Organisational Analysis of Different Modalities in Drug Administration

Lucio Buffoni (a), **Libero Ciuffreda** (a) , **Antonio Di Leva** (b), **Salvatore Femiano** (b)

(a) Centro Oncologico Ematologico Subalpino, A.S.O. San Giovanni Battista di Torino
C.so Bramante 88, 10126 Torino (Italy)
(b) Dipartimento di Informatica, Università di Torino - Corso Svizzera 185, 10149 Torino (Italy)

lciuffreda@molinette.piemonte.it, bufluc@libero.it, (dileva|femiano)@di.unito.it

ABSTRACT
The aim of the study is the organisational analysis of the care pathway for patients in the Oncology Division of a large hospital, in order to evaluate pros and cons of different drug administration modalities (the oral modality compared with the endovenous one). The study was focused on patients treated with the chemotherapic drug Navelbina in a day hospital setting, using a process analysis methodology. Starting from the pathway specification and from quantitative parameters of the workload, the efficiency of the patient pathway in terms of cycle time and resources exploitation has been assessed through simulations. This was done in order to highlight the real positive effect of the oral drug administration compared with the traditional one and also to point out solutions to improve the efficiency and to optimise the resources management. The study findings have confirmed the advantages of the oral type modality.

Keywords: business process modeling, software engineering

1. INTRODUCTION

Since a few years, hospital health care units are undergoing management reorganization in order to improve the service and to be more competitive with other health service structures; particular attention is given to budget problems.

It is a very complex task to manage the development of an integrated care department. Managers are facing a relevant number of favorable and unfavorable conditions. To deal with these conditions, they need methods that provide qualitative and quantitative information about care processes. Service quality is strictly dependent on the ability to coordinate different skills and duties, even more than on the ability to optimize each of them. In this scenario, new management tools and ideas are needed in order to conciliate service quality and budged optimization.

This paper presents a practical approach for a quantitative analysis of the Oncology Division (Centro Oncologico Ematologico Subalpino - COES) of the largest hospital in Torino, the *Azienda Ospedaliera San Giovanni Battista*. Aim of the project is to analyse the patient care pathway in the DH (Day Hospital).

A patient care pathway is the "route" that a patient will take from their first contact with a member of the COES staff, usually a nurse of the COES-DH, to the completion of their treatment. You can think of it as a process, on which every activity relating to treatment can be described.

Activities such as consultations, diagnosis, treatment, medication, assessment, and preparing for discharge from the COES-DH can all be mapped on this timeline. Thus the pathway gives an outline of what is likely to happen on the patient's journey, i.e. it details the essential steps in the care of patients with a specific clinical problem and describe the expected progress of the patient (Campbell, Hotchkiss, Bradshaw, Porteous 1998).

Specifically, our analysis is focused on the advantages of prescribing the drug *Navelbina* through the oral way and not by direct injection into the blood stream. The drug *Navelbina* is a very good study subject as it is available in both oral and injecting form and is widely used in clinical treatment. Two different reorganizations of this process, both aiming at increasing the service efficiency, are discussed below.

The first one introduces the oral way of drug administration with no need to modify the present organizational structure. The second one, in addition to what included in the first solution, introduces a change in the infrastructure and technology of the oncology division.

In the literature, there is a strong support for the reengineering of healthcare organizations. Enterprise methodologies originally developed for manufacturing processes are now used to improve the operations and competitiveness of hospitals (Lin., Jomon, 2005) (Detlev Smaltz 2005). Both qualitative (e.g. SWOT - Strengths, Weaknesses, Opportunities and Threats) analysis and quantitative (e.g. process evaluation based on discrete event simulation) analysis have been exploited in real life applications (Harding, Paul, Gillis and Kaye 1993) (Abu-Own A, et al 1999) (Bell CM, et al 2000).

This paper is structured as follows. The second section presents M*-COMPLEX, a general-purpose

open methodology that has been developed to study complex systems (Berio, Di Leva, Giolito, and Vernadat 1995) (Berio, Di Leva 2000) , which includes a business process analysis and reengineering phase.
The third section illustrates the case study, which aims to improve the efficiency and to optimise the resources management of the target organization: the oncological division of a large hospital in our city. Finally the fourth section presents some preliminary conclusions of our analysis.

2. METHODOLOGY

M*-COMPLEX is a structured framework which provides a step-by-step strategy ensuring consistent results. Itanalyses functional, behavioural, and organizational aspects of the object organization, and it strongly enforces an event-driven process-based approach as opposed to traditional function-based approaches for analyzing and designing computer-supported integrated engineering environments.

