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RECHTS- UND STAATSWISSENSCHAFTLICHE FAKULTÄT

Recent Research on Health Care Management

Steffen Fleßa

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Preface

Health Care Management is a global mission, i.e., neither diseases nor health care concepts can be addressed adequately with a limited focus on one particular country. For instance, multi-resistant bacteria do not respect national borders but are a challenge in Poland as well as in Germany. Any attempt to solve this problem in one country only is doomed to failure as bacteria will re-invade from the other country. At the same time, health care concepts developed in one country will likely be an innovation seedling for other nations. For instance, individualized medicine is likely to challenge the existing paradigm of health care provision. Although this concept is strongly fostered at the University of Greifswald, it might soon be of highest importance at the University of Stettin. Health Care Management is global!

For this reason, I am delighted to have the opportunity to present a series of papers on recent developments of health care management at the University of Stettin and learn from the experiences of my colleagues at this center of research. As scientists we share methodology and paradigms, and we unite in the fight for better health for the population of our nations. Health Care Management has much to offer to the health care systems, providers and programs. Based on evidence, efficient solutions can be sought to tackle life-threatening diseases and to improve the quality of life of millions of people. It is a privilege to share these insights with our Polish colleagues. And it is my sincere hope that this cooperation will bear fruit.

This booklet provides an overview of the papers presented in Stettin, May 2013. The papers do not focus on methodology but on decision-making relevance. For methodological insights, the reader is asked to contact the authors. Every author is responsible for their paper, but we conjointly submit this booklet to the reader hoping that they will be inspired by one of the most challenging scientific fields: Health Care Management.

Greifswald, May 2013, Prof. Dr. Steffen Flessa



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1 The Future of Small Hospitals in Germany by Steffen Fleßa

1.1 Introduction

Several studies and authors forecasted that small hospitals (in particular in rural, sparsely populated areas) will be closed or reduced to portal clinics merely sorting patients for referral. These hospitals with less than 300 or 400 beds – as it was diagnosed at the beginning of the new millennium – would have no future. The following paper discusses the facts which convinced the authors of these studies that small hospitals will disappear from the market within a few years. In addition, this paper will analyze whether these predictions have become true and why sometimes reality is better than well-grounded prognoses. Based on these analyses we will give some recommendations for the development of small hospitals in rural areas.

The study "Hospital 2015 – pathways out of the jungle of paragraphs" was published in the year 2000 by the well-known consultancy company Arthur Anderson. It became widely respected and pointed at the sad future of small hospitals, in particular in rural areas. (Arthur Anderson 2000). Among other aspects, it predict a reduction of the number of German hospitals from some 2200 to around 1800 within 15 years, a reduction of the number of beds by some 40% and the decline of the average length of stay to 3 days. The well-known German health economist and member of parliament Karl Lauterbach (Lauterbach and Lüngen 2003) went even beyond that and calculated that a theoretical number of 800 hospitals would suffice to cover Germany. Both studies outguess not only a quantitative, but also a qualitative structural change, i.e., private hospitals would crowd out public and non-profit hospitals, i.e., we would see a concentration on few hospitals with a high bed capacity in towns. Smaller, rural hospitals may have to go out of the market.

In fact, small hospitals have a number of disadvantages challenging their future. The main challenge is that the production of health care services requires a steady service availability which induces fixed costs (e.g. for personnel). It is obvious that the costs per case in a small hospital are higher than in a big hospital as the fixed costs of the bigger hospital can be distributed among more cases (Fleßa 2008). Consequently, small hospitals have a major disadvantage in comparison to bigger institutions.

Until the year 2004 Germany had a hospital financing system based on daily rates. Each hospital negotiated this rate directly with the health insurance, i.e., higher costs could be recovered by higher daily rates. In 2004 Diagnosis Related Groups became obligatory as rebate system for German hospitals. They are a case-based lump sum, i.e., the rebate is paid irrespective of the individual costs of a health care provider. They are calculated on central level for the entire state, i.e., they recover the average costs of the average hospital in this state. If a hospital has higher costs it is likely to run into a deficit. Consequently, everybody expected that the introduction of DRGs would result in an extinction of small hospitals and a complete restructuring of the hospital industry.

More detailed, the structural disadvantage of small hospitals has different dimensions:

• Minimum Quantities: The Act of Minimum Quantities (31.12.2003) requires hospitals to produce a certain minimum number of operations or cases in order to allow them to bill these services to the insurances. In the beginning, only specialized operations or cases were covered by this Act (e.g. transplantations). They were more or less irrelevant for small hospitals. However, the catalogue of services requiring a minimum

quantity was extended stepwise so that it covers procedures which are the core business of small hospitals (e.g. 158 appendectomies, 168 cholecystectomy, 107 knee replacement surgeries p.a. (Lüngen, Haverkamp et al. 2002)). Consequently, if this rule were strictly applied a major share of the revenues of small hospitals would be lost. Meanwhile, it is under discussion whether this law makes sense at all. Some argue that low quantities do not always imply poor quality or high costs.

- Risk: The standard deviation of costs per case within a DRG declines by the factor $\frac{1}{\sqrt{n}}$ where n denotes the number of cases. This implies that big hospitals have a lower risk of a deficit than smaller ones. Until the introduction of DRGs the health insurances covered the risk of severely sick patients as they had a longer length of stay resulting in more daily rates. The adoption of DRGs transferred this risk to the hospital. The more patients are treated in a hospital, even lower is the standard deviation of the average costs, i.e., small hospitals have an explicit disadvantage.
- Cost structure: The revenues per DRG are calculated to recover the average costs of an average hospital within a DRG. Several studies have shown (Breyer 1987, Rosko 1996) that hospitals have a traditional S-shaped cost function, i.e., small and big hospitals have higher unit costs than the average-size hospital. This empirical finding is logic as small hospitals have high fixed costs, even in areas that are financed by health insurances (such as personnel) and not such as buildings and equipment by the government. Therefore we receive a U-formed function of the costs per case, as shown in Figure 1.

After the implementation of the DRG system no more individual daily rates could be negotiated between the hospital and the insurances. Thus, these cost differences are not presented anymore in the revenues. Hospitals with a bed capacity between B_min and B_max can cover their case costs with a DRG, whereas smaller (and bigger) hospitals will suffer a loss.



Figure 1 Unit Costs of a Hospital

Source: (Rosko 1996)

• Monistic Financing: Hospitals have high fixed costs whereas a part of them is shouldered by the government. This will – most likely – change in future. Already the health care reform 2000 included a stepwise transition to a monistic financing, i.e.,

instead of providing funds directly to the hospitals the government would support health insurances which would add a mark-up to the existing DRG rebate to cover those costs currently re-financed by the government. Small hospitals have – ceteris paribus – higher fixed costs per bed and per patient. Thus, monistic financing would mean that they would have specific challenges to rebuild their facilities.

• Management Capacity: Professional hospital managers, e.g. physicians with an additional degree in business administration or academic managers with experience in the health care sector are rare and expensive in Germany. Consequently, only bigger hospitals can attract and pay these professionals.

In addition, the majority of small hospitals are situated in rural areas. Thus, the disadvantages of small and of rural hospitals overlap. Typical problems of a rural location are the following:

- Staffing: Rural hospitals have severe problems to attract and keep qualified staff. This is primarily not a question of the salary scale (which is almost the same within a region due to contracts with the labor unions) but of the willingness to work in this districts. Quite a number of positions of physicians in small, rural hospitals cannot be filled as young doctors prefer the convenience of towns, tend to live in places where their partners find appropriate jobs or assume that working in rural areas is a dead-end road of the career. All attempts to attract personnel from outside of Germany did not systematically change the disadvantage of rural hospitals in attracting qualified staff.
- Mobility: The mobility of the average population has strongly increased during the last decades. Consequently, patients "jump over" small rural hospitals and go directly to the centers where highly specialized health care institutions offer their services. The remaining catchment population is rather immobile, e.g., the elderly and disabled without private transport remain as the potential customers of rural hospitals.
- Political influence: Rural areas have a poor political lobby in the Government of the states. Thus, it can be expected that rural hospitals are systematically neglected when government funds are distributed for central hospital planning and dual financing.

This multitude of problems made it clear for many consultants and scientists: the future of small hospitals in the new millennium would be dark. In the following part we will analyses whether these prognoses have become true. For this purpose we use the example of Mecklenburg Western Pomerania.

1.2 Reality in Mecklenburg-Western Pomerania

The fourth central hospital plan of Mecklenburg-Western Pomerania states that a hospital has not to be further away from any citizen than 30 km. As the population density of this state is rather low, we can expect that its hospitals are comparably small so that all forecasts cited above are likely to become true. As Figure 2 demonstrates, the assumption of small hospitals is a matter of fact.



Figure 2 Hospital Infrastructure of Mecklenburg-Western Pomerania

Source: own, based on (Landeskrankenhausgesellschaft MV 2012)

However, the reality of Mecklenburg-Western Pomerania does not reflect the prognoses of the early millennium. Milski and Flessa show that the introduction of DRGs had no structural impact on the hospital industry in this state (Milski and Fleßa 2009). Instead, the number of hospital locations in Mecklenburg-Western Pomerania (39) has remained stable since 1999. Here it is necessary to distinguish between legal entities and locations. For instance, the fusion of the hospitals in Anklam and Ueckermünde reduced the number of legal entities, but it brought no change of hospital locations as both hospitals remained intact after the amalgamation. For the catchment population the legal entities are irrelevant, whereas the functionality at the location is crucial.

It seems that the most dramatic changes of the health care industry happened before the introduction of the DRGs. This statement is even true for the entire Federal Republic of Germany. The number of hospitals, beds and beddays has steadily declined since 2003 (comp. Figure 3), but the development seems to be rather stabile in comparison to the years before. We cannot talk about a "hospital extinction" due to the introduction of the DRGs. As Schmid and Ulrich show, the official statistics of hospitals in Germany are partly misleading (Schmid and Ulrich 2011), i.e., the number of hospital locations relevant for the catchment population is much more constant than the statistics might indicate.

4



Figure 3 Hospital Statistics in Germany

Source: (Statistisches Bundesamt 2011)

Even the introduction of a monistic financing system will most likely not have so adverse consequences as some expect. As Tübbicke and Flessa demonstrate for hospitals in Western Pomerania (Tübbicke and Fleßa 2010), the buildings and equipment of these institutions are in a relatively good condition. Merely three of 10 hospitals state that they would have a higher need of investments. Consequently, the question "What do you expect for your hospital if investment finances are added to the DRG rebate?" is answered with great enthusiasm. Merely 18% of hospital managers suppose that their situation will worsen, whereas 73% assume that their situation will improve.

Hence, we can state that some 10 years after introducing DRGs as the main financing mechanism of hospitals in Germany the dark prognoses for small hospitals have not become true. Therefore, we have to ask whether the forecasts were wrong or whether the hospitals have already reacted wisely in order to avoid the expected bankruptcy.

1.3 Strategies

It is a fact that the predicted changes of the financing system and their consequences materialized. Consequently, small hospitals must have managed to reduce their fixed costs and increase their quality of services so that they remained successful competitors with the bigger institutions and attracted a sufficient number of patients. This success is based on a number of strategies, such as

- consequent outsourcing,
- improvement of process management,
- professionalization of information technologies,
- training of staff, in particular DRG-coding.

In addition, hospitals managed to form networks with all partners of the health care system. As Figure 4 shows, hospitals have become the focus of the health care provision and are an important knot of the network of patient care. Based on telemedicine, mobile doctors, emergency services etc. hospitals extend their activities beyond the inpatient service and enter

new markets (Fleßa, Haugk et al. 2007). An intensified cooperation with local physicians is getting more and more important as it is the foundation of admissions. As Figure 5 shows, there is a clear tendency to admit patients to hospitals nearby. As studies demonstrate (Götz, Möller et al. 2011), this tendency can be strengthened by close collaboration with the general practitioners and specialists in the area.



Figure 4 Network of Hospitals

Source: own.



Figure 5 Admission in Western Pomerania

Source: (Götz, Möller et al. 2011)

Furthermore, small hospitals invested in recruiting and keeping professional staff. As studies show (Golombek and Fleßa 2011), the average duration on the job of nursing is significantly lower than it was a generation ago. The main reasons for leaving the nursing profession can be addressed by the hospital management, in particular the appreciation and the meaning of working as well as the professional climate of the institution. This implies that small hospitals utilize their comparative advantage and strengthen it, i.e. the family-like atmosphere. Contrary to bigger hospitals there is a big advantage of personal contact, informal discussions, short ways of decision-making and a degree of intimacy. Big organizations have bureaucratic structures and see the individual as an anonymous element. Smaller organizations are based on personal trust, fellowship and closeness which could form the foundation of efficient management.

In a nutshell: The future of small hospitals is by far not as dark as expected. They have a high importance for the health care system and provide crucial services to the population. Even in future they will play a role in the social system of Germany. However, the survival of these institutions is not guaranteed. Instead, wise political decisions have to be made and professional hospital management has to be implemented. Must crucial is a new mind-set that reflects the exceptionality of rural and peripheral settings as typical locations for small hospitals.

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2 Individualized Medicine – the Economic Perspective by Paul Marschall

2.1 Background

Since several years terms like "individualized medicine" (IM), "personalized medicine" (PM) or "stratified medicine" (SM) are widely used in health care. Some authors even argue that there is hype about them (Salari, Watkins et al. 2012). The aim of this paper is to outline their main characteristics and to stress the need for a proper economic assessment of concepts which have the potential of being translated into clinical routine. Based on the research program GANI_MED two examples will be presented and discussed. The paper concludes with an outlook on the future of IM.

Even though concepts like IM, PM or SM are mostly not congruent (Langanke, Lieb et al. 2012), they are affiliated with some common important attributes. For reasons of simplification the abbreviation IM is used in <u>this</u> section in place of all of these concepts.

First, they are connected with some *charisma of hope*. Everybody wants to life as long as possible in a good state of health. One important driving force behind IM (or its equivalents or variants) was the Human Genome Project and its dream that based on a deeper knowledge about functions of genes and proteins disease outbreaks can be prevented and/ or better cured (Jain 2009).

Second, the mentioned concepts are *predictive*. Omics based technologies in the field of biology, such as genomics, proteomics or metabolomics and biomarkers, i.e. biological molecules found in blood, other body fluids, or tissues that are regarded as a sign of a normal or abnormal process, or of a condition or disease, seem to be the key for guiding future medicine. By using biomarkers, medicine is able to identify what conditions a person might develop in the future and how the person will respond to a given treatment, enabling the development of a tailored health strategy (Snyderman 2009).

Third, these approaches, which are sometimes linked with the phrase "new paradigm", seem to be *focused at the individual person*. Everybody is different. There are tall, small, slim, thick, young and old people. Some of the causes of falling ill are well-known. People are deeply affected not only by their initial set of health capital received by birth but also as a consequence how they behave during their lifetime (Grossman 1972). Individual health related behavior with respect to nutrition, sports, smoking etc. influences the probability of getting sick. However, medical care is still focused at diseases and ignores its causes. Thus, from the perspective of IM, "standardized therapy" seems to be a taboo word and a source of evil.

One of the most important applications of IM is connected to the use of drugs. Pharmacogenomics is the study of how genes affect a person's response to drugs. This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that will be tailored to a person's genetic makeup. This is the opposite of the existing paradigm, which can be expressed as "one size fits all" approach (Mancinelli, Cronin et al. 2000). IM advocates argue that the maximization of therapeutic efficacy might minimize the risk of adverse drug reactions (ADR) (Phillips, Veenstra et al. 2001). These are appreciably harmful or unpleasant effects, resulting from an intervention related to the use of a medicinal product,

because not everybody has the same metabolism. This is the action of complex proteins called enzymes breaking down medications and drugs and allowing the body to utilize them. If for example a drug or medication is taken orally, it usually travels from the stomach to the liver, where most drugs are metabolized by enzymes. On such a journey anything could happen. Harmful side effects often are connected with a high burden for patients and considerable economic consequences. Although many ADR are considered as unpreventable, recent developments suggest that some of them may be avoided through individualization of drug therapies.

Fourth, personalized or individualized medicine is not always about creating medicines or selecting treatment unique to a patient, than rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Therefore the above mentioned approaches should be read as *stratified medicine*.

Fifth, physicians often argue that individual attention is practiced by members of medical profession since many years, e.g. nobody practices "impersonal medicine" by purpose. Are these "new approaches" nothing else but old wine in new bottles (Gadebusch Bondio and Michl 2010)? The new concepts are not rooted in the personal attention *per se*, but in the use of modern technology for generating more information and knowledge and thus a deeper understanding how *individual* persons function. According to these concepts modern medicine is able to identify which conditions a person might develop in the future and how the person will respond to a given treatment, enabling the development of a tailored health strategy.

