Can ICT Help to Solve the Clinical Appropriateness Problem?—An Experience in the Italian Public Health

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Abstract: Clinical exams are essential in modern medicine for disease screening, diagnosis and monitoring, but their misuse can lead to resources dissipation. In recent years there has been a significant increase in clinical exams demand. This can be seen both as a positive result of an improved health awareness, mostly in terms of prevention, and as the direct and logical consequence of the medical defensive behaviour, which arises from the potential occurrence of legal controversies and of the clinician’s unawareness and indifference about the cost of clinical exams. Often the reasons are related to practical problems, such as the lack of knowledge about an already performed exam, the unavailability or inaccessibility of previous test results, doubts about the reliability of the obtained result for a specific exam or, even, the loss of the previous medical report. In order to reduce the occurrence of inappropriate exams requests we propose an approach, mainly based on Open Data and Open Software, to enforce a suitable set of “appropriateness rules” which can be used to check the appropriateness of the request exam as soon as the request is submitted to the medical unit in charge to perform it. The appropriateness rules come from an open and update repository that can allow the total comprehension about the clinical appropriateness topic and facilitate discussions and debates on the theme. The paper discusses also an implementation of the proposed approach and its application to a public hospital, in Italy.

Key words: Open data, clinical appropriateness, open software, rule engine.

1. Introduction

The use of clinical tests is essential to obtain information about the health of a patient as concerning to the diagnosis, treatment and prevention of disease.

At the same time, laboratories are often overused and such usage is significantly increased over the last decades causing hence cost increase and excessive resources exploitation. Inappropriate and therefore unnecessary test requests are a primary reason for such increases.

In Italy, where the healthcare sector is essentially public, the appropriateness of health procedures is attracting considerable attention at this time, particularly in the light of the need to control the growth of healthcare costs. Appropriateness is in fact at the center of a healthcare reform, aimed to cut about 10 billion Euros in public health expenditures over the next five years.

Referring to the U.S., the largest contribution to laboratory medicine, in terms of test volume and economic value, comes from Clinical Pathology Wards [1] (66%, $31.9 billion), followed by Anatomic Pathology (19%, $9.0 billion) and Molecular Pathology (8%, $4.1 billion).

Trying to answer to the question “is the total number of clinical tests appropriate for diagnostic purposes?” several authors claim that, in clinical practice, there are too many requests. Daniels and Schroeder [2], for example, found a 20-fold difference in clinical tests utilization on patients with the same diagnosis, while others state that 30-50% of the performed tests lack valid motivations [3]. 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 [4].
Burke in 2002 [5] stated that “an appropriate test is one in which the result provides an answer to a question that enables a decision to be made and an action taken”. More formally, according to the definition of the College of American Pathologists [6], appropriateness in medical laboratories is “the extent to which a particular procedure, treatment, test or service is effective, clearly indicated, not excessive, adequate in quantity, and provided in the inpatient, outpatient, home, or other setting best suited to the patient’s needs”.

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 [7]. This last definition contains four basic concepts that can be summarized as: “do the right things, in the best way, at the right time to those who need it” [8]. In other words:

- performing the right tests means choosing tests that are able to change the clinical/diagnostic/therapeutic practice;
- 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. In addition, in order to make comprehensive evaluation, the patient’s care regimen has to be taken into account as well;
- 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 them (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.

The appropriateness of clinical 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 [9].

The increase in inappropriate clinical requests can be due to several behavioral and practical reasons. From the behavioral point of view, such increase can derive from [10]:
- the routine clinical practice that obligates to the adoption of strict protocols and guidelines;
- the frequent repetition of tests by apprentice medical staff because of uncertainty and inexperience;
- the medical defensive behavior, which arises from the potential occurrence of legal controversies and leads to diagnostic tests or treatments that are not necessary for the patient, but that can mainly serve the function to protect the doctor against the patient as potential accuser;
- clinicians’ unawareness and indifference about the resources consumption.

From the practical point of view, the increase in inappropriate requests arises from [11]:
- lack of knowledge about an already performed exam for a specific patient that is still valid;
- unavailability or inaccessibility of previous test results (in most cases this happens in multi-wards situations);
- lack of knowledge about the response time or the validity time for a given exam;
- doubts about the reliability of the obtained result for a specific exam.

Another crucial issue in such a context is about the absence of open data and open rules on the clinical appropriateness. To the best of our knowledge, does not exist an open and update repository that can allow

<table>
<thead>
<tr>
<th>Cause of inappropriate request</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong patient</td>
<td>Prostate specific antigen as a tumor marker females</td>
</tr>
<tr>
<td>Wrong test</td>
<td>Factor V Leiden genetics on a patient with a normal activated protein C test</td>
</tr>
<tr>
<td>Wrong time</td>
<td>Glycosylated haemoglobin bin (HbA1c) 1 week after the previous test</td>
</tr>
<tr>
<td>Wrong process</td>
<td>Renin/aldosterone in patients on some types of diuretic</td>
</tr>
</tbody>
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the total comprehension about the clinical appropriateness topic and facilitate discussions and debates on the topic. The discovery of new types of tests, the advent of new drugs and the adoption of new approaches to care, push for the question “what is the relation between new tests and the already existing ones?” and moreover “is a specific test compatible with itself and/or with other tests?”.

