QUALITY EVALUATION IN HAEMODIALYSIS TREATMENT THROUGH BENCHMARKING – A MEDICAL AND ECONOMICAL OUTLOOK

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Experience is the name that everyone gives to their mistakes – Oscar Wilde -

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2. INTRODUCTION AND OBJECTIVES

Most stakeholders in the health field want to minimize the burden of illness and have patients maintain their ability to work and enjoy an active, independent life (functional health status), receive the right care (appropriateness) at the right time (access) in a satisfying and efficient manner; and this with available resources avoiding unnecessary costs.[1] Growing evidence, however, suggests that the daily practice of care does not correspond to the standards that the medical profession itself puts forward. To improve care and to realise potential medical and economical benefits, policymakers are looking for methods to measure and benchmark the performance of health care systems[2].

In this context one of the key issues is quality, and in particular medial quality. Medical quality has been controversially discussed in Swiss and international health policy during the last few years and is becoming more important, in view of limited and possible diminishing resources for health care in the future[3]. Service providers such as the pharmaceutical industry and the medical community[4], payers such as insurers[5], health authorities[6] and the users[7] have an interest in demonstrating efficiency and efficacy of medical care and treatment methods. The legal bases are the Swiss constitution and the federal law on health insurance (KVG). In art.32 of the KVG it is clearly mentioned that the medical services have to prove their effectiveness, efficacy and efficiency. In article 43, paragraph 6 of the same law the dimension of quality is added by defining the responsibilities of the health authorities and the contractual partners in the production of medical services that are effective and the best quality possible at the lowest cost possible. Nevertheless, concise and applicable medical quality criteria have been scarcely developed and hardly put into practice. The Swiss Medical Association (FMH) and its medical expert commissions recommend the establishment and use of best practice guidelines but neither controls neither its applications nor the outcomes.[8]

This debate applies equally to the treatment of end stage renal disease (ESRD) that requires renal replacement therapy. This paper will only analyse dialysis as it is the major renal replacement therapy in Switzerland. Several guidelines exist on the national and international level, the most important being the American K/DOQI, the British guideline of the UK Renal Association and the European best practice guidelines.[9] In Switzerland however, the national society for nephrology has not yet developed a national guideline nor does it clearly recommend one of the existing ones.[10]

But why is the question of quality in dialysis treatment so important? Firstly, there are legal obligations which are set out in article 43 and 58 of the federal law on health insurance to which the different parties in health care are bound to produce the best quality possible at the lowest costs possible. There are remaining questions about the demand for this type of treatment, the economic impact and the feasibility of implementation of quality control measures. In view of an ageing population, the demand for dialysis treatment will soar in the coming years; in the US, the number of patients on dialysis is expected to double within the next decade[11]. In Switzerland the number of patients on dialysis and insured via the Swiss Federation for common tasks of the health insurances (SVK) increased by 11.8 % from 2003 to 2004[12]. This reflects a trend across Europe[13] which will continue with an ageing population and a higher incidence in ESRD. Patients receiving this type of treatment are, in general, chronically ill, nearly all on life-long treatment, have multiple associated pathologies and suffer from a high annual mortality (in the US still around 20 %) despite continuous advances[14]. Subsequently, they are in permanent medial care and at all times available to participate in quality improvement measures. Their general health state and their living quality depend essentially on the quality of the dialysis treatment which may encourage patients to participate actively in quality improvement, even accepting fundamental changes in dialysis patterns[15].

Despite the fact that in article 4 and 5 of the contract between provider (in- and outpatient facilities) and insurer (here SVK), clear reference is given to the principle of economicity and quality. Nationally accepted quality criteria for dialysis treatment do not yet exist. Other countries such as the United States (Medicare)[16] and Germany (QiN-system)[17] have gathered positive experience with their respective quality systems.

The SVK alone has access to data of 5.9 million people via their affiliated health insurance companies, meaning that in 2004 an estimated 80% of the patients receiving dialysis treatment were registered by the SVK, totalling 2773 patients.[18] This concentration of data and negotiation partners may constitute a positive factor for the implementation of quality assessment.

3730 dialysis treatments in 2003 were billed to the SVK that generated costs of approximately 173 million CHF[19]. It is estimated that the direct medial cost of dialyses is more than 200 million CHF/year which constitutes about 1% of the total cost of the obligatory health insurance. In other words, 0, 4 ‰ of the population (2938 patients) consume 1% of the resources, each patient costing on average 80.000 CHF/year[20]. These figures do not include the cost for the treatment of associated pathologies and some of the medication needed for the dialysis. This renders the dialysis treatment one of the most expensive individual treatments within the health care system.

In view of the above, it becomes evident that solid medical knowledge of quality criteria in dialysis treatment, the demand for treatment, the costs incurred and the good theoretical base for implementation within the existing health care system all indicate that priority should be given to the development of applicable national quality criteria.

The objective of the following study is therefore firstly to propose a very simple system of quality evaluation of haemodialysis based on widely accepted medical quality criteria, secondly, to demonstrate its implementation possibility via an assessment of retrospective clinical data and finally to give an outlook on its medical and economic implications as well as on the implementation procedure. The aim is to propose an applicable evaluation tool in order to enhance quality management in haemodialysis treatment.

3. PROCEDURE AND METHODOLOGY

In the first part of this study, key terms and key data are described followed by the definition of clinical, easily available and measurable parameters that give a accurate picture of the quality of dialysis treatment. These parameters are Urea Reduction Ratio (URR), Kt/V for dialysis efficacy; the amount of haemoglobin (Hb) and erythropoietin-dose for the control of anaemia; albumin, protein catabolic rate (nPCR) and body mass index for control of malnutrition; calcium phosphorus product and parathyroid hormones for control of calcium phosphorus balance as well as pre- and postdialytic blood pressure for the control of hyper- and hypotension. Other, not measured parameters will also be discussed.

The parameters have been obtained from a literature search and in a discussion with a nephrologist. An excel document "Monthly reporting sheet of haemodialysis patients" was prepared and sent with an accompanying letter to the Directors of four private clinics in Switzerland, including a description of the purpose of the study (annex 1-3). The clinics were chosen for the reason of their affiliation to the same clinic chain that showed an interest in quality measures. One clinic that did not answer was called up by phone.

Mean, median and standard deviation were calculated for the data obtained from the two participating dialysis centres. Standard statistical tests such as tests for comparison of means (e.g. t-test or ANOVA) were not performed due to the rather small sample size (n = 17 patients in both centres). The assessment and the interpretation of the clinical data is therefore of qualitative and indicative nature and is mainly used to demonstrate the feasibility of the reporting. The theoretical system of benchmarking and its implementation scheme is discussed. An interview was conducted with Ms. Chevrou-Séverac relating to methodological and statistical methods, and with Dr Yves Eggli for the question concerning "quality", both from the Institute of Health Economics and Management of the University of Lausanne (IEMS).

The literature search was carried out by the Centre de la santé publique of the University clinics of Lausanne (CHUV) on the 16/11/2005 and on the 24/11/2005 in collaboration with the author for the determination of the key words in English and French. The search path and the consulted databases are listed in annex 6. In order to complete the literature search and to have updated and non published data on the Swiss situation, a questionnaire with 18 to 20 open questions was prepared (annex 4). The questionnaire that had been slightly adapted according to the addressed institutions was then sent with an accompanying letter (annex 5) and the description of the study (annex 2) to key institutions involved in medical quality in general and to those involved with medical quality in dialysis treatment. The institutions were the Swiss Federal Office of Public Health (BAG), the Swiss Medical Association (FMH), the Swiss Society of Nephrology (SGN), its President and its chairman of the dialysis commission, the Swiss Federation for common tasks of the health insurances (SVK), the Swiss association of kidney patients (VNPS) and the pharmaceutical company Baxter on recommendation of the Director of the SVK. The answering deadline was four weeks. In the case of non replies, e-mail and phone reminders were sent and the deadline extended to six weeks. The answers to the questionnaire are included in the chapters "results" and "discussion".

4. RESULTS

4.1 DEFINITION AND DISCUSSION OF KEY TERMS AND INDICATORS

4.1.1 Quality and Benchmarking

Most quality improvement systems base their quality definition on the concept of the triad structure-process-outcomes entities, an approach introduced by Donabedian in the 1980's and widely used in hospital care management.[21] This approach is also used by the two dialysis quality systems that will be discussed within this study. Eggli and Halfon proposed a different concept that is independent of "outcome" and replaced by the concept of "effect", with customers, people, society and key performance results being different aspects of "effects".[22] The advantage of this model is that the patient is considered differently, being placed in the centre of medical care and being attributed a more active role. This seems to be particularly important in dialysis treatment as the patient undergoes three times a week a life-long and demanding treatment with discomfort or even severe side-effects clearly attributable to the quality of the dialysis treatment. Therefore patient satisfaction, patient comfort and patients' participation in the treatment process is of high importance in dialysis management. The purpose of this study however is to evaluate the quality of the dialysis on clinical criteria that are directly linked to patient well-being. In this context it has to be pointed out that patient or risk adjustment is important in order to prevent distortion of results, in particular if small sample size groups are compared.

The OECD[23] has developed selection criteria for quality indicators for macro systems such as health care systems but also for several pathologies and they define three dimensions for the importance of an indicator, for example quality of diabetes care;

- Its impact on health. What is the impact on health associated with this problem? Does the measure address areas in which there is a clear gap between the actual and potential benefits?
- Policy importance. Are policymakers and consumers concerned about this area?
- Susceptibility to being influenced by the health care system. Can the health care system meaningfully address this aspect or problem? Does the health care system have an impact on the indicator independent of confounders like patient risk? Will changes in the indicator give information about the likely success or failure of policy changes?

