An Open Data Approach for Clinical Appropriateness

Mario A. Bochicchio[1], Lucia Vaira[1(✉)], Marco Zappatore[1], Giambattista Lobreglio[2], and Marilena Greco[2]

[1] Department of Engineering for Innovation, University of Salento, Lecce, Italy
{mario.bochicchio, lucia.vaira, marcosalvatore.zappatore}@unisalento.it
[2] Department of Clinical Pathology, Vito Fazzi Hospital, Lecce, Italy
patologiaclinica.polecce@ausl.le.it, grecomarilena@gmail.com

Abstract. In recent years there have been partially unexpected qualitative and quantitative increase in clinical exams demand. Although on the one hand this is the positive result of better health awareness, mostly in terms of prevention, on the other hand it is the direct and logical consequence of the defensive behaviour, which arises from the potential occurrence of legal controversies and of the clinician's unawareness about the cost of examinations. To reduce the occurrence of unnecessary clinical tests we propose an approach based on Open Data and Open Software that can be adapted to existing medical information systems to enforce a suitable set of "appropriateness rules". The idea is to directly intervene at the moment of the request emission, in order to avoid unnecessary demands, which have no urgent and valid motivations and/or no value for patients.

Keywords: Open data · Clinical appropriateness · Open software · Rule engine

1 Introduction

The use of clinical laboratories has significantly increased over the last decades, while healthcare budgets worldwide are facing increasing pressure to reduce costs, improve efficiency and maintaining quality of care [1]. This is relevant because clinical laboratory practices contribute in a decisive fashion to the 70 % of the medical diagnoses and this means that the primary role of the laboratory in the diagnostic and clinical paths is by now certain, accepted and widely recognized. The largest sector in lab medicine in terms of test volume and revenue is clinical pathology [2] (66 %, $31.9 billion), followed by anatomic pathology (19 %, $9.0 billion) and molecular pathology/esoteric testing (8 %, $4.1 billion).

Many authors claim that too many laboratory tests are ordered in clinical practice. Daniels and Schroeder [3] found a 20-fold difference in laboratory utilization on patients with the same diagnosis, while others state that 30–50 % of tests conducted are required without valid motivations [4]. Several studies have suggested that

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inappropriate test requests are a primary reason for such an increase [5]. The rate of inappropriate test requests ranges from 4.5 % to 95 %, as shown in the systematic review of laboratory clinical audits by van Walraven and Naylor [6].

The appropriateness of clinical, or more generally, medical requests plays hence a key role in programs for quality improvement, a challenging task in the healthcare domain that can benefit from the use of a wide variety of tools and methods [7]. The increase in inappropriate requests stems from several factors including the routine clinical practice that leads to the adoption of strict protocols and guidelines; the defensive behaviour, which arises from the potential occurrence of legal controversies; the excessive frequency of repeat tests by apprentice medical staff because of uncertainty and clinician's unawareness about the cost of examinations [8]. Furthermore, by comparing hospitals from different countries, and those in the same country [9], great differences can be found in laboratory usage, which can be classified in at least four families of inappropriateness [10]:

- lack of knowledge about an already performed exam for a specific patient;
- unavailability or inaccessibility of previous test results;
- lack of knowledge about the response time for a given exam;
- doubts about the reliability of the obtained result.

In Italy, where the healthcare sector is essentially public, the Slow Medicine[1] movement, founded in 2001 [11], has launched the "*doing more does not mean doing better*" campaign similar to "Choosing Wisely"[2] in the United States, which aims to improve clinical appropriateness through the reduction of unnecessary tests and treatments. The campaign deems medicine as soaked with inappropriateness, wastes, conflicts of interest, and many cliché induce professionals and patients to consume more and more healthcare services in the illusion that this can improve health. The repeated request for tests is a component of the inappropriate usage of the laboratory that may be subject to evaluation and improvement initiatives. Several attempts to control inappropriate requests have been presented in literature so far, which included: rationing tests, redesigning of request forms, educating about appropriate tests for various conditions by discouraging futile repeat tests, educating about costs, issuing feedback information, and using protocols [12]. Unfortunately, the majority of these strategies has proven to be scarcely effective and those which have actually reduced requests were often been expensive in terms of time and/or manpower and have had no sustained effect once they were withdrawn.

In its broadest sense, an inappropriate request is one that should not be processed, generally because it is requested for the wrong patient, at the wrong time, in the wrong way, or is for the wrong test [13]. This last definition contains four basic concepts that can be summarized as it follows: do the right things, in the best way, at the right time to those who need it [1]. In other words:

- performing the right tests means choosing exams that are able to change the clinical/diagnostic/therapeutic practice;

[1] http://www.slowmedicine.it.

