An Adaptive Decision Support System for Risk Management in Haemodialysis Departments

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Abstract

The dependability of health care organizations may be improved limiting clinical risks and adverse events. This paper describes a project, implemented in a haemodialysis department, which is aimed at exploiting the results of a dialysis monitoring system to dynamically extract risk profiles for the patients and the clinical centres. These risk profiles allow defining decision support strategies able to adaptively minimize risks and improve patient safety. We focus on the problem of managing clinical risks, in terms of events which influence the risk of hospitalization and mortality and their expected costs. The developed tool takes advantage of an "Incident Reporting System" (Hemostat) and exploits a Bayesian network approach to estimate clinical risk and to propose therapeutic and strategic decisions.

Introduction

Health care organizations (HCOs) have nowadays evolved into complex enterprises, in which the capability of managing risks is a key factor of success for what concerns both the efficiency (including economic results) and the efficacy (outcome results) of the delivered care. Risk management involves all activities and actions performed to improve health care performances and to guarantee security of patients; the security is also based on learning from events [Clements 1995].

In HCOs we can distinguish two different kinds of risk management: "innate" risk management and clinical risk (CR) management. The former is the management of the generic risks of any company (such as fires, natural disasters, liability lawsuits, work injuries, and other types of accidents or legal actions). The latter is linked with the particular service supplied, i.e. the health care delivery. In general, an adverse event is defined as an unwanted damage and uneasiness due to health service's supply which provoke morbidity, mortality or a longer hospital stay; the damage and the uneasiness should not be related to the natural worsening of patient disease. Malpractice is defined as a medical care under average standard of a person with specialized training and education [Committee on Quality of Health Care in America, Institute of Medicine 1999, Commissione tecnica sul rischio clinico 2003].

The events which provoke a damage and financial losses are more frequent during the health service's supply than in other activity (Fig. 1); denunciations and insurance premiums are rising since patients started to actively protect their rights. Sometimes, in the United States physicians have difficulties to work due to the high costs of professional insurances. It is therefore crucial not only for the patients' benefit but also for the overall healthcare system to develop methods for adaptively assessing risks and to take decisions to reduce or hold them [Walshe 2001].
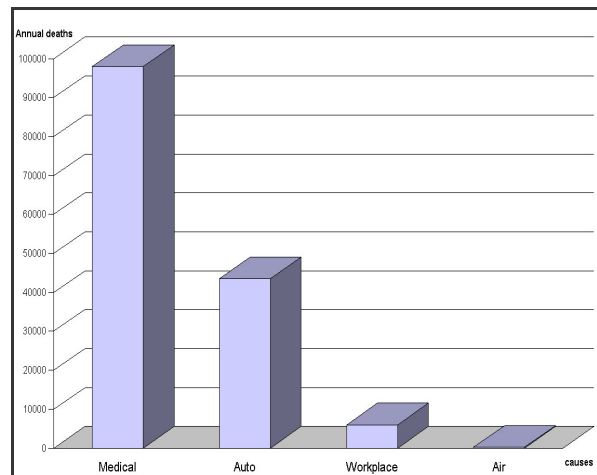

Figure 1: Different causes that provoke annual accidental deaths in the United States.

In our case, we will concentrate on the problem of managing clinical risks in haemodialysis departments. We will focus on patient safety, i.e. the basic problem that diagnostic and therapeutic practices may cause adverse events that influence the hospitalization and mortality risks of patients. We also analyze how the clinical risk impacts on expected costs both for the patients and the clinical department. In the paper we describe the decisional and adaptive features of the developed tool, consisting of two elements: an "Incident Reporting System" (called Hemostat) and a graphical model (Bayesian Network).