To break this down quality indicators should be relevant, understandable, measurable, behaviour- oriented and achievable. OECD also defines the standard of care as a case- and time-specific analytical process in medical decision-making that produces a clinical benchmark of acceptable medical care, this benchmark used to evaluate and guide the practice of medicine.

They introduce here the term of benchmarking[24], a concept originally stemming from industry practices and first described by Robert C. Camp. It can be defined as a method searching for solutions that are based upon the best methods and procedures of the industry practice, the so-called best practices. Two basic ideas of this concept have to be mentioned here: first the aim of increasing the competitiveness of the enterprise and second, the comparison with other enterprises, industries, thus looking beyond its own environment. Procedures, processes and methods are questioned in comparison with a reference point, the benchmark; usually compared to the so-called "best in class". Industries compare their practices very often on an international level, even on a global level. The utility of the Benchmaking is the profound analysis, the identification of strengths and weaknesses and the elaboration of practice alternatives and solutions to problems. Conditions for success are that the benchmarking process is supported by the management; that the benchmarking team has a clear task description; that enough time and resources are devoted; and

that changes are accepted and implemented. Leaving the industry and looking at the reality in the Swiss health system, the utilization of benchmarking in the classical sense is rather rare for the simple reason that the main aim "increased competitiveness" is not a major objective in a non competitive environment.

In the medical field Sackett et al.[25] can be considered as the founders of the evidence based medicine concept (EBM), a concept that proposes to use some of the benchmarking tools in order to define best practices, with the aim to provide best quality possible across different health systems and different practices. The guidelines subsequently developed in various medical disciplines often represent a kind of step plan or decision tree to follow that defines medical practice. The success of its implementation however is rather doubtful as the medical practice continues to vary not only across countries but also within countries and regions[26,27].

Better quality will not automatically be achieved through better measuring or better control but it is the first step to change clinical practice in order to obtain better quality results. The management of the quality lies then with the responsible institution or medical officer. The variety of management tools is large and can even lead to the application of accounting procedures.[28]

4.1.2 Medical terms and indicators[29]

Function of the kidney[30] - One quarter of the total blood output from the heart gets to the kidneys through the renal arteries. Two renal arteries arise from the abdominal section of the aorta; each artery supplies a lobe of the kidney. The incoming artery divides into four or five branches, eventually forming arterioles, each of which leads to the compact ball of capillaries called the glomerulus. Cell waste is discharged in the veins for excretion through the kidneys. The body circulates about 1000 litres of blood through the kidneys on a daily basis, but only about a thousandth of this is converted in urine. The remainder goes back into circulation through the renal veins. From the Bowman's capsule, the blood is carried through the compact network of capillaries that forms the glomerulus within the capsule. The capillaries eventually reconverge into small venules which lead to the larger renal veins. There are two renal veins, one extending from each lobe of the kidney, and opening into the vena cava. The nephron is the functional unit of the kidney, responsible for the actual purification and filtration of the blood. About one million nephrons are in the cortex of each kidney, and each one consists of a renal corpuscle and a renal tubule which carry out the functions of the nephron. In summary the main functions are regulation of salt, water and acid-base balance, excretion of nitrogenous and metabolic products, endocrine-metabolic with production of hormones (e.g. Erythropoetin and vitamin D3), blood pressure regulation and regulation of calcium phosphorus metabolism via the parathyroid hormone.

End stage renal disease (ESRD) is loss of renal function due to a chronic, irreversible loss of renal cells that requires treatment with any form of chronic dialysis or transplantation. Dialysis is inevitable in kidney failure that is attained at a glomerular filtration rate (GFR) of <10 - 15 ml/min/1.73m^2 body surface area.

There are different modalities of **renal replacement therapy** such as dialysis (haemodialysis and peritoneal dialysis) and transplantation. Renal transplantations have become a widespread surgical procedure but the demand in human kidneys exceeds by far the offer with Switzerland having one of lowest rates of kidney transplantations in Europe. This underlines even more the importance of dialysis treatment as demand rises. Peritoneal dialysis and home haemodialysis play a minor role in renal replacement therapy as the "classical" in-centre haemodialysis (HD) that accounts for most of the treatment modalities worldwide. In Switzerland 89 % of all dialysis patients were treated with HD in 2005[31] that accounted for nearly 92 % of the direct costs of renal replacement therapy in 2003.[32] For this reason we will only discuss the in-centre haemodialysis treatment.

The principle of haemodialysis is to remove nitrogenous (and other) waste products, and to correct the electrolyte, water, and acid-base abnormalities associated with renal failure. Dialysis does not correct the endocrine abnormalities of renal failure, nor prevent cardiovascular complications. It requires the use of a semi-permeable membrane that will allow the passage of water and small

molecular weight such as urea and creatinine. Dialysis, in fact refers to the diffusion of solutes across a semi-permeable membrane down a concentration gradient. At its simplest, a dialysis machine simply pumps blood and dialysate through a dialyser, the dialysate being a solution of water, sodium, potassium, magnesium, calcium, chloride, dextrose and bicarbonate. The blood and dialysate are kept separate within the dialyser by a semi-permeable membrane. As the dialysate contains no waste, products of metabolism (urea, creatinine, etc.) these will diffuse from blood into dialysate.

Most of the guidelines (K/DOQI and European best practice guidelines) and the quality in nephrology QiN-system propose to measure indicators that reflect seven main problem areas in dialysis. These are dialysis adequacy, hypertension/cardio-vascular system, renal anaemia, calcium-phosphate metabolism, malnutrition, vascular access and inflammation[33]. In the following all the criteria chosen for the assessment in the haemodialysis reporting sheet (see annex 3) are discussed.

Dialysis adequacy – an adequate dialysis maximizes well-being, minimizes morbidity, and helps a patient retain social independence. An optimum dialysis is a method of delivering dialysis producing results that cannot be further improved. There are several factors influencing the dialysis adequacy but in the criteria it is focused on the Kt/V that reflects the adequacy of the delivered dose of haemodialysis and its relation to effects on the patient[34]. The amount of dialysis delivered during a single treatment is measured by the computed terms Kt/V or Urea Reduction Ratio (URR). Kt/V means the clearance of the dialyzer multiplied by the time of dialysis, with this value divided by the patient's urea volume (38%-63% of the patient's weight, essentially the total body water). Kt/V is calculated in a manner similar to Urea Reduction Rate (URR). URR is usually expressed as a percentage, sometimes as a ratio (R). It is calculated from the pre- and post blood urea nitrogen. The two methods of measurement are mathematically equivalent when all factors are considered. The mortality seems to decline the higher the Kt/V[35], the European practice guidelines recommending a Kt/V $\geq$1.4 and the UK Renal association a URR of $\geq$ 65%.

Hypertension/cardiovascular system – the cardiovascular risk in dialysis patients is considerably increased with a nearly nine fold higher probability to die of a cardiovascular disease compared to the general population[36] and cardiovascular causes being the most common reason for death in dialysis patients[37]. Cardiovascular management is included in some of the indicators already presented but the blood pressure should be measured to control hypertension as one of the most important risk factors for cardiovascular mortality. The recommended target value is a blood pressure (BP) of $\leq$ 130/80 mmHg according to the K/DOQI guidelines. In this study pre-and postdialytic BP were measured the predialytic BP for the evaluation of hypertension and the postdialytic BP for the monitoring of eventual hypotension, a common phenomena after dialysis and an indicator for patient well-being immediately after dialysis.

Renal anaemia is primarily due to a lack of erythropoietin (EPO). Other causes are uraemic and cytokine inhibition of the erythropoesis, deficiencies of iron, folic acid and vitamin B12, as well as hyperparathyroidism and haemolysis. Most importantly erythropoietin and iron have to be replaced in order to obtain sufficient haemoglobin (Hb) levels that are 11-14 g/dl according to EBFG[38]. Each decline of 1g/dl Hb below 11g/dl Hb increases the mortality risk by 13 %[39] and the partial correction of anaemia by maintaining haemoglobin in the range of 11-12 g/dl is associated with a 10% to 74% decrease in the risk of death and a 7% to 58% decrease in hospitalization compared with lower Hb levels[40]. Haemoglobin is also a key parameter as performance, living quality[41] and cognitive functions improve with higher Hb levels and as cardio vascular symptoms, ventricular hypertrophy and hospitalization rate[42] and frequency decrease if the target values are achieved[43]. The dose of erythropoietin is monitored in order to diagnose an EPO resistance that would then need further investigation.

Calcium-phosphate metabolism – hyperphospataemia is a predictable consequence of chronic renal failure and is present in most patients on dialysis, contributes to renal osteodystrophy but more importantly increases the risk of cardiovascular death in this population as abnormalities in calcium phosphorus product ($CaxPO_4$) and parathyroid hormone (PTH) levels result in vascular and visceral calcification[44]. Odds ratio for mortality increased in a nationwide study by 1.34 for $CaxPO_4$ levels between 5.89 and 10.65 $mmol^2/l^2$ [45]. In a more recent study, patients exceeding the

target values had a 27% higher mortality than patients within the target range[46] and a Dutch study found that all-cause mortality risk increased in haemodialysis patients by 40% if $CaxPO_4$ was greater than the K/DOQI targets[47]. The recommended target values are ≤ 4.44 $mmol^2/l^2$ for $CaxPO_4$ and 16.5-33 pmol/l for PTH[48].

Malnutrition is a common phenomenon as patients spontaneously reduce their protein intake as well as their overall calorie intake with some becoming severely cachectic. For evaluation of malnutrition Body Mass Index (BMI), albumin and protein catabolic rate (nPCR) are used the latter defining the protein intake[49]. These parameters are easy to measure and to calculate and give a good picture of a nutrition status, the BMI being the parameter for the general nutrition status and closely associated with survival in haemodialysis patients[50]. It seems that the higher the BMI and the percentage of muscle mass[51], the better the survival rate. Severely and moderately malnourished patients had a higher mortality risk compared with those well nourished: 33% and 5 % higher, respectively[52]. Albumin is a parameter for the general nutrition and a reliable predictor of mortality for patients undergoing haemodialysis[53]. Target value for albumin is ≥40 g/l and for nPCR = 1.2 g/kg body weight/day[54].

