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Representation and Communication of Pharmaceutical Expert Information

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REPRESENTATION AND COMMUNICATION OF PHARMACEUTICAL EXPERT INFORMATION

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Abstract - Pharmaceutical expert information is characterized by steady increase in extent and complexity as well as by strong interweavement and penetration with interdependent references. These properties suggest the utilization of modern hypermedia technology, organizing knowledge as a network of linked pieces, enabling more intuitive, faster and easier navigation within the growing information space. There is a need for a suitable, role oriented external representation of pharmaceutical expert information.

The application of pharmaceutical expert information when analyzing medications for contraindications and interactions is mainly mechanical in nature. It requires to follow references and to compare codes. The electronic availability of medication information, which is often forced by drug dispensing systems, is not exhausted when these procedures are performed manually at the screen. There is a need for automatization of these procedures. This automatization requires a suitable internal representation of pharmaceutical expert information.

The universality of pharmaceutical information systems leaves open their conceptual environment. The different kinds of application scenarios pose strong requirements on the formalization of expert information. A universal representation has to be found which captures the nature of pharmaceuticals including common properties of drug classification systems. The diversity of the latters within the different healthcare organisations is to be regarded as the most serious barrier aggravating global communication within the healthcare system.

I. MOTIVATION

The main concern of healthcare management has ever been embodied by two conflicting goals. These are improving care quality while reducing care costs. Information technology already has proven its positive impact on both goals. While general administrative tasks are being performed more efficiently for some decades, expert oriented systems are entering the medical domain with increasing support capabilities for domain specific therapeutic procedures leading to more secure and efficient therapy planning, monitoring and control.

The demands on quality and effectiveness of care are posed by social, legal and political areas, resulting in growing expectation, uncertainty and pressure concerning health care professionals' use of expert information. These circumstances are cornering medical practitioners. A variety of role specific information problems may be identified which finally can be attributed to the non-availability of suitable represented expert information as well as to missing automatization of medical procedures. In their entirety they indicate two major information problems in healthcare.

The *representation problem* consists of the lack of a universal representation of pharmaceuticals which formally describes their common properties as well as their behavior within groups of simultaneously applied drugs. Internal representation affects granularity and precision of information as well as the functionality of the application system. External representation affects suitability of access and navigation mechanisms, which depend on the user's role and situation. An internal representation may meet the needs of many applications, while an external representation can only be as suitable as the internal representation allows.

The *communication problem* refers to the communication capabilities of a representation delivered by a solution of the previous problem. There is nearly no benefit of a pharmaceutical information model if information is not suitable for transportation. This means that the impact of an internal representation reaches interorganizational cooperation capabilities. This affects particularly the diversity of semantic reference systems used by local representations. The communication problem consists of finding means to enable organizations to exchange information with a minimum of human intervention.

As the information jungle continues to grow healthcare costs and treatment quality change to worse. The patient has to bear the consequences. While his contribution on treatment costs increases, no one can guarantee that the medication designed by the physician is optimal in both therapeutic and economic sense. For instance, many expensive commercial brand products of major manufacturers may be substituted by more beneficial, therapeutically

equivalent generics, but without this information at his fingertips the physician will continue to prescribe products with concise and habitual names.

II. APPLICATION DOMAIN

The application domain targeted by pharmaceutical information systems includes any medical subject area affected by information on properties of pharmaceutical products. This comprises the treatment situation at the physician's desktop, drug dispensing procedures in hospital pharmacies, pharmaceutical consultation at the drugstore as well as patient home information. Although differences exist among role and situation specific external representations of user oriented information, any application of pharmaceutical information systems relates to some properties of pharmaceuticals.

This universal applicability of pharmaceutical information systems leads to their architectural role as a subsystem within a not further specified superordinated medical information system. Many applications may exist. Thus, these systems are highly polymorphic in nature and the need for a single universal internal representation can be justified with reusability, integrity and universality. The role leaves open any assumptions of the application domain. Any usage is specific to the superordinated application system. However, three principle applications of pharmaceutical information systems may be considered.

