Securing drug prescription and administration: the case of chemotherapy

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Summary
Decision support, order entry, drug and care administration with their respective documentations cannot be seen as independent actions, especially in terms of medical approach and patient safety. Chemotherapy offers a good illustration of the varied implications of technology information in these multifaceted and intricate processes. Chemotherapy administration can be a highly complex process. It can take place over a variable period of time ranging from hours to several months. Usually it involves numerous actors around the patient, such as physicians, pharmacists and nurses.

Chemotherapies can be produced specifically for a given patient and can have dramatic effects if errors occur. Chemotherapy depends on various information, including patient-specific data such as temperature, weight or laboratory findings; drug-specific knowledge such as side effects or administration directives amongst others. At the University Hospitals of Geneva (HUG), critical process reengineering accompanied by new applications covering the whole chain of processes involved in chemotherapy, from prescription to administration including preparation, have been developed. This paper presents the overall approach leading to computerisation of these processes.

Introduction
The need for increased safety and efficiency in care production is an important goal in healthcare [1]. Optimisation of care production and greater efficiency of care logistics, while improving quality and safety, is, however, a challenging task. Information technologies make it possible to reach both goals.

Information technologies make it possible to reach both goals. However, reaching these goals involves embedding information technologies at all steps of the process, clearly identifying all actors and objects involved and, usually, in-depth reengineering of these processes, the associated procedures and the way they are (often historically) carried out. To illustrate this, we present developments surrounding chemotherapy at the HUG.

The HUG is a consortium of hospitals in four campuses and more than 30 ambulatory facilities in the state, comprising more than 2'000 beds, 5'000 care providers, over 45'000 admissions and 750'000 outpatients' visits each year. It covers the whole range of in- and outpatient care, from primary to tertiary facilities. The HUG is the major public healthcare facility in the Geneva region and the adjacent area of France. A computerised patient record (CPR) developed in-house is used in all facilities and runs on more than 4'500 PCs. Over 20'000 records are opened every day by more than 4'000 care providers from all functions [4].

Chemotherapeutic agents are prescribed for various oncological and haematological disease states. Although they are considered to be the treatment of choice for many cancers, these medications are associated with serious and potentially life-threatening side effects. The toxicities of these anti-cancer drugs and the multidisciplinary actors involved in the whole treatment process create a very high risk of devastating medical errors. In an effort to minimise the potential for chemotherapy-related errors, the HUG has spent the last few years launching important developments and prospective risk analyses, with a view to lowering the criticality of the whole process [5]. A partial result is that the preparation of all chemotherapies administrated at any of the HUG facilities has been centralised at the pharmacy. Centralisation guarantees processes, quality and traceability of the preparations and their components and – very important – operator safety. This first phase served to justify the need and the pertinence of a single description of the substances used and their associated protocols. One major task was the creation of a global database containing all substances, materials and a description of procedures that can be used for in-house preparations. This could not be done without reaching a consensus among all the actors involved. Building the protocols is one of the very complex tasks performed in close collaboration with and under the supervision of specialists. This database can then be used by the applications developed to request new preparations, manage pending requests, organise the actual preparations and
manage traceability before, during and after the production process.

The prescription side

On the prescription side we have developed a family of tools including components to assist the creation and management of specific protocols, to use them for given patients, and also to assist in the follow-up of all patients under chemotherapy. The last point is illustrated (figure 1) and shows the list of patients and their respective chemotherapy protocols. For each patient a large amount of information is visible, such as the protocol type, the number of the cycle involved, the first day and the next day of chemotherapy. This feature helps oncologists to follow their patients and the current status of all running protocols, while also providing a powerful tool for evaluation of the treatment, its efficacy and prevention of side effects.

At the time of prescription, physicians can choose the appropriate protocol and use it with the data pertaining to the correct patient. The system will help in adjusting doses and the chronology of procedures, as well as all elements pertaining to the chemotherapy regimen selected (figure 2), including preparation of the chemotherapy if required.

The system can produce alerts (figure 3) in some situations, e.g. overlapping dates and regimens. Other alerts may be added in the future, such as a warning if renal function is worsening or the white blood cell count too low.

The pharmacy side

In many cases the regimen associated with a protocol does not exist per se commercially, but must be produced specifically by the HUG’s central pharmacy.

The tools developed for the pharmacy allow the management of most of the logistics needed to produce drugs from raw substances. This includes reception of the raw substances and their identification/validation, tagging, stocking and localisation, batches follow-up and usage. They also ensure complete traceability of all actions on these substances or their derivatives, up to the final product preparation and its distribution. The production of products must follow strict production protocols, distinct from prescription protocols, which include materials, procedures, validation steps and safety behav-
This production includes specific chemotherapy treatments, but also a wide range of in-house prepared products, such as cough syrup or disinfectants amongst others. The computerised production protocols can be adapted to a large number of parameters, ranging from patient specific data to mass production variables. Drugs validation and laboratory analyses are often performed both at the level of raw substances and on the final product (figure 5). These analyses ensure the quality of the raw components and of the final product used for patient care. Until a product, raw or final, has been validated, it is left in “quarantine” and cannot be used. The system makes it possible to track all batches, production and expiration dates, suppliers, end users, remaining stocks, and the position of the product in the production workflow (figure 6). It ensures standards in the production chain and increases operators’ safety. In parallel, a computerised high precision balance is used to reduce the risk of errors during production (Cato®1). This tool automatically determines the volumes of the preparations to be produced, and the data are used to ease validation of each step by controlling the plausibility of the result.