[2] http://www.choosingwisely.org/.

- performing tests in the best way implies the selection of the most suitable analytical methods and systems, by endorsing in the evaluation: sensitivity, specificity, accuracy, reliability, timing and productivity;
- performing tests at the right time means applying the appropriate diagnostic window in order to make the exam "clinically useful";
- performing tests to those who need (to the right patient) contains within itself the concept of efficiency: tests should be carried out taking into account two main attributes, that is the purpose and the optimal usage of resources.

Each clinical test has to respect some constraints (often of a temporal nature) in order to be appropriate but, at the same time, it has to be compatible with the patient status (drugs assumption, allergies, pathologies, nutrition …) as well. Such compatibility can be verified by adopting several kinds of mechanisms, but in general, the idea is to directly intervene at the moment of the request emission. To the best of our knowledge, this kind of "validation" is often provided as a supplementary feature by the commercial software adopted in the Operative Unit, under payment of additional fees. Therefore, due to the lack of resources and/or to political/institutional reasons, this service is often not taken into consideration. Another crucial issue in such a context is about the absence of open data and open rules on the clinical appropriateness.

For these reasons, in this paper we propose an approach, mainly based on Open Data and Open Software, which can be easily adaptable to existing clinical information systems in order to verify the appropriateness of laboratory test requests. Particular attention has been posed to sensitive information, which are mainly protected by applying proper anonymization techniques.

The paper is organised as follows: after the introduction in Sects. 1 and 2 presents background and related works in the field of clinical appropriateness looking for potential correlated studies. In Sect. 3 we delineate our proposal, analysing the potential solutions and presenting the software agent and the whole block architecture. In Sect. 4 we present a retrospective evaluation showing the potential savings reachable when using our proposed system. Finally the last Section is for conclusions.

2 Background and Related Works

Although the considerable relevance of the above-discussed "appropriateness" problem, only few contributions are available in literature on the topic. Efforts to remedy this problem have been tried for decades as well, but the problem still seems to exist [14]. In numbers, a search on Scopus,[3] IEEE Xplore,[4] ACM Digital Library[5] and PubMed[6] databases, for papers published from 1990 to 2015, returns 246 publications matching the "*clinical appropriateness*" pattern and 115 publications on "*medical appropriateness*". Most of them are "off-topic" or discuss about appropriateness

[3] Scopus Database, http://www.scopus.com/home.url.

[4] IEEEXplore Digital Library, http://ieeexplore.ieee.org/Xplore/home.jsp.

[5] ACM Digital Library, http://dl.acm.org/.

[6] PubMed Database, http://www.ncbi.nlm.nih.gov/pubmed.

considering a specific medical sector (not the "laboratory test" demands). Furthermore, most of the literature refers to the 90's, when the adoption of ICT on the theme was less developed. A synthetic report of the literature review process is depicted in Table 1 where each search pattern is associated to the number of contributions found, by differentiating them into "off-topic" publications and relevant ones. Among these works, the one by Charles et al. [15] is the most similar to our approach, although it dates back to 1998. In that paper, an Internet-based system for the construction and maintenance of ontologies for clinical appropriateness criteria is presented. The system allowed users to edit the indexing terms and the semantic network that form the ontology for a set of appropriateness criteria.

Table 1. Literature review report from 1990 to 2015

	Scopus			IEEE Xplore		
	Total	**off topic**	**relevant**	**Total**	**off topic**	**relevant**
clinical appropriateness	123	117	6	6	6	0
medical appropriateness	50	46	4	8	4	2
filters	Title, abstract, keywords			Full Text and metadata		

	ACM DL			PubMed		
	Total	**off topic**	**relevant**	**Total**	**off topic**	**relevant**
clinical appropriateness	7	7	0	110	103	7
medical appropriateness	17	14	3	40	36	4
filters	Any field			Any field		

3 Our Proposal

The aim of the proposed approach is to develop an Open Software Agent (OSA in the following) based on Open Data, easy to adapt to existing systems and able to verify the appropriateness of laboratory services requests, hence increasing the level of operators' awareness about the clinical tests and ensuring a better level of service.