Medication Analysis is a procedure that aims to identify any critical problems within a given input medication. A set of problems is computed, each of which may be a contra-indication, an interaction or an overdose. It is desirable that this procedure also adds links to further information found in local or external documents. Medication analysis can significantly improve security of drug dispensation.

Medication Transformation is a procedure that aims to construct a new medication which is therapeutically equivalent to an input medication, and which meets certain optimization criteria. The most beneficial criteria refer to cost reduction. Then, some of the prescribed drugs are substituted with the most beneficial but therapeutically equivalent products available. This procedure relates to Managed Care (Prescription Benefit Management), as is practiced in the United States as an intervention of insurance companies in the prescriptions of physicians. Medication transformation can significantly improve prescription efficiency.

Medication Synthesis is a procedure that aims to construct a medication based on its desired properties. The input is a specification of these properties in terms of wanted and optionally unwanted effects, and the output is a medication with a maximum of conformity with the specification and a minimum of undesired properties, concerning both therapeutic and economic issues. Until now, medication analysis is to be regarded as a theoretical application and is mentioned because it formally is the opposite procedure to medication analysis.

The application goal for the physician seems to be clear: The goal is to be able to define an optimal medication for a patient with a given disease within a given situation. In this context the term 'optimal' refers to both the therapeutic suitability and the economic effectiveness of a medication. While this task is impossible to accomplish manually in reasonable time, distributed information services could provide techniques to compare costs and therapeutic properties of pharmaceutical products automatically. For instance, the physician could select some brand drug and ask for any generics with the same composition and effects.

Within the scope of a hospital pharmacy two principal uses of pharmaceutical expert information may be distinguished. The main purpose is the drug dispension, usually performed automatically by a machine controlled by a special software system. Up to date this is the primary reason for electronic representation of medication information. The second task of the pharmacy is to check each medication for certain errors and inconsistencies, e. g. contra-indications or serious interactions. This analysis, which is regular and mechanical in nature, is still done manually. Pharmacists sit in front of the screen and analyze medications using a book. There is a need for the automatization of medication analysis.

From the patient's point of view there is a need for information on the drugs he takes, on their usage and influence on his disease. This information has to be presented in a way understandable by the patient. This means that descriptions and instructions should not contain expert terminology and should not require a deeper understanding of the medical domain. This property of presentation has great influence on the patient's discipline. Apart from medical or scientific oriented scales, good patient information must be regarded as one component of a good therapy.

For any expert oriented application it is desirable to access local and external documents, which are relevant to a given situation or which explain some statement made by a system. For instance, if medication analysis reports a critical interaction, links

should also be presented allowing the user to immediately access further information from standard literature or product documentation. This also suggests an application for medical students where a system can analyze their prescriptions and generate hints and advices.

III. PROBLEMS OF INFORMATION MANAGEMENT

Healthcare in general is characterized by high specialization and division of labour. Many professionals practice services for many patients, and data is produced at many places and may be needed at many others. Mobility of patients and the free choice of medical practitioner makes this situation worse, as the individual's moves through the healthcare system leave trails consisting of distributed heterogeneous medical data. Thus, mobility of patients requires the mobility of data.

Pharmaceutical product information is distributed and heterogeneous in a similar way as is patient data. Furthermore, it is subject to fast change and reconditioning. It partly refers to patient medical data, as is with contra-indications or age specific dosage instructions. As a conclusion one may notice strong interconnections and dependencies between patient specific medical data and pharmaceutical product information. Product documentation refers to patient specific conditions, and patient therapy documentation refers to applied products.

The scattering and heterogenity of both patient history data and pharmaceutical product information lead to a variety of information problems for the different actors in the healthcare system. These problems refer to the availability of information in general and to the suitability of its representation in particular. Any of these role specific information problems may finally be attributed to the two major problems of healthcare information management: representation and communication of expert and product information.