We feel that an open and sharable data source could allow the publication and the subsequent availability of the appropriateness rules so that each Operative Unit can exploit it for free. 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 and personal information, which are mainly protected by applying proper anonymization techniques.

The paper is organized as follows: after the introduction in Section 1; Section 2 presents background and related works in the field of clinical appropriateness; In Section 3 we present our proposal, analyzing the potential solutions and in Section 4 we delineate the overall architecture of the proposed system; In Section 5, we present a retrospective evaluation showing the potential savings reachable when using our proposed system and we discuss the findings; Section 6 is for conclusions.

2. Background and Related Works

A common conviction for professionals and patients is that consuming more and more healthcare services, which is equivalent to “doing as much more exams as possible”, could improve health.

Undeceiving health professionals and patients of such cliche is one of the aims of the Slow Medicine movement, founded in Italy in 2001 [12] which has launched the “doing more does not mean doing better” campaign (similar to “Choosing Wisely” in the United States) and that aims to improve clinical appropriateness through the reduction of unnecessary tests and treatments. The repeated request for clinical tests is a large 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 repetition of tests, educating about costs, issuing feedback information, and using protocols [13]. Unfortunately, the majority of these strategies have proven to be scarcely effective and those that 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. Other studies have been focused on analyzing the frequency of appropriate/inappropriate requests in order to assess how frequently patients request medical tests or treatments, what types they demand, the clinical appropriateness of their demands, and how frequently clinicians comply. In Ref. [14], authors presented the frequency of demanding patients, clinical appropriateness of their demands, and clinicians’ compliance with them in relation with requests for cancer tests and treatments and found that in oncology, “demanding patients” seem infrequent and may not account for a significant proportion of costs.

In Ref. [15], we have presented a literature review about clinical and medical appropriateness in order to demonstrate that, although the considerable relevance, only few contributions are available in literature on the topic.

Searching on the major and most used research-oriented digital libraries (Scopus, IEEE Xplore, ACM Digital Library and PubMed) we found 361 papers published from 1990 to 2015, about “clinical appropriateness” and “medical appropriateness”. Most of them were “off-topic” or
discuss about appropriateness considering a specific medical sector (not the laboratory test demands) and only 26 can be considered “relevant” for the topic.

Furthermore, most of the literature refers to the 90’s, when the adoption of ICT (internet and communication technologies) on the theme was less developed.

The exploitation of Information and Communication Technologies (ICT) may significantly contribute to decreasing the frequency of these repeated requests by adopting different kinds of mechanisms, such as:

- introducing time blocks between two consecutive requests;
- showing the results obtained in the previous exams;
- presenting the probability that the test gives pathologic results.

Such approach can be pursued in order to improve the appropriateness of the request for laboratory tests, establishing the main criteria that must be met by the applicant, in the absence of which the request for exam will not be generated. In this way, each clinical test will respect temporal constraints in order to be appropriate but, at the same time, it will be compatible with the patient status (drugs assumption, allergies, pathologies, nutrition …) as well.

Such compatibility can be accomplished by directly intervening at the moment of the request emission. To the best of our knowledge, this kind of “validation” (when and if present) is often provided as a supplementary feature by the commercial software adopted in the Operative Units, 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.

3. The Proposal: CLAP System

The aim of the proposed approach is to develop an OSA (open software agent in the following) based on Open Data, easy to adapt to already existing systems and able to verify the appropriateness of laboratory test demands by using appropriateness rules coming from an open, accessible and continuously updated repository. The open repository is essential to overcome the main limit of the existing commercial systems, based on proprietary and predefined set of rules, which are largely subject to obsolescence and not open to the scientific debate.

In this scenario, the collaboration of health professionals, patients and pharmaceutical companies can help to continuously update and improve the appropriateness rules dataset in order to improve the comprehension, facilitate the discussions on the topic and better support the validation of rules.

Whenever new rules are proposed, validated and approved by a scientific committee, such repository will be updated and each Operative Unit, which is interested in evaluating the clinical appropriateness, will be able to adopt them for free.

The content of any clinical appropriateness criteria can be directly translated into IF-THEN rules. The THEN part is in charge to define if a specific exam is appropriate/inappropriate; the IF part represent the list of the patient and treatment conditions and/or hypothesis. From the technical point of view, in Ref. [15], we discussed the possibility to adopt rule engines or mapping rules.

The decision on which of the two possibilities is better depends on several factors (e.g., rules complexity, software and hardware constraints etc.). Rule engines are often considered easier to. 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.
The direct implementation of the rules as database queries (e.g., in SQL) can be less resource-demanding and more efficient. In this case, rules can be converted in SQL statements, which return a Boolean value (yes/no) reflecting the appropriateness of the specific test. The data flow is straightforward: data representing each new demand for clinical test coming from a specific ward, is passed to the OSA that controls the appropriateness rules for that test and, if appropriate, transmits it to the laboratory to be fulfilled. It is hence in charge to interactively approve/reject clinical exam requests.