Drug administration: the nursing side

One of the complex tasks in computerisation of this process is drug administration. Before the chemotherapy is administered, complete instructions are printed in the ward for nurses, including information on drugs, side effects and their prevention (e.g. nausea), and precautions for the administration itself. These precautions cover many aspects, such as solution incompatibilities, administration temperature, administration route or protection against light (figure 7).

The last step in the process is bedside traceability of administration of the drug to the patient. To be able to properly trace all administration steps, it has been necessary to tag all infusions and actors, the nurses involved and the patient. This phase is currently still under development. A solution based on a pocket PC is being developed. The goals of this module are the following:

- verification that it is the right preparation for the right patient;
- automatic check that the preparation is still administrable (use-by date);
- verification at the bedside that no withdrawal instructions have been issued meanwhile;
- complete traceability up to the “last mile”.

1 Computer Aided Therapy for Oncology (cato).
http://www.cato.at
These functions require correct identification of the three “partners” involved: the patient, the nurse and the preparation. While there are many ways of identifying the partners, proprietary or non-proprietary, we decided to start using international numbering of objects and selected GS1’s EAN, UCC (formerly EAN – European Article Numbers) coding schema. All three partners thus have their own code which can be read by the pocket PC and validated on-line according to the information stored in the Hospital Information System (HIS): patient and nurse have their own permanent EAN. UCC codes and each preparation produced by the pharmacy receive a single identification code enabling tracking in the institution. All EAN codes use the EAN-128 encoding scheme.

EAN/UCC encoding can be used on various transporters, such as “D” barcodes, data matrix, radio-frequency tags, etc. The problem with the barcodes arises from the size of the printed code: 2-D formats are rather large, and data matrices are not commonly read by classical readers. The labels on infusions and other preparations are devoted to human-readable information, thus reinforcing humans’ ability to cross-check information (Figure 8). For this reason we decided not to use printable codes. To achieve this, the use of labels with integrated RFID chips has been chosen for electronic identification of preparations as well as patients (using a wristband with an RFID sticker) and nurses.

The labels for preparations are printed at the pharmacy before production and joined to the raw material required for fabrication, while the patient labels are produced at the admission desks (they are currently produced at the pharmacy until the trial is complete). This solution enables the use of a single reader at the bedside in safely establishing the identities of the patient, the nurse and the preparation to be administered. The RFID reader is used with a PDA (iPaq) with WLan connexion to the CPR. Validation checking can thus be done in real time and at the bedside.

Discussion and conclusion
Implementing such a system is a challenge, merging virtual and real worlds. It involves numerous actors and cannot be achieved without careful management of the organisational impact. Analysing the complete process of chemotherapy, from the design of a protocol to prescription, production, administration and follow-up as a coherent and shared workflow is an important paradigm in improving both the safety and efficiency of the process.

On the clinician’s side this process has initiated a global formalisation and sharing of protocols and guidelines. Except in special cases, the prescription of drug regimens not agreed within protocols is no longer possible. Only adjustments pertaining to patient characteristics are allowed; doses are then validated according to several variables that cannot be overstepped. Prescription has gained in transparency and readability. In the pharmacy the benefits are numerous, from better management of raw substances and traceability to increased safety and standardisation of the operators’ work. For nurses, validation of the administration and confidence in the overall process should be increased when the final phase is introduced. At this stage clear benefits have
already been derived thanks to the standardisation, completeness and readability of treatment directives.

The system has been well accepted by all the actors involved. The importance of the quality of the information is well recognised and the tools do offer a significant improvement. However, it must be emphasised that the formalisation and validation of all processes, including each protocol, impose significant time demands, especially on oncologists.

The initial project for support of the prescription and production of chemotherapies has been successfully deployed and is well accepted by its users. The second phase, bedside validation of the administration of medications to patients, is in development and should be used in a pilot ward within a few months. We expect a significant improvement in the overall security of patient care, thanks to several factors: better documentation in the patient record, elimination of handwritten orders, controls at prescription, elimination of multiple retranscription, production and administration levels, etc. The use of pocket PCs and radio-frequency technologies at the bedside is expected to grow as real-time application and complete traceability are progressively introduced.

The patient will be the final beneficiary of the system, gaining from a globally improved process with increased safety and traceability. Further studies will be conducted once the bedside administration validation system is in production.

References
1 ITAC. Report to the President, Revolutionizing Health Care through Information Technology. President’s Information Technology Advisory Committee June 2004.