At the organization level, M*-COMPLEX views the world from two orthogonal points of view. First of all, an enterprise can be analyzed in terms of organization elements that can be classified as organization units (units for short), which control other units at a subordinated level, and so on. Units at the bottom level are called work centres.

Units define areas of responsibilities and authorities and must be analyzed in order to identify their functions, i.e. things to be done and services to be provided. Top-level functions are decomposed at different levels of detail, until the bottom level in which activities are carried on by work centres.

From the other point of view, activities are executed by resources, processing or producing different objects (pure information or material objects). They are subject to scheduling or planning and can be coordinated into organization processes. Thus, an enterprise can be seen as a collection of concurrent processes that define the flow of actions and are triggered by stimuli called events.

Each process specifies the complex control flow between enterprise activities: it shows which activities should be performed at a time for achieving process objectives. The Organization Analysis phase of M*-COMPLEX is structured into two major steps: As-Is analysis and To-Be analysis.

The aim of the As-Is analysis step is to provide managers and engineers with an accurate model of the enterprise as it stands, out of which they can make a good assessment of its current status. The As-Is analysis step encompasses the following sequential tasks: Structural Analysis, Functional Analysis, Process Reconstruction, and Validation.

Other than modelling activities, those tasks also suggest how to report current problems concerning the represented enterprise components, new requirements, and how to discover and report potential and unknown problems.

The To-Be analysis provides guidelines for transforming schema developed during the As-Is analysis and it encompasses three major sequential tasks: Diagnosis, Restructuring, and Validation. The Diagnosis task should point out the potential causes of the current problems reported during the As-Is step.

A matrix cause/solution suggests the guidelines to perform the Restructuring task that modifies models issued from the As-Is step. Finally, adopted solutions are validated against current problems and new requirements during the Validation task.

The analysis is supported by a set of modelling languages, i.e. a set of concepts and constructs which need to be used and shared both by analysts and business users. The integrated model that is developed in the As-Is step consists of a functional model and a process model. These models are based, respectively, on the IDEF0 and the BPMN languages.

The IDEF0 language, due to the simplicity and intuitive appeal of its graphical notations, represents the most widespread formalism for the functional modelling and analysis of enterprises (*IEEE Std 1320.1-1998*).

Complying with business process standards, the BPMN (Business Process Modelling Notation) language has been selected for the description of the process model. BPMN is a graphical notation that has been specifically designed to coordinate the sequence of processes and the messages that flow between different process participants in a related set of activities (BPMN.org 2006).

Moreover, BPMN specifications can be simulated by means of discrete event simulation tools, nowadays available on the market (like iGrafxProcess (igrafx.com). Through simulation, the block designer can manipulate building blocks to check their semantic correctness and to see where inefficiencies lie.

It is also important to remember that the simulation allows an effective "what-if" analysis, checking hypothetical business scenarios, and highlight workloads, resources (in terms of costs and scheduling), and activities (durations, costs, resource consumption).

At last, BPMN objects can be mapped in BPEL, that is the Business Process Execution Language for Web Services (Business Process Execution Language for Web Services). For instance, iGrafxProcess, the tool that has been used in our research, is able to convert BPMN diagrams into BPEL files that specify the sequence of Web Services to be executed.

3. CASE STUDY: THE PATIENT CARE PROCESS IN THE COES-DH ONCOLOGY CENTRE

The COES is a multi-disciplinary research and health care structure, and is one of the most important centres in Italy and Europe. COES research activities take place among many medical specialities (oncology, haematology, endocrinology), diagnostics specialities (molecular biology, tutor immunology, cytogenetic), and radiant treatment. In this study we have paid

attention to the Day Hospital (COES-DH), where usually antiblastic therapies for the care of all solid tumours are administrated.

3.3 Process analysis

During the meetings with medical and nursing staff, several problems concerning the patient care management inside the COES-DH have been pointed out. Among them, infrastructure lacks as absence of integration of tools, scarce automation, logistics problems and hardware resources lack if compared with the workload can be noticed. To face these problems, it is important to describe and analyze the patient care process in the COES-DH.

Patients, after having been accepted, wait for blood test. Then, the patient waits again the results of haematic and chemist exams. Patients that have to be pre-hydrated are immediately hydrated after their blood test. At the same time, blood testtubes are sent to the Laboratory by auxiliary staff. The doctor, during the wait, visits the patients and prepares a draft of the chemotherapy for each of them in order to optimize waiting times.

When the doctor receives the results of the exams, he goes on with the study of results with the aim of customising and fix the therapy. If the results show some problems (toxicity, fever, few neutrophil,) the doctor could decide to prescribe a support therapy and defer the chemotherapy in the next week, otherwise the doctor prints the request of the therapy and sends it to the internal Pharmacy by fax.