2.2 Individualized Medicine and Economics

The discussion in the first years of individualized medicine was basically a question about "what is possible", mainly from the perspective of biomedical science or pharmacology. Because of the enormous total costs of the human genome project (about 3 billion US\$) it became clear that it is very important to consider the economics of IM, because we are living in a world of scarce resources. This is especially true concerning the transfer and translation of research programs into clinical routine. With regard to economics the main questions are: Does IM has the potential for being a cost-saving technology, or will it automatically multiply existing health care costs? Who has to pay the bill? Will it be only a dream for rich persons? (McClellan, Avard et al. 2013). Thus, addressing these new approaches is also an important issue from the social perspective. Based on theoretical considerations there are many pros and cons concerning economic consequences of IM. Some of them are listed in table 1. It is quite evident, that there is a need for detailed economic research to analyze the effects.

| | Increased costs | Decreased costs | | |
|------------------|---|--|--|--|
| Patient | Higher drug prices | Reduced likelihood of adverse events | | |
| | Pharmacogenomic test costs | Avoidance of ineffective medication | | |
| | | Improved medication compliance | | |
| | | Improved health outcomes | | |
| Providers/payers | Higher drug prices | Reduced health care resource utilization | | |
| | Pharmacogenomic test costs (including costs | Avoidance of treatment for those who | | |
| | of false positive and false negative tests) | do not need it | | |
| | Expanded patient populations for drugs Improved response rates for tr | | | |
| | | of diseases | | |
| | Expanded patent protection for drug and test | Avoidance of unsafe medications | | |
| | combination (potentially) | | | |
| | Genetic test training, interpretation | Decreased liability and malpractice | | |
| Pharmaceutical | Higher development costs in short term | Improved decision making and lower | | |
| industry | (development and validation of biomarkers) | attrition | | |
| | Evolving regulatory environment (test | Focused discovery and development | | |
| | approval process for diagnostics becoming | programs | | |
| | more rigorous) | | | |
| | Loss of blockbuster drug business model | Earlier approval of new therapies | | |
| | Cultural differences between drug and | Greater confidence in postmarketing | | |
| | diagnostics industries | surveillance systems | | |
| | | Expanded patient populations for drugs | | |

Table 1 Potential economic consequences of pharmacogenomics

Source: (Deverka, Vernon et al. 2010)

2.3 GANI_MED – Greifswald Approach to Individualized Medicine

The emerging field of IM has become a research area across multiple disciplines. The GANI_MED (Greifswald Approach to Individualized Medicine) research program, which was installed in October 2009 and basically funded by the German Federal Ministry of Research and Technology, was the first attempt to establish an IM program at a German university hospital. The GANI_MED-syndicate assembles experts from various national and international academic institutions as well as industrial partners (see figure 1) that help to study individualized medicine comprehensively and holistically. It is the commitment of GANI_MED to test promising concepts of individualization for its applicability to the treatment of patients. In contrast to other IM research projects GANI_MED is focusing on disease phenotypes outside of oncology, especially common diseases.

GANI_MED was initiated by the five faculties of the Ernst-Moritz-Arndt-University in Greifswald. The University Hospital, one of the most modern of its kind in Germany, has a broad expertise in biochemical diagnostics and hospital informatics. In addition, the Study of Health in Pomerania (SHIP), a population-based cohort study, provides important information about the distribution of risk factors, subclinical disease and clinically overt disease in the general population and serves as reference population for the patient cohorts in GANI_MED.

The research project consists of several areas: The structural area is providing the infrastructure in terms of biomedical informatics and the biobank for the three project areas:

- Project Group 1 is engaged with modern bio-analytical methods, especially in the field of proteomics, metabolomics, and pharmacogenomics.
- Project Group 2 focuses on several previously defined disorders. Several cohorts of patients, e.g. with cardiovascular or cerebrovascular and endocrine-metabolic diseases are recruited and compared with healthy subjects from SHIP study.

• Project Group 3 deals with ethical and economic issues of IM. Thus, this concept is examined for medical-theoretical requirements and its conceptualizations of health/disease, and for new ethical risks. It is the aim of the health economic approach to assess selected examples of IM.

From an economic perspective an evaluation only makes sense if the object of study is clearly defined. Based on the GANI_MED concept IM can thus be defined as a set of research approaches and care practices for which the method of biomarker-based disease and/ or therapeutic success prediction through more precise stratification is crucial (Langanke, Lieb et al. 2012). This definition also includes the unique characteristic of GANI_MED with respect to common diseases.



Figure 1 The GANI_MED Syndicate

Source: (GANI_MED 2009)

2.4 Economic Assessment of IM – some examples

The application of evaluation methods to collect reality-based data provides evidence-based results. Their use is an important precondition for decision-making and also a significant contribution of economics (Drummond, Sculpher et al. 2005). As outlined before IM can be interpreted as a new kind of technology which has to be assessed regarding to its ability to replace the current technology. From a societal point of view this is first and foremost a question of its cost effectiveness in comparison to the technology used under the "pre-individualized medicine" paradigm. Well-established concepts of health economic evaluation can be applied for conducting the comparison. Analogous to the principle of comparing costs and benefits, the advantages from innovative IM diagnostics and therapy and their effectiveness should thus be confronted with its corresponding costs. Even if time does not seem to be ripe to adopt or adapt the new technology in a special area, changing parameters can modify the decision in future times (Fleßa and Marschall 2012). Secondly, it is also a question of the corresponding stakeholders and their incentive structures: the level of costs they have to bear and their chance of realizing cost savings.

2.4.1 Adverse drug reactions

Phenprocoumon is an anticoagulant normally used in the prevention of thrombosis and thromboembolism, the formation of blood clots in the blood vessels and their migration elsewhere in the body respectively. The intake of this drug can result in some severe side effects in terms of bleeding. (Schwebe, Marschall et al. 2012) examined the hospital costs of gastrointestinal bleeding effects among those drug users. They used the database of the Pharmacovigilance Center Greifswald between 2006 and 2009 (n= 80). Based on information provided by the Hospital Information System of the University Medicine Greifswald, which can be regarded as a monopolist within a rural area, DRGs were calculated. Findings for the included 40 men and 40 women were quite similar. The average age was 74 ± 10 years. On average a patient spent 10 ± 7 days in hospital. All patients were multi-morbid (average number of diagnoses: 15 ± 7) and used several drugs (average number of co-medication: 9 ± 3). The hospital received on average \notin 2,820 per patient, with a range between \notin 350 and \notin 5,900. Hospital revenues are the costs of the statutory health insurances. It could be possible to reduce this economic burden by testing ex ante, if the patient might get an ADR. The effects are illustrated in figure 2:



Figure 2 Decision analysis¹

Source: (Schwebe, Marschall et al. 2012)

¹ Test: Genotyping; P: Phenprocoumon intake without testing; DA: Dabigatran intake; T+: test positive; T-: test negative; U+: ADR; U-: no ADR; C: costs.

According to that study Phenprocoumon intake will induce costs in case of no ADR equivalent to C = \notin 76.65, but in case of ADR total costs are \notin 76.65 + \notin 2,820.00 = \notin 2,896.65. The costs of performing genotyping, as identified by a time study, were € 57.00. In case of tested negative (T-) the intake of Phenprocoumon is probably no problem at all, therefore total costs are \notin 57.00 + \notin 76.65 = \notin 133.65. But if the test result is negative, Phenprocoumon is not adequate. In this case Dabigatran (DA), a new drug, which avoids the Phenprocoumon's side effects, might be appropriate. The problem is that Dabigatran is still expensive (€ 1,839.70). However, based on the characteristics in that regime, performing genotyping can be a good idea. Whether it is possible to decrease the corresponding economic burden or not depends first of all on the corresponding drug price level. Innovative drugs are expensive. Nevertheless, their prices will probably decrease over time with the consequence that the return from applying Dabigatran in comparison to ADR costs might increase. A proper assessment of genotyping also has to consider its reliability. In this case false-positive test results are rather unlikely. As the health insurance company who has to pay additional costs of this regime also gains from cost saving, the corresponding incentive-structure favors IM. However it has to be seriously checked, if self-management performed by patient is superior (Schwebe, Marschall et al. 2012).

2.4.2 Common diseases

Heart disease is one of the most common diseases worldwide (Bleumink, Knetsch et al. 2004). In Germany it was listed within the three leading causes of death in 2011 (Statistisches Bundesamt 2012). Because mostly old people are affected by that syndrome, its importance will increase during the process of double aging. Dilated cardiomyopathy (DCM) is one the most important causes for getting heart disease and heart transplantation. There is an ongoing research project at the University Medicine Greifswald about DCM, in which immunoadsorption therapy (IA) is used to analyze its effects regarding cardiac performance and clinical status in heart failure patients. IA can be interpreted as a special blood purification in which autoantibodies are removed by passing a patient's plasma over columns that remove immunoglobulins. Until recently, the state of art was that IA leads to hemodynamic improvement and reduces myocardial inflammation. It was also recognized, that only 60-70% of DCM-patients profit from that therapy. A research team from Greifswald University showed that based on gene analysis prediction of response is possible. This study result demonstrated that the transfer of biomarker based prediction to decision-making with respect to common diseases is promising from a biomedical research perspective (Ameling, Herda et al. 2012).

However, from an economic point of view it has to be carefully evaluated if the health care system of Germany is ready for the adoption of that new technology into clinical practice. Table 2 presents the results of a time study, which was conducted to identify the actual costs of immunoadsorption (Flessa, Marschall et al. 2012). For conducting a gene analysis as prerequisite for answering the question if IA is appropriate, a myocardial biopsy is necessary. In addition some further diagnostics like echocardiography or spiroergo-oximetry have to be conducted. Their total costs per case are on average \notin 202.09. The total costs of gene analysis (homogenization, RNA-isolation, array analysis & evaluation) per sample are highly dependent on the sample size, due to high fixed costs. Increasing their number from 18 to 100 samples implies a cost reduction from \notin 4,067.49 to \notin 842.12. However, under the current reimbursement scheme the hospital only generates revenues by IA therapy in the narrow sense. For immunoglobulins and filter systems additional charges (Zusatzentgelt) can be earned. By now additional costs have to be invoiced for example by Patient Clinical Complexity Level or operation/procedure-keys (OPS).

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Total |
|-------------------------|--------|--------|--------|--------|----------|----------|
| Personnel | | · | · | • | • | |
| Staff costs health care | 56.20 | 56.20 | 45.30 | 42.58 | 46.23 | 246.50 |
| Staff costs (MD) | 42.03 | 0.83 | 1.29 | 1.54 | 1.33 | 47.02 |
| Ward round | 4.53 | 4.53 | 4.53 | 4.53 | 4.53 | 22.66 |
| Materials | | | | | | |
| General materials | 349.33 | 349.33 | 349.33 | 349.33 | 349.33 | 1,746.65 |
| Filter system | 11378 | 0 | 0 | 0 | 0 | 11377.78 |
| IA-Kit | 530.89 | 530.89 | 530.89 | 530.89 | 530.89 | 2,654.45 |
| Laboratory | 217.48 | 216.98 | 216.98 | 216.98 | 216.98 | 1085.38 |
| Drugs | 8.45 | 8.66 | 8.59 | 8.03 | 6.17 | 39.90 |
| Immunoglobulins | 0 | 0 | 0 | 0 | 1,491.96 | 1,491.96 |

Table 2: Costs of immunoadsorption therapy in €

Source: (Flessa, Marschall et al. 2012)

105.45

22.21

105.45

22.21

105.45

22.21

Assessing the relevance of the full costs of the immunoadsorption does also mean that these cost figures have to be compared with the costs of cardiac transplantation and its effectiveness. It is obvious that the question about the appropriate treatment for the individual patient is not easy to answer. There is a need for further research.

105.45

22.21

105.45

22.21

527.25

111.06 19,350.61

Anyhow, the current reimbursement system in Germany does not provide enough incentives for translating this type of IM into clinical routine, as costs are not fully covered. There is no incentive for implementing gene analysis. This could be avoided if extra additional charges (Zusatzentgelt) would be introduced or the treatment of DCM would be better depicting within the DRG frame. According to the hope of IM the number of promising candidates for translating into clinical routine will rise in near future. If every individualized therapy would be described by DRG, the system would not be manageable any more.

2.4.3 Outlook

Overheads

Admin. Allocation Department overheads

Biomedical research has identified some promising candidates for individualized medicine. Many more will probably follow. But will the results of research be translated into clinical practice? It now seems that the major barriers are increasingly related to economics (Davis, Furstenthal et al. 2009). Analogous to markets outside of the health sector, many individualized products and services will be offered directly to clients, who are willing to pay the bill on their own. The market for these products will be defined by the success of the providers in making profit. Closely related, IM services might have good perspectives at the level of private health insurances, because the insured persons are able to define their own benefit packages. Within the framework of social security the market potential and thus the perspectives of IM look different. From a societal perspective a concrete IM product is beneficial if its cost effectiveness is better than the corresponding result of any alternative. In reality we are not confronted with a beneficial social planer with an infinite time horizon. In Germany the health care system is rather complex. Many stakeholders and interest groups have a quite short time horizon. Services which are paid by health insurances are generally defined by the benefits catalogue of the statutory health insurance funds, included in the Social Security Code. The Federal Joint Committee (G-BA), an autonomous self-government body in the German healthcare system, issues directives for the benefit catalogue.

Accordingly, IM products, which will be included in these directives, will be paid by the insurances. Beyond that the concrete incentive structure at the level of each sickness fund matters. If an innovative therapy is highly expensive, like immunoadsorption, and the same stakeholder benefits from cost savings in the future, the time preference seems to be the most critical variable. Until recently the perspectives of IM seemed to be bad, because the price competition between the insurances was more intensive. It was not profitable to finance high cost therapies outside the general directives. A higher premium rate would have been the consequence with some members leaving to the competitors. By now the situation improved marginally. A social security fund was established ensuring a unique contribution rate, and the price competition is rather limited to an additional contribution in case of economic difficulties (Jacobs and Wasem 2013). As a result, the willingness of the insured persons to migrate has decreased. Because of morbidity-based risk adjustment between the sickness funds some financial risks are socialized within the health care system. Nevertheless, there is still an enormous pressure to save expenditures within the social health care system. Thus there is a need for economic studies about existing barriers at the stakeholder level and how to overcome them.

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3 Management of infections with multiresistant bacteria in hospitals - An economic approach in the HICARE-project *by*

Anja Sachse, Claudia Hübner, Steffen Fleßa

3.1 Introduction

Over the past few decades, multiresistant bacteria have become an increasing challenge for the healthcare systems worldwide. Although recently gram-negative bacteria play a growing role, Methicillin-resistant Staphylococcus aureus (MRSA) still represents the most important antibiotic-resistant pathogen. The bacterial resistance means a serious problem because treatment options for MRSA infections are limited (Quintel and Witte 2006). MRSA infections prolong the length of hospital stays and increase the probability of morbidity and mortality, especially in patients who suffer from a weak immune system and severe illnesses (Siegmund-Schultze 2012). Furthermore MRSA infections cause significant additional costs in the healthcare system (Gould 2006).

Taking into consideration the individual and economic consequences, it requires a successful management of multiresistant bacteria to counteract this alarming development. This may not be sectorial or locally restricted, but still needs to be developed as a regional concept involving all stakeholders such as hospitals, rehabilitation facilities, nursing homes, medical practitioners, pharmacies, health insurance, public health services and industry (Ried 2011). The model project Health, Innovative Care and Regional Economy (HICARE) – Health region Baltic Sea coast is one of the biggest and most important network structures in Germany to combat the spread of multiresistant bacteria in a multidimensional approach.

3.2 Background

3.2.1 Medical and epidemiological basics

"Multiresistant bacteria" is the generic term for bacteria with resistance to several antibiotics. MRSA, as one of the most important representatives of multiresistant bacteria (Kramer et al. 2005), shall be introduced exemplarily.

In 1961 MRSA strains were isolated for the first time (Jevons 1961). Opportunities of antibiotic treatment for MRSA infections are limited due to the resistance of the bacteria (Geipel and Herrmann 2005, Füssle, Biscoping and Sziegoleit 2002).

MRSA exists primarily on the skin and mucosa, especially in the nasal vestibule, pharynx and perineum. Less frequently it is found in the colon or rectum (Gatermann 2012). The bacteria are transmitted directly via colonized or infected parts of the body or indirectly through contaminated hands, surfaces, areas and food (Pitten et al. 2012). Colonization means the presence of microorganisms on the skin and/or mucosa without symptoms of being ill (Bhakdi, Hahn and Miksits 2009, Neß 2010). Invasive infections may develop, if the pathogen is able to intrude the organism. Furthermore MRSA could cause septicemia, endocarditis and intoxication (Gatermann 2012).

According to data of the European Antimicrobial Resistance Surveillance Network (EARS-Net) the resistance rate in Staphylococcus aureus isolates has been increasing up to 21 % in Germany over the past years. In 2011 a downward trend was noticed with 16.2 % (European Antimicrobial Resistance Surveillance Network 2013b). Figure 1 shows a map with the proportions of MRSA isolates in EARS-Net participating countries in the year 2011.



Figure 1: Proportion of Methicillin resistant Staphylococcus aureus isolates in participating countries 2011

Source: European Antimicrobial Resistance Surveillance Network 2013a.

In 2011 German hospitals reported 44,579 MRSA cases to the German National Reference Center for Surveillance of Nosocomial Infections (302 hospitals participated in the surveillance system). Out of these cases 38,300 (85.91 %) MRSA cases were community-onset² and 6,279 (14.09 %) hospital-onset³ (German National Reference Center for Surveillance of Nosocomial Infections 2012).

Actual studies (Robert Koch Institute 2010, Reich-Schupke et al. 2010, Chaberny et al. 2008 etc.) show an MRSA prevalence of 1.2 to 5.3 % in all inpatients. Looking more precisely at inpatients with risk factors or in risk areas such as patients in intensive care units, there can be found higher MRSA prevalence rates (3.9-20.6 %) (Schulz, Nonnenmacher and Mutters 2009, Chaberny et al. 2008, Wernitz et al. 2005b). Remarkable are the differences in the designs of these studies, which make it difficult or impossible to compare them (Tübbicke et al. 2012).

² MRSA diagnosis is present at the patient's admission or detected by samples taken within the first three days of a hospital stay.

