“*Programma Operativo Nazionale (PON) Ricerca e Competitività 2007-2013*”) dedicated to convergence regions, which are assigned funds for industrial research and technological innovation. The HealthSOAF project has led to the creation of a framework of plug-and-play services, based on the SOA paradigm and meeting the following HSSP international standards (figure 1; figure 2):

1. Health Record Services, for the management of patients' clinical-health records (RLUS);
2. Health Identity Services, for access to multiple identification systems (IXS);
3. Health Terminology Services, for management of terminology (and correspondence) used by different

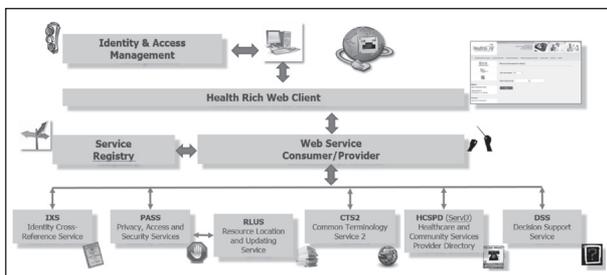


Figure 1. Framework of plug-and-play services, based on the SOA paradigm and meeting the HSSP standards

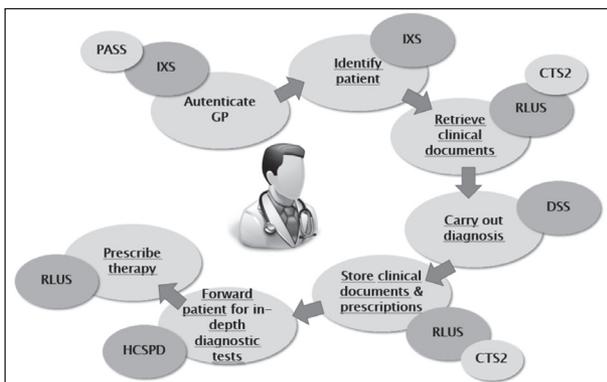


Figure 2. Diagnostic-therapeutic care pathway in the network of HealthSOAF services

healthcare facilities (CTS2);

4. Health Directory Services, for finding, selecting and accessing operators (and facilities) on the basis of both diagnostic and therapeutic requirements (ServD);
5. Health Privacy Services, for management of the right of access to clinical data and for monitoring such accesses (PASS);
6. Health Decision Support Services, for finding, interrogating and using decision aid modules (DSS).

In conjunction with the research, HealthSOAF has also developed a training programme aimed at young graduates in technical and scientific subjects and at healthcare workers. The aim of the programme is to provide, through two separate courses, know-how on integrated management of health metadata, and to transfer — to healthcare workers — the experience that has been acquired through the conducting of the project: a wealth of expertise that, today, is indispensable for more “modern” management of the social-healthcare sector. The following participated in the project as partners: Almagiva S.p.A., project leader; the Department of Mechanical, Energy and Management Engineering (DIMEG), University of Calabria; TE-BAID - Research Consortium; E-bag s.r.l.; Dedalus S.p.A.; LP1 s.r.l.; Headache Centre, “Pugliese-Ciacchio” Hospital, Catanzaro; Calabria Regional Headache Network (Demonstrator).

The HealthSOAF project and the Calabria Headache Network

HealthSOAF project research is specialised through a Demonstrator that, through a distributed architecture, implements, tests and validates the HSSP services in a real clinical healthcare setting, in this case, the Calabria Regional Headache Network. In the context of the present research, therefore, the Demonstrator validated a technological platform capable of providing services to support the integrated clinical management of headache patients, and created a collaborative and cooperative environment that, through the acquisition, integration and processing of data, combined with information and clinical-health knowledge, provided decision support to all the domain's health professionals. Indeed, as part of this pi-

lot study, important industrial research has been done to define and create Directory Service and Decision Support Systems modules specifically for the headache domain. In this context, the Clinical Decision Support System (CDSS) implements the algorithm that supports the Headache Network's diagnostic, therapeutic and care pathway, which rests on the existence of innovative care and treatment pathways designed to integrate various settings (specialist, primary, domiciliary). The abovementioned algorithm can be specialised for the clinical management of other chronic conditions requiring different diagnostic, therapeutic and care pathways. The Calabria regional authority, and more specifically its Department of Health Protection and Health Policy, lays down guidelines to optimise the available resources, channelling them towards those levels of care that combine the best possible service effectiveness and cost effectiveness, thereby increasing the efficiency and potential of the regional health service. To ensure that planning of healthcare activities is based on the principle of appropriateness, negotiations need to be organised between provincial health authorities and hospitals, with a view to planning regional specialty networks and drawing up diagnostic-therapeutic pathways aimed at transferring resources away from improper uses in hospitals, and towards local services. General practitioners and district specialists need to be involved in these negotiations, in order to agree what type of services can progressively be moved from the ambit of ordinary inpatient care to day hospital or outpatient care. The following are currently participating voluntarily in the HealthSOAF pilot project: the Headache Centre at the "Pugliese-Ciaccio" Hospital, Catanzaro (regional reference centre); district neurologists from the districts of Catanzaro Lido and Soverato, and GPs at the primary care units of Catanzaro Lido, Borgia, Soverato. The aim is to put together, through the various levels, a picture of the situation so as to clarify the most appropriate management strategies for the individual local health authorities in the Calabria region, starting from the hub-and-spoke model that constitutes the legislative and operational model of reference. Making improvements to the care of headache patients through a management model that can be adapted to the Calabria region's individual hospitals and local health services

may lay very solid foundations in several ways:

- by making regional management of demand revolve around instruments for demand control rather supply control (clinical governance);
- being translated into concrete operational and organisational models the will to favour, for headache patients, care solutions other than the traditional hospital one;
- by supporting network health professionals in clinical and organisational decision making (through a strategy of quality information); having quality knowledge is desirable for good health protection, but in addition to this it is extremely important for the management of economic resources, given that behaviours are often determined by improper habits rather than based on solid evidence of effectiveness.