Managing clinical risks in haemodialysis departments

End Stage Renal Disease (ESRD) is a severe chronic condition that corresponds to the final stage of kidney failure. Without medical intervention, ESRD leads to

death. More than 80% of the ESRD patients are treated with Hemodialysis (HD). In HD the blood passes through an extra-corporal circuit where metabolites are eliminated, the acid-base equilibrium is re-established and the water in excess is removed: a device called hemodialyzer regulates the overall procedure. In general, HD patients undergo a dialysis session for about four hours three times a week in day-hospital [Wolff et al. 2001].

The dialysis treatment has very high costs and it is very demanding from an organizational viewpoint: a medium size centre may manage up to 60 patients per day and this treatment plans periodically provided by nephrologists [Saran et al. 2003]. For our purpose, non-adherence is defined as the failure to follow a prescribed treatment during a dialysis session; as a consequence, at the end of dialysis sessions, one or more patient monitoring variables will not attain their target. We denote the non-adherence as the *adverse event* occurring during dialysis sessions.
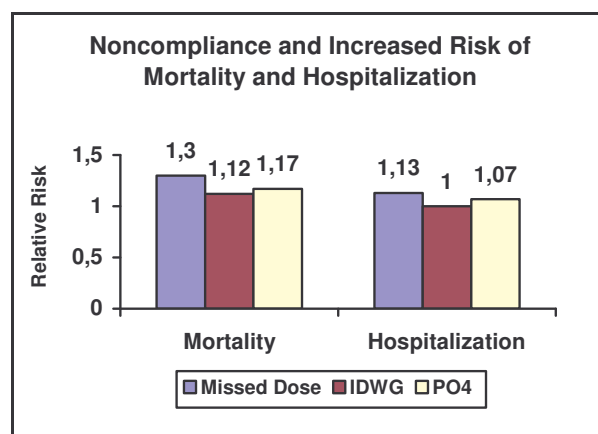

Figure 2: Associations with mortality, hospitalization and non-adherence [Saran et al. 2003]. Missed dose means missing one or more dialysis session per month (vs. not missing); IDWG = Interdialytic Weight Gain; PO4= Phosphate levels > 7,5 mg/dL.

It is possible to define also "near miss events". They occur whenever controls (e.g. automatic system or staff interventions) avoid adverse event to happen. "Near-misses" have a double function: they inform teamwork on critical aspects of a patient's dialysis sessions and the vulnerability type (e.g. efficiency of the hemodialyzer or dialysis, see above) [Brennan et al. 1991]. They're useful to sort the adverse event into foreseeable and unforeseeable ones. In this way, staff or governance may choose the optimal decisions to manage, reduce and hold clinical risks.

We define as a near-miss a session in which the compliance with the therapeutic protocol is reached after an intervention not foreseen in the therapeutic protocol itself.

Data Sources for estimating Clinical Risk

To monitor non-adherence we have implemented an Incident Reporting System, called Hemostat [Bellazzi et al. 2004] (Fig. 3), which collects automatically the data measured during each dialysis session, compares them

process requires highly specialized personnel, day hospital beds, and at least 30 hemodialyzers plus the disposable material. HD patients, besides the natural worsening of ESRD, undergo several clinical risks affecting their safety and the health care performances. In particular, the main risks are *re-hospitalization*, due to cardiovascular complications, vascular access problems, septicaemia, and *death* [Rayner et al 2004].

Recent clinical studies have shown that such risks are increased by several factors (see Fig. 2), mainly related to a poor adherence of patients and health care givers to the with the treatment plan and provides statistics about the achievement of the treatment goals [Leape 1999]. This
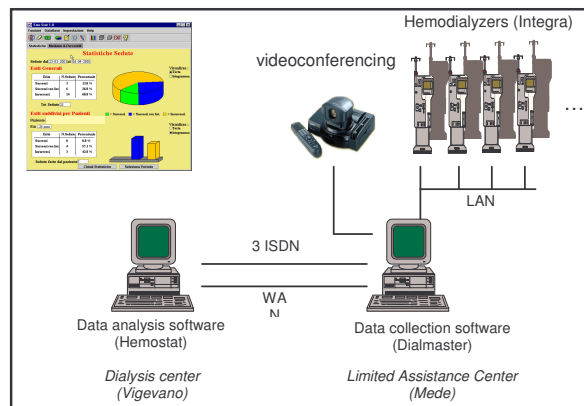