The *physician's information problem* refers to the treatment situation, where medications are composed and pharmaceutical products are compared. Far too much information would have to be taken into account in order to determine the most effective drugs regarding to both therapeutic suitability and economic benefit. The problem consists of not having means to consult all of the available information sources manually, without the help of information technology.

The *pharmaceutical company's information problem* refers to both the communication of product information to the practitioners who prescribe it and the reflow of information gained through observation and experience. There are incentives for the industry to pass actual findings delivered by research and practice to the practitioners. There are also incentives to get informed on unknown drug effects.

The *insurance company's information problem* refers to the economic optimization of prescriptions through substitution of products. Under care and attention of the critical constraint of therapeutic equivalence the substitution of brand products with generics bears a high potential of cost saving but effect keeping transformation. But this transformation requires knowledge and is desired to be performed automatically.

The *patient's information problem* refers to his situation at home, after being undeceived and instructed concerning drug application by the physician. In general, additional questions arise within this situation and many aspects on disease, treatment, medication and instructions are not covered by the short and expensive consultation. From the patient's point of view there is a need to be able to get informed on these aspects whenever he wants to. From the physician's point of view there also is a need to delegate standard explanations to public media.

In the advent of the approaching information age these information problems would not exist, if there were reasonable means of applying information technology on the use of pharmaceutical expert information. This leads to the very question of information exchangeability within the healthcare sector regarding to pharmaceutical products. As with any other kind of information on entities, the attributes of which are represented as references into certain external classifications, drug information may only be interpreted in regard to respective semantic reference systems.

There is one major conclusion to be drawn from the variety of role specific information problems illustrated above. They have in common the need for information retrieval and processing concerning pharmaceutical products as well as its preparation in a suitable external representation. It seems that the reason for missing availability of pharmaceutical information is not its absence but the different languages existing in healthcare. Starting from that today there are means to transport information from one site to another, one may realize that the problem cannot be the absence of communication infrastructures. The answer is much more simple and complex at the same time: The problem lays within the information itself. The most serious problem

blocking global communication in healthcare results from the lack of common languages.

IV. MODELING PHARMACEUTICAL EXPERT INFORMATION

The formation of a universal information model for pharmaceutical products and their properties relates to domain specific coherencies concerning drugs and chemical substances as well as many aspects of software engineering in general. The former involves some understanding of the applications and effects of pharmaceuticals as well as the interdependencies among the different kinds of properties a drug may have. The latter involves design strategies and modeling techniques which meet today's requirements on compactness, reusability, flexibility and consistency of an internal representation. Any pharmaceutical information model will be measured by its applicability in both fields.

The most fundamental awareness of any drug characteristics describing information model must be the distinction of two kinds of properties which may be regarded in different layers. These are properties, which refer to a pharmaceutical product in isolation, on the one hand, and its behavior within the society of a group of drugs, on the other hand. The former are constant for a drug and will not change. The latter depends on the combination of drugs, the patient's state and on many other aspects of its situation. This distinction may be captioned by the following assignments.

Static pharmaceutical information refers to drug properties which will not change when the drug's role within a medication or therapy changes. These properties include name, manufacturer, composition as well as obligatory information. Some of these properties may be represented as isolated data elements. This means that they are consistent on their own, and their interpretation is independent of certain external formalisms. Other properties (e. g. indications) are to be regarded as references into external semantic reference systems, and may not be interpreted without the awareness of these formalisms. For instance, an indication can be regarded as a reference into an indication classification system. Of course one could model such properties as simple text fields. But in this case, only humans could understand this information.

Dynamic pharmaceutical information refers to drug characteristics concerning their behavior within a medication, especially the interplay of therapeutic effects. These characteristics are dynamic in nature because they may change with a drug's membership within different medications. They depend on various parameters of a clinical situation, including disease, patient demographic data, and, of course, other prescriptions. A drug may change the effect of other drugs and its effects may be changed by others.