3.1 Open Data Approach

Open Data holds a great potential in the health sector [16]. Their adoption for the definition of appropriateness criteria (or rules) allows to overcome the main limit of the existing commercial systems based on a pre-defined core of rules which are subject to obsolescence and not open to the scientific debate. On the other hand, the usage of open software and the resulting possibility to share the design, construction and maintenance costs among the interested users allows to overcome the problems related to the high costs of commercial systems. In this perspective, the collaboration of doctors, patients and pharmaceutical companies can help to continuously update and improve the appropriateness rules. This is in clear contrast with the existent systems, in which every single department or hospital needs to update its own private repository. The idea is to create an open and sharable "appropriateness rules" repository, which can improve the comprehension, facilitate the discussions on the topic and better support the validation

of rules. For example, assuming that doctors discover a new appropriateness rule (e.g. that screening a pregnant patient for hemoglobinopathy after the first pregnancy is redundant) then, after the approval of a scientific committee, this is added to the shared repository and immediately applied by all the OSA operating in the connected laboratories to block this kind of inappropriate requests.

3.2 Appropriateness Rules Management

The content of any clinical appropriateness criteria can be directly translated to IF-THEN rules. Considering the same example of hemoglobinopathy, the rule can be thought as the statement:

IF the patient is pregnant AND pregnancy IS NOT the first
THEN hemoglobinopathy is inappropriate

From a technical point of view, this can be managed in two different ways:

1. adopting a rule engine, which filters the exam requests and gives the adequate response (appropriate/inappropriate requests);
2. exploiting the existing conceptual model (a mapping between database and appropriateness rules). The rules are considered as SQL query statements, which return a Boolean value (yes/no) reflecting the appropriateness.

In the first case, the rule engine allows to separate business logic from application logic. The behaviour of the system can then be modified without code changes or recompilation/redeployment cycles. Rules are stored in a file so they can be changed with a rule editor and each rule consists of a conjunction of conditional elements corresponding to the IF part (left-hand-side or LHS) of the rule, and a set of actions corresponding to THEN part (right-hand-side or RHS) [17]. Data are stored in database connected with the main software for clinical appropriateness and the rule engine will pick the necessary data from the concerned tables. The data flow is straightforward: data representing each new request of clinical test is passed to the engine, rules are executed and later, if appropriate, each request is transmitted to the laboratory to be fulfilled. In our context, this can be done interactively, when requests are submitted by the personnel of each ward. In more details, each element of the request is evaluated by the rule engine, then the RHSs of those rules are evaluated and the request is approved/rejected. In the second case each appropriateness rule is described in terms of SQL queries. These queries are directly applied to request data. In case of inappropriateness the same queries can notify the violated constraint. The decision on which of the two possibilities is better is quite hard, depending on several factors (e.g. rules complexity, software and hardware constraints etc.). Rule engines are often considered easier to use and integrate than database tables. In fact, they can provide high flexibility since there are no queries, no tables, and no code. The rule engine controls all the logic, in addition rules are easier to understand than SQL code and they can be effectively used to bridge the gap between business analyst and developers. Finally, keeping rules in one place leads to a greater reusability. In summary, rule engines are considered appropriate for general setting. On the other hand, they also bring lots of extra costs, complexities and performance consumptions while performing checks on database with the help of

normal SQL queries can be less resource-demanding and more efficient. The conceptual model of the Database of Rules (DoR in the following) is shown in Fig. 1. A given "Rule Statement", which is expressed in natural language, can be composed of other, more basic "Rule Statements" and each rule is implemented in SQL by a "Rule Expression". SQL clauses (e.g. WHERE, HAVING, GROUP BY and ORDER BY) are represented in figure by the "Condition" class; logical operators (AND/OR/NOT) are used to combine conditions. In this way, a "Rule Expression" is composed by one or more "Condition". The appropriateness concept is here exposed by means of the "Error" class.

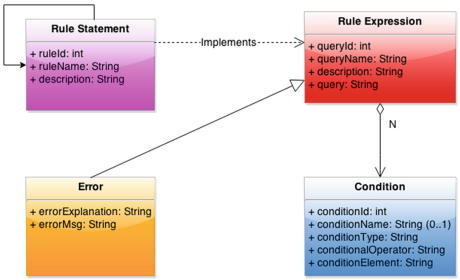

Fig. 1. Conceptual model of the database of rules

3.3 Architecture Overview

In this subsection we will discuss about the "as is" architectural model and the "to be" one in order to demonstrate the impact of usage for our proposed OSA. As represented in Fig. 2a, each single ward represents an applicant. Whenever a ward demands for an exam for a specific patient, it will use the management software shared by each ward in order to activate the exam request process. The request is taken over by the software installed in the Clinical Pathology Lab (CPL-Sw). Our software agent, named CLAP (CLinical APpropriateness) system, will be "placed before" the main software in the operative unit of clinical pathology as depicted in Fig. 2b. It will be in charge of