³ MRSA diagnosis is based on samples taken after the first three days of a hospital stay.

3.2.2 Intervention strategies in hygiene management

The intention of the management of multiresistant bacteria in hospitals is to prevent their further spread and to reduce the number of colonized and infected persons. Subsequently, costs caused by MRSA should be decreased (Hübner, Hübner and Kramer 2009).

Interventions in hygiene management can be divided into measures of primary, secondary and tertiary prevention (Hübner et al. 2010):

- **Primary prevention**: Aim is the prevention of the transmission of multiresistant bacteria (e. g. admission screening with pre-emptive isolation) as well as reducing the selection pressure and the risk of getting colonized (antibiotics guideline, eradication, disinfection etc.).
- Secondary prevention: Intention is the identification and treatment of patients with multiresistant bacteria at an early stage (e. g. screening and eradication of contact patients).
- **Tertiary prevention**: Measures comprise the management of outbreaks of multiresistant bacteria (e. g. closing hospital wards, refresh training of medical staff in basic hygiene and infection prevention).

3.2.3 Costs

Colonization and infection with multiresistant bacteria are a significant cost factor in the healthcare system. From an economic perspective costs can be divided into three types (Hübner et al. 2010):

- **Direct costs** are the monetarily assessed consumption of goods and services in a healthcare system caused by diagnostics and therapy of a disease. Specified to MRSA direct costs include costs for prolonged hospital stays, additional treatment (e. g. antibiotics), isolation and disinfection material as well as costs for screening etc.
- **Indirect costs** consist of productivity losses related to lost or impaired ability to work due to morbidity as well as lost economic productivity related to early retirement and death.
- **Intangible costs** include limitations in the quality of life of people suffering from sickness as well as of their relatives. Examples for intangible costs due to MRSA are pain, emotional damage and mental stress.

Especially the indirect and intangible costs of MRSA colonization's or infections are often underestimated because of difficulties in measuring and assessing these costs. However, a realistic reflection of the overall costs should include direct, indirect and intangible costs (Hübner et al. 2010).

Estimation of costs for MRSA colonization's

Colonized patients cause additional costs for hospitals due to isolation and eradication procedures. Isolation measures induce expenses for gloves, gowns, disinfection etc. Furthermore additional costs arise for blocked beds due to isolated patients. Interferences in diagnostic and therapy areas of the hospital due to MRSA are also very important. In different studies (Herr et al. 2003, Kanerva et al. 2007, Björholt and Haglind 2004, Diller et al. 2008) it is displayed that costs for blocked beds concerning isolated patients as well as disturbances in hospital logistics are main cost drivers.

Moreover colonized medical staff produces productivity losses because staff cannot work at the ward whilst being treated (eradication). Undetected colonization's may lead to infections and occupational invalidity (Zastrow and Popp 2010).

Besides monetary effects intangible costs of colonization are substantial. In the past years several authors pointed out that poor medical care and psychological trauma due to isolation procedures are relevant (Henderson 2006, Safdar and Maki 2004). Furthermore colonization may lead to a higher risk of mortality in the long term (Suetens et al. 2006). Higher risks of mortality are particularly caused by the colonization as an important risk factor for an infection (Safdar and Bradley 2008).

Estimation of costs for MRSA infections

MRSA infections have a major impact on patient outcome due to increased morbidity and mortality. For example Nixon et al. noticed a twice as high mortality risk in orthopedic patients with an MRSA infection (Nixon et al. 2006).

Other main consequences are a prolonged hospital stay and further burden for patients because of antibiotic treatment, eradication as well as medical and psychological consequences of the isolation (Hübner et al. 2010).

Infections with multiresistant bacteria greatly increase the cost of treatment in hospitals. The costs per MRSA case compared with a patient without MRSA are estimated in several studies (e. g. Resch, Wilke and Fink 2009, Herr et al. 2003, Greiner et al. 2007). Additional costs vary between 1,622 \in per day and MRSA case (Geldner 1999) and 29,277.25 \in per MRSA case (Wernitz et al. 2005a) for different MRSA infections in different hospital settings.

Depending on the setting MRSA infections induce an up to three times prolonged hospital stay for the patient (Hübner et al. 2010).

Costs due to MRSA infections were analyzed by different statutory health insurances in Germany. The Deutsche Angestellten Krankenkasse (DAK) reported additional direct costs of at least 600 Million \in for the inpatient sector in 2006 (Helfrich 2008), not included were productivity losses of medical staff, expenses for surveillance and screening, insurances, increased mortality and costs in the outpatient sector (Hübner et al. 2010). In an analysis of the Techniker Krankenkasse (TK) costs of 0.07 (best case) up to 1.26 Billion \in (worst case) were ascertained for the inpatient sector (Möws 2010).

3.3 Model project HICARE - Action Alliance against Multiresistant Bacteria

HICARE (Health, Innovative Care and Regional Economy) is a model project in the Health region Baltic Sea coast funded by the Federal Ministry of Education and Research. The project period is from 2011 to 2014. Aim of HICARE is the development and testing of effective, standardized and transferable intervention strategies to combat against the spread of multiresistant bacteria. The project focuses on six project fields:

- 1. Pathogenic agents: Diagnosis of multiresistant bacteria and prevalence analyses
- 2. Intervention: Development of a trans-sectorial hygiene concept
- 3. Innovation: Clinical application studies on multiresistant bacteria effective products
- 4. IT & Epidemiology: Centralized data and information management
- 5. Health Economics: Cost-benefit analyses

6. Transfer: Utilization strategies for transferring the project results into praxis

Project field 5, Health Economics, targets on giving economically evidence for the decision of implementing the HICARE intervention strategies in the standard service of statutory health insurance. Project related cost-benefit analyses are necessary to quantify and compare the cost effectiveness of the HICARE interventions. The aim of project field 5 is to capture all costs caused by multiresistant bacteria and by the HICARE interventions. In addition the macroeconomic advantages of the strategies will be verified (HICARE 2013a).

In the following passages some of the present project results are introduced:

MRSA admission screening in hospitals

MRSA screenings target on the early identification of MRSA carriers. Additionally measures of primary prevention should be initiated such as pre-emptive isolation. However, screening and subsequent measures cause significant costs (Hübner et al. 2010).

Prior to the introduction of a screening program several questions need to be clarified such as:

- Which patient groups are comprised in the screening program?
- Which laboratory technique is efficient for the hospital (rapid, precise and cost-effective)?
- Should screened patients be put in pre-emptive isolation until the test result is available? (Tübbicke et al. 2013)

Figure 2 shows a decision tree including 19 possible screening strategies. Assuming the hospital decides to implement a screening: first of all it needs to be clarified if all admitted patients shall be screened (universal screening) or if the screening program includes only high-risk-patients and patients from high-risk hospital areas (targeted screening). In addition the hospital elects the laboratory technique: polymerase chain reaction (PCR) method, culture technique or a combination of both. If the hospital decides for a combination of both methods it has to be defined whether both tests are performed simultaneously or if the culture method is only used to confirm a positive result of the PCR test. The last decision for the hospital is to determine whether screened patients are put in pre-emptive isolation until the test result is available or not (Tübbicke et al. 2013).



Figure 2: Decision tree with screening strategies

Source: Tübbicke et al. (2013).

Results of the decision tree analysis are based on a systematic literature research and sensitivity analyses. As shown in Figure 3 a universal screening of all patients being admitted is significantly more expensive than a targeted screening of high-risk patients (Tübbicke et al. 2013).

The decision for or against an MRSA admission screening integrates economical, medical and epidemiological aspects. Influences on the decision have the MRSA prevalence rate of the hospital depending on the risk structure of the patients as well as time and costs invested for diagnostics (Kramer et al. 2013).

Analysis of process times: Turn-around time of MRSA laboratory samples

The turn-around time (TAT) of laboratory samples is an important factor for the rapid provision of screening test results. As shown in Figure 4, the diagnostic process is generally divided into pre-analytical phase (collection of sample, transport to the laboratory), analytical phase (laboratory test) and post-analytical phase (initiating therapy measures) (Guder 2005). The TAT comprises the time between collecting the sample and the availability of the test result to commence therapy measures. By decreasing the TAT it is possible to initiate effective and pathogen-specific treatment at an earlier stage. However, the reduction of the TAT requires an improvement of technical opportunities as well as continuous process checks related to MRSA in the entire hospital (Kramer et al. 2013). Turn-around times depend on the transport time (material logistics), the duration of communicating the test results to the ward (information logistics) and commencing treatment measures according to the test result (Hübner et al. 2010).

35.000.000€ strategies pursuing universal screening 30.000.000€ 25.000.000€ no screening Expected costs per year 20.000.000€ strategies pursuing targeted screening 15.000.000€ 10,000,000€ 5.000.000€ 0€ S R L K Q 0 Ν М p Т I н В A D G E C F Strategies

Figure 3: Expected costs for decision tree strategies

Source: Tübbicke et al. (2013).





Source: own, based on Guder and Nolte 2005.

In a study in cooperation with the University Medicine Greifswald and the Friedrich Loeffler Institute of Medical Microbiology Greifswald turn-around times for MRSA samples were measured. The aim was a comparison of the TAT between the PCR-method and the culture technique. Based on this analysis, process optimization in the laboratory diagnosis can be controlled. In general PCR-methods are clearly more expensive but time-saving compared to conventional culture techniques (cheaper and more precise, but time consuming) (Hübner et al. 2010). Results of the analysis were turn-around times of approximately 17.25 h for the PCR-method and approximately 49.5 h for the culture test (Bielang 2012). These results are similar to data found in a systematic literature research: TAT of approximately 15 h for the PCR-method and 48 to 72 h for the culture test (Tübbicke et al. 2012).

3.4 International approach: Baltic Amber

Not only Germany is challenged by multiresistant bacteria - resistant pathogens are a serious danger for European healthcare systems as well as worldwide. Together with the HICARE project the initiative "Baltic Alliance against Multi-Resistant Bacteria - Baltic Amber" started its work in 2011. Aim of Baltic Amber is the development of concepts to transfer HICARE conclusions and results to a cross-border level. Cross-border exchange and cooperation with experts from countries of the Baltic Sea region to topics like the situation of multiresistant bacteria, measurements and their efficiency in the different countries shall be promoted.

Several successful Baltic Amber events took already place in different countries, for example the Baltic Amber workshop "Diagnostics and Innovation in multiresistant organism management" in Tampere (November 2012) and a study tour to examine best practice models in Turku and Stockholm in December 2011 (HICARE 2013b).

3.5 Future prospect

Multiresistant bacteria cause enormous additional costs in the German healthcare system. There exist several opportunities to reduce these costs by applying efficient hygiene interventions such as MRSA screening. Hygienic interventions need to be precisely coordinated and planned in cooperation of the hygiene department and the hospital management. Necessarily intangible costs for patients with multiresistant bacteria and their relatives have to be taken into account.

HICARE project field 5, Health Economics, focuses on analyzing the overall costs of multiresistant bacteria and of the HICARE interventions. On this basis macroeconomic benefits and incentives for implementing the interventions can be identified. Furthermore this implies opportunities of reducing the prevalence and incidence of multiresistant bacteria as well as improving health care of the population.

3.6 Literature

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4 Using Discrete-Event Simulation to analyze the process of cataract intervention at a university hospital outpatient department by Olav Götz, Claudia Bullmann, Maria Zach, Frank Tost, Steffen

Fleßa

4.1 Introduction

Health Care systems have faced a lot of changes during the last years. Changing or new laws and in particular the development of new financing principles are important challenges. Hospitals were able to reduce costs by using outsourcing, reducing personnel or closing inefficient departments, but it also showed that there is a rising importance of economic analyzes of the treatment process and the performance itself (Zapp 2002).

The operation theatre has a special role for the economic success of a hospital. A suboptimal workflow, e.g. of timely, personnel or patient related can harm the whole treatment process and lead to inefficiencies of the hospital. Therefore, the operation theatre represents a good start for analyzing and improvement of processes (Busse 2010).

In addition, prices for German hospital services are almost fixed. Therefore hospitals compete with other hospitals by having a high quality focus and high quality standards. That anon includes the waiting times of the patients and the treatment process through the total system (Fleßa 2010).

Consequently, the analysis should not be limited to the operation theatre area. The whole process of the treatment from admission to discharge should be under investigation. One possibility of such a comprehensive analysis is an ambulatory surgery, for example the cataract intervention with its growing importance as a mostly geriatric disease in an aging society (Lang 2008; Köpp 2010).

The total treatment process in a hospital is complex and uncertain (Robinson 2005; Cardoen, Demeulemeester et al. 2010). Thus, an economic analysis of this process must reflect these properties.

Simulation with its ability to model uncertainty, stochastic processes or complex interactions in general and Discrete-Event Simulation (DES) in particular can help to work on the problems mentioned above. This has been used as a commonly modeling technique in many ways in analyzing health care services (Jun, Jacobson et al. 1999; Fone, Hollinghurst et al. 2003; Robinson 2005; Brailsford, Harper et al. 2009; Cardoen, Demeulemeester et al. 2010; Leskovar, Accetto et al. 2011).

However, often DES models in the hospital industry are not based on empirical data (Ramirez, Fowler et al. 2009; Reindl, Monch et al. 2009), i.e., they properly reflect the structure of the simulated system, but distribution functions and the respective parameters are chosen without or little empirical evidence. Consequently, those simulation models are not likely to represent the real system convenient, produce meaningful results for the real decisions and convince decision-makers to implement the results of the simulation.

This paper is based on the assumption that DES must be based on empirical data and proper distribution fitting. We would like to demonstrate that it is possible to collect precise data as input for this model and prepare an economic analysis of the cataract operation based on DES.

In the course of this paper we describe basics of the cataract intervention and will give a brief overview how necessary data was gained. Furthermore, we describe the data analysis and preparation for using in the basic model which was written with MedModel (ProModel Corporation 2008). We explain the Discrete-Event Simulation model including its verification and validation and discuss its basic output.

4.2 Background

We studied the cataract intervention at a university hospital outpatient department. According to the routine steps of simulation (Shannon 1998; Harrell, Ghosh et al. 2000; Banks 2005; Law 2007) at first the problem was defined and the study was planned. Upon conversation with the medical staff, the focus of the study was put on the whole process of the cataract intervention, which started at the point the patient entered the outpatient department until he left the clinic. Beside the patient flow other common statistics in analyzing health care facilities (Murray J 1999) were of special interest. These included utilization of the facility and medical personnel, waiting times together with time spent at the health care system at all.

Before we built the simulation model, a deeper view of the cataract treatment process was obtained. We studied the guidelines of treatment, daily routine of the health care personnel and inspected the outpatient department of ophthalmology. On this basis a data entry form was constructed to create the database for the simulation. This database contained especially times for each process and used personnel. The main steps of the intervention are outlined in figure 1.

There are three major processes of the cataract pathway, which are characterized by the location where they are performed. These parts are i) before the operation (pre-surgery) at the outpatient department, ii) in the central operation area (surgery) and iii) after the operation (post-surgery) again at the outpatient department. These major processes are divided into sub-processes and listed in the track form, which is also separated into the three major processes. To gather the necessary data input for the simulation model a stopwatch based time study was performed (REFA - Verband für Arbeitsstudien und Betriebsorganisation e.V. 1992; Schnell, Hill et al. 2008). The measuring persons followed the patient through the clinic from entering until leaving documenting the times of each separate part.

After a short exploratory survey, we reviewed the data entry form and a revised new schedule was used to collect the data in a period of four weeks during the opening times of the department from Monday to Friday from 7.00 o'clock a.m. to 5.00 o'clock p.m. In addition several operations' related data was collected from the hospital information system to be compared with the data collected during the time study. Furthermore, a briefing of the involved personnel about the study was conducted.

During the time study 66 complete outpatient cataract surgeries could be documented. The analysis of the data, which will be presented in the next section of this paper, was mainly conducted with the help of Microsoft Excel 2010 \bigcirc and Stat::Fit \circledast (Geer Mountain Software Corp. 2006).



Figure 1. Outpatient cataract surgery pathway

4.3 Data Analysis and Preparation

Out of the 66 patients, 29 were male (43.94 %) and 37 (56.06 %) were female. The average age of male patients was 69.1 years (\pm 11.9 years). The average of female patients was 74.2 years (\pm 10.2 years). The overall average was 72.0 years (\pm 11.3 years).

The distinction between normal patients and patients with a high intraocular pressure is necessary to describe the overall time and the three main part times of the duration of a patient inside the clinic. A summary of the corresponding times is shown in table 1.

| | total time (| hh:mm:ss) | total time outpatient | total time central | total time outpatient department (post-surgery) (hh:mm:ss) | | |
|--------------------|-----------------------------------|---------------------------------|--|---|---|---------------------------------|--|
| | normal intraocular pressure | high intraocular pressure | department (pre- surgery) (hh:mm:ss) | operation area (surgery) (hh:mm:ss) | normal intraocular pressure | high intraocular pressure | |
| Ν | 60 | 6 | 66 | 63 | 65 | 2 | |
| mean | 05:10:49 | 06:05:52 | 00:45:00 | 03:26:49 | 00:47:03 | 01:45:08 | |
| minimum | 03:24:41 | 04:47:17 | 00:14:10 | 01:55:49 | 00:14:42 | 01:25:51 | |
| maximum | 07:39:50 | 07:14:24 | 01:31:30 | 06:20:01 | 02:09:37 | 02:04:24 | |
| standard deviation | 00:56:53 | 00:52:03 | 00:18:09 | 00:55:43 | 00:22:12 | 00:27:16 | |
| | | | | | | | |

Table 1. Summary of time patients spent in the hospital

Source: own

Table 1 demonstrates that a patient with a normal intraocular pressure on average stayed $05:10:49 \ (\pm \ 00:56:53)$ inside the clinic. In comparison a patient with a high intraocular pressure spent $06:05:52 \ (\pm \ 00:52:03)$ in the clinic.