In Fig. 1, it is shown a simplified version of the conceptual model of the Database of Rules (DoR in the following), which represents a sort of rule catalogue that is continuously feed by the open and sharable repository of rules.

A given “Rule Statement”, expressed in natural language, is recursively decomposed in terms of simpler “Rule Statements” which are finally implemented in SQL by means of suitable “Rule Expressions”.

Since each rules can be subject to several constrains, a “Condition” class is used to express such constraints in terms of triggers (mathematic expressions) connected by logical operators (AND/OR/NOT). In this way, as shown in Fig. 1, a given “Rule Expression” is composed by one or more “Condition”. The “Error” class is used, in case of inappropriateness, to explain in natural language which rule or constraint/expression has been violated, why the request is considered inappropriate and how to make it appropriate. This means that, in case of inappropriateness, it is the same query that notifies the violated constraint.

The error messages are intuitive and simple to understand, for example:
- test not legitimate according to its previous value (with the possibility to look at the report);
- exam already requested in the last 15 days (the temporal value change according to the rule);
- test already performed and not repeatable;
- exam not appropriate for a woman (or a man);
- test inappropriate if patient has no cardiac pathologies (or other kinds of specific patient’s conditions).

4. Architecture Overview

As anticipated before, one of the strength of the proposed approach is about the possibility to adapt the
CLAP (CLinical APpropriateness) system to existing clinical information systems. In Fig. 2 it is depicted the overall architecture of the proposed solution.

Each single ward represents an applicant (i.e., a subject enabled to request clinical tests). The “Clinical Pathology Lab sw” is the software normally adopted by the test laboratory to manage the incoming requests, and does not include any appropriateness evaluation.

Our CLAP System is then interposed between the Clinical Pathology Lab Software and the front-end used by the wards, so that each single request is checked and, only if appropriate, it is sent to the Clinical Pathology Lab Software. The DoR includes the whole set of clinical appropriateness rules applied to the coming requests. Such database is weekly aligned with the “Rules db” which represents the open and sharable clinical appropriateness rules catalogue that is feed by the Scientific Community.

The process related to the proposal, validation and approval of new appropriateness rules requires the definition of the different states that a rule can assume. A rule can be:

- proposed: as long as it is in this state, it is possible to discuss about it;
- validated: the scientific committee validates the proposed rule according to several criteria;
- approved: one of the possible outcomes of the validation phase that precedes the rule publication;
- rejected: it is one of the possible outcomes of the validation step. It must be supported by one or more suitable motivations;
- awaken: a previously rejected rule can be reconsidered in a second moment.

Only validated and approved rules are included in the DoR. The behavior of the CLAP System can be summarized as follows:

- check on the temporal distances between two test requests (being the temporal check the principal
Can ICT Help to Solve the Clinical Appropriateness Problem?

constraint);
- proactive behavior 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).

The proposed approach does not modify in any way the existing software architecture; the CLAP System, based on data-scraping techniques, is interposed between the department’s wards and the “Clinical Pathology Lab sw”, in order to apply the clinical appropriateness rules to each new test request coming from the wards’ acceptances. The idea is hence based on the possibility to capture the data constituting the exam request directly from the source, at the acceptance ward.

In this way, the system can also enforce a “continuous learning” strategy toward the medical staff, in order to constantly expand their skill-set. Just to make an example, if a cholesterol test has a value greater than 240, the requesting physician is remembered by the CLAP System that the rate of heart disease risk for the patient is very high.

5. Results and Discussions

Inappropriate test requests are a primary reason for cost increase and resources exploitation. In order to have an overall idea about the potential savings, before actually using it, we have performed a retrospective evaluation by analyzing exam requests in 6 months (Sept. 2014-Feb. 2015) in the unit of Clinical Pathology of the main hospital of Lecce, in Italy. The details about results are presented in Ref. [15]. Shortly, the retrospective evaluation has shown direct potential savings estimated at about €600,000 per year. 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.

Apart from the money savings, the openness of the proposed approach generates also a series of indirect benefits: it increases the visibility in the research community, which can represent a real incentive for contributors; it makes the Clinical Pathology Units cutting edges departments, etc.

The foundation of a scientific committee for the creation, diffusion and sharing of clinical appropriateness rules can represent a first intervention which is needed to unblock a political and administrative obstacle for the free circulation of such rules.

6. Conclusions

The reduction of inappropriate clinical exams 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 development of an automated system that can efficiently supervise the tests’ requests making use of an open and sharable repository which centralize all the information related to the clinical appropriateness may be a first solution to the problem.

Professionals should disseminate knowledge on the proper use of diagnostic prescriptions and laboratory requests.

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.

As future work we plan to begin in the next two months a field trial in the Department of Otolaryngology of the main hospital of Lecce, in Italy, in order to measure the potential direct savings.

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