Figure 3: The architecture of the Incident Reporting System.

system is designed to overcome the open problems of obligatory or voluntary reporting, since the automation allows to not modify the usual clinical workflow. Moreover it treats non-adherence events as incidents; on the contrary, in general, staff acknowledges them as natural consequences of health care's supply and disease.

Hemostat allows building a data base where the adverse events and the "near-misses" are reported every time they happen. In more detail, the data collected on each patient during HD monitoring are related to:

i) dialysis efficiency, evaluated by measuring the blood flow in the extra-corporal circuit (QB), the body weight loss (WL) and the dialysis time (T);

ii) efficiency of the hemodialyzer, evaluated through the pressures of the extra-corporal circuit after blood extraction (arterial pressure, AP) and before blood re-entry (venous pressure VP);

iii) body water reduction and hypotension episodes, measured through the systolic and diastolic blood pressures and the cardiac frequency;

iv) overall patient's status, measured through the difference with the "ideal" weight at the end of dialysis (PS), phosphate level (PO_4), albumin and residual creatinine clearance;

v) staff intervention on AP, VP, T, QB and WL through drug administration or target change.

We exploit the following patient measures of non-adherence:

i) the comparison of the median HD session levels of *VP*, *AP* with pre-defined thresholds;

ii)   the difference (*QBR*) between the prescribed QB and its median values;
iii)   the difference (*TR*) between the prescribed dialysis time and the observed one;
iv)   the difference (*WLR*) between the prescribed weight loss and the weight loss measured at the end of the dialysis;
v)   the difference between the weight reached at the end of the dialysis and the target weight of the patient (*PSR*).

Data collection comprehends personal data and patients history, such as age, gender, comorbidity and number of days from the first dialysis session in the department; moreover quarterly follow-up updates are also collected, including Kt/V (i.e. a fraction that compares the amount of fluid that passes through the dialyser with the amount of fluid in the patient's body), albumin, residual creatinine clearance, phosphate level and parathyroid hormone.

The whole data are aimed at managing CR: exploiting the results about non-adherence we dynamically derive risk profiles for the patients and we estimate the overall risk assessment of the clinical centre; these risk profiles allow defining decision support strategies able to adaptively minimize risks and improve patient safety.

An adaptive decision risk management system

In general, a risk is defined as the combination of the probability of occurrence of an harm and the severity of that harm. Risk management comprehends two aspects: assessment and control (Fig. 4).

Clinical risk assessment is the process involving risk analysis and risk evaluation. The former is the systematic use of available data sources to identify CRs and estimate them; it also includes the choice of a methodology taking into account a given context (e.g. HCO, HD department or patient); the latter is the judgement, on the basis of risk analysis and context, of whether a risk is acceptable (for example, through cost/benefit analysis or outcome results versus targets). Whenever a risk is not acceptable, it is necessary to take decisions, in order to avoid it or to reduce its probability. This phase is defined as "risk control".

In our application risk assessment and risk evaluation are performed by the HD department through the evaluation of the data collected by the Hemostat system. Such evaluation is performed with an approach based on Bayesian Network (BN) [Jensen 1996, Heckerman 1996, Cornalba and Giudici 2004]. BNs are also applied to perform the decisions needed in the risk control phase.

BNs are particularly suited for CR management. They allow to clearly express the relationships between the problem variables and to learn risk profiles from the available data. Furthermore, they may add knowledge on the dependences among adverse events and their causes (i.e. measures of non-adherence) and help to take the optimal decisions and interventions to minimize risks. Thanks to BNs' decision theoretic approach, it is also possible to evaluate interventions, strategic decisions effects and their economic impact.