A more detailed view on the path was necessary to use the collected times for a DES. Therefore the three major processes were divided into 20 sub-items. We analyzed the collected data during the time study for each sub-process. With the help of distribution fitting with Stat::Fit **(B)** a theoretical distribution function on the basis of the sample data of function times could be calculated. The results of this distribution fitting for a continuous distribution with an unbounded distribution are presented in table 2 to 4. To analyze how good the theoretical distribution functions fit the underlying data we used a goodness of fit tests, e.g. the Kolmogorov-Smirnov test (K-S-Test) or the Anderson-Darling test (A-D-T) (Banks 2005; Duller 2008). All calculations were conducted on a significance level of $\alpha = 5$ %. The results of these tests are also presented in table 2 to 4. In addition we compared graphics of the sample data, e.g. histograms, with the graphical expression of the theoretical distribution functions on the base of time units in seconds.

| Tabl | e 2. | The | ore | tical | distrib | ution | fur | ncti | ons | pre | e-surg | gery |
|------|------|-----|-----|-------|---------|-------|-----|------|-----|-----|--------|------|
| - | | | | | | | | | | - | | |

| function (number of data) | distribution function | p-value |
|------------------------------------|--|----------|
| | | K-S-Test |
| | | A-D-Test |
| deviation of arrival time and | Beta (-3.29e+004, 720, 45.3, 2.21) | 0.636 |
| appointment time (N=61) | | 0.483 |
| duration pre-examination (nurse) | LogNormal (25.8, 6.06, 0.383) | 0.98 |
| (N=66) | | 0.989 |
| duration pre-examination (doctor) | LogLogistic (-166, 5.89, 471) | 0.943 |
| (N=66) | | 0.956 |
| time until transportation order is | Inverse Weibull (-27.9, 1.57, 1.34e-002) | 0.474 |
| released (N=56) | | 0.613 |
| waiting time for transportation | Logistic (626, 261) | 0.393 |
| (N=57) | - | 0.163 |
| duration transportation (N=64) | Pearson6 (120, 278, 7.86, 27.5) | 0.994 |
| | | 0.99 |

Table 3. Theoretical distribution functions surgery

| function (number of data) | distribution function | p-value |
|--|--|----------|
| | | K-S-Test |
| | | A-D-Test |
| time until surgeon arrives in prep- | Beta (-150, 3.34e+004, 1.51, 43.2) | 0.869 |
| room (N=36) | | 0.756 |
| time until surgeon arrives in OP | Inverse Weibull (-1.1e+003, 7.07, 7.07e-004) | 0.901 |
| (N=57) | | 0.964 |
| time until OP-clearance (N=57) | Pearson5 (-1.28, 2.68, 378) | 0.961 |
| | | 0.954 |
| time from OP-clearance to OP-start | Lognormal (-222, 6.18, 0.158) | 0.982 |
| (N=66) | | 0.973 |
| time OP-start to OP-end (N=66) | Pearson5 (431, 3.08, 1.01e+003) | 0.857 |
| | | 0.853 |
| time OP-end to leaving OP (N=66) | LogLogistic (5.67, 4.79, 148) | 0.975 |
| | | 0.989 |
| time OP-end to surgeon leaves OP | LogLogistic (-3.38, 3.43, 104) | 0.711 |
| (N=29) | | 0.779 |
| duration prep-room (N=66) | Gamma (-49.4, 3.07, 143) | 0.963 |
| | | 0.958 |
| time until transportation order is | Normal (3.43e+003, 1.09e+003) | 0.965 |
| released (N=56) | | 0.892 |
| waiting time for transportation (N=56) | LogLogistic (-1.27e+003, 8.97, 1.97e+003) | 0.947 |
| | | 0.919 |
| duration transportation (N=66) | LogLogistic (82.9, 5.01, 150) | 0.984 |
| | | 0.966 |

Source: own

| function (number of data) | distribution function | p-value |
|---------------------------|---|----------|
| | | K-S-Test |
| | | A-D-Test |
| duration post-examination | Weibull (72.9, 1.47, 306) | 0.878 |
| (nurse) (N=66) | | 0.913 |
| duration post-examination | Pearson5 (-31.2, 8.73, 2.26e+003) | 0.991 |
| (doctor) (N=66) | | 0.997 |
| duration post-examination | Inverse Weibull (-1.56e+003, 11.1, 5.28e-004) | 0.97 |
| (nurse) (N=65) | | 0.981 |

4.4 Discrete-Event Simulation Model

For simulating the cataract intervention in an outpatient department of ophthalmology we used a DES and wrote the simulation model using MedModel (Version 7.5) (ProModel Corporation 2008).

First, we constructed a basic model as a representation of the cataract pathway and treatment of the real system for investigating the key aspects, e.g. waiting and flow times of the patients, resource and personnel utilization. After validation and verification the basic model was used to compare it with the results of different model scenarios.

The validation and verification of the basic model was achieved in several steps. Finally, we coded an initial model and compared the results with the collected data from the time study. Secondly, a calibration of the input data was executed until the overall mean time values in the three main parts of the real system and the basic simulation model were comparable (Harrell and Price 2003; Banks 2005; Law 2007). The results are illustrated in figure 2.



Figure 2. Overall mean time values - time study and basic model

Source: own

Thirdly, animation, debugging, trace-mode and discussions with medical personnel as possible methods for verification and validation (Balci 1997; Sargent 2005) were used in this simulation study.

After several back and forth iterations steps and the acceptance of the basic model as a good representation of the real system the simulation was run over a period of nine days with 900 replications of these nine days. So, all in all 8100 days were simulated. Based on three cataract surgery days per week in the outpatient department corresponds this to 51.92 years of surgery.

On the basis of the basic model several scenario calculations were constructed. The scenarios represent the research questions posted by the management of the hospital key decision-makers of the respective departments. For example, it was of special interest how a changing appointment policy would affect the waiting times or the utilization of personnel and locations. The analysis of the time study revealed that a patient leaves the pre-surgery area and reaches the waiting room of the OP-area after an average time of 48 min 20 sec (minimum 17 min 31 sec). A share of 74.24 % of the observed patients spent less than one hour in the pre-surgery area. Therefore in Scenario 1 the pre-OP-path time was fixed to one hour.

Table 5 provides a description of the other scenarios.

| Scenario | Description |
|----------|--|
| 1 | How does a different appointment policy (appointment of the patient fixed to one hour before operation) affect the model output? |
| 2 | How does a fixed waiting for transportation (fixed to 10 minutes) affect the model output? |
| 3 | How does a reduction of the time until the surgeon arrives in OP to a maximum of 10 minutes affect the model output? |
| 4 | How does an additional nurse (third nurse in prep-room) from 7:15 a.m. to 2:15 p.m. affect the model output? |
| 5 | How does an additional doctor in the prep-room affect the model output? |

Table 5. Scenarios of the simulation study

Source: own

The results of the basic model with regard to the total time, utilization of personnel and utilization of locations and the activity times of the patient in comparison to the different scenarios are presented in figure 3, 4, 5 and table 6 and 7.

The results of scenario 1 show that a reduction of the mean time in the pre-surgery and surgery part of 4.47 min and even 20.44 min respectively with a small increase of time in the post-surgery part of 0.8 min is possible by just changing the appointment policy. The highest decrease of mean time has been reached in scenario 5 with a reduction of 59.36 min in the surgery part with a small decrease of 0.65 min in the pre-surgery and an increase of 4.38 min in the post-surgery part (table 3).



Figure 3. Overall mean time values - basic model and scenarios

The changed variables in the different scenarios have also effects on the total time an entity spends in the system, on the waiting times and on the times in operation (e.g. examination of nurses, treatment of physicians, moving through the system). As shown in table 4, scenario 1 and 5 have the most dramatic influence on the mentioned times. There is a time reduction of the total time in system by 24.2 min (scenario 1) and 54.31 min (scenario 5) even so the other scenarios are able to reduce the total time in system (figure 4). Another important aspect of the study was the patients' waiting time. The different constellations represented by the scenarios show effects on this important factor. Again it can be said, that scenario 1 and 5 have the biggest impact on the waiting times – scenario 1 with a reduction of waiting time of 26.04 min and scenario 5 with 28.36 min (figure 4).



Figure 4. Mean entity times - basic model and scenarios

Source: own

The following tables present the utilization of personnel resources (table 6) and the utilization of the locations per day (table 7). There is only a little change between the basic model and the different scenarios for the physician used in pre- and follow-up examination. We found only a small increase of physicians' utilization time of 4.08 min in scenario 5 in comparison to the basic model. The highest effect on the 'nurse'-time can be found in scenario 5 changing the totalized utilization times from 922.27 min (basic model) to 699.56 min (scenario 5). On the other hand there is an increase of totalized utilization times for doctors of 55.96 min (528.32 min in basic model to 584.28 min in scenario 5).

Table 6. Personnel mean utilization

| | time used per day in minutes | | | | | | |
|--------------------|------------------------------|----------|----------|----------|----------|----------|--|
| | basic | scenario | scenario | scenario | scenario | scenario | |
| | model | 1 | 2 | 3 | 4 | 5 | |
| doctor | 216.01 | 216.48 | 216.35 | 216.69 | 216.59 | 220.09 | |
| nurse policlinic 1 | 253.61 | 249.99 | 255.54 | 255.96 | 257.39 | 269.07 | |
| nurse policlinic 2 | 21.40 | 25.08 | 19.77 | 19.47 | 18.00 | 6.03 | |
| nurse prep-room 1 | 253.06 | 247.26 | 254.05 | 251.89 | 210.21 | 155.00 | |
| nurse prep-room 2 | 74.97 | 81.47 | 74.26 | 76.07 | 50.13 | 20.83 | |
| nurse prep-room 3 | | | | | 67.49 | | |
| nurse op | 319.23 | 319.74 | 319.38 | 307.38 | 320.11 | 248.63 | |
| surgeon | 312.31 | 312.10 | 311.74 | 312.12 | 312.51 | 259.80 | |
| doctor prep-room | | | | | | 104.39 | |

Source: own

| | time used per day in minutes | | | | | | | |
|----------------------------------|------------------------------|----------|----------|----------|----------|----------|--|--|
| | Basic | scenario | scenario | scenario | scenario | scenario | | |
| | model | 1 | 2 | 3 | 4 | 5 | | |
| examination room | 301.66 | 301.71 | 302.16 | 302.31 | 302.14 | 301.80 | | |
| treatment room | 204.41 | 204.45 | 204.58 | 204.59 | 204.40 | 204.53 | | |
| waiting room OP | 1262.74 | 1089.50 | 1233.86 | 1233.05 | 1072.20 | 848.21 | | |
| prep-room | 627.77 | 609.47 | 628.74 | 614.84 | 667.24 | 485.21 | | |
| OP | 319.23 | 319.74 | 319.38 | 307.38 | 320.11 | 248.63 | | |
| waiting room examination room | 297.02 | 291.90 | 263.55 | 301.40 | 302.90 | 329.17 | | |
| waiting room treatment room | 384.76 | 356.71 | 388.33 | 388.86 | 389.01 | 409.15 | | |

Table 7. Location mean utilization

Source: own

The overall location utilization time per day has the major shift again in scenario 5 with a reduction of 570.89 min, from which a large percentage is upon the time reduction in the OP. In scenario 5 the OP is used 70.6 min less than in the basic model (table 7). Beside these changings in scenario 5 scenario 1 leads to a reduction of the total location utilization time, too. In numbers there is a shift of 224.11 min from the basic model (3397.59 min) to scenario 1 (3173.48).

These results can also be presented in the changing of the utilization rate in percent. The utilization of the basic model is set to a utilization of 100 % (figure 5). The main effect shows scenario 5 with a reduction of the utilization rate of 32.83 % in the waiting room OP, a minus of 22.71 % in the prep-room, a decrease of 22.72 % in the operation theatre, an utilization rate close to the basic model in the examination and treatment room and a small increase in the waiting room examination room (plus 10.82 %) and waiting room treatment room (plus 6.34 %).



Figure 5. Location utilization in percent per day

4.5 Conclusions

Due to different challenges in the health care sector, the focus of economic analyzes is going more and more towards the whole process and performance (Zapp 2002). Questions of waiting times, utilization rates for personnel and locations are getting more important for the management. Discrete-Event Simulation is a very useful way for analyzing processes and support management decisions (Harrell, Ghosh et al. 2000).

In this paper a Discrete-Event Simulation of the cataract intervention at an outpatient department was presented. After analyzing the pathway of the patient, the transformation of the gathered input data from a time study, the development, verification and validation of the basic model, several different scenarios were computed. The results of the simulation show, that the aspects, waiting time, utilization rates of personnel and locations, can be influenced by the different scenario assumptions. The main effects were reached by changing the appointment policy to a fixed time of one hour before the operation should start (scenario 1) and by implementing an additional physician at the prep-room (scenario 5). Scenario 5 influenced the total time of the patient inside the system, the waiting times, utilization of the personnel resources and especially the utilization rates of the locations. Here, a main result is the reduction of utilization rate of the operation theatre, which is one of the most cost-

intensive areas in a hospital. Further research should focus on these costs avoiding to only implement the costs into the cataract simulation model but to extend it to other interventions, too.

These results do not significantly differ from findings of other studies based on fictive data. However, our DES was by professionally collected data and distribution fitting along a basic simulation fully convincing the decision-makers that this model represents their real-life situation. Consequently the willingness to accept the results of the scenarios was high- higher than it could have been with fictive data.

For using as a base for the input data it was possible to follow 66 cataract patients through the system and collecting the related times for each sub-process. On the one hand the number of N=66 is not very large. Stat::Fit \mathbb{R} advises 200 data points for the used tests (Geer Mountain Software Corp. 2006). On the other hand gathering of empirical data can be a very time consuming task, e.g. during stop watch studies.

In addition, the results should always be interpreted in the background of the question, whether underlined scenario assumptions can be implemented. While the different appointment policy might be established with little effort the additional physician in the preproom might be a more difficult and expensive task.

Nevertheless, our study proves the power of simulation as a tool to analyze patient flow times, waiting times as an important quality aspect, the utilization of personnel and resources. It is the means of choice for the medical and administrational management to focus on the growing importance of process and economic analyzes in health care systems.

The strength of this study by working with real empirical data could be also enhanced in further investigations by including the costs of resources, personnel and locations, to the simulation model or widen the focus to other interventions in a hospital or outpatient department. The acquired insights into the cataract intervention could lead to a deeper understanding of the processes in different areas of the health care sector and help to focus on important questions for the success of a hospital and its outpatient departments in the future.

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5 Personnel time consumption in case of inpatient intermittent dialysis by Markus Krohn, Sylvia Stracke, Steffen Fleßa

5.1 Introduction

The hospital financing system "Diagnosis Related Groups" (DRG) implicates special challenges for every hospital. Due to this system the prices for every case are central level calculated lump sums (Mühlbauer 2004). Furthermore special procedures – if they are not part of the DRG – can be compensated by national similar additional charges. Typical for those additional charges are dialysis (Fleßa 2010). Consequently, the prices for medical treatments are externally given in each case. Because of the immutability of the revenues, the hospital has to focus on the costs.

Concerning this situation, the focus should be on the extraction of meaningful information and data. Only in this way the cost coverage can be improved by implantation of found potentials (Mühlbauer 2004).

Personnel expenses are of especial relevance, since they cause up to 70 % of total costs in hospitals (Fleßa 2010). To calculate the personnel costs in case of intermittent (recurrent, at regular intervals) dialysis, it is necessary to get information about the time consumptions. Referring to the required focus on the own hospital it is not appropriate to use extern information. Such extern information could be gained from the 2004 DAGKN-study (acronym for "German committee for clinical nephrology"). The given time consumptions serve as a basis for negotiating of additional charges (DAGKN 2004). It can be assumed that these data are more political in nature than a picture of reality. Therefore, a determination of personnel time consumptions at the University Medicine of Greifswald seems to be necessary.

The University Medicine of Greifswald is a hospital of maximum treatment with 926 beds. In the year 2012 166000 patients were treated, 38322 of them inpatient (Universitätsmedizin Greifswald 2013). The service portfolio of the dialysis unit includes common (extracorporeal, intracorporeal; intermittent, continuous) and specific blood cleaning procedures. In case of intermittent dialysis the relevant renal replacement therapies are hemodialysis and hemodiafiltration. To understand the content of the time consumptions it is essential to explain some technical and medical basics. This will be done in the following part of the paper.

5.2 Background

5.2.1 Technical basics of hemodialysis (HD)

Hemodialysis is an extracorporeal procedure to remove waste products and free water from the blood (Kramme 2007). The hemodialysis is used in case of acute kidney injury and ESKD. ESKD stands for "end stage kidney disease" and describes the terminal stage of chronic kidney disease (Renz-Polster and Krautzig 2013). The following figure shows the system of hemodialysis.