Vascular access patency is crucial for patients with ERSD as haemodialysis access failure has become the most frequent cause for hospitalization among ERSD patients[55]. The problems caused are mostly due to the lack of patency which requires intense treatment such as surgical interventions or catheter interventions. A shunt infection is a rare but severe complication. Patency and infection rate with a variety of causes should be monitored for each patient on a yearly basis. This is the reason why this criterion has not been included in the reporting sheet.

Inflammation[56] - CRP predicts outcomes and improves inflammatory risk prediction. Therefore, it would be beneficial to assess CRP levels in dialysis patients on a regular basis, and to seek sources of infection or inflammation. A highly sensitive method for measuring CRP is recommended but has not been measured due to local clinical practice and due to non-reimbursement by the health insurer. Various causes of inflammation may be identified in dialysis patients. Overt and occult infectious processes require appropriate treatment. Factors associated with dialysis treatments that may provoke an inflammatory response include impure dialysate (due to endotoxin or bacterial contamination), back-filtration, and bio incompatible dialysis membranes.

In conclusion the quality indicators chosen measure the effects of the dialysis on the patient via clinical parameters or laboratory values. These parameters are evaluated routinely in clinical settings either on a monthly (Hb, $CaxPO_4$) or a quarterly basis (PTH, Kt/V, URR, nPCR). Albumin is measured every six months. All other parameters can be evaluated by calculations or simple non-laboratory procedures such as BP measuring.

4.2 DATA OF THE REPORTING SHEETS AND OF THE QUESTIONNAIRE

Two out of the four clinics responded and sent the monthly reporting sheet for the month of November 2005, for the individual clinical patient data (see annex 7). The two dialysis centres had each gathered data on 17 patients. The sheet was judged self-explanatory by the participating medical doctors, therefore no assistance was required. Mean; median and standard deviation (StD) are presented in table 1. As mentioned in the chapter procedure and methodology, a statistical analysis was not performed despite the fact that the goal of the benchmarking is to compare different data sets. The presented data does not show whether the difference in mean and median can be attributed to variance in medical care or to the variance in the patient groups. Therefore, routine statistical tests such as t-test (also called student test) for comparing the means of two groups or the ANOVA, which compares equality of means in several groups were not performed as some of the prerequisites of the model such as equal standard deviations between groups could not be assured. Other, more elaborated statistical procedures would need to be applied here such as non-parametric tests but this would go beyond the scope of the present study.

However, in the case of the implementation of a quality system this issue would deserve particular attention in the methodology, as a risk adjustment for different patient groups would be necessary, and as quite a few of the 79 dialysis centres in Switzerland are small in numbers of treated patients. Looking at the data it can be stated that gender, age, attendance and BMI are similar in both clinics. The variance of PTH in clinic 2 is striking and the difference in kt/V single pool is noticeable. Clinic 1 exceeds here with a mean of 1.74 the values recommended by most guidelines and clinic 2 reaches the target value. Apart from these differences it can be said that taking into consideration all methodological constraints the quality outcomes are not very different given a similar population in terms of gender and age, in particular as most of the target values of the chosen guidelines are met. The exception is the blood pressure which is in both clinics higher than recommended in the guidelines and seems to be higher in clinic 2 than in clinic 1. The EPO doses differ in the two clinics but are not interpretable due to the wide individual variation. The costs for the treatment with EPO are approximately 48 CHF higher per patient/week in clinic 1 than in clinic 2 based on an average price of 23.54 CHF/1000 units EPO with significant variations pending on the volume.

Four hours were needed by both clinics to gather the data and to complete the sheet for 17 patients. Clinic 1 evaluates the proposed quality criteria regularly; the other did not evaluate nPCR, EPO/kg and BMI in their regular scheme. This implies that in both clinics no additional laboratory were generated and in clinic 2 nPCR, BMI and EPO/kg can be simply calculated. The overall estimate for the implementation costs for completing the form can be estimated at most, at four hours working time of the physician or a trained nurse and sums up to approximately 160-200 CHF/evaluation for the nurse and 420 CHF/evaluation for the nephrologist based on average Tarmed position 00.0140 (physician service in absence of the patient)[57], thus meaning that a quality evaluation with the proposed system costs on average between 10 - 25 CHF/patient evaluation and approximately 40 - 100 CHF/patient/year. One clinic expressed its regret not to participate for the reason of a new incoming head of nephrology and in the other clinic, the responsible nephrologist confirmed firmly by phone the "danger" of such a study that lies in comparing different dialysis centres.

As mentioned in chapter 3 the questionnaire in annex 3 has been sent to eight different institutions representing the different parties involved in medical care. Surprisingly, the Swiss Society of Nephrology (SGN) and the President of the dialysis commission, concerned primarily with the issue, did not answer, neither to several e-mails nor to letters. The FMH referred to the SGN for further questions and the BAG did not see itself in the position to answer for the lack of human resources. The patient organization (VNPS) responded that their medical collaborator would take care of the response. Finally the only questionnaire received in time came from the health insurers who confirmed their interest in participation and in the results of the study. Baxter and VNPS responded after the deadline so that the answers could only partly be taken into account.

TABLE 1: OVERVIEW OF CLINICAL DATA (N=34), SEE ANNEX 3 FOR EXPLANATIONS OF THE CRITERIA, THE CRITERIA IN BOLD ARE MAIN CRITERIA FOR DIALYSIS QUALITY. THE TARGET VALUES ARE DEFINED IN CHAPTER 4.1.2.

CRITERIA	MEAN CLINIC 1	MEAN CLINIC 2	MEDIAN CLINIC 1	MEDIAN CLINIC 2	STD CLINIC 1	STD CLINIC 2	**TARGET VALUE**
GENDER RATIO MALE/FEMALE	1.8	1.8	-	-	-	-	**-**
AGE RANGE	4.2	4.9	4.0	5.0	0.9	1.0	**-**
ATTENDANCE IN %	100	100	100	100	0	0	**-**
HB (G/DL)	11.8	12.6	11.9	12.4	0.8	1.1	***≥ 11***
BMI (KG/M2)	24.6	22.1	24.0	22.0	5.4	2.9	**-**
CA X PO_4 MMOL^2/L^2	3.58	4.33	3.68	4.42	0.84	1.01	***≤ 4.44***
KT/V SINGLE POOL	1.74	1.43	1.75	1.41	0.33	0.29	***≥ 1.4***
EPO DOSE (UNITS)	8676	6533	6000	6000	6065	2850	**-**
EPO/KG BODYWEIGHT	129.8	109.3	86.9	115.0	98.8	48.1	**-**
PTH (PMOL/L)	14.0	30.6	12.7	14.1	8.8	42.7	***16.5-33***
URR (%)	77.0	70.1	79.0	70.5	6.1	7.1	***≥ 65%***
NPCR (G/KG/DAY)	1.04	1.17	1.07	1.19	0.14	0.29	***1.2***
ALBUMIN (G/L)	37.0	37.1	38.0	38.0	4.7	3.4	***≥ 40***
PREDIALYSIS SYST. BP (MMHG)	151	161	157	164	22	36	***130***
PREDIALYSIS DIAST. BP (MMHG)	78	81	80	79	10	16	***80***
POSTDIALYSIS SYST. BP (MMHG	135	149	130	148	23	31	**-**
POSTDIALYSIS DIAST. BP (MMHG)	72	78	71	80	12	14	**-**

5. DISCUSSION

One of the basic questions that could be asked is why is it necessary to measure quality if there is good and similar quality prevailing in Swiss dialysis centres? A very simple answer is that nobody knows that the quality is good and similar across Swiss dialysis centres as systematic evaluations have not yet been published or carried out. In the minutes of a meeting of the dialysis commission of the SGN in September 2002 it can be read that a registry shall be established and that this registry shall incorporate quality control and quality assurance measures[58]. However, the literature search, the search of the website of the SGN and the answers to the questionnaires has not produced any answers. Significant differences in quality are common across countries. Patients on dialysis have a 30 % higher mortality in the US than in Europe and the mortality rates differ within European countries too[59] and these cannot solely be reduced to patient mix. The German[60] and the American[61] experience show that there are significant differences in medical quality between dialysis facilities and within regions. Furthermore quality programmes lower mortality (up to 31%), decrease costs[62] and improve quality of life[63]. Therefore it is in everybody's' interest to have data about mortality and living quality of dialysis patients in Switzerland, that, according to the findings of this study are non-existent. The conclusion is that quality differences are to be expected within Switzerland and between different dialysis treatment facilities and that it is necessary to measure quality in order improve quality, and consequently mortality and living quality. In the following the need for the proposed quality evaluation from different perspectives and an implementation proposal will be critically discussed.

5.1 MEDICAL CONSIDERATIONS

As described in chapter 4.1.2 several evidence based guidelines on dialysis treatment exist defining different target values according to findings in randomized controlled clinical trials. They constitute the base for a sufficient relationship between clinical parameters and mortality as well as living quality. The two main initiatives launched in the closing years of the past century with the goal of improving the treatment outcomes of patients with kidney failure were the Kidney Disease Outcomes Quality Initiative, which formed expert panels to develop evidence-based clinical practice guidelines, and the Dialysis Outcomes and Practice Patterns Study (DOPPS), which gathers data on practice patterns in dialysis facilities in 12 countries, including the United States. Three years ago, the Kidney Disease Improving Global Outcomes (KDIGO) program was established to promote worldwide coordination and integration of initiatives to develop and implement clinical practice guidelines and to provide new opportunities of cooperation with the international scope of DOPPS. Collaboration between the DOPPS and KDIGO should lead to broader dissemination of relevant information to nephrologists, health care providers, and patients. Linking the DOPPS scope of work with the KDIGO goals should help develop continuous quality improvement programs and the provision of direct feedback to participating dialysis centres throughout the world. This should establish an essential component in the translation to clinical practice of evidence-based guidelines worldwide[64].