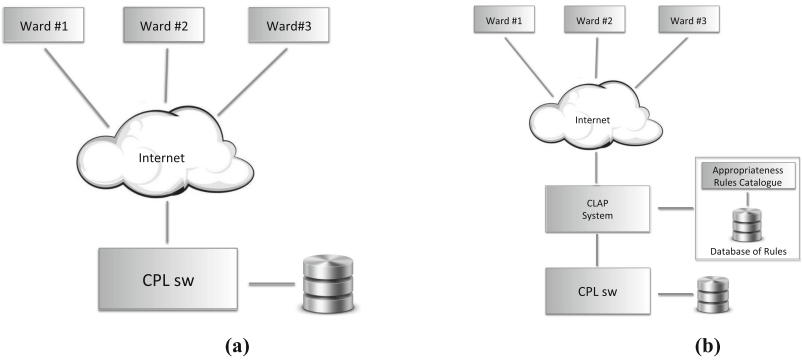

Fig. 2. (a) AS-IS and (b) TO-BE

checking the requests and, if appropriate, to send them to the CPL-Sw. The DoR will include the whole set of clinical appropriateness rules that are applied to each request. This is built as an open and sharable clinical appropriateness rules catalogue so that every operative units of each interested department could use it.

The behaviour of the CLAP System can be summarized as:

- check on the temporal distances between two test requests;
- proactive behaviour of the system (presenting the exam as already done and showing the result if the test validity period is still effective);
- check on the clinical profile of the patient (preventing the execution of inappropriate tests based on particular conditions).

4 Experimental Evaluation

The adoption of the CLAP system in clinical laboratories could allow significant savings for diagnostic tests. In order to prove this assertion we have performed a retrospective evaluation by analysing exam requests in 6 months (Sept 2014 – Feb 2015) in the unit of clinical pathology of the main hospital of Lecce, in Italy. Such operative unit generates costs of about 3 M€ per year (reagents, consumables, machinery maintenance, …) and serves nearly 1 million of patients. In Fig. 3 are reported the numbers and the percentage of test services in 2013 distinguished by diagnostic area.

	# tests	%
Clinical chemical and biomarker	1.780.376	72,92%
Coagulation	248.801	10,19%
Haematology, autoimmunity, allergology	190.005	7,78%
Hormonology	81.807	3,35%
Toxicology	55.694	2,28%
Electrophoforesis	32.254	1,32%
Virology	25.538	1,05%
Urine	27.082	1,11%
Total	2.441.557	

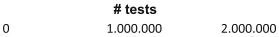

Fig. 3. Clinical services performed in 2013 in the OU of clinical pathology

A retrospective evaluation has shown direct potential savings estimated at about €600.000 per year. In particular, of 1.200.128 exam requests, approximately 218.000 (18 %) were considered inappropriate, about 110.000 (9 %) were uncertain, and near 880.000 (73 %) were deemed to be appropriate. By considering the Italian price list for the specialist outpatient care (of January 2013), and a cost of 1,2€ per clinical service, the overhead due to inappropriate requests in the investigated period was calculated at about €250.000. The details are represented in Fig. 4. Such savings, however, largely depend on the degree of computerization in the healthcare area and on the integration among the involved systems, but they represent a first signal of improvement.

Months	Appropriateness			Total
	Appropriate	Uncertain	Inappropriate	
Sept - Oct	168.983 (*72,80%*)	16.248 (*7,00%*)	46.888 (*20,20%*)	232.120
Nov - Dec	246.424 (*74,20%*)	13.284 (*4,00%*)	72.400 (*21,80%*)	332.108
Jan - Feb	457.848 (*72,00%*)	79.488 (*12,50%*)	98.565 (*15,50%*)	635.900
Total	873.255 (*72,76%*)	109.020 (*9,08%*)	217.852 (*18,15%*)	1.200.128
Estimated cost	€ 1.047.907	€ 130.824	**€ 261.422**	€ 1.440.153

Fig. 4. Economic burden of clinical services performed during September 2014 - February 2015

5 Conclusions

The reduction of unnecessary clinical tests and the enforcement of specific "appropriateness rules" can save considerable resources to public health. A retrospective evaluation performed on real data at the operative unit of clinical pathology of the main hospital of Lecce, in Italy, showed potential direct savings estimated at approximately € 600.000/year. The achievement of clinical appropriateness cannot, however, be reduced to a mere matter of saving money, but it should be inspired by the need to raise awareness among professionals and disseminate knowledge on the proper use of diagnostic prescriptions. The development of an automated system that can efficiently supervise the tests' requests making use of an open and sharable repository may be a first solution to the problem. For these reasons we feel that the development of a proposal based on open source technologies and open data may represent an opportunity for savings resources while enhancing the quality and efficiency of the laboratory analyses.

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