Figure 1: Concept of hemodialysis

Source: (Mann 2002)

For extracorporeal dialysis two liquid circulations are required. In the dialysate circulation the dialysis fluid is proportioned (consisting of pure water and salt concentrates), heated and degassed. The ultrafiltration control compares the volume of fresh and used dialysis fluid and keeps it on the same level. The conductimeter monitors the composition of dialysis fluid. In event of deviations from the reference value the bypass is opened. The ultrafiltration pump is located behind the dialyzer. This pump removes – through regulation of transmembrane pressure in the dialyzer – free water from the blood. At the end of circulation the fluid is checked for hemoglobin (blood leak detector) to exclude possible damages. In the blood-carrying circuit, the blood is pumped from the vascular access towards the dialyzer. Together with measuring the arterial pressure the anticoagulation is administered in this section. Downstream the dialyzer the pressure is measured again (venous pressure) and the blood is reviewed for air bubbles (air detector). If air bubbles are identified, the dialysis machine locks the clamp immediately to prevent air embolism. The exchange of matter takes place in the dialyzer where the substances diffuse across a semi-permeable membrane (Mann 2002).

Furthermore, the procedure of hemodiafiltration (HDF) is applied at the University Medicine of Greifswald. In addition to ultrafiltration and diffusion the hemodiafiltration also uses convection for the replacement of substances (Mann 2002). However, it is not necessary to picture that detail, because it does not determinate a higher personnel time consumption (Kramme 2007).

5.2.2 Medical basics of vascular access

A vascular access is inevitable for extracorporeal blood purification. It is possible to distinguish between acute and chronic accesses. The favored acute access is the Shaldon-catheter, which is fast to place but only can be used for a short time. Such a catheter can be placed into veins in the neck or groin area. In case of chronic access it is possible to use arteriovenous fistulas (also called shunts) or implanted catheters. An arteriovenous fistula is defined as a native or synthetic connection between artery and vein. Shunts are usually located in the forearm area. Is there no possibility to construct such a connection (e.g. because of the vascular situation) implanted catheters are used. The best known example of this is the

Demers-catheter. In comparison to the Shaldon-catheter the implanted version is tunneled and suitable for a longer time (Nowack, Brick and Weinreich 2009).

5.2.3 Medical basics of anticoagulation

Due to the contact between blood and unphysiological surfaces in the extracorporeal circuit, there is an increased tendency of blood clotting. To prevent coagulation, this tendency needs to be suppressed. Within the study, two different methods for anticoagulation are relevant. The standard procedure is the administration of heparin. In addition to reducing the coagulation, the risk of bleeding is elevated (Nowack, Brick and Weinreich 2009). In the event of heparin intolerance or bleeding risks, citrate can be used for regional anticoagulation. In this method, citrate is added to the extracorporeal circuit downstream the vascular access. The compound between given citrate and existing calcium (in the blood) prevents the coagulation. In the dialyzer the accruing citrate complex is removed nearly completely. By administration of calcium at the venous side of the circuit the blood coagulability is restored (Stracke, Doslic and Keller 2006). Compared with the use of heparin, the citrate anticoagulation is considered to be more time-consuming for the dialysis personnel.

5.3 Methodology

In order to obtain durations for one inpatient intermittent dialysis, a two-step approach was applied. The first step focused on the process structure of one dialysis. Five team members observed the processes at the dialysis unit on two days. The visible processes where divided in four categories.

| Category 1: | direct care (marked blue) |
|-------------|---|
| Category 2: | indirect care (marked green) |
| Category 3: | general activities, not relatable to one dialysis (marked gray) |
| Category 4: | medical service (marked red) |

In a second step we measured durations for every process. Nine team members measured process times over three weeks using stop watches.

5.4 Results

5.4.1 Results of process analysis

Figure 2 shows all encountered processes in relation to one dialysis. Furthermore, it is important to note that dialysis also can take place on intensive care units. So we have to distinguish between treatments on dialysis unit (DU) and intensive care unit (ICU). For intensive dialysis it is needful to consider the travel time from DU to ICU and back. The following example includes such time and shows a completely nursing process (dialysis on ICU with heparin) excluding general activities, which are carried out during the stay on DU.

START – preparations on DU – way to ICU – preparation, puncture, connection, documentation – way to DU – way to ICU – documentation (after 1h) – way to DU – way to ICU – documentation (after 2h) – way to DU – way to ICU – documentation (after 3h) – way to DU – way to ICU – documentation (after 4h), disconnection, postprocessing (part 1) – way to DU – way to ICU – postprocessing (part 2) – way to DU – documentation (hospital information system) – END



Figure 2 Process structure

5.4.2 Results of time measurement

To present all arithmetic averages in a compact way the patients have to be assigned to three levels of care. The first level includes the chronic dialysis. Chronic dialysis can be performed by shunts or catheters. Since a vascular access is already present, catheter placements (CP) are not necessary. Also there is no need for councils. In contrast to the chronic level catheter placements (0.09 per dialysis) and councils (0.21 per dialysis) need to be included in level two. This level includes the acute dialysis, which are carried out with catheters anyway. Level three comprises intensive dialysis. Beside the common variants of vascular access a connection to blood circuit of extracorporeal membrane oxygenation (ECMO) can be used to link patient and dialysis machine. We also have to look at the need of one-on-one-care. This need exists when a dialysis is carried out with citrate and the machine type "Gambo" (Raedel 2013). The alternative type is called "Genius". Finally it should be mentioned that catheter placements are not included because they are not task of dialysis unit. The following table shows the results of time measurement.

| Level | Chronic – DU (50%) | | Acute – DU (26%) | | Intensive – ICU (24%) | | |
|--------------------|--------------------|----------|------------------|--------|-----------------------|--------|-----------------|
| Direct care | Shunt | Catheter | Cath | neter | Shunt Cath | | er ECMO |
| | (53%) | (47%) | 53n | 106s | (59%) | (23%) | (18%) |
| | 1h00m16s | 53m06s | | | 39m34s | 20m24 | s 29m40s |
| | | | | | with one-on- | one w | rithout one-on- |
| | | | | | (6%) | | one (94%) |
| | | | | | 3h48m35 | 5 | 34m31s |
| CP (direct) | - | | 02m | n30s | | - | |
| Indirect care | Heparin | Citrat | Heparin | Citrat | Heparin (94 | %) | Citrat (6%) |
| | (75%) | (25%) | (75%) | (25%) | 06m34s | | 34m00s |
| | 40m29s | 53m44s | 40m29s | 53m44s | Gambro (71 | 0(_) | Conjus (20%) |
| | | | | | 22m58a | /0) | 20 - 21 = 21 |
| | | | | | 55m588 | | 30m318 |
| CP (indirect) | - | | 02m | n57s | - | | |
| General activities | 46m29s | | 46n | 46m29s | | 46m29s | |
| Medical service | 36m | 19s | 36m | n19s | 39m36s | | |
| Council | _ | | 07m | n44s | 07m44s | | |
| CP (medical) | - | | 02m | n50s | | - | |

Table 1 Time consumptions

Within the results two limitation of combination have to be respected. For the one thing a "one-on-one-care" is only necessary in case of the combination "citrate and Gambro" and for another thing ECMO only can be combined with the anticoagulation "heparin". Overall 16 combination options are possible, four in level of chronic, two in level of acute and ten in level of intensive dialysis.

5.5 Discussion

Table 2 gives an overview of the measured personnel time consumptions and the DAGKN data. The individual durations are derived from the combination of the possible alternatives.

| Content | Source | Chronic | Acute | Intensive | |
|-----------------|--------|---------------------|---------------------|---------------------|--|
| Direct care | DAGKN | 2h05m00s | 3h24m00s | 5h00m00s | |
| | Own | 53m06s - 1h00m16s | 55m36s | 54m55s - 4h28m09s | |
| Indirect care | DAGKN | 2h08m00s | 2h08m00s | 2h08m00s | |
| | Own | 1h26m58s - 1h40m13s | 1h29m55s - 1h43m10s | 1h23m34s - 1h54m27s | |
| Medical service | DAGKN | 50m00s | 1h00m00s | 1h20m00s | |
| | Own | 36m19s | 46m53s | 47m20s | |

Table 2 Study comparison

Source: own, based on (DAGKN 2004)

As can be seen from table 2, the differences are partly huge. For chronic and acute direct care the DAGKN reasons the durations with high time consumptions because of monitoring, advice giving, communication and therapeutic measures. Admittedly the activities were carried out, but not with a corresponding duration. In the intensive area DAGKN calculates with five hours for direct care. This is justified by a general one-on-one-care. In comparison, the durations of study amounted 4h08m59s and 4h28m09s. However, in the majority of cases (94 % without one-on-one-care) the duration was between 54m55s and 1h14m11s. Although the 6 % are not representative but a small one-on-one amount can be assumed because "citrate" is actively avoided (Stracke 2013). So an amount up to 30 % can be possible (Raedel 2013). Also in the area of indirect care a reduction was observed. The fluctuations of the observed data (from 1h23m34s up to 1h43m10s) mainly are the result of the anticoagulation. Here, citrate can be seen as substantial costlier in the personnel area. As opposed to this, the

DAGKN considers citrate only in the area of material costs. Overall, it must be noted that DAGKN indirect and medical service data additional include personnel time for treatments on other wards and times for on-call duties. The personnel of dialysis unit estimates the additional durations to be low. Relevant consumptions only arise from activities like initial patient assessment, organization, communication and catheter placements on ICU (Dabers 2013). Out of this an additional effort up to 10 % of nursing time (except for monitoring in case of one-on-one care) can be possible (Raedel 2013). The comparison of medical service data is extremely difficult because the DAGKN gives no information about the reasons for arrange them. In the study the process "documentation" is approximately regarded as equal over all dialysis (Dabers 2013). Altogether it was not possible to find such distinctions.

5.6 Outlook

Although the study delivers new eligible data, it is important to take a look at the future development. What does the future holds for the dialysis unit? An extrapolation from the University Medicine of Greifswald expects for 2023 an increasing number of older patients, while the total number approximately remains on the same level (Radicke, van den Berg and Hoffmann 2013). Since kidney diseases usually increase with higher age, (Frei and Schober-Halstenberg 2008) an advanced number of dialysis can be assumed. If we still expect an increasing multimorbidity in case of older patients, it seems to be inevitable that direct – depending on a higher need of care – and indirect time consumptions – because of the amount of citrate dialysis – will increase in the course of time.

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6 The use of the Balanced Scorecard in health care centers *by*

Magdalena Jaworzyńska

6.1 Introduction

Strategic management has been the subject of interest of heath care centers managers for many years. However, the polish legal system imposes on many hospitals the procedure of creating the strategy of organization that seems to be impossible to realize, the managers didn't carry into effect any strategic control.

The report that was published in September 2008 by the Supreme Chamber of Control states abnormalities in the formulation of the reorganization of strategic plans as well as in the realization of those plans. In 31% of the controlled hospitals it was acknowledged that the strategies had been prepared in an unreliable way on the basis of not possible to realize intentions or other actions on which the managers had no influence. The strategies only comprised the will of the strategy creator.

On account of this it should be considered what kind of actions need to be undertaken for the strategic management of a health center to bring expected effects. Rules of strategy building for health care institutions can be reduced to a number of conditions (Briman 2002)

- a health care center needs to have a well organized system of internal information,
- a health care center needs to state its own future position precisely by the use of all accessible knowledge sources and it must state its possibilities of influence on environment,
- a health center has to define internal conditions of the strategy realization, that is the recourses that a health care center will have at its dispose,
- a health care center has to make the most advantageous choice from several options of strategies elaborated by the managers, creating body as well as by employees. In order to choose the options several critical determinants that considerably influence the future of a hospital need to be distinguished,
- a health care center has to elaborate a strategic plan that is the path to the proposed solutions applying at the same time the resources it has,
- the managers of a health care center need to obtain the support of their team for the strategy being implemented,
- the manager of a health care center should ensure a current supervision and control over the strategy realization progress at every level of strategy implementation and later at the level of its realization.

Not only do these activities give a guarantee to elaborate a good strategy but also they give the future stability and a smaller risk connected with the changes within the environment.

6.2 The Balanced Scorecard

The differences in the elaboration and implementation of strategies in health care centers are obvious. Among many difficulties, at the level of strategy formulation that we can encounter in health care centers, we ought to enumerate (Stępniewski 2008):

• the difficulties with stating which of the supplied serviced in a health care center are the most important,

- the lack of common organization goals for doctors, nurses and administrative personnel,
- the lack of coordination and proper cooperation between the personnel of a health care center with doctors as well as with medical employees who take care of a patient before and after hospitalization,
- the threat of stopping the functioning of the organization on the local of medical supply of services,
- the lack of balance between the quality of medical care, patients' satisfaction, employees' satisfaction and scientific research and financial goals,
- the problem of internal communication and the communication of the highest rank managers in the field of strategic goals,
- the difficulties with meeting the legal requirements as for the environment protection,
- the increase of employee' dissatisfaction.

In order to balance the above mentioned difficulties and problems a mission should be elaborated and then it's necessary to think over how to put the defined goals into practice.

One of the ways of putting a strategy into an operational practice is the Balanced Scorecard proposed by R.S. Kaplan and D.P. Norton. The Balanced Scorecard as the concept of management was created in the 90's of the 20th century. The research initiated by Robert S. Kaplan from Harvard Business School and David S. Norton, a founder and the chairman of Renaissance Solution Inc., constitute the beginnings of the Balanced Scorecard. The research referred to the measurement of results in organizations.

The bigger the need to apply the Balanced Scorecard in the public sector the more the subjects of this sector have to compete for the clients and funds. At present the number of public sector subjects that are willing to obtain limited funds from sponsors, grantors, associations, foundations and government organizations is growing. Health care units need to implement the mechanism of strategic management that allows for survival and development (Tuzikiewicz 2007).

The Balanced Scorecard gives the managing board a universal tool to turn their visions and strategies of organization into the set of logically connected efficiency measures (Kaplan, Norton 2001).

An essential advantage of this concept is the connection of subject measures with indicators of a particular organization's strategy of actions. It's not the method that is used to build the strategy of activity – it's the starting point in preparing the card. The implementation of BCS is used to monitor the realization of the strategy and it may influence – finally- the strategies improvement (fig.1). The basic task of the card is to indicate the key actions that are to improve the results and create the values in institutions (Dąbrowski 2011).

The Balanced Scorecard is a system of varied measurement and evaluation of a unit's achievements. It goes beyond the limits of management used mainly on financial measures. It describes and explains what should be measured in order to obtain a defined level of strategy effectiveness (Zdrowie i Zarządzanie 2012).

The Balanced Scorecard is a set of measures grouped into perspectives tightly connected with the mission and the strategy of an organization. The measures can be elaborated for key workers, departments and the whole organization. This scheme allows for (Kautch 2010):

- the adjustment of all the resources to the realization of the strategy,
- putting the strategy onto operational goals,

• the connection of every day activities of workers with the realization of the strategy, introduction and monitoring of organization changes.



Figure 6 The process of creating and using a Balanced Scorecard

Source: (Dąbrowski 2011)

The strategy of health care centers (ma character) of the collection of hypothesis that refers to the change from an actual state of the center to the moment it reaches the demanded state in the future. The Balanced Scorecard groups those hypothesis into four perspectives and combines them into the coherent body owing to the existing cause and effect relations between them (Świerk 2005).

The construction of the Balanced Scorecard is based on the four perspectives: financial perspective, client's (patient's) perspective, internal perspective and knowledge and development perspective. The description of actions necessary to undertake in each of the perspectives is defined by the use of operational actions that constitute strategic initiative for every perspective. All the perspectives are created in the same way, that is strategic goals, detailed goals, measures and actions are defined in every perspective.

Identification of dependencies between the perspectives constitutes an important factor of the choice of evaluation measures and it can obtain the coherence of different activity, goals of a health care center in all of the perspectives.

A financial perspective indicates the management of financial of a unit and answers the question: "what kind of financial results should be in order to satisfy the expectations of the owners?" However, from the point of view of a health care center, that has the main goal to balance the costs with the incomes and to maintain the financial liquidity, the following answer to the question is more important "how to survive on the medical service market, how to maintain a considerable financial liquidity and how to rationalize the costs maximally?" Due to the fact that the price of a medical procedure is imposed by a payer , it should be measured whether the medical procedure is surved at appropriate costs in the light of a financial perspective (Kludacz 2009).

Health care centers can choose as the strategic financial goals : the increase of income, the reduction of costs, the improvement of resources usage. These aims should constitute a reference point to the goals and measures formulated within the frame of other perspectives.

Indicators applied in financial perspective should comprise the development of a hospital and within its frames the development of the evaluated field (Kludacz 2009).

In the health care centers at the financial level typical financial measures such as return on equity or assets, profitability of individual medical services together with the specific ones are combined together. Specific measures should be adjusted to the kind of business and to the strategy that is reached (e.g market share of medical services) (Skoczylas 2005).

The financial perspective illustrates the results of the strategy accepted for the realization directly where the value of the planned in the perspective measures constitute the consequences of the undertaken actions and effects obtained in other perspectives.

The patient's perspective answers the question: "How do clients evaluate us? Patients constitute the most important group of clients in the health protection sector. The process of diagnosy and therapy wouldn't be possible to take place without patients. In this perspective it should be defined who is a patient of a hospital, how a hospital wants to compete for a patient and what kind of medical services are mostly expected and desired from the patient's point of view (Kludacz 2009).

In this perspective there are the following typical goals: client's satisfaction, the increase of client's loyalty, gaining new clients and their profitability. In health care centers relations between the payer and the medical personnel are substantial. They on the behalf of the client contract and finance a unit's activity. However the goals and measures that reflect them have to take into account the needs of both groups clients, and their realization should contribute to the improvement of a financial situation (Kludacz 2009, Skoczylas 2005).