Rather interestingly, our goal will be not only to enhance the patient safety, but also to improve the performance of the overall HD department. Our proposed system will allow to obtain an organizational learning, i.e. a "double loop-learning", which learns at the patient and at the system level, as better explained in next paragraphs.
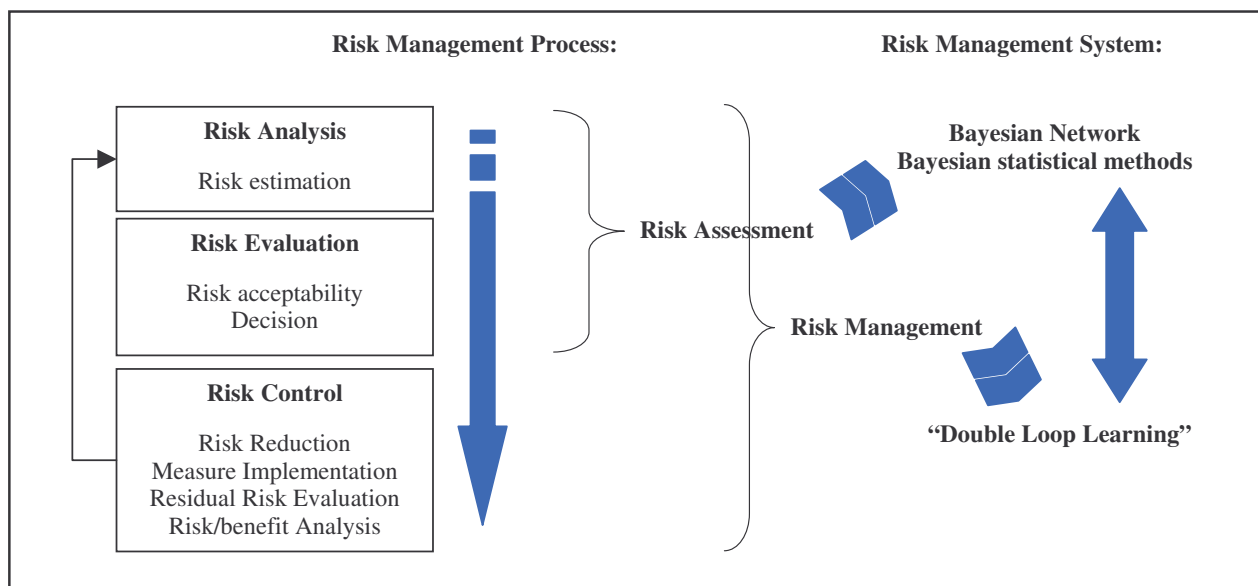

Figure 4: The risk management process.

Bayesian Networks for defining risk profiles

In our system we have identified two clinical "damages"; re-hospitalisation and survival; moreover, we have identified an organizational risk: the expected cost. Knowing that such risks are related to non adherence to treatment protocol [Saran et al. 2003], we have exploited non-adherence monitoring results to extract risk profiles for patients and clinical centres. In particular, there is a positive association between hospitalization and time of dialysis sessions and phosphate levels, while mortality is also related with interdialytic weight gain (figure 2, see before).

Data for estimating risks are obtained from the data collected through Hemostat, from the personal data and the patient history. They are summarized through a set of discrete stochastic variables. A Bayesian Network model has been defined. The BN represents the probabilistic relationships

    i)   among the monitoring variables, and
    ii) between such variables and the re-hospitalization and mortality risks.

The probabilistic relationships between the outcome variables and the risks of re-hospitalization and of death are derived from a Cox regression model previously published [Saran et al. 2003]. Such model includes risk factors such as sex, age and type of renal disease. The relationships among the monitoring variables are learned from data. The model also includes direct expected costs, calculated through DRGs reimbursement rates.

To complete the risk management system with risk control capabilities, the BN has been augmented with decision nodes, expressing the therapeutic protocol (see above).