The waiting times for the drug preparation and results of the blood exams are long. As a consequence, the cycle time of a patient in the COES-DH is very long.

In Fig. 3.1 the "As-Is" process for the intravenous administration of Navelbina is shown.

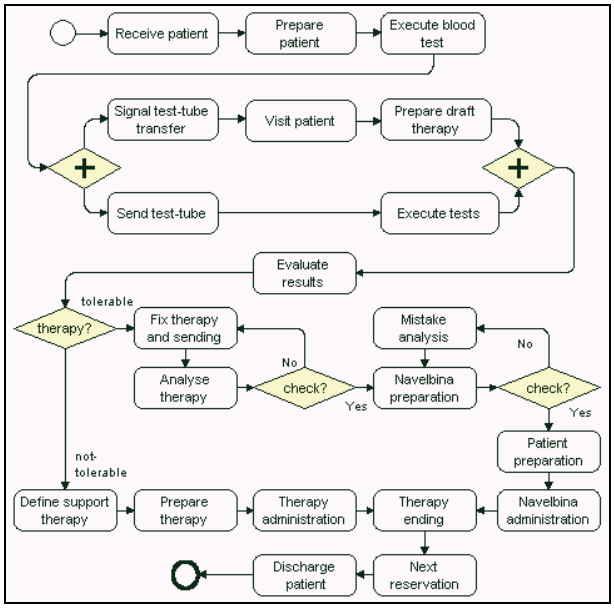

Fig.3.1 – "As-Is Analysis" – the "intravenous administration" process

3.3 Simulation

After the mapping of the process, we prepared an observation chart where, for patients that used the Navelbina drug, times related to all activities of the process can be collected.

To evaluate the real workload, the activities have been observed for a week. For each activity we measured the starting/ending point, the arrival time of patients, sending fax time, and results and drugs arrival times.

The process uses the following resources (5 nurses and 3 doctors with different schedules):

Table 1

Resource	n.of	schedule
Doctor	1	from 8 am to 3 pm
Doctors	2	from 9.15 am to 4.30 pm
Nurses	2	from 8 am to 3 pm
Nurses	2	from 8.30 am to 4.30
nurse	1	from 3 pm to 11 pm

The activities'duration of the model have been deduced from the experimental measures. A normal distribution has been used in the event that the Kolmogorov-Smirnov & Shapiro-Wilk test returns positive values. Otherwise, a triangular distribution based on *min*, *max*, and *mode* values of the sample has been selected. Results of this analysis are displayed in Table 1.

Activity name	Resources	Time (min)
Receive patient	1 nurse	UnifDist(1;2)
Prepare patient (blood test preparation)	1 nurse	TriangleDist(35;41;38)
Execute blood test	1 nurse	UnifDist(2;3)
Signal test-tube transfer	1 nurse	UnifDist(1;3)
Visit patient	1 doctor	TriangleDist(5;8;7)
Prepare draft therapy	1 doctor	UnifDist(5;7)
Send test-tube (send test-tube to Laboratory)	Staff	UnifDist(26;35)
Execute tests	Laboratori	TriangleDist(37;63;47)
Evaluate results (evaluation of exams and patient examination)	1 doctor	UnifDist(3;5)
Define support therapy	1 doctor	TriangleDist(3;7;5)
Prepare therapy (prepare support therapy)	1 nurse	TriangleDist(2;5;3)
Therapy administration	1 nurse	TriangleDist(10;20;12)
Therapy ending	1 nurse	TriangleDist(3;5;4)
Fix therapy and sending (the therapy is fixed and then will be sent by fax to the Pharmacy)	1 doctor	UnifDist(7;12)
Analyse therapy	Pharmacy	UnifDist(4;7)
Navelbina preparation	Pharmacy	NormDist(52;14)

Mistake analysis (the doctor settles any problems in the drug preparation)	1 doctor	TriangleDist(5;7;6)
Patient preparation	1 nurse	TriangleDist(2;5;3)
Navelbina administration	1 nurse	UnifDist(10;15)
Therapy ending	1 nurse	TriangleDist(3;5;4)
Next reservation	1 doctor	UnifDist(3;5)
Discharge patient	1 nurse	UnifDist(6;8)

By means of a simulation of this "As-Is process", it is possible to obtain some significant parameters as cycle time (range of time that a patient spends in the COES-DH) and resource utilization of the more critical resources (doctors and nurses). In our case, the following results have been obtained:

Resource utilization:

- doctor 57%
- nurse 53%

Cycle time: 205 minutes.