The perspective of internal processes that is an identification and improvement of the most important actions and key processes for the goals formulated in the patient's financial perspective. It answers the question: 'what kind of processes need to be improved in a particular unit?" In this perspective it is important to concentrate on the effectiveness of realized key internal processes. Those processes are considered to be effective only when they satisfy the client's in an reliable/ appropriate way within the financial measures. Internal processes of a health care center should be widely understood and they should comprise: innovations, a proper medical process and the care of a patient after the medical process has been finished (Skoczylas 2005).

Goals and their measures formulated in the perspective of internal processes should be concentrated on those internal processes, that will have the most important influence on the patient's satisfaction and on what financial goals reached. They may refer to, for example, the time of reaction for the patient's needs, the excess to new methods of treatment, time and cost of realized medical procedures. Internal processes perspective has a substantial influence on the defined aims in other perspectives. The goals in this perspective allow for a quicker and better as for the quality patients' service, they also increase the effectiveness of a hospital's actions what is reflected in the economic results (Kludacz 2009).

The perspective of development answers the question: "Is the further development possible and if it is possible to create the value? The cause and effect chain of strategic aims going through all of the four perspectives starts in the development perspective (Kludacz 2009).

The perspective of development defines the resources that are necessary to implement the changes of actions realization that are enumerated in the patient's, financial and internal processes perspectives. Medical resources and qualified medical staff should constitute an essential area of hospital's interests.

The aims set out in this perspective constitute the basis of a longterm development and improvement of an organization and they are obtained within a longer period of time. They can be connected with the conducted by a health care center development strategies of such areas as the implementation of a new medical procedure, the development of new methods of management, the development of the applied medical technologies or the development of medical personnel competences. Individual aims should be defined for medical personnel (Kludacz 2009).

The measures applied at this level are connected with the not material assets and abilities essential in the future. They can take into account the development of employees, their loyalty and the development of new services (Skoczylas 2005).

The contemporary approach to the BSC method allows for its modification. At the moment of the construction of the measure system and the evaluation of the hospital's achievements the four basic perspectives should be used. It's also necessary to consider whether the following perspectives need to be taken into account (Rudawska, Urbańczyk 2012).

Keeping the functioning conditions of a health care center in mind at the moment of the BSC construction the following additional areas of measure can be proposed: stakeholder and competition.

There is a big number and a varied group of stakeholders in a hospital. The most important, apart from the patients and their families, are the owners and founder's organizations, the payers of health services, public administration organizations that create a health policy, doctors that cooperate with a hospital, employees and their trade union organizations, medicine, medical materials as well as the medical equipment and apparatus deliverers, service deliverers (transport, media, energy), financial institutions (creditors, insurance agents), sector vocational organizations and local community. They have a big influence on a hospital activity, therefore the perspective of stakeholders in a hospital should take into account the interests of all interested groups of information receivers (Hass-Symotiuk 2011).

Another important area, from which point of view a health care center should be evaluated is the competition within the conditions of a creating market of medical services. This perspective comprises an analysis and evaluation of a unit's activity from the point of view of its position on a regional services market. It is directly connected with the other perspectives especially with the perspective of development (Hass-Symotiuk 2011).

Particular areas of the Balanced Scorecard are directly connected with each other and they have an influence on one another. Additional perspectives of evaluation that have been mentioned constitute a proposition of BSC concept enlargement, taking into account hospitals specification. The collection of those areas of a hospital's evaluation is not closed. It is expected that the practice of implementation of this tool will bring next areas reflecting the needs of a hospital within this domain. However, it should be remembered that in the view the clarity the number of perspectives should not by bigger then six (Hass-Symotiuk 2011).

An example model of the Balanced Scorecard and its perspectives for the units of health care is presented in figure 2.



Figure 2 The model of the Balanced Scorecard in hospital

Source: (Hass-Symotiuk 2011; Rudawska, Urbańczyk 2012)

The application of the Balanced Scorecard allows for the integrity of all the actions around a health care center strategy can contribute to the enlargement of its realization efficiency.

6.3 The Balanced Scorecard in practice in hospitals

In the conducted research a questionnaire has been sent to 11 independent public health care centres in Lublin via e-mail. The choice of the trial for the research was done on the basis of health care centers register of Lubelskie province. Independent public health care centers with the resort code HP^4 . For the use of the empirical research a research tool was elaborated – questionnaire. The questionnaires were addressed to the economic directors or to the main

⁴ HP 1-5 is a ministerial code of certain types of organizational units of the plant resulting in Annex 2 to the Regulation of the Minister of Health of 16 July 2004 on the system of departmental identification codes for health care organizations and detailed rules for their transmission (Journal of Laws of 2004, No. 170, item. 1797).

accountants of health care centers and they were sent by e-mail. The research was conducted in December 2012.

Within the frame of the conducted research there were 5 answers sent back which constitutes 45%. The result is satisfactory from the perspective of how efficient questionnaires are.

Unfortunately none of the health are centers that were researched had the Balanced Scorecard implemented. When we look at the activity of the researched units we can see that health care centers have some elements of the Balanced Sore Card introduced, but they haven't been transformed into a system. There does not exist a complex attitude to the strategy in the researched health care centers.

It is necessary to consider how it is possible to improve this process. A map of strategy needs to be built that consists of strategic goals situated in 4 perspectives: financial, patients, processes and development ones.

A map of strategy shows how logical is the accomplishment of a superior organisation goal – the mission. Health care centers are created to answer the need of the public and serve the whole or a certain group of the community. Due to that the basic aim of those subjects is to satisfy the needs of a particular group and not to generate the profit. In the researched health care centers a patient's perspective is noticeable due to the fact that the subjects look after the patients' satisfaction and they look after the access to the offered services. Those centers have to consider how to adjust the scope of the offered services to the local needs and they have to strengthen their own reputation. However, in order to obtain this the centers will have to improve organisational processes. It will be necessary to improve medical care over a patient, implement programmes that will rise the level of operational quality and effectiveness. It comes from the conducted research that 80.0% of respondents use the measures that are characteristic for the perspective of internal processes such as indicators of how many beds are used or an average length of stay in a hospital per bed.

Two following areas are important for the realisation of those purposes. Due to the fact that organisation processes are done by employees health care centers will have to look after an appropriate level of qualifications of personnel as well as the personnel satisfaction. The employees should be secured with back up of applied information systems that will be helpful to make standards of efficiency of realised organisation processes higher.

In all of the researched health care centers the financial perspective is perceived. Financial condition constitutes a typical aim in this perspective. Therefore, the studied health care centers should pay attention on both increase strategy as well as effectiveness strategy

6.4 Summary

The application of the Balanced Scorecard in the management of health care centers can bring many advantages, among which we can find (Jabłoński, Jabłoński 2006):

- the patients' satisfaction increase
- the improvement of the relationships with patients
- the definition of key needs in the area of personnel education
- the increase in the market participation
- infrastructure improvement
- the course of the process improvement
- transparency of costs
- the improvement in the costs control

The Balanced Scorecard due to the integrity of financial and nonfinancial information presents a complex evaluation of a center's effectiveness. The system of effectiveness measurement should only constitute a mean to gain the goals – the system of financial planning. It helps the managing board realise the strategy easier and allows for the monitoring of the development of its realisation.

6.5 Literature

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7 Managing the accredited laboratory on the example of the Department of Influenza Research laboratory, National Influenza Centre of the NIPH-NIH in Poland *by Agnieszka Woźniak-Kosek and Lidia B. Brydak*

7.1 Introduction

The National Influenza Centre, designated by the Minister of Heath, is one of 140 Centres working in 107 countries and is recognized by the Word Heath Organization (WHO). Simultaneously, the National Influenza Centre is the only institution of that kind in Poland, thus is a reference centre for influenza on the national level. The National Influenza Centre collaborates with WHO and is a member of the international scientific networks, such as the European Influenza Surveillance Scheme (EISS), Community Network of Reference Laboratories for Human Influenza In Europe (CNRL), and FluNet (Global Influenza Surveillance Network WHO).

The regular tasks and duties of the National Influenza Centre are the following:

- 1. to perform virological surveillance of influenza,
- 2. to perform antigenic analysis of the influenza strains isolated in the National Influenza Centre as well as in the local laboratories of the Voivodeship Sanitary-Epidemiological Stations (VSESs),
- 3. to maintain exchange of information with WHO Collaborating Centre for Reference and Research on Influenza in London, including informing of the isolated influenza virus strains and sending these isolates for more detailed analysis,
- 4. to coordinate, at the national level, integrated virological and epidemiological influenza surveillance SENTINEL, where the participants are VSESs and a representative number of family physicians,
- 5. in the aim to maintain the appropriate quality of the influenza surveillance SENTINEL that is performed according to the guidelines prepared by the National Influenza Centre, to verify methods, procedures and instructions used by VSESs,
- 6. to train laboratory staff of VSESs and physicians on laboratory methods regarding diagnostics of infections caused by influenza virus and other respiratory viruses, on methods of the specimen collection, storage and transport of the specimens and other issues related with the SENTINEL influenza surveillance,
- 7. to develop and update laboratory procedures and instructions regarding virological and epidemiological influenza surveillance in Poland as well as forms used by VSESs to prepare weekly epidemiological reports and weekly virological reports that are then sent to the National Influenza Centre; these reports are the basis for weekly national reports that are prepared by the National Influenza Centre and sent to FluNet (WHO) and EISS,
- 8. to prepare weekly collective reports with virological and epidemiological data for the entire country to send to EISS and FluNet,
- 9. to perform virological and serological diagnostics of influenza and influenza-like infections,
- 10. to assess immunity of the population for the influenza virus strains present in a given epidemic season in Poland by serological surveys,

- 11. to perform national control of influenza vaccines available in Poland in each epidemic season and giving opinions on such preparations,
- 12. to perform, together with clinicians, studies on the immunological response to influenza vaccination in patients from high-risk groups,
- 13. to work in the area of the national preparedness for influenza pandemic,
- 14. to take various actions regarding public health issues in the aim to increase influenza vaccination rates in Poland through the promotion of credible knowledge on influenza, its prophylaxis and threats of avian influenza and pandemic influenza.

Accreditation is an objective evidence that the laboratory operates in accordance with the best laboratory practice. Fig. 1. shows a diagram of the process of accreditation.



Figure 1 A diagram of the accreditation process. (Document PCA DA-01, PCA DA-08, PCA- DAB-07)

A virological laboratory, which provide tests for medical facilities, that wish to obtain a certificate of accreditation should demonstrate to the accreditation body, such as the Polish Centre for Accreditation (PCA) that is competent to perform certain actions. To do this, it must follow the guidelines set out in the standard ISO 17025:2005, "General requirements for the competence of testing and calibration laboratories", as well as according to the documents identified by the PCA. A detailed list of documents can be found on the website of the PCA <u>www.pca.gov.pl</u>. The whole process of preparation of a virological laboratory to apply for accreditation can be divided into two stages.

7.2 STAGE ONE

In this stage an appropriate documentation of the management system must be prepared, which includes the elaboration of the quality manual, general and testing procedures, instructions and other documentation related to the virological laboratory equipment. Most often in a given facility there are several different diagnostic laboratories and the main body applies for accreditation, hence at elaborating the documentation it is necessary to separate the general documentation from the testing one in specific organizational sections, e.g. such as the virological documentation. The expert group preparing the general documents should be trained in the PN-EN ISO 17025:2005 standard, and the way of creating documents in its basis. The task of the team will include the elaboration of the documentation related to the Quality Manual and general procedures in such a way as to describe the existing work rules, and customize those which are not described, or modify them be compatible with the system described in the PN-EN ISO 17025: 2005(Michalski Mytych 2008).

For the elaboration of the testing documentation in the case described for the virological laboratory it is best to assign persons who work in the laboratory and perform analyses. If the laboratory does not use the research described in the standards, it is required to describe the actions performed in the appropriate testing procedures. In the case of the Department of Influenza Research, National Influenza Centre, it is a Testing Procedure with a specific labelling PB-02/LEI/D "The determination by a PCR method of the genetic material of viruses causing respiratory tract infection". The prepared procedure must be reviewed and approved by the Head of the Laboratory and subject to approval by the management.

7.3 STAGE TWO

It begins at the time of approval of the above mentioned documents(Pawełczyk 2007).. The best method to implement the documentation is by training the employees. The effects of these actions can be checked in the best way by conducting internal audits. The standard PN-EN ISO 17025: 2005 does not specify how many internal audits should be held throughout the year. It is assumed that at least once a year such verification should be performed. To be well prepared for the audit one should prepare an audit schedule with a division into specific organizational units of the facility. Managers of individual laboratories should be informed of the scope of the audit and about the date. In the case of non-compliance, the person responsible for the given area of testing should determine the cause of non-compliance and suggest corrective actions to eliminate inconsistencies and prevent their recurrence.

7.4 The accreditation in a virological laboratory: benefits or problems

At each step of the implementation of the order to perform the virological analysis of the material, the so-called evidence of the work carried out must be maintained. These documents are necessary to reproduce the whole testing process of each sample analysed in the case of complaints from the party ordering the test or in case of non-compliance (Mytych,Łyko

2008). Such actions make it necessary to create a variety of records, which at a great number of tests may make the work extremely difficult. Our experience shows that if a laboratory decides to keep the management system documentation in paper form, it must be well prepared to manage these data. Too many of these documents may discourage the authorized staff of a laboratory to comply with the implemented system. The introduction of an electronic system for storing documents may be considered, where the required list can be generated automatically. However, it should be kept in mind that before a computer system is introduced, the employees must be previously trained and got acquainted with all the assumptions of the electronic management system. The lack of a proper training can lead to a conduct of the laboratory staff which is incompliant with the operating procedures.

It is difficult in research units to reconcile the implementation of research with commercial testing. Scientific researchers should not be required to resign from research at the expense of the increase of the number of commercial research. Financial issues are an important element at the stage of development and implementation of a quality management system in the laboratory, as well as maintaining the existing one. Research units should very carefully calculate the costs associated with the accreditation process. It may be that the financial expenses required to carry out repairs, purchase of equipment, or the maintenance of equipment after the implementation of the management system are too high. In such a situation the EU funding might be helpful, which can enable the possibility to purchase the equipment, but also to prepare the laboratory to obtain a certificate of accreditation.

7.5 Quality Manual, General Procedures, Testing Procedures, Detailed Instructions in the work of a laboratory diagnostician of the virology laboratory of the Department of Influenza Research, National Influenza Centre.

The obligation of the laboratory that intends to apply for accreditation is to provide documentation related to the management system (Stychlerz 2008).. This documentation formulates the requirements and declares their compliance. The most important document of the management system is the quality policy formulated in writing (Mytych, Łyko 2009).. It describes the laboratory strategy related to the operation, development and improvement of the management system. It should include the statements of the management on the use of requirements, standards, on continuous improvement, on the allocation of the necessary funds for this purpose, identifying and meeting the expectations and the needs of potential recipients of medical services. The Quality Policy consists in ensuring that the research carried out in the laboratories of the given company are performed at the highest level possible and in accordance with good laboratory practice. The implementation of the quality policy should ensure the impartiality and independence of research carried out by:

- creating such rules that will ensure full accountability of the staff in the performance of analytical tests. Hence, the need for highly qualified personnel with authorization and the right to perform the position of a laboratory diagnostician.
- continuous improvement of the competence of personnel and immediate response to customer needs,
- introducing the principle that staff remuneration is not dependent on the number of tests performed and is in no way associated with the results obtained in the analytical tests.

Another important document in the management system is the Quality Manual. It is a source of information on the management system in the laboratory and in particular the implementation and maintenance of the system (Michalski Mytych 2008)..

The diagram of a standard documentation structure of the laboratory management system is shown below in Fig. 2:



Figure 2 The overall structure of the management system documentation

The top of the pyramid shows the documents which are essential for the functioning of the management system in the laboratory. The documents from the top of the pyramid refer to the documents from the lower levels.

The Quality Manual prepared for the laboratory should include:

- the quality policy,
- measurable quality objectives,
- descriptions of the processes and their relationships,
- the structure of the organization, including responsibilities and powers,
- a description of the quality management system,
- the structure and the distribution rules concerning the management system documentation.

When creating the Quality Manual it is necessary to make all the wording clear and unambiguously interpreted. The structure of the Quality Manual with the division into chapters, layout, page numbers should be arranged in such a way as to provide the possibility to easily change or replace outdated pages.

General procedures (GP) and the procedures concerning measurement processes: measurement procedures (MP) and/or testing procedures (TP) are essential for the proper functioning of the management system for the whole laboratory. The purpose of the procedures is to determine the relationship between the entities or persons covered by a particular element of the system, and to determine the way of performing these activities. A General Procedure should provide answers to the questions as to "what, how and when to do something" and identify the person who is personally responsible for a certain task.

The document in question should include the following points:

- the purpose of the procedure,
- the object of the procedure,
- the range of application,
- responsibility,
- definitions,
- the description of the conduct,
- documents and records,
- enclosures,
- the status of the edition.

Measurement and testing procedures have a similar structure, however, they are extended to

cover:

- monitoring of the environmental conditions,
- equipment used for virological testing,
- test methods,
- the method to determine the measurement uncertainty,
- documenting the results of virological testing.

All the procedures in the laboratory are subject to the same layout and marking that will allow for easy identification, updating and supervision of the document.

Other documents operating in a virological diagnostic laboratory are instructions. They have features of purely internal documents and serve to regulate the recommendations for a specific task, such as weighing, pipetting, etc.