However, the reality seems to be different as education and treatment guidelines alone are not likely to be effective: there are numerous barriers to physician adherence to treatment guidelines, such as lack of awareness, lack of agreement, and the inertia of previous practice[65]. Guidelines for dialysis treatment are, in general, accepted among the medical community but the adherence to guidelines still seems questionable as the conclusions of several articles dealing with dialysis topics expressed: "The magnitude of potential savings in life years should encourage greater adherence to guidelines and practices that are significantly associated with better survival"[66]; "while there is evidence that the guidelines are slowly being adopted, there remains much room for improvement in their implementation"[67]; or "although some improvements can be documented in anaemia

management practices in the years after the publication of international guidelines, wide variations in anaemia management are still observed among countries"[68]. Another reason for non-adherence to guidelines may be the definition of target values that are practically difficult to achieve even after adjustment of case mix. Several studies report either the low percentage of patients achieving one or several target values or they criticise the validity of the target as such. In a study on the bone and mineral metabolism, PTH levels were within the values recommended by K/DOQI guidelines in only 20% of the determinations and only 7% of the determinations met all four criteria of bone and mineral metabolism simultaneously. They conclude that current practice for the management of bone and mineral metabolism in haemodialysis falls far short of meeting K/DOQI guidelines[69]. Another study found that the mean haemoglobin in erythropoietin-treated haemodialysis patients varied substantially and was between 10.9 and 11.2 g/dl. They also conclude that the K/DOQI recommended haemoglobin range appears to be too narrow in clinical practice[70]. Kt/V, the key indicator for dialysis adequacy is at the forefront of these discussions. The higher the Kt/V the better the survival time as proven in several studies[71], (see also above), but there is evidence that a higher dialysis dose than Kt/V > 1.2 will not improve survival but that it is much more important to reducing to zero the number of times the dialysis dose is delivered at a Kt/V < 1.2[72]. An Italian study adds that they found the optimal cost-effectiveness for the dialysis dose at a Kt/V of 1.3[73] thus questioning the recommendation of the European practice guidelines of a Kt/V > 1.4 that has been chosen as the target value in this study.

Putting oneself into the position of a physician in charge of a dialysis unit it may be understandable that adherence to guidelines may be complicated if most of the targets are difficult to meet and not knowing whether these targets reflect in fact best clinical practice as the example of discussion of the indicator Kt/V shows. The variations will not increase adherence in particular if a set of guidelines is not clearly recommended by the local or the national professional body as in the case of Switzerland. Furthermore observational studies only reveal associations and are limited by selection bias and confounding. The Kidney Disease Outcomes Quality Initiative guidelines (K/DOQI) as well as all other guidelines on dialysis adequacy are based on results of observational studies and expert opinion[74]. Another possible bias that may be considered in the drafting of guidelines is the financial contribution of the pharmaceutical industry to organisations that are in charge of the guidelines, e.g. the National Kidney Foundation (NKF). Unfortunately the annual report of the NKF did not clearly indicate the financial support received from the industry[75]. However Amgen, an important Erythropoietin producer is a "Platinum sponsor" of the National Kidney Foundation (NKF) responsible for the K/DOQI guidelines[76] and EPO products increase the haemoglobin levels. Thus it could be of economic advantage for Amgen that higher haemoglobin values are recommended in guidelines. Despite these raised questions about the confidence in guidelines it is believed that the medical evidence is strong enough to propose the reporting sheet used in this study as the potential benefits outweigh methodological constraints.

As said in the introduction the purpose of this study is not to evaluate different dialysis centres but to demonstrate the application of a system that is practical and that can be easily included in daily practice. This has been confirmed by the participating nephrologists who confirmed the self explanatory nature of the formula. Added criteria for example the evaluation of the vascular access; inflammation; and of living quality of the patient should be added and shall form an integral part of any quality assessment. In order to keep the implementation costs as low as possible and in order to reduce the implementation resistance to a minimum and in order to keep the system as simple as possible it is proposed to reduce even further the chosen criteria to five; namely to Kt/V for dialysis adequacy, blood pressure for hypertension, Haemoglobin for renal anaemia, $CaxPO_4$ for calcium-phosphate metabolism and body mass index for malnutrition. An evaluation of these indicators shall be monitored quarterly and BP is measured routinely before each dialysis. These indicators will sufficiently cover all main areas for dialysis quality. Target values will not be mentioned in the reporting sheet as the responsible medical bodies have not yet recommended a guideline nor target values to be achieved.

If there is no variability in the data the necessity of a further quality control could be questioned. However the likelihood of finding variability of the data is very high. It is then important to identify

whether the variations are related to dissimilarity in the process of care or due to the case mix[77], in particular as the dialysis centres are small in patient numbers and normal distribution of patients cannot be taken for granted. In the example of the two clinics it can be seen that the mean in the PTH levels in clinic 2 is more than twice the level in clinic 1 which is most probably due to one or two patients having an excretional dysfunction explaining these high levels of PTH. These outliers would need to be identified for the comparison of the two populations.

Even if the comparison between the two dialysis centres is statistically difficult and only of indicative and qualitative nature certain differences can be clinically observed that may partly be influenced by different medical practice. First of all it must be said that nearly all target values are achieved which is rather uncommon looking at other findings in literature. Apparently there is a selection bias as the two clinics voluntarily participated in the study and it can be presumed that they have an interest in the quality issue and provide therefore good care. However the hypertension management is in both clinics not optimal and in clinic 2 slightly worse than in clinic 1. This may be explained by either the guidelines not matching the reality as a nearly normal blood pressure is the target value which is difficult to reach in a population of older age or in a population with several comorbidities. Another explanation may be indeed medical practice; here the antihypertensive therapy may not be following the recommendations of evidence based medicine. In this context a clinical centre in Germany has clearly demonstrated how the antihypertensive medication has been reduced due to better quality control in dialysis treatment[78].

What criteria are used by others in evaluating quality in haemodialysis treatment? Here the biggest insurer of dialysis treatment worldwide, Medicare uses three criteria for three areas of dialysis quality, namely haematocrit for renal anaemia; Urea Reduction Ratio (URR) for dialysis adequacy; and patient survival for the outcome. The first two criteria allow only a limited assessment of the quality of dialysis as explained in 4.1.2. Therefore haematocrit should be replaced by haemoglobin and the URR by Kt/V being more reliable indicators. Medicare benchmarks the facilities in comparison with other facilities in the region and in the US as a whole. The results and the dialysis facilities characteristics are made publicly available on the net at www.medicare.gov. The Quality in Nephrology (QiN) programme[79] uses a very extensive set of indicators covering all main areas of dialysis quality, living quality of the patient as well as morbidity via hospitalization rate and mortality. The results are available for the participating facilities but can only be compared on a single blind basis. After five years of implementation the results are very positive with a better living quality and a significantly better dialysis quality in nearly all parameters. The targets for Hb, Kt/V, $CaxPO_4$, and BMI are met and reach similar values than the two participating clinics in this study. The only difference lies in the Blood Pressure levels, QiN nearly meeting the targets with levels lower than the two clinics in Switzerland. The most important finding is that the quality improved in the participating centres without any economic or other linkage but simply caused by the fact of comparing different facilities between each other. This may be attributed to the awareness effect and the better consideration of guidelines in the daily medical practice.

Another important factor, particularly in view of the small dialysis centres in Switzerland is the risk adjustment in order to avoid patient selection bias. In the US example[80] the case mix measures are age and two body measurement variables, body surface area and body mass index whereas the German experience[81] uses age, albumin, diabetes mellitus, eventually gender and others according to the analyses. This study proposes a case-mix adjustment for age, diabetes mellitus and hospitalization which is an indirect indicator for severe comorbidities. Looking at these experiences abroad, the following indicators should be included in the evaluation but do not need to be included in the regular reporting sheet; vascular access problems; and hospitalization rate and duration that can be retrospectively evaluated for each patient via the patient history file. The living quality and the patient participation will be discussed in chapter 5.3.

In conclusion, several quality programs exist and they vary extensively. Benefits for the patient can be expected via quality control measures and the medical evidence seems to be sufficient to justify the proposed reporting sheet. The return of only one questionnaire raises concerns about the interest in a transparent quality control system of the different actors and in particular the medical community.

5.2 ECONOMIC CONSIDERATIONS

The basic question to ask here is whether it makes sense to evaluate quality and to foster quality management from an economical perspective. Renal replacement therapy for end-stage renal replacement disease has arguably been among the first medical technologies to be assessed with regard to its costs and outcome. This is certainly related to the large and vastly expanding number of potential beneficiaries of such treatments, in combination with large per patient treatment costs. Since then hardly any other medical technology has been assessed so regularly in so many countries. One reason for this "popularity" seems to be the decision of the US government to entitle patients with ERSD to reimbursement of the costs of renal replacement therapy within the Medicare programme in 1972. This was the first and thus far the only time that health coverage was granted in the US solely on the basis of a diagnosis. This may have had an effect on the European and the Swiss reality as access to renal replacement therapy (RRT) is in principle guaranteed; thus the provider structure influencing access and choice of treatment. The UK however has age restrictions on access to RRT[82]. This guaranteed access to RRT in Switzerland may change in the future if revenues tend to fall and health expenditure keeps growing as demand rises. As the achievement of the impossible is impossible the relationship between the resources spent and the health outcomes or health effects obtained will be increasingly and controversially discussed[83]. In this regard policy makers will increasingly want to know what they pay for and then it will be important to prove the necessity and the quality of the intervention, here haemodialysis treatment. Unfortunately and due to the lack of studies on the relationship between dialysis treatment, financial burden and quality in Switzerland the following discussion has been constructed with the assistance of foreign data and must not be mistaken with a full-fledged economic evaluation.