It must be pointed out that the resource utilization applies to the particular care process we have studied and not to the whole activity executed in the COES-DH. Indeed if we insert in the process any other kind of chemotherapy, all resources turn out to be heavily used.
In analysing simulation results it must be pointed out that main difficulties are related to the long waiting times to obtain exams results of analysis from the laboratory and drugs from the Pharmacy. Let us analyse these problems separately.

LABORATORY
Waiting time to receive results from the Laboratory depends on three factors:

- - Test-tube labelling.
- - Test-tube transport from COES-DH to Laboratory.
- - Test result availability notification.

Test-tube labelling is a process that influences the waiting time to obtain exam results. Indeed, bad printing of the label or its wrong positioning on a test-tube results in the arrest of the analysis automated line.

This requires intervention by a technician to resume the line. In order to prevent this event, robots have been developed to produce test-tubes in which the labels are correctly printed and positioned.

Test-tubes are currently transported from COES-DH to Laboratory by auxiliary staff. This process is time consuming (it requires about 30 minutes) and this is a relevant part of the total waiting time. A good solution to this problem would be the employment of a Pneumatic Mail tube system in substitution of the auxiliary staff; this would result in a considerable save in transport time.

Regarding test result notification, at present doctors, in order to know test results, have to repeatedly check the result availability with queries to a software application. A possible solution would be the use of acoustic and visual signals to let the doctors know as soon as the test results are ready. This way, waiting time would be reduced from the current 26- 35 minutes to about 4-5 minutes.

PHARMACY
Waiting time to receive drugs depends on two factors:

- Transmission of therapy requests.
- Drug preparation and transport.

At present, doctors have to insert a therapy request into the LIS (Local Information System), print it and then send it by fax to the Pharmacy. It might happen that the doctor decides to make some changes to a therapy on the base of the patient's condition. Some times the doctor introduces these changes by writing on paper and not on LIS. Since the paper form is the only request form officially accepted in the Pharmacy, the pharmacist has to add further effort to his job, and introduces new manual activities in the procedure. This also introduces in the process an element of risk. A possible solution would be the use of a new certified computerized procedure in place of the fax procedure.

The second factor which influences the waiting time depends on the time which is necessary to prepare the drug and to transport it by means of an auxiliary staff. We have measured it takes about 52 minutes to obtain the drug. A possible corrective action would be the use of the same drug, but administered by oral way instead of intravenous way.

This solution would allow eliminating inquiry, preparation and delivery times if just the COES-DH can manage the oral chemotherapy in a local warehouse.
Computer and telematic resources computer and telematic resources of the COES-DH department are insufficient. Indeed, simulation shows that three PC and one telephone line, used for both fax and voice, are inadequate for the workload.

A solution could be the addition of a telephone line and of a wireless LAN into the COES-DH. This last improvement would allow doctors to use a tablet PC, one per doctor, to define chemotherapy right at the side of the patient bed.

3.3 Reorganization of the patient care pathway

The oral administration of Navelbina implies some changes in the "As-Is" pathway. The analysis of the oral administration has been conducted according to the restructured "To-Be" care pathway illustrated in Fig. 2.

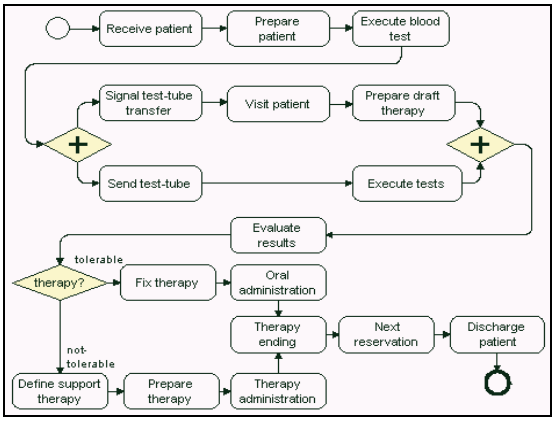

Fig.3.2 – "To-Be Analysis" – the "oral administration" process

The new activities, *Fix therapy* and *Oral administration*, are illustrated in Table 2.

Activity name	Resources	Time (min)
Fix therapy (the therapy is fixed and then the oral drug is delivered to the patient)	1 nurse	UnifDist(2;3)
Oral administration	1 doctor	UnifDist(1;2)

Table 2

Using as a starting point the results of the simulation of the As-Is care process, we have defined two reorganization scenarios:

Scenario A:
The working hypothesis is the variation in therapy administration, from intravenous to oral way. This solution implies a significant variation of the interactions between COES-DH and Pharmacy. Oral administration of the therapy allows reducing the interactions between the two business units. In this hypothesis, the COES-DH has to manage a local warehouse with the oral chemotherapy (Navelbina) supplied by the Pharmacy.