On the basis of the instructions, one can, step by step, perform a specific laboratory action. They should include:

- the way of performing the described activity,
- necessary materials, equipment, instruments,
- people performing various tasks or positions in which the work is performed,
- conditions that must be met to maintain the repeatability of operations,
- the principles for documenting analytical activities, registration, evaluation, etc.

Sample instructions applicable in the Department of Influenza Research laboratory, National Influenza Centre, are shown below:

General instructions applicable under the Quality Manual

- Principles for Working in the Diagnostic Laboratory of the Department of Influenza Research.
- Monitoring the environmental conditions in the Diagnostic Laboratory of the Department of Influenza Research.
- Proceedings in the case of the need to expand diagnostic testing with new pathogens, changes in the testing matrix or introduction of new methods of research in the Diagnostic Laboratory of the Department of Influenza Research.

Specific instructions resulting from the General Procedures of the Quality Manual

- Instructions for handling reference materials in the Diagnostic Laboratory of Department of Influenza Research.
- Instructions for handling waste generated in the Diagnostic Laboratory of the Department of Influenza Research.
- Instructions for handling clinical specimens and infectious non-clinical samples for PCR testing in the Diagnostic Laboratory of the Department of Influenza Research.
- Instructions for preparing materials used in the Diagnostic Laboratory of the Department of Influenza Research.
- Instructions for preserving pipettes used in the Diagnostic Laboratory of the Department of Influenza Research.
- Instructions for checking thermometers.

Detailed instructions on the Testing Procedure - methods of marking the presence of genetic material of influenza viruses by the PCR method

- Isolation of viral RNA,
- PCR for the influenza virus type A and B,
- Detection of PCR products by agarose gel electrophoresis,
- Instructions for handling reagents for PCR testing in the Diagnostic Laboratory of the Department of Influenza Research.

Detailed technical instructions on using the equipment necessary for the proper performance of the analysis in accordance with the applicable Testing Procedure.

- Instructions for using an analytical balance,
- Instructions for using a thermoblock,
- Instructions for using a centrifuge,
- Instructions for using a thermocycler,
- Instruction for using a set for electrophoresis,
- Instructions for using the system for computer data storage after electrophoresis in agarose.

An important internal document for the operation of the laboratory are forms, developed and maintained to record the data, which enable to demonstrate the compliance of the operation of the quality management system in the laboratory with the requirements of governing documents, such as, e.g. standards. It is recommended that the forms were approved, legible, updated, accessible and easy to find. They should also be protected against destruction, loss and damage throughout the storage period.

7.6 Changes in the scope of accreditation

Accreditation is to be understood as recognizing by the accreditation body the competence of the laboratory to perform certain analytical and testing actions (Stychlerz 2008).. Changing the range of accreditation in a virological laboratory is possible in the case of:

- 1. new objects, tested with already accredited methods,
- 2. new research techniques or testing methods,
- 3. new technical areas of diagnostic services throughout the NIPH-NIH.

7.7 Summary

The implemented and certified quality management system in a virological laboratory allows not only for ordering the diagnostic work, but also facilitates the activities of the entire facility. The main goal of having accreditation for the National Institute of Public Health -NIH is the introduction of a structured system of work throughout the facility. It presents, in a clear, explicit manner, the scope of responsibilities and competencies for each employee, establishes clear and easy-to-communicate procedures in certain cases, not only the diagnostic ones, and allows systematically, according to the assumed schedule, to improve the qualifications of the staff.

It should also be noted that the introduction of a quality system in a testing laboratory brings benefits not only for the unit implementing the system, but also for consumers of medical services, both individuals and organizations, which use the services of an accredited unit; it also brings benefits to the whole country J. o. L. No. 204, 2004, item 2087.

Accreditation is a mechanism used to ensure public confidence in referring to quality and credibility of proceedings, which are very important from the perspective of public health. In order to confirm high quality of the virological research carried out, the Department of Influenza Research Laboratory, National Influenza Centre, participates for the fourth time in the cycle of accreditation in the research of WHO, *External Quality Assessment Programme* (EQAP) for Detection of Influenza Virus Type A by PCR, conducted by a Certified Institute Public Heath Centre Laboratory Services Branch Centre for Heath Protection Hong Kong SAR, every year obtaining the Certificate of Complementation. Participation in proficiency testing is one of the most important documents assessing the competence of a diagnostic laboratory in obtaining the Certificate of Accreditation.

The National Institute of Public Health - NIH meets the requirements of PN-EN ISO/IEC 17025:2005 and has the Accreditation Certificate of Testing Laboratory No. AB 509. The certificate of accreditation is valid until July 14, 2016. Accreditation was granted July 15, 2004.

The fact of having a valid certification document is very often an important qualification criterion for research units which are to be competent in implementing the legislation (Stychlerz 2008). In addition, the accreditation can be a tool that can greatly facilitate the access to the global market according to the principle "once tested or certified – everywhere accepted".

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Website: <u>www.pca.gov.pl</u>

Website: <u>www.pzh.gov.pl</u>

8 Building Patient-Provider Relationships in Medical Services in Poland *by Iga Rudawska*

8.1 Introduction

The public health service has not seen the establishment of a consumer market, and therefore has not been subject to competition or the need to care for the client in anything but the medical sense. Until recently attempting to attract or retain patients was unheard of in outpatient clinics and health centres. The lack of price competition or a system of financial incentives, an undifferentiated and relatively low quality of services, and above all zoning requirements virtually ruled out client care. Clients who were not satisfied with the quality of service and with the services themselves turned to private clinics which were generally thought to provide services of higher quality and have a more friendly attitude towards clients. However, even in the case of private clinics the loss of a patient was not a problem of any significance, as long as new patients were arriving. The only disadvantage of the large patient turnover were the growing costs associated with administration (setting up of patients' records, patients' charts, registration) and the large amounts of time spent providing preliminary information concerning the functioning of the practice, and taking the history of patients.

Because of changes taking place in the direct environment of the healthcare service, as well as reform of its operations, it is now imperative to shift its focus away from the product and onto the marketing. Bearing in mind the growing competition in the medical services market it would be unreasonable to say that there will always be new patients requiring treatment. Even when a practice (public or private) has a full register of clients, their profile (scope of preferences) may not correspond to the profile of the clinic (its equipment, qualifications and specialisation of personnel). In such cases marketing procedures may be helpful, for example segmentation and positioning of offers.

8.2 Specific features of medical services

Characteristic features of medical services fundamentally determine all marketing operations. The most important feature is that there is no guarantee that medical services will be effective. A patient visiting a doctor is given no guarantee that he will be cured, even if he receives the most expert or expensive treatment. Medical services are therefore merely a complex of professional activities involving the use of the available equipment. The client must confide in the doctor and listen to his advice. He/she is also deprived of any ability to objectively assess the value of services, not only before, but also after he/she has received them [Kotler et al. 2002]. Furthermore, if he is dissatisfied he often has difficulty making a complaint or obtaining a replacement (for example dental fillings). Another distinctive feature of the medical services is that demand for them is often invisible (because of clients' difficulties in identifying and articulating their health needs), and is often negative (fear of pain or failure to understand the importance of preventative measures). In the case of most private medical practices and some services provided by public establishments it may also be difficult to manipulate prices as a marketing tool. This does concerns not only costs but also evaluation of qualifications and areas of competence of particular service providers. The abovementioned descriptors indicate that, if we assume that all healthcare centres observe binding quality standards and scientific and ethical norms, positioning and differentiating of services is a difficult.

8.3 The role of marketing and relationship marketing

Having in mind the specify of the health care products it would be advisable to provide services which allow the client to feel that his hopes for good, reliable service are fulfilled, that he is treated properly by staff, that he is able to voice his opinions and doubts, and that the health centre which he visits was created with him and his needs in mind. Such an approach to the client is known as the marketing approach [Kotler et al. 2011]. Unfortunately in Poland the application of marketing philosophy in the area of professional services is often perceived as a sign of an unprofessional attitude. Not only has the lack of a tradition of applying marketing philosophy, but also legal regulations and professional ethical codes (for example medical deontology) restricted the scope within which marketing may be applied. Therefore efforts should be focused on educating professionals about the usefulness of a marketing units in their structure and in 16 % of them there is a single person responsible for marketing activities. Unfortunately, in the majority of health care institutions (66%) marketing function is not distinguished at all (figure 1)



Figure 1. Marketing as a distinguished function in health care organisations

Source: [Iwankiewicz-Rak 2012, p. 101].

One may suppose that after the preliminary stage of public healthcare reform (the requirement to select a specific healthcare centre or even a specific doctor), the pressure will shift from the process of attracting clients to the process of retaining them. Relationship marketing is beginning to replace transactional marketing. Its chief aim is to encourage loyalty in the patient by constantly supplying him with values that satisfy him to a greater degree than could be achieved by the competition. Some medical services show a relatively high degree of regularity of service provision (for example dental treatment, vaccinations, and preventative examinations of infants). Therefore it is all the more important to pay attention to the creation of loyalty in patients as their possible marketing goal. According to the majority of them, gaining competitive advantage and creation of positive image are the two most important aims of marketing activity (figure 2).



a- Improving the quality of service process

- b- Meeting patients' needs
- c- Increasing the profit
- d- Gaining the competitive advantage
- e- Creating positive image
- f- Increasing the number of delivered services
- g- Improving qualifications of the workers
- h- Survival in the market
- i- Increasing the market share

j- Modernisation

Figure 2. Hierarchy of the marketing goals in the health care organisations

Source: [Iwankiewicz-Rak 2012, p. 106].

A client's original choice of a particular medical offer among several available on the market is based on an assessment of a combination of its features (examples of criteria could be: perceived quality, time of availability, place where services will be provided, price, waiting time for services [Guide 2007]). The process of looking for an offer with the maximum utility is determined by the knowledge resources possessed by the client, the time he has at his disposal, his mobility, and sometimes his income. The expected value of the service is therefore the result of a subjective assessment, and not the sum of objective factors existing in the environment. This assessment will also affect whether the client continues or ceases to take advantage of the services of a particular medical centre.

8.4 Assessment of satisfaction with medical services

The client who becomes a patient of a selected clinic compares his expectations with his impressions, especially his first impression. Together these constitute his experience. During a visit the client assesses the clinic and its services with regard to its ability to satisfy his particular preferences, also taking into account perceived qualifications and the personal characteristics of staff (sensitivity, ability to listen, empathy). Their behaviour is also subject to assessment (are they trustworthy, punctual ?), as well as the way they communicate (ability to provide information, relations between employees), and the general atmosphere of the clinic. One should also bear in mind that the result of this evaluation will depend on the emotional state of the patient in each case. For example, a patient with severe toothache will perceive his environment differently from a patient awaiting preventative treatment.

The quality of the patient/client relationship has a fundamental impact on the level of satisfaction with medical services, and in the long-term on the loyalty of the patient to a particular provider of services [Rudawska 2009]. The overall level of satisfaction with medical services depends on the balance between the initial expectations of the client, which are determined by chance, and the impression he forms on receiving the services. If there is a conflict between these two factors the result will be client dissatisfaction, and if they correspond clients will be satisfied. The service provider must aim to ensure that the client receives more than he expects i.e. that the perceived benefit outweighs the costs incurred. Costs may be of a financial nature (payment for services) as well as psycho-social (rejection of old behaviour patterns and habits such as tobacco smoking; time and energy, overcoming fear and pain). If the first visit is positively assessed by the client he will continue to build his expectations during subsequent visits, which will be supported by his own experience, perhaps by opinions expressed by other patients and non-personal signals sent out by the service provider (diplomas confirming qualifications, titles on doors etc.).

Methods of measuring satisfaction widely used in the consumer services sector may also be used with regard to medical services. Examples are boxes placed in waiting rooms where patients can leave filled in questionnaires, and unstructured written comments. Another method are 'hotlines' which provide direct contact with a representative of the clinic and allow rapid response to complaints. Both methods require an active role on the part of the client, which in practice one may not always depend on. When dissatisfied many patients prefer to stop taking advantage of services, or transfer their custom to the competition, than actively intervene (submitting complaints or written comments etc.). For this reason better results may be achieved when the organisation initiates the contact. It may use postal or telephone questionnaires aimed at a representative group of respondents as a research tool. Some medical centres in developed countries even provide a representative whose job it is to arrange regular meetings with clients. In the course of these meetings clients' preferences are discussed, as well as their appraisal, both positive and negative, of the services. Such initiatives are worth implementing, especially since research proves that there is a fundamental conflict between a patient's real expectations and assumptions of professionals regarding these expectations [Rudawska 2005]. Monitoring of the level of client satisfaction also involves keeping track of patients who have stopped visiting a particular health centre. In this case the most effective approach is to investigate the motives for this decision.

The entire organisation is responsible for measures aimed at ensuring client satisfaction, and not just those persons performing medical services. Every contact between the client and the medical organisation, from registration (personal or by telephone) until the patient leaves the clinic, are so-called 'moments of truth'. It is therefore necessary to investigate the level of satisfaction resulting from non-medical relations. Some examples of these are: time spent waiting for the telephone to be picked up; the degree of complication in the registration procedure; and the competence and civility of the receptionist.

The measure of the healthcare centre's success is client/patient satisfaction with the services he has received and therefore the establishment of a long-term relationship between the client and the institution. A loyal client, even if he himself does not experience any health problems, may recommend the institution's services to other potential patients. This kind of promotion (word-of-mouth) is extremely effective in the case of professional services. It is therefore of great importance to maintain the relationship with the client. This relationship may be broken up into the following levels [Morgan, Hunt 1994]:

- service provider provides services on one occasion,
- service provider provides services and encourages repeated contact if the client is dissatisfied or has doubts,

- the organisation makes contact with the client in order to ensure that his wishes have been fulfilled and to note any suggestions he may wish to make,
- the organisation works with the patient in order to develop new products, which may fulfil the client's needs more fully.

Examples of ways in which a dialogue with the client may be developed are 'open days', public speaking at meetings of local organisations (e.g. a housing estate club, association or union), or organisation of a 'guest evening' involving selected clients and a medical authority of a particular specialisation.

8.5 Conclusion

The result of running a health centre on the basis of relationship marketing is:

- better, more effective allocation of the organisation's resources (time, money, and staff)
- innovation,
- reinforcement of the organisation's market position,
- increased satisfaction in the segment of the market in question,
- increased appeal for potential patients, employees and investors.

Relationship marketing certainly does not guarantee that a healthcare organisation will be commercially successful. It is, however, a way of increasing the quality of the relationship between the client and the service provider, and it is this relationship, together with services of a strictly medical nature, which determine an organisation's efficacy and its usefulness for the patient.

8.6 Literature

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9 The Level Of Debt In Regional Hospitals In West Pomeranian Voivodship Between 2008-2011 by Wanda Skoczylas and Andrzej Niemiec

9.1 Introduction

The demographic situation of Poland and in the region, newer and more expensive technologies, resulting from advances in medicine and the increasing public expectations to the quality and accessibility of health services results in increased demand for source of development of health practitioners financing for sure. Local hospitals in the market of medical services must compete in both terms: medical and economic. Due to often cost and income of the current activities imbalance, the availability of own capital becomes limited. For this reason, demand for financing from foreign sources of funding increase, which results in an increase in their debt. In any case, the debt level requires optimization. On the one hand, allows the development of healthcare and thus increase the quantity and improve the quality of the services provided, that is the task of local government. On the other hand, excessive, may be a reason for the break continuity of local hospitals activity and strain on the local government budget. For this reason the debt is the subject of the current monitoring. The results of which are the basis for taking appropriate action.

The purpose of this article is to assess the level of liabilities of regional hospitals in West Pomeranian Voivodship as the result of their dynamic development.

The subject of the research are regional hospitals in West Pomeranian Voivodship in the years 2008-2011. This is the basic group of health practitioners in the region, providing fixed-line services in the field of healthcare. Assessment of the debt level of these entities will be made against the background of regional hospitals across Poland.

Source of information is data derived from the resources of the Main Statistical Office and the statistical bulletin of the Ministry of Health.

9.2 Potential of regional hospitals in the West Pomeranian Voivodship

Proper evaluation of the regional hospitals' debt in the West Pomeranian Voivodship requires a brief characterization of the potential (tab. 1).

| Content | | 2008 | 2000 | 2010 | 2011 | Growth rate | | | |
|--|-----|----------|----------|----------|----------|-------------|-------|-------|--|
| | | 2008 | 2009 | 2010 | 2011 | 4:3 | 5:4 | 6: 5 | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| The number of hospitals | (a) | 1393 | 1383 | 1269 | 1253 | 99,3 | 91,8 | 98,7 | |
| with the subsidiaries | (b) | 39 | 40 | 37 | 36 | 102,6 | 92,5 | 97,3 | |
| Number of beds hospitals along with subsidiaries | (a) | 183565 | 183040 | 181077 | 180607 | 99,7 | 98,9 | 99,7 | |
| | (b) | 7971 | 7952 | 7786 | 7746 | 99,8 | 97,9 | 99,5 | |
| The sum of assets in a | (a) | 20103194 | 22466385 | 23907996 | 24980587 | 111,8 | 106,4 | 104,5 | |
| thousand PLN | (b) | 766645 | 943151 | 1108255 | 1243941 | 123,0 | 117,5 | 112,2 | |
| Total population in thousand | (a) | 38136 | 38167 | 38530 | 38538 | 100,1 | 101,0 | 100,0 | |
| | (b) | 1693 | 1693 | 1724 | 1723 | 100,0 | 101,8 | 99,9 | |
| Number of inhabitants per one regional hospital | (a) | 27,4 | 27,6 | 30,4 | 30,8 | 100,8 | 110,0 | 101,3 | |
| | (b) | 43,4 | 42,3 | 46,6 | 47,9 | 97,5 | 110,1 | 102,7 | |
| Number of beds per 10 | (a) | 48 | 48 | 47 | 47 | 100,0 | 97,9 | 100,0 | |
| 000. the inhabitants of | (b) | 47 | 47 | 45 | 43 | 100,0 | 95,7 | 95,6 | |

Table 1. Local hospitals in the West Pomeranian Voivodship on the background of the all Polish regional hospitals in the years 2008-2011⁵

a) Poland total

b) West Pomeranian Voivodeship

As is evident from the data presented in table 1, the number of regional hospitals in the West Pomeranian Voivodship and number of beds owned by them systematically decrease. This is the result of making a restructuring. The process of decreasing of this particular healthcare base is in opposition to a growing number of inhabitants. This problem cause, that health service have to be offered to growing number of inhabitants. In the same time number of beds per 10 000. Inhabitants decreases. Presented a trend change is compatible with this existing for the whole regional hospitals in Poland. Comprising result for the regional, West Pomeranian Voivodship, and national, it is clear that the number of inhabitants per one hospital in West Pomeranian Voivodeship is greater than in the country. Regrettably, less is also the number of beds per 10 thousand inhabitants. Both of these volumes affirm the lower availability of this type of health services in the region, than the average in the country. In addition, during the period of time, this availability decreases.