First of all the potential demand for this type of treatment in the future will be looked at. The prevalence of kidney failure in the US population is approximately 0.2%. Added to this, 0.2 % of the US population is living with severe kidney damage with a GFR of 15-29 likely to develop at some stage ESRD. Mean incidence of ESRD across Europe between 1990 and 2000 rose from 79 to 117 new patients per million population per year (PMP). The unadjusted prevalence of dialysis in France was 513.1 patients per PMP in 2003, one of the highest in the world[84]. The prevalence in Switzerland in 2000 was 332 PMP and the incidence 145 PMP with a sharp increase over the last years.[85] Interesting in this respect is a study of 1973 that counted 376 patients on dialysis in Switzerland compared to more than 3000 today and that estimated some 135 PMP with ERSD for the beginning of the 80's[86].

A survey indicates that the annual average global increase of ERSD is about 6% with Europe being at lower increase rates[87]. The two main reasons are higher incidence of diabetes type 2 in the western society and the ageing of the population, diabetes and Glomerulonephritis accounting for 40% of the causes for ESRD in Europe whereas in the US diabetes is the leading cause with 44% of all patients starting dialysis being diabetic. In the UK prevalence increased hugely with age from 78 PMP in those < 40 years and to 58913 PMP in those ≥ 80 years.

Subsequently this has lead to a higher demand and will lead to an even further increase in renal replacement therapy as the European and Swiss population are ageing. The trend of the US with where the proportion of diabetic patients starting dialysis doubled over the last 20 years is making its way to Europe and can be partly attributed to the alarming increase in obesity. Diabetes in Germany is already the main cause for ERSD with 36% of all causes.[88]

Comorbidity is increasingly common in patients with ESRD with heart failure, diabetes and coronary artery disease at the top of the list. Nevertheless the death rate of dialysis patients has decreased over the last years which again may increase the demand for ERSD as patients will profit from a better survival rate.

Looking at these incidence and prevalence data I conservatively estimated a yearly increase of 8% for patients on dialysis in Switzerland that is a compromise between the 6% increase of ERSD of the study above and the 11.8% increase registered by the SVK. 8% of about 3000 patients on

dialysis is "only" 240 new cases each year but implying an added yearly financial burden of direct medical dialysis treatment costs in the range of 19.2 million CHF (240x80.000 CHF) constituting a 10% increase each year that is well above the 5% increase in the total health costs between 2002 and 2005 and still higher than the expected yearly increase of 3-4% up to 2010[89].

Winckelmayer et al.[90] conducted a meta-analysis on cost-effectiveness studies in ERSD and found that the only cost element in all studies included were direct (medical) costs. Hardly any study made an attempt to include lost earnings, patient time cost for treatment, informal caregiving or transportation, thus meaning that indirect costs or human costs are in general not available. They concluded by stating that their analysis makes it tempting to recommend the use of RRT as a referent for the lower boundary of societal willingness to pay for an additional life year that would translate into approximately $ 61000 (≈ 80.000 CHF) per quality adjusted life year (QALY). The study however includes renal transplantation as a method of RRT and reviewed only literature published in English. This figure adjusted for different purchasing power reflects approximately the direct dialysis medical costs per patient in Switzerland. In this context it would be interesting to know about other costs in order to get a full picture of the costs and to forecast cost development.

These other direct medical costs are for example better and more expensive technology (new and more expensive versions of Erythropoietin, new generations of filter systems etc.) and treatment costs for associated pathologies. The estimated yearly increase that has been calculated (19.2 Mill. CHF) includes only the costs of the treatment as specified in the contract of the SVK with the service providers[91]. According to this contract a haemodialysis treatment is reimbursed on a flat-rate basis with 448-497 CHF comprising all services of the haemodialysis treatment except the reimbursement for EPO. The treatment costs of most of the complications as well as the treatment costs of other pathologies remain with the individual insurer who bears nearly all financial risks. Despite the fact that art.5 of this contract says that the dialysis providers commit themselves to participate in efforts to control and assure quality, a concise contract or memorandum of understanding concerning quality has not yet been established between the SVK and the provider.

In conclusion there is hardly any economic incitation for a provider to deliver good quality of haemodialysis treatment and not much more for the SVK either as the costs for the treatment of the comorbidities (e.g. hypertension and diabetes) are with the individual health insurer of the patient. These findings are confirmed in several studies, admittedly in a different health care concept, here the US system. In 1994 already it was stated that the Medicare ERSD programme can hope to provide quality patient care only through a systematic linkage of cost and quality measurements[92]. This has been confirmed and emphasized six years later by putting forward a more effective model which is to improve quality, and which called for inclusion of external standards and quality assurance; internal, confidential quality improvement programs in all dialysis facilities; and the provision of sufficient information to the Health Care Financing Administration (HCFA) and state regulatory agencies on processes and outcomes of care[93]. Some European countries introduced or have begun to introduce regulatory mechanisms or economic incentives considering health effects or health outcome in dialysis. In Germany a legal bill is to be expected in which certain standards on structure and dialysis effects are to be reported. Monetary penalties are planned in case that the results are more than 15% below target value[94] whereas in France a global concept has been implemented related to the accreditation process in the hospital reform of 1996 that provides guidelines for clinical practice but also sets standards for quality indices and the control process[95]. In Switzerland though nothing of all this has been done so far and once the formal accreditation is granted the provider may operate without reporting any data on quality[96].

In order to justify the effort of quality evaluation and quality control an important question is whether good quality has an impact on several key indicators such as mortality, living quality and direct medical costs. As described in chapter 5.1. mortality is likely to decrease if good quality treatment is provided but unfortunately studies that combine the impact on mortality if several target values are achieved and longitudinal studies are not available. If mortality decreases, which is a trend observed, this also leads to higher costs for the health care system as patients remain longer on a very cost- intensive treatment, this however not being different from other life extending interventions.

The living quality increases if the target values for several indicators are met as discussed in chapter 4.1.2 and 5.1. Only one study mentioned that the use of EPO increases the quality of life but that its use imposes a 10% rise in the cost per life year saved[97]. Unfortunately this article does not reflect the European reality. Another article treated the cost factor of technology diffusion to the elderly while estimating the medical cost for patients > 75 yrs. 10% higher at the example of bypass operations and dialysis[98].

Does a good quality dialysis have an impact on direct medical costs? Erythropoietin is a hormone that stimulates the production of red cells and is a mainstay in the treatment of patients with anaemia of chronic renal failure, decreasing transfusions and improving the quality of life of patients who receive it. About 12% of the average annual cost per patient on dialysis is spent on medication according to a British study[99]. This percentage may even be higher in Switzerland as the prices of medication and in particular EPO are significantly higher. Patients that developed hypertension in dialysis treatment will need about 40% more EPO than those without pre-existing hypertension[100], thus implying if hypertension is better controlled the costs for the EPO treatment could decrease by 40%. Another publication found that EPO costs are 13% higher (140 CHF/patient/month, extrapolated by the author) in case where patients are not dialyzed adequately[101]. The savings due to reduced hospitalisation rates through the use of EPO were mentioned several times in the chapters 4.1.2 and 5.1 but only one publication tried to evaluate the potential savings in monetary terms and despite certain methodological constraints the benefits may be considerable[102]. These findings emphasise the economic benefit on direct medical costs that can be derived from a good quality management. The potential savings will outweigh the costs of the quality system by far as the QiN experience indicates, even though no monetary benefits were calculated.

In conclusion, the demand for a very expensive medical intervention will rise significantly and the costs will too. The payment to the service provider is independent of the quality effects produced although the medical costs may be positively influenced by good quality treatment. Therefore the service providers shall be firmly encouraged to participate in the quality evaluation by applying art.5 of the contract between service provider and insurer. Furthermore it is recommended to conduct a thorough economic cost-effectiveness or cost-benefit study examining at least all direct medical costs of patients on dialysis treatment in Switzerland.

5.3 THE ROLE OF THE PATIENT

As mentioned in the first sentence of the introduction, the health systems' basic aim is to make lives better for most of a given population that is experiencing some kind of illness. It seems logical that the consumer, client or patient, whatever term is used depending on the perspective, should be the focus of all action. Unfortunately there are severe barriers to this achievement as Domenighetti et al. state in an article of 1997[103]. These are the myth surrounding the effectiveness of medicine that seems still to be prevalent among the public and the paternalistic patient-physician relationship that is still predominant in the clinical environment of many countries. He proposes the empowerment of the patient via informing him that may lead to an aware customer putting pressure on the health care professional so that the latter will finally change from opinion or market based medicine to evidence based medicine. A systematic review[104] on this subject however comes to the conclusion that patients have contributed to the planning and development of services (mainly on structure and information sources) across a range of settings but that the effects of this process on the quality and effectiveness of services are unknown, mentioning a possible barrier on the policy side, as strong patient opinions can influence health care decisions to the disadvantage of policy makers. A similar barrier may be expected from the medical side as a demanding and well-informed patient may lead to a power struggle with the "expert"[105].