Dependencies among stochastic variables have been fixed before the learning phase, in order to express well-established medical knowledge. Figure 5 shows the network topology constraint.
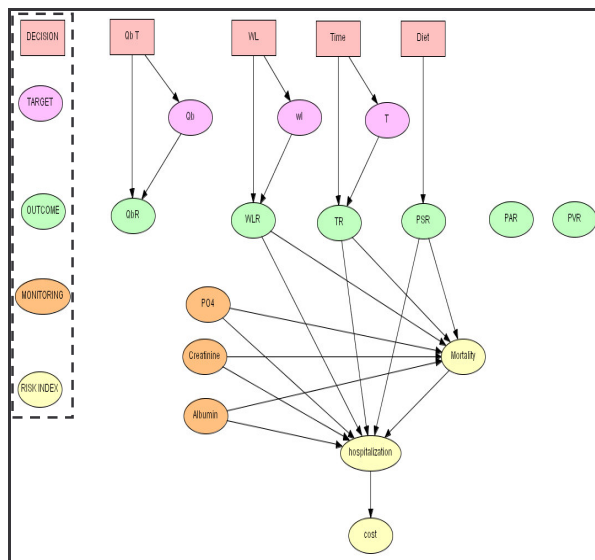

Figure 5: The structure constrains and node's typology.

After the learning phase each patient's network may have some new dependences discovered in the data (see above). The result is a therefore a different Bayesian Network for each patient, expressing the individualized risk profile. Such profile identifies all possible causes of non adherence and their relationships. The conditional probability distributions, learned exploiting the data coming from each dialysis session, complete the risk profile assessment.

Our proposed risk assessment model gives us not only the probability of hospitalisation and mortality but also the statistical summaries of not adherence and their probabilistic relationships with the other monitoring variables. The overall model can be periodically updated in order to adapt both the structure and the conditional probabilities to the new data coming from patients' monitoring. We decided to perform the updating of the conditionals quarterly, while the structure is changed with a sliding window of one year.

The next step of the risk management process is risk evaluation: nephrologists and health care managers judge the acceptability of the risk of each patient of hospitalization, mortality and the expected costs.

Thanks to the availability of decision and utility nodes, the model can also assist users in testing the effect of a change in diet or treatment (a longer dialysis session, a different blood flow in the extra-corporal circuit or body weight loss) and in taking proper decisions both at the patient and at the organizational level. In this way also risk control may be reached by using our system.

Statistical analysis and results. A retrospective analysis has been performed on data coming from 46 patients without any residual renal function and with similar demographic characteristics (age, nationality and race) from the Limited Assistance Centre[1] of the hospital of Mede (PV), Italy. The patients have been monitored for more than two years, and more than 6000 dialysis sessions have been collected.

To simplify the assumptions, we suppose that the probability distributions of the database are unbiased. Moreover, the prior probabilities of the model are taken from literature; in case no information is available we assume that the variable has a uniform distribution.

Two BNs derived for two different patients are shown in Figures 6 and 7. The network topology and the marginal distributions are different from each other. In the first network, a non-adherence in the dialysis session duration (TR) influences interdialytic weight gain non-adherence (WLR), while in the second one a monitoring variable, PO_4, influence non-adherence for WLR.

For what concerns the individualized risk profile for hospitalisation, we can see that the first patient presents a yearly risk lower than the second one. Of course, also the costs for re-hospitalization are lower.