This way all the steps of drug request, drug preparation and waiting time, and all the backup procedures necessary in case of faulty delivery are removed. The doctor once received the exam results and having assessed the patient therapy, delivers the oral chemotherapy to the patient.

Scenario B:
Resource improvements described above, such as the use of a robot for test-tube labelling, a pneumatic mail test-tube system and a certified computerized system to advice doctors that exam results are ready.

The analysis of this new process, using the scenario A, shows the following results:

Resource utilization:

- doctor 47%
- nurse 48%

Cycle time: 141 minutes.

We observe an overall reduction in the patient cycle time of about 31%.

Let's now study scenario B. The process includes the previously described suggestions, which allow reducing crucial waiting time steps, such as exam result notification. The process is the same as in scenario A, we just have changed the temporal characteristics of the activities that are involved in the adoption of new technologies. The analysis of the new
process shows the following results:
Resource utilization:

- doctor 43%
- nurse 42%

Cycle time: 107 minutes.
Thus the overall reduction in the patient cycle time is about 48%

CONCLUSIONS

In this paper we present a methodology that responds to some of the problems organisations are faced with in their process analysis projects. The main objective of the paper is to investigate some potential benefits and outcomes of introducing new processes that could be assessed in advance by using simulation modelling.

In this research, the patient care process in the COES-DH was modelled using a process mapping and simulation tool, iGrafx Process. It has been proved to be a very useful tool for business process analysis and design which offers a way to understand the behaviour of existing and restructured processes without be involved in costly deployment procedures.

This analysis is still under study and the results obtained are influenced by low cardinality of statistical units analyzed. Nevertheless the results obtained seem to be a good estimation of the reality. The benefits of the restructured process has been analysed and two different scenarios were compared.

The first solution just changes the way to administrate the therapy, with no changes in the COES-DH organization.

The second solution is based on the first one, but introduces all the technology innovations previously described. We observe that both solutions provide relevant improvements with respect to the original process. Specifically, referring to the patient cycle time (the overall time a patient spends in the COES-DH), the two solutions allow reducing the cycle time of about 31% and 48% respectively.

It must be pointed out that the development trend of pharmaceutical companies will be based on investments on new molecules with oral administration that can be delivered at patient' home. In the near future we intend to investigate how this trend could impact on the organization of the oncological division and to analyse the benefits of a solution that take into account this new kind of administration.

Bibliography

Abu-Own A, et al, 1999. "Vascular surgical society of Great Britain and Ireland: integrated pathways for vascular surgery" *British Journal of Surgery* 86(5):703.

Bell CM, et al, 2000. "Methodological issues in the use of guidelines and audit to improve clinical effectiveness in breast cancer in one United Kingdom health region" *European Journal of Surgical Oncology* Mar; 26(2):130–6.

Berio G., Di Leva A., Giolito P., and Vernadat F, 1995. "The M*-OBJECT Methodology for Information System Design in CIM Environments" *IEEE Trans. on System, Man, and Cybernetics* 25: 68-85 .

Berio G., Di Leva A, 2000. "The M*-COMPLEX Approach to Enterprise Modeling, Engineering, and Integration", Conceptual Modeling for E-business and the Web, *LNCS Springer Verlag* n.1921, pp. 7-18.

BPMN.org, Business Process Modeling Notation, 2006. *BPMN 1.0: OMG Final Adopted Specification*.

Campbell H, Hotchkiss R, Bradshaw N, Porteous M, 1998. "Integrated care pathways" BMJ;316(7125):133-7, Jan 10.

Detlev H Smaltz et al, 2005. " Making sausage--effective management of enterprise-wide clinical IT projects "*Spring*;19(2):48-55.

IEEE Std 1320.1-1998. IEEE Standard for Functional Modeling Language—Syntax and Semantics for IDEF0. New York: IEEE.

iGrafx.com: Unlocking the Potential of Business Process Management.
http://portal.igrafx.com/downloads/documents/bpm_whitepaper.pdf

Harding MJ, Paul J, Gillis CR, Kaye SB, 1993. "Management of malignant teratoma: does referral to a specialist unit matter?" *Lancet*;341:999–1002.

Lin L., Jomon P, 2005. "Simulation and Lean Six Sigma Integration for Improvement of Hospital Operations" *Proc. 19th Annual Society for Health Systems Conf.,* New Orleans , 2007.; 19:48-55

Business Process Execution Language for Web Services V1.1: http://dev2dev.bea.com/webservices/BPEL4WS.html