What is the situation in the treatment of patients on dialysis? The patient on dialysis is a chronically and severely ill patient who is on life-long treatment if he cannot expect a kidney transplant. He is dependent on the regular dialysis treatment as he would otherwise die in a short

time span. He spends on average 3 times a week 4 hours of intense treatment in a clinical setting with possible side effects ranging from hypotension, cramps, nausea, to vomiting and headache, all this linked to the treatment itself. He spends at least 15 hours a week a clinical setting never sure of how he will feel afterwards and knowing that the mortality rate is high. The living quality of this person is therefore substantially decreased. The setting is very stable as the patient usually does not change the dialysis facility and modality of treatment. This may alter the relationship of patient to nurse/physician compared to other diseases such as cardiovascular diseases with short term interventions and often higher living quality. The patient on dialysis seems to be the "ideal" patient for involvement in the treatment process as his mental state is not affected and that the treatment as such influences greatly his living quality[106]. This attitude is mainly shared by the medical profession on theoretical level or as one article states[107]: "customer relationship management assumes that the patient is seen as a client, is encouraged to make decisions on their treatment and also emphasises the professionalism of nursing". Bath et al. reported that the need for good quality information, the need for a suitable dialysis environment and the importance of social and family support were evident for haemodialysis patients[108].

Several other publications report positive experiences with patient involvement of any kind; a Dutch study demonstrates the feasibility of the implementation of changes which were asked for by the patients two years ahead and confirmed this procedure as a useful tool in quality improvement[109]. A Swiss report found a significant positive correlation in similar patient groups between the amount of dialysis self-care and subjective well-being, thus implying that active participation in the care process increases living quality[110].

Two articles treated the patient-nurse/physician relationship with one even observing a relationship between patient satisfaction with care with their nephrologist and attendance at dialysis sessions, indicating that interventions aimed at improving the patient perception of physician support may improve patient adjustment and possibly survival[111]. The other publication emphasises that dialysis patients are willing to participate in shared-decision making[112]. Shared decision making could however become difficult if as an American study describes 75% of patients would choose a high dose over a lower dose of dialysis if it increased length of survival by 20%, but more than 30% would not switch modality, even if it increased survival by 100%. This implies that dialysis patients have strong preference for their current modality[113].

Despite all methodological constraints of the above mentioned publications and the rather weak relationship of patient involvement and its effects on health care, the patient involvement remains indispensable for several reasons. The patient involvement can result in better implementation of clinical guidelines; improve safety and quality of care by engaging patients in the designing of processes and in better satisfaction with care[114]. Beyond that it is an ethical and legal obligation as patients need at least to be informed about their treatment.

Subsequently it will be necessary to apply adequate and reliable tools that are reliable, valid and in line with the HRQL concept for the translation of the patient involvement into practice. Health-related quality of life (HRQL) can be simply understood as how people are feeling. The basic question to ask then is whether the treatment will make the patient feeling better and whether the surrogate measures are adequate depends on how confident we are of the link with how people feel. These relationships are often modest and highly variable[115]; not so in haemodialysis treatment. The indicators chosen and discussed in 4.1.2 give a clear indication of the patients' living quality and dialysis is a definite instrument to make the patients feel better. Nevertheless responsive, valid and interpretable instruments measuring experiences of importance to most patients on haemodialysis should increasingly help guide clinical decisions.

But the participation of patients in the design of quality programmes is still not common practice as a even recent European quality assessment programme[116] shows. This is most probably due to cultural differences between the US and Europe, as in the US powerful patient advocacy bodies defend patients' interests. The European Kidney Patient's Federation (CEAPIR) formulates in their quality programme for renal care in art. 5 that all renal patients have a right to be clearly and fully informed prior to all methods of treatment and that the choice of treatment must be in accordance with the patients' own choice and medical condition[117]. A clear demand for quality

programmes however is not formulated. The Swiss kidney patient association (VNPS) which is a member of CEAPIR mentions in article 3[118] that the dialysis treatment should be of utmost quality mentioning a few details of quality control measures that seem to be either common practice or slightly outdated. The author cannot withhold his impression that the patient places himself in a position of a health care receiver. There is no hint of the wish for an active participation in the medical care or care process at least in the documents mentioned. This may also explain the response of the organization that the questionnaire sent would be treated by their medical adviser. Another fact which is difficult to interpret is that all the consulted patient organizations are sponsored by the pharmaceutical industry.

In view of the above and in view of the existence of several tools to measure patient preferences, patient satisfaction etc. it is proposed to evaluate first the knowledge of dialysis patients in Switzerland on their disease, treatment methods, patient rights and obligations linked to eventual better information provision. At the same time the SVK should take up the point of evaluation of "patient experience" as one of the areas for quality measuring in art. 5 of their contract with the providers as the case in the UK.

Following the argumentation above it may be surprising that in the present study "patient criteria" or patient involvement has not been measured. Although judged of importance it would have exceeded the frame of the master thesis and it came by surprise that the patient organisation did not engage further that would have facilitated a better coverage of the viewpoint of the patient.

5.4 IMPLEMENTATION MENU

In the following implementation menu the existing reality as described in the preceding chapters has been taken into account. The lack of any control or reporting of quality in haemodialysis treatment and the lack of participation of the involved community (except the health insurer) in this study has bee described. Furthermore Swiss specific conditions, different from the neighbouring countries need to be considered. Switzerland is a federal country with strong local powers thus patients are used to finding full-fledged health care structure including dialysis facilities in all of the regions. This implies that the facilities are often small in size and that patients do not cross regional borders to seek treatment out of the canton. For this reason the quality evaluation needs to be applied nationwide to guarantee access to best care for most of the population, as patients will not behave competitive and look for best quality this even more so as transport is one of the key issues in patient comfort, and Switzerland being a mountainous country with long travel times in the rural areas. Competitive approaches can therefore be excluded.

The proposed comprehensive information gathering could provide clinical data for numerous clinical questions in a relatively brief time frame, in contrast to more costly randomized clinical trials that address one question and take years to complete. This may render the data interesting for the public health field, the medical community, the insurer and the pharmaceutical industry thus assuring the financing of the implementation.

5.4.1 Step plan (the dates in brackets are the dates of expected achievement)

1. The SVK takes the initiative and asks an independent scientific institution specialised in health economics to prepare a quality evaluation tool (reporting sheet) based on this study with the help of an independent nephrologist – March 2006.
2. The SVK presents the elaborated evaluation tool to its contractual partners within its regular commission meetings and makes the evaluation tool legally binding taking reference to article 5 of the Swiss dialysis contract. – May 2006.
3. The research institution (RI) makes contact with all participating clinical centres and contacts if needed the ethical commission – September 2006.

4. The data gathering begins and the first set of raw data is obtained from all centers - December 2006.
5. Evaluation of the data – benchmarking – reporting to the institutions - June 2007

In principle three different possibilities of benchmarking are possible within haemodialysis treatment;

- defining the "best in class" as target value for all kinds of indicators on a world-wide or a national level
- determining the national mean value as target for all kinds of indicators
- determining the target values of chosen existing guidelines as target values for all kinds of indicators

The reality in the medical field nearly imposes the option for the last version by passing as a first step through the determination of a mean on a national level. In a second step adherence to guideline targets should become the favoured option. Depending on the results observed in the centres, those with quality below average and below target values should be addressed by the SVK or the Swiss Society of Nephrology (SGN) in order to assist with quality improvement favouring an educational approach. The German experience has proven that simply the information on quality data was one of the keys to improvement. Therefore regulatory and financial interventions shall not be applied but may not be excluded. One option is to link the level of dialysis reimbursement to treatment quality on the condition that the impact on health effects is clearly demonstrated[119].

5.4.2 Implementation costs

Implementation and running costs of quality control systems seem to be treated as a poor cousin in medical care. Even large quality systems do not evaluate or mention quality monitoring costs or the added financial burden for the providers, as Medicare[120] and QiN shows. However, the average evaluation costs in QiN were roughly estimated to be in the range of 1-2 € (1.5 – 3 CHF) per dialysis[121].

As already said in chapter 4.1.2, the criteria proposed are routinely evaluated. Additional laboratory costs are therefore not to be expected. The data is generally available or easy to measure or to calculate. The fees for the presented reporting sheet were 40-100 CHF/patient/year, thus meaning that with an average of 70 CHF/patient/year x 3000 patients, the overall costs for filling out the formula can be estimated at 210.000 CHF/year born by the participating dialysis centres. If the German figure with an average of 2.25 CHF is applied the evaluation costs are approximately 1 Mill. CHF. It has to be said however that the German system is a very complex and complicated system and that the investment needed for Switzerland is estimated at 600.000 CHF/year for the reason of its simplicity. Looking at the financial burden of 200 Mill. CHF for dialysis treatment each year a sufficient quality evaluation could be made for roughly 0.3% of the expenditure.

This proposal has been elaborated by the author and has been judged realistic in its implementation schedule by a scientific institution experienced in this field, but it should be mentioned that the attributed roles were not discussed with the involved parties and chosen by the author. In this regard the resistance or the willingness to participate in the implementation may be difficult to estimate but the absolute silence of the Swiss Society of Nephrology (SGN) concerning the participation in this study may not be a very positive sign for their collaboration but the legal obligations are there and the advance of the neighbouring countries may exert a certain pressure too.

6. CONCLUSION

This study answers one of the questions of what evidence based medicine is supposed to answer; it is best for the patient that a good and Swiss wide controlled quality system for haemodialysis treatment is installed under the condition that the patient is included as a partner in its development and implementation. The criteria chosen comply with the OECD criteria for indicators that are the impact on health, the policy importance and the susceptibility to the influence of the health care system. The second question on how to distribute health care resources is not answered in this study but indications are there that a good quality dialysis care reduces mortality, enhances living quality and may reduce associated costs of medication and the frequency and duration of hospitalizations. However a final judgment on the overall potential economic benefits or potential economic drawbacks cannot be made but should be evaluated in an economic evaluation.