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[1] A limited assistance centre is a dialysis centre where the permanent staff is composed only by nurses.
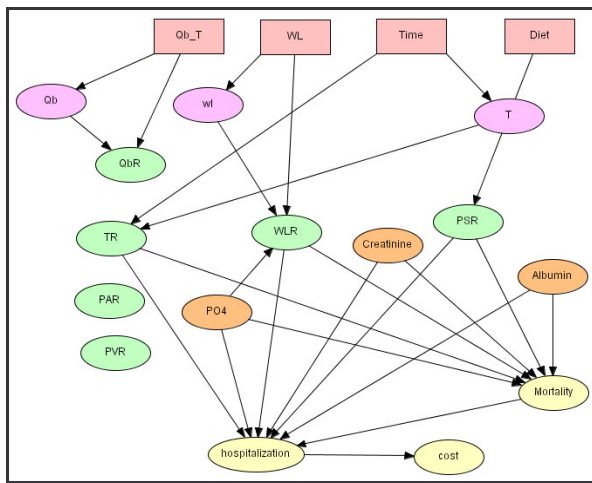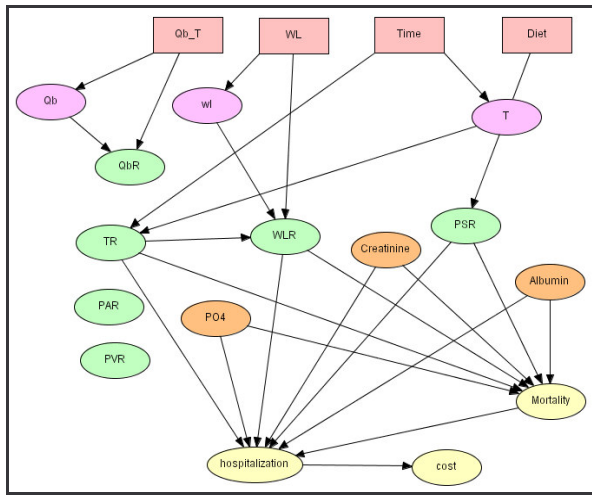
Figure 6: The two BNs learned for two patients over a monitoring period of one year. BNs have been learned using the Hugin™ package.
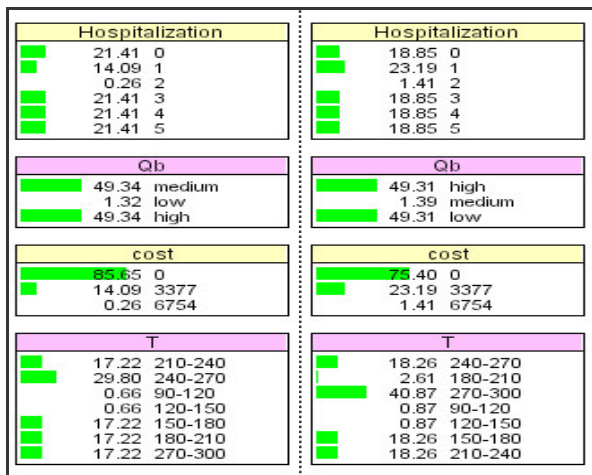
Figure 7: The marginal distributions learned for the two patients described in the example.

We have performed several scenario analyses to evaluate how the hospitalization's and mortality's risk and costs change, after the introduction of evidence in the network. The purpose is to complete the risk assessment phase.