A universal pharmaceutical information model should not refer to some specific classification system. Instead, it should refer to an abstract meta-structure which is capable of being instantiated by any classification. *Groupings*, as such meta-structures will be called in the following, are abstract trees representing inheritance hierarchies with implicit IS-A semantics. Inheritance is the principal property these structures provide: Any information associated with some group is also valid for each of its subgroups.

The universality of a pharmaceutical information model results from two major design properties. First, not one but a set of groupings reside in the knowledge base, providing a language for describing drug properties. Secondly, any drug may be assigned into not one but into any number of groups belonging to different groupings. The first design issue (multiple groupings) allows the consideration of different classification strategies and therefore the provision for different applications. Each grouping represents some specific view on the domain, focussing specific attributes of pharmaceutical products. The second design issue (multiple assignments) allows a maximum of precision concerning the representation of drug properties. One single assignment represents some feature of a drug. The entirety of assignments *characterizes* a drug.
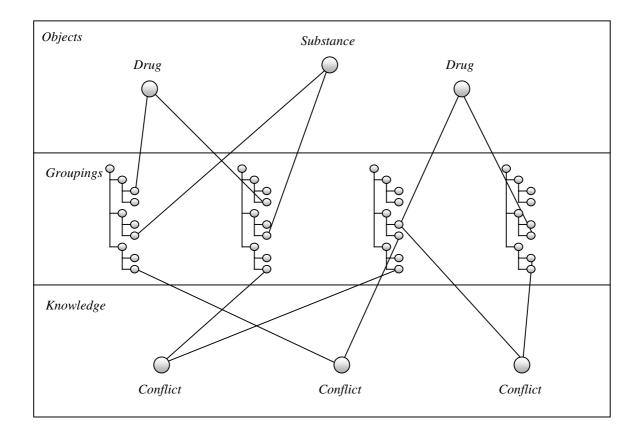
Groupings provide the vocabulary to specify relations between groups of drugs. *Conflicts* may be defined which relate one group to another and state that a combination of respective group members may cause a critical interaction. Additional conditions may be attached to such a conflict (e. g. indication, dosage) that further refine the set of cases where a conflict indicates an interaction. In this way, medication analysis may be reduced to the evaluation of group combinations.

Analytic processing capabilities of pharmaceutical expert information belong to the most beneficial properties a suitable information model can provide. Examples for their applications include automatic medication analysis, product comparison and even medication analysis. There is no loss in functionality comparing to low structured representations, because simple text documents may always be generated from precise representations. In addi-

tion, such a generation may take respect to the user's role and situation through inclusion and exclusion of information components, detail level determination and through terminology selection.

The universality of a pharmaceutical information model based on the abstract grouping concept presented above may be illustrated by the following scenario. Assume a hospital pharmacy which is responsible for the daily validation of medication information. The pharmacy uses their own drug classification system which is tailored to the set of locally applied pharmaceuticals. The automation of medication analysis is desired on the condition that the local classification system needs not to be replaced.

A medication analysis system based on the abstract grouping model meets these requirements. It suggests the following installation steps. First, the local classification system is entered into the system as a set of groups organized in a hierarchical structure. Secondly, the set of drugs is acquired focussing on static information and, thus, resulting in a linear list of records. Then, drugs are characterized by assigning one or more groups to each drug. Finally, conflicts are defined by selecting sets of groups the elements of which form a critical combination.

Then, medication analysis can be performed automatically. The system may be configured to let pass standard medications and to identify occurrences of critical drug combinations. In these cases the system may notify the users and the medication can be reviewed manually. From the pharmacist's point of view, automatic medication analysis can significantly reduce the number of cases which need human attention, while the local classification system can be used to specify the electronic knowledge needed for medication analysis.

Interplay between objects, groups and conflicts

V. Further Research

The formation of a universal pharmaceutical information model may suggest an internal representation within the context of pharmaceutical information systems, but it cannot provide solutions for problems resulting from the distinct roles, views and interests among the different actors in the healthcare system. Political agreement of common organization of expert information cannot be concern of medical informatics.