In view of

- the legal obligation to control and improve quality,
- the increasing demand and the increasing costs,
- the potential gains in mortality reduction and improved living quality,
- the eventual economic benefits,
- the solid medical knowledge in this field,
- the absence of national guidelines on dialysis treatment,
- the difficulty in adherence to guidelines,
- the non existence of published data on quality in dialysis treatment in Switzerland,
- the highly regarded medical self-responsibility favoured by the different medical bodies,
- the simplicity, the practicability, the reliability and validity of the proposed quality tool
- the implementation facility and the low cost of the proposed quality tool,
- and above all for the ethical responsibility for the severely ill patients on a life long treatment

there is no time to lose to implement a system of quality care in haemodialysis treatment based on the model described and summarized in the table below;

Finally this Master thesis may be taken as a "kick-off" event in order to do something tangible about quality in haemodialysis treatments or as in the words of the Swiss Medical Association (FMH) "Every physician has the ethical obligation to provide the best possible treatment to his patients"[122]. Then, simply do it in a simple way.

TABLE 2: OUTLINE OF THE QUALITY EVALUATION TOOL

CRITERIA	TARGET VALUE, MEAN, TOOL OR INFORMATION SOURCE
GENDER RATIO MALE/FEMALE	MEAN
AGE RANGE	MEAN
ATTENDANCE IN %	100
HB (G/DL)	≥ 11
BMI (KG/M2)	-
CA X PO_4 MMOL^2/L^2	≤ 4.44
KT/V SINGLE POOL	≥ 1.4
PREDIALYSIS SYST. BP (MMHG)	130
PREDIALYSIS DIAST. BP (MMHG)	80
VASCULAR ACCESS	MEDICAL HISTORY FILE
INFLAMMATION	MEDICAL HISTORY FILE
HOSPITALIZATIONS/YEAR	MEDICAL HISTORY FILE
HOSPITALIZATION DURATION	MEDICAL HISTORY FILE
QUALITY OF LIFE	EVALUATION TOOL SUCH AS QUESTIONNAIRE
RISK ADJUSETEMENT (CASE-MX)	AGE, DIABETES, IN-PATIENT, EVENT. GENDER AND OTHERS
PATIENT KNOWLEDGE AND PATIENT PARTICIPATION	INTERVIEWS, QUESTIONNAIRES, EDUCATIONAL PROGRAMMES

7. BIBLIOGRAPHY

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ANNEXE

- Annex 1 – Accompanying letter to clinics
- Annex 2 – Outline of the study
- Annex 3 – Reporting sheet
- Annex 4 – Questionnaire
- Annex 5 – Accompanying letter to questionnaire
- Annex 6 – Search strategy
- Annex 7 – Reporting sheets from the clinics

Annex 1

Dr. Jörg Spieldenner
Ch. de la Borgnette
1965 Ormône/Savièse

Herr Direktor
Name
Address

12. November 2005

BETR.: QUALITÄTSMANAGEMENTSTUDIE DIALYSE

Sehr geehrter Herr X,

wie ich von meinem geschätzten Kollegen, Herrn Dr. XX in der Klinik XXX erfahren habe, ist die XXXXgruppe sehr am Qualitätsmanagement interessiert wie von Ihrem Kollegen Herrn XXXXX bestätigt wurde (Brief im Anhang).

Ich möchte Sie deshalb bitten wollen, im Rahmen meiner Master Arbeit in Gesundheitsökonomie und Gesundheitsmanagement der Universität Lausanne auf anonymisierte klinische Laborwerte von Patienten der Hämodialysestation zugreifen zu dürfen. Es handelt sich hier um eine Studie zum Qualitätsmanagement der Hämodialysebehandlung. Einen Überblick der Studie finden Sie im Anhang.

Ich würde mich über einen kurzfristigen positiven Bescheid Ihrerseits sehr freuen und stehe jederzeit für weitere Auskünfte gerne bereit

Mit freundlichen Grüssen

Jörg Spieldenner

Anlage (2)

Annex 2

Outline of the Master thesis within the Post graduate course – "Master in Health Economics and Management" of the Institut d'économie et management de la santé of the University of Lausanne

QUALITY EVALUATION IN HAEMODIALYSIS TREATMENT THROUGH "BENCHMARKING" – A MEDICAL AND ECONOMICAL OUTLOOK

INTRODUCTION:

Medical quality is a controversially discussed subject in Swiss and international health policy over the last years. Service providers such as medical doctors, payers such as insurers and health authorities have an interest in demonstrating efficiency and efficacy of medical care and medical treatment methods. Each group has different interests but the main aim is similar - providing good quality health care at bearable costs to most of the citizens. Nevertheless concise and applicable medical quality criteria are scarcely developed and even less so put into practice.

This is not different in the treatment of renal pathologies that require dialysis. (Only haemodialysis is being considered as this treatment is the most common dialysis therapy) Despite the fact that in article 4 and 5 of the contract between provider and insurer (Dialyse Vertrag SVK) clear reference is given to the principle of economicity and quality, agreed upon quality criteria of the dialysis treatment do not yet exist on national level.

But why is quality in dialysis treatment so important? In view of an aging population, the demand for dialysis treatment will sour in the coming years. Patients receiving this type of treatment are in general chronically ill, often on life-long treatment and with multiple associated pathologies. Their general health state and their living quality depend essentially on the quality of the dialysis treatment.

Beyond these medical considerations economic considerations are to be taken into account. According to the data of the SVK (Schweizerischer Verband für Gemeinschaftsausgaben der Krankenversicherer) 3730 patients received dialysis treatment in 2003 that generated costs of approximately 173 Mill.CHF. Most of these costs are caused by haemodialysis, each patient costing on average approximately 77000 CHF a year. The costs for the treatment of associated pathologies and the costs for the drugs needed for the dialysis are not reflected in these figures whereas a good quality dialysis has an impact on associated pathologies and the amount and type of medication needed.

In view of the above said it becomes evident that the dialysis treatment should be given priority in the development of applicable national quality criteria in particular as the proposed medical criteria are evaluated and available in the dialysis centres and as the SVK alone has access to data of 5.9 Million insured clients for this type of therapy.

PROCEDURE AND METHODOLOGY:

In the first part clinical, easily available and measurable parameters will be discussed that give a concise idea on the quality of the dialysis treatment. These parameters are Urea Reduction Ratio, Kt/V (dialysis efficacy), amount of haemoglobin, erythropoietin-dose (control of anaemia); albumin, protein catabolic rate, body mass index (control of malnutrition), calcium phosphorus product and parathormones (control of calcium phosphorus balance) pre- and postdialytic blood pressure and some demographic data.

This will be followed by an assessment of clinical data (retrospective) from some clinical dialysis centres. These data will be used to demonstrate the practical application of the quality model and to give an indication for the Benchmarking.

In the second part we will be looking at possible economical mechanisms with the aim to improve the medical quality of the dialysis treatment. Attention will be paid to practical economic tools and the possible impact on the overall costs of the dialysis treatment.

The research will be concluded by a critical outlook and the possibility of implementation of such a model.

Director of the thesis: Prof. Gianfranco Domenighetti

Annex 3

Monthly reporting sheet of hemodialysis patients

Hemodialysis Centre *Code*

Month November *Year* 2005

Patient	Sex	Age Range *	Attendance in %**	Hb (g/dl)	EPO Dose*** (units)	EPO/KG	BMI (kg/m2)	Ca x PO_4 (mmol2/l2)	PTH (pmol/l)	kt/V single pool	URR (%)	nPCR (g/kg/day)	Albumin (g/l)	Predialysis syst. BP (mmHg)	Predialysis diast. BP (mmHg)	Postdialysis syst. BP (mmHg)	Postdialysis diast. BP (mmHg)
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	
11																	
12																	
13																	
14																	
15																	
16																	
17																	
mean																	
STD																	
median																	

*Age range

1 - <18 **2** - 18 - 44 **3** - 45 - 59 **4** - 60 - 69 **5** - 70 - 79 **6** - ≥ 80

**Attendance

attendended hemodialysis treatments/planned hemodialysis treatments

*** EPO E/week: recalculated in case of Aranesp application (correction factor 200)

Annex 4

Fragenkatalog an die X im Rahmen des Master of health economics and management der Universität Lausanne

1. Ist die X an einer Qualitätsevaluierung und einer Qualitätssteigerung der Dialysebehandlung in der Schweiz interessiert?

2. Wenn ja was plant oder tut die X oder die Y um die Qualität der Dialysebehandlung und hier insbesondere um die der Hämodialysebehandlung zu evaluieren und zu sichern?

3. Hat die X oder die Y „practice guidelines" zur Dialysebehandlung entwickelt oder empfiehlt sie die Anwendung von practice guidelines und wenn ja welche (K/DOQI, European etc.)?

4. Gibt es Ihres Wissens nach Studien oder Untersuchungen, die den Zusammenhang von Dialysebehandlung, Qualität und ökonomischen Daten in der Schweiz untersucht haben? Können Sie hier welche nennen?

5. Gibt es in der Schweiz andere Adressen oder Institutionen die gesammelt Daten zur Dialysebehandlung entweder besitzen oder sogar aktiv erheben, z.B. nationales Register

6. Gibt es nach Meinung der X oder der Y Zugangshürden, die die langdauernde Dialysebehandlung erschweren oder unmöglich machen, so z.B. Alter, Krankheiten oder mangelnde Dialysekapazitäten?

7. Kann ein Dialysepatient frei zwischen verschiedenen Dialysezentren wählen, also auch ausserkantonal gehen, selbst wenn innerkantonal ein ausreichendes Angebot besteht?

8. Werden Daten erhoben, die Aussagen über die Patientenzufriedenheit und Dialysequalität ermöglichen?

9. Wie und durch wen werden Dialysezentren- praxen akkreditiert?

10. Hat die X Einsicht in die Abrechnungsdaten aller dialysierten Patienten in der Schweiz oder nur in die Daten der von ihr abgerechneten Patienten?

11. Sollte die X nur Daten der über sie abgerechneten Patienten besitzen, kann die X in etwa schätzen welcher Prozentsatz aller Dialysen ausserhalb des Abrechnungssystems der X abgerechnet wird und wie viele Patienten das in etwa betrifft?