Figure 8 shows the results obtained after three different scenarios analysis. In the first column, we can see the current hospitalization risk profile for a patient, the probability distributions for of dialysis duration (T), PO_4 and Blood Flux (QB). Finally, the expected cost is also shown. In the second and third column we can evaluate what happens on risk and costs if we perform some actions on either Qb or T. In the second column we force the value of Qb to be in the range of "medium" values. In the third column we can evaluate the effect of forcing T to be in the interval 240-270 minutes. Rather interestingly, the hospitalization risk is better controlled with an action on Qb then strictly controlling the dialysis time. Also the distribution of expected cost shows that a tight control of Qb to medium values may lead to better results than fixing the dialysis time to (240-270) minutes.
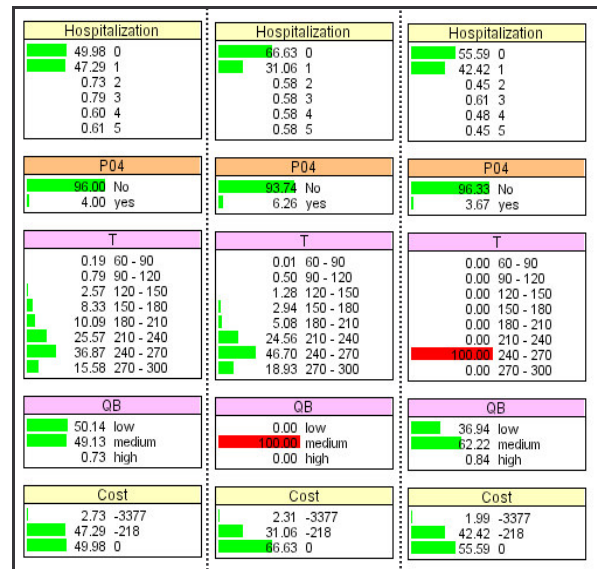
Figure 8: Three different scenario analysis and their marginal distribution, without introducing evidence, with Qb = "medium" and with T = "240-270 minutes", respectively.

Another interesting capability of our system is to dynamically adapt the estimates of the patient's risk after conditional probability update. In Figure 9 it is possible to see how the marginal probability distributions change after a quarterly update. In this case the patient's hospitalization risk worsened, due to a decrease of dialysis duration and a dramatic decrease of the blood flux. The latter was a consequence of a clinical problem, related to a bad functioning of the arterovenous fistula.

Hospitalization		Hospitalization	
22.55	0	21.41	0
26.73	1	14.09	1
4.75	2	0.26	2
0.87	3	21.41	3
22.55	4	21.41	4
22.55	5	21.41	5

Qb		Qb	
4.22	low	49.34	medium
91.55	medium	1.32	low
4.22	high	49.34	high

cost		cost	
67.65	0	85.65	0
27.60	3377	14.09	3377
4.75	6754	0.26	6754

T		T	
1.52	90 - 120	17.22	210-240
0.92	120 - 150	29.80	240-270
0.46	150 - 180	0.66	90-120
0.46	180 - 210	0.66	120-150
44.63	210 - 240	17.22	150-180
50.32	240 - 270	17.22	180-210
1.21	270 - 300	17.22	270-300

Figure 9: Marginal distributions for a patient in the first and the second update.

As far as we have seen, scenario analysis allows to highlights the critical elements which may have impact on patient's risk. However, it is important to understand if there are aspects which are common to all patients, so that the dialysis department may suffer from the so-called "Vulnerable System Syndrome" (VSS). This issue may be dealt with the "double-loop learning" strategy.

"Double loop learning"

The "Vulnerable System Syndrome" (VSS) is usually present in every HCOs: adverse events and risks which affect each patient are also related to the organization and its context. To manage correctly the factors which determine VSS we need first to recognize them and then to apply effective methods to control them. This requires the so-called organizational learning. The basic level of organizational learning is the detection and correction of errors or unjustified clinical actions. This type of learning

is known as *"single loop learning"*: it is implemented with the model described in the previous section. However, single loop learning tends to leave organisational goals and design of processes unchanged. More sophisticated learning which changes fundamental assumptions about the organisation is possible. This type of learning leads, for example, to redefine the organisation's goals, management strategies, or design of processes. We can consider this organizational learning approach as a *"double-loop learning"*: it deals with the very nature of the management of a complex process, such as the workflow of a haemodialysis department. Double loop can overcame the current notion of human failure and identify and correct organizational conditions which generate a VSS [Reason, Carthey and De Leval 2001].

Using the scheme in Figure 10 it's easy to understand how our system can be viewed as a tool for supporting organizational learning: single loop learning is implemented by learning the BN on each patient.