Having regard to the changes in the size of the assets of the existing healthcare centers, it can be concluded that hospitals remaining on the market developing intensively. Growth rate of assets throughout the whole period in West Pomeranian Voivodeship was 162.2% at the end of 2011, which means that assets in this hospitals have grown by 62.2%. The same rate for Poland is 124,3%, including cubage and medical equipment. For regional hospitals in West Pomeranian Voivodeship the growth is three times greater then in Poland. The largest

⁵ Source: own elaboration based on GUS, www. stat.gov. (accessed 04.2013), Biuletyn Statystyczny Ministerstwa Zdrowia (2009, 2010, 2011, 2012), Centrum Systemów Informacyjnych Ochrony Zdrowia.

investments took place in 2009. The following years are characterized by lower growth both in the region and the country. As a result of this investments, the fixed assets level in regional hospitals in West Pomeranian Voivodeship clearly increased. However, it still does not reach the size of the average for the country. So you can consider that hospitals continue to remain in West Pomeranian Voivodeship was under-funded. Moreover, that these investments were realized mainly in five units.

In the light of presented external and internal conditions, it becomes substantiate to examine their impact on the financial situation of the hospitals. Intensive development is associated with the debt increase, which in extreme cases can cause financial difficulties of healthcare practitioners.

9.3 The debt level in regional hospitals in West Pomeranian Voivodeship in the years 2008-2011

The debt level of hospitals in West Pomeranian Voivodeship in the years 2008-2011 on the background of regional hospitals debt in Poland lists in table 2.

| Content | | 2008 | 2009 | 2010 | 2011 | Growth rate | | |
|--|-----|---------|---------|---------|----------|-------------|-------|-------|
| | | | | | | 4: 3 | 5:4 | 6: 5 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Liabilities and provisions | (a) | 8808731 | 9118685 | 9572280 | 11249901 | 103,5 | 105,0 | 117,5 |
| for liabilities in thousands. PLN | (b) | 230678 | 282948 | 368839 | 485048 | 122,7 | 130,4 | 131,5 |
| Percent of liabilities of hospitals in West Pomeranian Voivodeship to all | | 2.62 | 3.10 | 3.85 | 4.31 | 118,5 | 124,2 | 111,9 |
| The General Debt ratio in % | (a) | 43.8 | 40.6 | 40 | 45 | 92,7 | 98,5 | 112,5 |
| | (b) | 30.1 | 30 | 33.3 | 39 | 99.7 | 111.0 | 117,1 |
| Debt to one bed in | (a) | 48,0 | 49,8 | 52.9 | 62,3 | 103,8 | 106,1 | 117,8 |
| thousand PLN | (b) | 28.9 | 35.6 | 47,4 | 62.6 | 123,0 | 133,1 | 132,2 |
| Debt per capita in PLN | (a) | 231,0 | 238,9 | 248,4 | 291,9 | 103,4 | 104,0 | 117,5 |
| | (b) | 136,3 | 167.1 | 213,9 | 281,5 | 122,7 | 128,0 | 131,6 |

Table 2. Regional hospitals debt in the years 2008-2011⁶

a) Poland total

b) West Pomeranian Voivodeship

In the light of the data presented in table 2, it is clearly visible that global debt increases in regional hospitals during the period. Liabilities and provisions for liabilities total in the regional hospitals in West Pomeranian Voivodeship doubled. It was also the largest increase

⁶ Source: own elaboration based on GUS, www. stat.gov. (accessed 04.2013), Biuletyn Statystyczny Ministerstwa Zdrowia (2009, 2010, 2011, 2012), Centrum Systemów Informacyjnych Ochrony Zdrowia.

of liabilities and provisions for liabilities among general hospitals in all 16 provinces in Poland. The same can also be said that it had a greater growth rate than this in Poland. Between 2008 and 2011 debt of all regional hospitals in the country increased by 27.7%. As a result, the share of debt in regional hospitals in West Pomeranian Voivodeship to all hospitals in the country also grows substantially.

Increase of liabilities and provisions for liabilities is reflected in the size of the overall debt. This indicator during the period grows from 30% to 39%. But this growth was the strongest in the last year. The level of the debt ratio, in regional hospitals in West Pomeranian Voivodeship, despite dynamic growth, however, is significantly lower than the debt ratio for all general hospitals in Poland. West Pomeranian Voivodeship takes 5th place among the least indebted local hospitals in Poland, Opole Voivodeship, Kuyavian-Pomeranian, Masovian and Greater Poland Voivodeship.

The growing rate of the general debt rate is less than the value dynamics of liabilities and provisions for liabilities. Investment in the development of regional hospitals are financed not only by debt but also equity. Equity of regional hospitals in West Pomeranian Voivodeship increased by 41.6% in the years 2008-2011. This is almost double the growth faster than the capital gain amounted to general hospitals in Poland (21.6%). Sources of capital gain will not be able through profit creation. Between the years 2008-2010 local hospitals have reported profits in West Pomeranian Voivodeship. In 2011, however, reported a loss. Nevetheless, the situation in the country, is noticeably worse. Profit appears only in 2008. From 2009 until 2011, local hospitals have increasingly larger losses. Equity grows as a result of the grants received for the implementation of investment projects of the European Union.

Completely different situation will take place when the value of debt will be divided by number of beds or per capita. There are two contrary trends. First of them is caused by increase of debt and the second is reducing the number of beds, which will result in a dynamic increase in the debt ratio per one bed. In 2008, the level of this indicator in West Pomeranian Voivodeship was equal to 60% of the calculated indicator for the entire country. However, in the last years of analyzed period (2011) exceeded the national average. Similar trends are occurring in the debt ratio per capita. To a growing number of this population, however, the rate of increase is lower. In total, the debt per capita local government hospitals in the West Pomeranian is growing, but does not exceed the quantity for the entire country.

Regardless of debt measurement in regional hospital in the West Pomeranian Voivodeship it is growing in the last test.

Subject to the above study was general debt, so debt-both long-and short-term, but also provisions for liabilities and accruals. These two are potential liabilities, which in accordance with the principle of prudence have been qualified for liabilities. Assessment debt only as long-and short-term [liabilities (*)] the size and level of debt, the general hospitals in the years 2008-2011 is as follows (table 3).

| Content | | 2008 | 2000 | 2010 | 2011 | Growth rate | | | |
|--|-----|---------|---------|---------|---------|-------------|-------|-------|--|
| | | 2008 | 2009 | 2010 | 2011 | 4: 3 | 5:4 | 6: 5 | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| Liabilities (*) in thousand PLN | (a) | 7694303 | 7620683 | 7572885 | 7573028 | 99,0 | 99,4 | 100,0 | |
| | (b) | 184206 | 206338 | 230271 | 251450 | 112,0 | 111,6 | 109,2 | |
| Share of liabilities (*) of the West Pomeranian to all in% | | 2,4 | 2,7 | 3,0 | 3,3 | 113,1 | 112,3 | 109,2 | |
| The debt ratio | (a) | 38,3 | 33,9 | 31,7 | 30,3 | 88,5 | 93,5 | 95,6 | |
| | (b) | 24 | 21,9 | 20,8 | 20,2 | 91,3 | 95,0 | 97,1 | |
| Liabilities (*) to one bed in | (a) | 41,9 | 41,6 | 41,8 | 41,9 | 99,3 | 100,5 | 100,2 | |
| thousand PLN | (b) | 23,1 | 25,9 | 29,6 | 32,5 | 112,1 | 114,3 | 109,8 | |
| Liabilities (*) per capita in | (a) | 201,8 | 199,7 | 196,5 | 196,5 | 99,0 | 98,4 | 100,0 | |
| PLN | (b) | 108,8 | 121,9 | 133,6 | 146 | 112,0 | 109,6 | 109,3 | |

Table 3. Long-and short-term debt of the regional hospitals in the years 2008-2011⁷

a) Poland total

b) West Pomeranian Voivodeship

Debt without provisions for liabilities and accruals is a slightly different view of the level of debt. Regional hospitals debt[1] does not grow, but decreases. A similar trend has shown all the debt level of local government in the country. Debt counted for 1 bed and per capita in the region is significantly lower, especially in the last year, but also has a growing trend. In both cases, his height is, however, lower than the average in the country.

The differences in both approaches to assessment of general hospitals debt heavily are the result of investments from the European Union.

The subject of particular attention are due liabilities. Their height and intensity indicators are presented in table 4.

⁷ Source: own elaboration based on GUS, www. stat.gov. (accessed 04.2013), Biuletyn Statystyczny Ministerstwa Zdrowia (2009, 2010, 2011, 2012), Centrum Systemów Informacyjnych Ochrony Zdrowia.

| Content | | 2008 | 2000 | 2010 | 2011 | Growth rate | | | |
|--|-----|---------|---------|---------|---------|-------------|------|-------|--|
| | | 2008 | 2009 | 2010 | 2011 | 4: 3 | 5:4 | 6: 5 | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| Due liabilities in thousand | (a) | 1369256 | 1493280 | 1314768 | 1462047 | 109,1 | 88,0 | 111,2 | |
| PLN | (b) | 5172 | 22934 | 17509 | 19234 | 443,4 | 76,3 | 109,9 | |
| Share of due liabilities (*) of the West Pomeranian to all in% | | 0,4 | 1,5 | 1,3 | 1,3 | 406,6 | 86,7 | 98,8 | |
| Due liabilities in total liabilities % | (a) | 6,8 | 6,6 | 5,5 | 5,9 | 97,1 | 83,3 | 107,3 | |
| | (b) | 0,7 | 2,4 | 1,6 | 1,5 | 342,9 | 66,7 | 93,8 | |
| Due liabilities on one bed | (a) | 7,5 | 8,2 | 7,3 | 8,1 | 109,4 | 89,0 | 111,5 | |
| in a thousand PLN | (b) | 0,6 | 2,9 | 2,2 | 2,5 | 444,5 | 78,0 | 110,4 | |
| | (a) | 35,9 | 39,1 | 34,1 | 37,9 | 109,0 | 87,2 | 111,2 | |
| Due naointies per capita | (b) | 3,1 | 13,5 | 10,2 | 11,2 | 443,4 | 75,0 | 109,9 | |

Table 4. Due liabilities in regional hospitals in the years 2008-2011⁸

a) Poland total

b) West Pomeranian Voivodeship

Due liabilities in regional hospitals dynamically grows, regardless of how it is measured, in 2009, and then in the year 2011. Regional hospitals have the same problems as all the local hospitals in the country in those years. Part of the nature of the liabilities in the regional hospitals in West Pomeranian Voivodeship, however, is significantly lower than on a national scale. The same conclusion can be made regard to the level of due liabilities per 1 bed or capita.

The important is the debt level, but moreover its structure.

9.4 Multidimensional evaluation of long and short term debt structure

Long and short-term debt from the structure point of view is presented in table 5.

The largest share of structure have other liabilities. Their participation grows during the period. Important positions are social insurances and payroll liabilities. These, however, in the years 2008-2011 falls.

⁸ Source: own elaboration based on GUS, www. stat.gov. (accessed 04.2013), Biuletyn Statystyczny Ministerstwa Zdrowia (2009, 2010, 2011, 2012), Centrum Systemów Informacyjnych Ochrony Zdrowia

| | 2008 | | 2009 | | 2010 | | 2011 | | Growth rate | | | |
|-------|--|---------|------|-----------|---------|-------------|------|---------|-------------|--------|------|--------|
| | Content | PLN 1K | % | PLN 1K | % | PLN 1K | | PLN 1K | % | PLN 1K | % | PLN 1K |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| | | | | | Polanc | d | | | | | | |
| Α | Liabilities (*) | 7694303 | 100 | 7620683 | 100 | 7572885 | 100 | 7573028 | 100 | 0,99 | 0,99 | 1,00 |
| A.I | Social insurance | 1157921 | 15 | 1158928 | 15 | 925840 | 12 | 826247 | 11 | 1,00 | 0,80 | 0,89 |
| A.II | National Disabled Persons Rehabilitation Fund | 44781 | 1 | 48881 | 1 | 37289 | 0 | 36210 | 0 | 1,09 | 0,76 | 0,97 |
| A.III | Energy, gas, water, other media | 174620 | 2 | 197558 | 3 | 195828 | 3 | 198185 | 3 | 1,13 | 0,99 | 1,01 |
| A.IV | Payroll liabilities | 639020 | 8 | 659410 | 9 | 676692 | 9 | 648805 | 9 | 1,03 | 1,03 | 0,96 |
| A.V | Other liabilities | 0 | 0 | 5555905 | 73 | 5737236 | 76 | 5863582 | 77 | 0,00 | 1,03 | 1,02 |
| | | | | West Pome | eranian | Voivodeship | | | | | | |
| Α | Liabilities (*) | 184206 | 100 | 206338 | 100 | 230271 | 100 | 251450 | 100 | 1,12 | 1,12 | 1,09 |
| A.I | Social insurance | 20173 | 11 | 28514 | 14 | 26485 | 12 | 18402 | 7 | 1,41 | 0,93 | 0,69 |
| A.II | National Disabled Persons Rehabilitation Fund | 600 | 0 | 570 | 0 | 886 | 0 | 483 | 0 | 0,95 | 1,55 | 0,55 |
| A.III | Energy, gas, water, other media | 4567 | 2 | 4912 | 2 | 5962 | 3 | 5271 | 2 | 1,08 | 1,21 | 0,88 |
| A.IV | Payroll liabilities | 17486 | 9 | 17558 | 9 | 16816 | 7 | 13335 | 5 | 1,00 | 0,96 | 0,79 |
| A.V | Other liabilities | 141380 | 77 | 154784 | 75 | 180122 | 78 | 213959 | 85 | 1,09 | 1,16 | 1,19 |

Table 5. Long-and short-term liabilities by type⁹

⁹ Source: own elaboration based on the Biuletyn Statystyczny Ministerstwa Zdrowia (2009, 2010, 2011, 2012), Centrum Systemów Informacyjnych Ochrony Zdrowia.

9.5 Conclusions

As a result of undertaken restructuring processes decreases the number of hospitals and number of beds held by them. The availability of services provided by these services units in the region is lower than the average in the country. However, the several hospitals by using the assigned European Funds undertakes the wide-ranging investment activities. Pre-financing, investments of low profitability or even losing requires external financing in the form of grants and bank loans. Pre-competitive development results in debt rising. Fortunately, it is not large enough for local hospitals in West Pomeranian Voivodeship to lost their financial independence.

To limit the scope of the debt evaluation only to long and short term liabilities allowed to determine that provisions for liabilities and accruals are significant. Liabilities and provisions for liabilities are much greater than only short and long term debt both in Poland and in local hospitals in West Pomeranian Voivodeship. According to the times also due liabilities have changed. Local hospitals last year examined in particular have a loss.

In order to ensure the continuity of activity were appropriate solutions to reduce secondary purchase and sale of regional hospitals liabilities. Greater importance will grow with the original agreement with creditors in West Pomeranian Voivodeship.

In the structure of short and long term liabilities social insurances and other liabilities are predominant. They are the basic components also of due liabilities.

Analysis focused on the size and structure of the debt. At the heart of his greatness lies a whole range of external and internal factors. To external factors included high and rising demand on health services, getting newer and more expensive medical technologies and rising expectations of the public regarding access to services and their quality. Despite of external conditions, there is internal mechanism of substantial indebtedness. It appears in extending time of residence of the patient, or (Kautsch 2008a and 2008b) lack of financial discipline (Malinowska-Misiag, Misiag, Tomalak, 2008)

9.6 Literature

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- Kautsch M., (2008b), Analiza praktyk zarządczych i ich efektów w zakładach opieki zdrowotnej, których organem założycielskim jest Samorząd Województwa Dolnośląskiego, opracowanie dla Urzędu Marszałkowskiego Województwa Dolnośląskiego.
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Ustawa z dnia 30 sierpnia 1991 r. o zakładach opieki zdrowotnej, Dz. U. z 2007 r. Nr 14, poz. 89, z późn. zm. art. 53, pkt 6

^[1]Calculated as relationship obligations long and short-term in liabilities total

^[2] the law of 30 August 1991 on health care establishments, OJ 2007, No 14, item 89, as amended. – Article 53, paragraph 6

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