Pilot study in the field of headache care

The aim of the HealthSOAF project pilot is to identify, within the diagnostic-therapeutic pathways of headache and migraine patients, a series of scenarios of use, as well as sets of clinical-healthcare processes typically associated with these scenarios, which might prove useful for testing and evaluating the correctness, effectiveness and efficiency of the services provided as part of the project. This required the prior analysis and formalisation of new organisational-management models for the clinical management of chronic diseases. These models are based on: the design of innovative care and treatment pathways that integrate various settings (specialist, primary, domiciliary); identification of the players acting within the specific context, with definition of their roles and functions; implementation of mechanisms to support collaborative cooperative approaches among the players; procedures for the planning, organisation and operational management of the overall health resources involved; and finally, planning, production and delivery of the most appropriate clinical services for the specific domain (5), (6). Accordingly, the present pilot experience has made it possible to test a technology platform capable of delivering services that support integrated clinical management of headache patients, and to create a collaborative and cooperative environment able, through the acquisition, integration and processing of data, information and

clinical-health knowledge, to provide information and decision support to all the “players” within the domain.

The specific treatment and care pathways that have been outlined are characterised by a series of interactions between the standard HealthSOAF services, which can be summarised as follows:

- request for identification of patient / health worker (HIS service);
- request for consultation of clinical documents (HRS service);
- verification of authorisation policies (HPS service);
- request for insertion of electronic document, in standard format, in a document repository (HRS service);
- request for authorisation policy insertion (HPS service);
- evaluation request (HDSS service);
- request for access to the Reference List (HTS service);
- search request (HDS service).

The infrastructure that is being created in support of the healthcare process, in order to allow complete application interoperability, will also provide for the implementation of a component for orchestration of the single services. Several clinical-health indicators for the evaluation, at prototype level, of the effectiveness and efficiency of the proposed solutions are currently being defined.

Materials and methods

Between December 2014 and June 2015, 15 primary care general practitioners in Catanzaro Lido,

Borgia and Soverato, three secondary care neurologists, and one multidisciplinary tertiary care team from the Headache Centre at the Pugliese-Ciaccio Hospital in Catanzaro, used the pilot client software and accessed the HealthSOAF platform.

Results

In the period considered, general practitioners recruited 197 patients with headache diagnoses made with the support of the technological platform: 19 (9.64%) had a suspected diagnosis of secondary headache and were referred to emergency rooms; 74 (37.56%) were diagnosed with episodic primary headache and managed exclusively by general practitioners at primary care level; 36 (18.27%), also with episodic primary headache, were managed by both general practitioners and outpatient neurologists, again in the primary care setting; 68 patients (34.52%) were sent to the reference headache centre. The preliminary data from the pilot study, showing an approximately 50% reduction in inappropriate referrals to the hospital reference centre (15.42% vs 7.35%), indicate enhanced diagnostic accuracy and appropriateness of referrals within the coded diagnostic, therapeutic and care pathways.

Conclusions

In this experimental pilot study, use of the HealthSOAF platform was found to be associated with great-

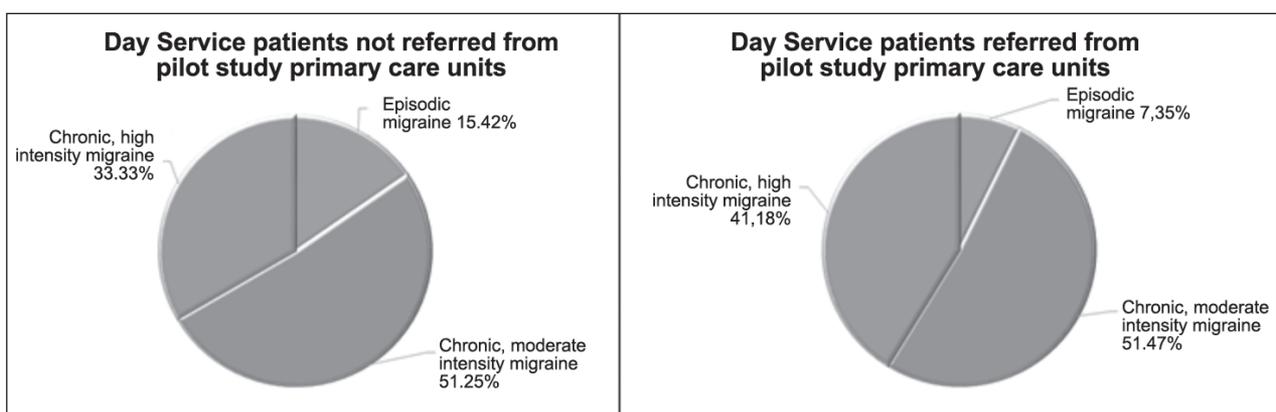


Figure 3. Diagnostic-therapeutic care pathway in the network of HealthSOAF services

er appropriateness of diagnosis and access to care at the three levels of the headache network. The use of ICT support in clinical decision making and management processes is a valuable aid in clinical practice. The HealthSOAF project is the first at a national level and among the first at international level to study, define, test and validate a new approach in the software development cycle, designed to guarantee interoperability of distributed and highly heterogeneous health information systems, of the kind that are increasingly necessary to support continuity of care, diagnostic processes, integrated therapeutic care, prevention activities and public health protection. For this reason, the HealthSOAF project has been placed at the centre of important initiatives at national and international level, so that this knowledge might be made available to the technical-scientific community and constitute a best practice for introducing innovation into the production of clinical-health information systems.

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