To move to the double loop learning, we must scale up our proposed patient's model to a department one. Figure 11 highlights the double loop learning system implemented with BNs. Information on overall survival and hospitalisation risk is calculated taking into account all patients' risk. It is therefore possible to evaluate the effect of the current strategy, in terms of personnel devoted to assist patients or the presence of self-management educators. Moreover, considering that the modifications of such policies have a direct impact on the probability of non adherence, it is possible to forecast the effect and to evaluate cost/utility of each alternative strategic actions both at the single patient and at the department level. In this case the tool is a patient-department-patients system.
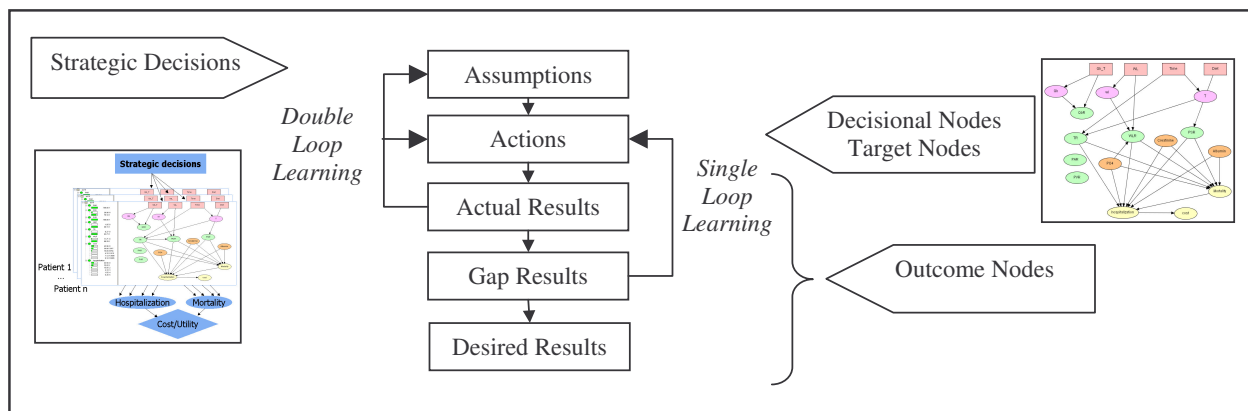

Figure 10: Single-loop versus double loop learning [Reason, Carthey and De Leval 2001].

Figure 11: Double loop learning with BNs. The patient's models allow to derive the risk profile of the dialysis centre and to make proper strategic decisions, which change the single patient policies.

Conclusion and upcoming efforts

The risk management process comprehends the identification, assessment and control of adverse events. Our proposed system implements such steps relying on two different tools: the Hemostat software, that collects data on each dialysis session, thus allowing to detect adverse events and "near-misses" and a Bayesian networks based risk assessment system, to derive risk profiles for single patients and HD departments.

In this paper we have described the BN-based approach which analyse the available database to estimate a current risk profile for patients and departments. This approach also supports the prediction of the decision effects on the expected costs and utility thus allowing to choose the optimal treatment strategy to minimize risk: The BN probability distributions and topology are updated during the health care process, so that the risk assessment and risk control is made adaptive.

There are intrinsic difficulties in empirical study of the BNs since they need to choose the prior distributions: we have derived them from the literature when possible, trying also to put some constraints in variables causal relationships. However, when the network topology is learned from data the overall conditional independence assumptions may change, and this may lead to network instability. For these reasons we are working on the selection of the most proper frequency of BN structure updating (actually, yearly).

Moreover, we are currently working on the complete definition of the double loop learning system. In particular we are defining the possible alternative decision support strategies at an organizational level, such as the presence of a dietician in HD department and the change of facility size; moreover we are also trying to design a sound probabilistic model to describe the effect of those changes

into non adherence measures. Other research directions that we are currently investigating are related to introduction of more variables, such as demographic ones and to the possibility of cluster patients with the same BN structure, in order to understand if there are classes of common behaviours. Later on, we will plan a prospective study in order to assess the impact of such system in clinical practice.

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