The *unification problem* of healthcare refers to the chasm between universality and specifity of semantic reference systems. A universal classification system will not be suitable for specific applications and a classification which is suitable for a specific application will not be suitable for others. There seems to be no way out: The unification of semantic reference systems appears to be the only solution.

The *standardization problem* refers to the development of semantic reference systems and to the institutionalization of their coordination. Starting from that diversity exists between different applications, roles and interests, it would be desirable to have these differences controlled by a global institution. The question is: Who will act as a global standards defining institution and which interests will be covered?

The major problem of internal drug representation is the formation of a universal information model. This in turn leads to the challenge of developing one universal drug classification system. Since any classification is a direct result of respective design strategies and focused applications, a universal drug classification system must be the result of common design strategies and common goals. The question is: What should be the major design strategy regarding to a universal drug classification system?

The universality of scope claimed by uniformity of representation leads to the property of suitability. A universal classification system is exhaustive with regard to the focused domain, and in all probability it is oversized for small applications. This holds for monoaxial classifications. There is no proof for the theoretical existence of a universal (possibly multi-axial) classification which meets suitability of all applications. The question is: Can a universal pharmaceutical classification system meet the needs of specialized applications?

In the past many innovative concepts were developed to help overcome information problems in healthcare. Many projects failed at the requirements of data security. The latter has emerged to a political rather than a technical barrier of healthcare communication. In many cases, data security requirements for technical procedures exceed the requirements for equivalent manual procedures. For instance, the German electronic health insurance card was originally intended to store medical data on a patient's history. Today these cards do not contain any medical data. Under full agreement to the importance of data security, the question is: Will data security issues continue to barrier information processing and communication in healthcare?

Taking the diversity and heterogenity of pharmaceutical classification systems for granted and immutable one possibility remains. This is the automated mapping of semantic references between different classification systems. This means that a reference into some classification may be automatically translated into a reference into another classification. Since almost any pair of classification trees consists of similar layers, such a translation is always possible. However, information loss is the price for this automated mapping, when differences between classifications are too large.

VI. Discussion

The two-sided challenge of representation and communication of pharmaceutical product information illustrates the interdependency between information modeling and distribution in healthcare. Both dimensions affect the application of expert information. A pharmaceutical information model may be suitable for some applications and it may be suitable for communication. But it seems to be very difficult to design a model which is suitable regarding both dimensions.

As with any kind of information which is used in different application contexts, pharmaceutical product information may be structured in many ways, resulting in different and in most cases incompatible reference systems. Pharmaceuticals may be classified by indication or contra-indication, their composition of chemical substances, their pharmacological effects or therapeutic use. Any of these characteristics implicates certain applications of the resulting classification. In general, a classification system incorporates an application specific strategy of decomposition. Strong interdependencies exist among properties like universality, complexity and suitability.

These circumstances suggest doubts on the theoretical existence of a universal classification system

for a knowledge domain covering all application scenarios and meeting all requirements. These doubts get stronger under the consideration of suitability, which correlates extent and complexity of a classification system with extent and complexity of an application scenario. For instance, the german drug classification system provided by the 'Rote Liste' covers about 9000 commercial pharmaceutical products, while small hospital pharmacies deal with only about 800 drugs, which in their combination cover all medications. It seems that a universal classification system for a knowledge domain, which is exhaustive in nature, must be oversized for the needs of small applications.

A scientific point of view enlightens many aspects of domain specific classification development which identify the real problems predominantly within the expert domain itself. Many applications of classification systems make use of their hierarchical structure and object-oriented nature, if given. In fact, properties of classifications are applied in terms of inheritance and polymorphism. There exist reasonable doubts on the awareness of the object-oriented modeling paradigm in the community of classification developing medics. This can be proved with several classifications developed in medicine, which in general match the requirements of knowledge representations, but fail at the vital design properties (e. g. ICD, ICD-O, ATC).

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