12. Wie viele Patienten befinden sich zurzeit in einer Dialysebehandlung und wie hat sich diese Zahl in den letzten Jahren entwickelt? Wie sehen sie die weitere Entwicklung/Zunahmen? Haben sie Schätzungen dazu? - bitte hier aktuelle Inzidenz/Prävalenzzahlen

13. Wie viele Dialysezentren gibt es in der Schweiz und welche Anzahl von Patienten behandelt jedes Dialysezentrum (hier wenn möglich Tabelle)

14. Wie ist die prozentuale Verteilung von Peritonealdialyse und Hämodialyse jeweils nach Zentrums- sowie Heimdialyse getrennt?

15. Wie viele Patienten befinden sich in Hämodialysebehandlung und wie viele davon in Hämodialysezentren? (Ratio Heim/Zentrumsdialyse (auch Prozentsätze möglich)?

16. In welchem Zeitrahmen rechnet die X mit den Leistungserbringern ab (monatlich, vierteljährlich, halbjährlich, jährlich)?

17. Erhebt die X oder hat die X Erkenntnisse über die Gesamtkosten eines Dialysepatienten, z.B. über medikamentöse Kosten (Erythropoetin etc.) sowie über die Behandlungskosten für Begleiterkrankungen ? Wenn ja, kann die X einen Durchschnittswert für diese Kosten pro Hämodialysepatienten angeben, auch Schätzung möglich?

18. Erhebt die X oder hat die X Zugang zu Qualitätsdaten der Dialysebehandlung wie z.B. Mortalitätsstatistiken, life years gained etc.?

19. Durchschnittliche Überlebensrate , z.B. 1-Jahres Mortalität der Hämodialysepatienten und/oder aller Dialysepatienten in der Schweiz?

20. Wie lange bleibt ein Patient durchschnittlich in Hämodialysebehandlung und/oder Dialysebehandlung?

Annex 5

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Name
Address

12. Dezember 2005

BETR.: QUALITÄTSEVALUATION DIALYSE

Sehr geehrter Herr X,

im Rahmen meines postgradualen Masterstudienganges in Gesundheitsökonomie und Gesundheitsmanagement der Universität Lausanne habe ich das Thema Qualität in der Hämodialysebehandlung als Abschlussarbeit gewählt.

Im Rahmen dessen möchte ich Sie bitten, mir den beigefügten Fragenkatalog soweit als möglich bis spätestens 15.1.06 zu beantworten und mir allfällige Unterlagen zu senden. Es bleibt selbstverständlich Ihnen überlassen auf welche Fragen sie antworten wollen und können. Dazu kann ich Ihnen selbstverständlich auch das Dokument als e-mail senden wenn sie dies wünschen. Einen Überblick der Studie finden Sie im Anhang.

Ich möchte mich bereits im voraus für Ihre Mitarbeit bedanken und sehe den von Ihnen gesandten Informationen mit Interesse entgegen, stehe jederzeit für weitere Auskünfte gerne bereit und verbleibe

mit freundlichen Grüssen

Jörg Spieldenner

Anlage (2)

Annex 6

Recherche effectuée pour Dr Jörg Spieldenner 16.11.05 & 24.11.05/ tbr

« 1. Stratégie de recherche Medline = Pubmed
www.pubmed.gov
Database: Ovid MEDLINE(R) <1966 to November Week 3 2005>
Search Strategy:
---

1 kidney disease outcomes quality initiative.ti. (8)
2 Renal Dialysis/ (50876)
3 Renal Dialysis/ec (852)
4 exp "Quality of Health Care"/ (2674802)
5 BENCHMARKING/ (4480)
6 2 and 4 (13808)
7 3 and 4 (350)
8 2 and 5 (15)
9 *Renal Dialysis/ (33475)
10 *renal dialysis/ec (373)
11 Renal Dialysis/sn, ut [Statistics & Numerical Data, Utilization] (898)
12 SWITZERLAND/ (18378)
13 exp EUROPE/ (721012)
14 11 and 12 (3)
15 11 and 13 (253)
16 limit 15 to yr="1998 - 2005" (144)
17 limit 16 to yr="2000 - 2005" (107)
18 *Renal Dialysis/sn, ut (392)
19 17 and 18 (57)
20 from 19 keep 1,9,23,29,43,55 (6)
21 5 and 10 (0)
22 3 and 10 (373)
23 10 and 4 (118)
24 exp *quality of health care/ (298024)
25 10 and 24 (18)
26 from 25 keep 1-3,6,8-9,11,13,16 (9)
27 *health policy/ (16266)
28 24 and 27 (1171)
29 limit 28 to "review articles" (183)
30 2 and 29 (0)
31 2 and 28 (2)
32 from 31 keep 1 (1)
33 doqi.mp. (328)
34 2 and 33 (178)
35 doqi.ti. (99)
36 1 or 35 (102)
37 2 and 36 (54)
38 from 37 keep 2,9-11,13,16,18,20,46 (9)
39 20 or 26 or 32 or 38 (25)
40 "Quality of Life"/ (49768)
41 *Patient Satisfaction/ (9071)
42 9 and 40 (654)

43 *quality of life/ (21294)
44 9 and 43 (317)
45 9 and 41 (35)
46 limit 45 to yr="2000 - 2005" (20)
47 from 46 keep 1-2,4-6,11,13,15-16,18 (10)
48 from 47 keep 1-10 (10)

2. Recherche dans la base de données SCOPUS
www.scopus.com
(TITLE-ABS-KEY(k/doqi) AND TITLE-ABS-KEY(haemodialysis))
(TITLE-ABS-KEY(swiss) AND TITLE-ABS-KEY(haemodialysis)
(TITLE-ABS-KEY(switzerland) AND TITLE-ABS-KEY(haemodialysis)
(TITLE(economic) AND TITLE-ABS-KEY(haemodialysis))

3. Recherche dans la Banque de données Santé Publique
http://www.bdsp.tm.fr/
Faites une recherche « tous champs »
mcl=qualite AND mcl=hemodialyse

4. Recherche dans le catalogue Saphir
www.saphirdoc.ch
Recherche → Recherche avancée
Descripteurs MeSH : Renal Dialysis »

Annex 7A

Monthly reporting sheet of hemodialysis patients

Hemodialysis Centre Y *Code* 1

Month November *Year* 2005

Patient	Sex	Age Range *	Attendance in %**	Hb (g/dl)	EPO Dose***(units)	EPO/KG	BMI (kg/m2)	Ca x PO4 mmol2/l2)	PTH (pmol/l)	kt/V single pool	URR (%)	nPCR (g/kg/day)	Albumin (g/l)	Predialysis syst. BP (mmHg)	Predialysis diast. BP (mmHG)	Postdialysis syst. BP (mmHG	Postdialysis diast. BP (mmHG
1	M	4	100	12.7	12'000	130.4	32	4.59	2.5	1.54	74.2	1.11	39	172	70	128	67
2	F	5	100	11.9	8'000	86.9	35	2.34	7.2	1.31	67.0	0.84	34	125	70	145	57
3	M	5	100	12.6	5'000	68.0	26	3.51	16.1	1.82	79.0	0.9	41	161	77	144	69
4	F	4	100	11.2	10'000	238.0	19	2.85	8.6	1.26	70.0	0.79	27	150	80	130	80
5	F	5	100	13.2	18'000	288.0	25	4.67	14.2	1.63	78.0	1.12	40	170	83	168	80
6	M	5	100	11.0	4'000	67.2	23	2.37	6.9	2.15	80.0	1.23	35	180	85	105	60
7	M	4	100	12.0	8'000	98.8	28	3.02	5.5	1.75	79.0	1.1	36	137	80	111	64
8	M	3	100	12.9	6'000	78.4	24	4.31	11.2	1.61	74.8	1.07	43	120	75	120	80
9	M	5	100	11.0	24'000	342.9	21	2.37	16.1	1.51	68.0	1.23	28	175	85	115	60
10	M	4	100	11.5	6'000	70.9	27	3.92	40.3	1.9	79.5	1.02	38	165	85	130	80
11	F	5	100	10.9	4'000	85.1	15	2.74	7.3	1.98	83.0	1.25	38	140	75	150	80
12	F	5	100	13.0	1'500	26.3	21	4.5	16.7	1.77	83.0	0.78	39	138	56	171	71
13	M	4	100	11.0	5'000	87.0	21	4.35	16.2	2.24	84.0	1.13	38	175	92	114	83
14	M	3	100	11.9	2'000	26.8	21	4.25	22.0	1.47	73.7	1.03	45	157	89	186	99
15	F	4	100	10.7	12'000	157.9	31	3.24	11.4	2.18	84.0	1.02	33	160	82	138	67
16	M	2	100	11.5	16'000	293.6	19	3.68	23.0	2.21	84.6	1.1	35	121	82	117	79
17	M	5	100	12.0	6'000	61.2	30	4.14	12.7	1.23	68.0	1	40	113	60	116	55
mean		**4.24**	**100**	**11.8**	**8'676**	**129.8**	**24.6**	**3.58**	**14.0**	**1.74**	**77.0**	**1.04**	**37.0**	**151**	**78**	**135**	**72**
STD		**0.90**	**0**	**0.8**	**6065**	**98.8**	**5.4**	**0.84**	**8.8**	**0.33**	**6.1**	**0.14**	**4.7**	**22**	**10**	**23**	**12**
median		**4.00**	**100**	**11.9**	**6'000**	**86.9**	**24.0**	**3.68**	**12.7**	**1.75**	**79.0**	**1.07**	**38.0**	**157**	**80**	**130**	**71**

*Age range

1 - <18 **2** - 18 - 44 **3** - 45 - 59 **4** - 60 - 69 **5** - 70 - 79 **6** - ≥ 80

**Attendance

attendended hemodialysis treatments/planned hemodialysis treatments

*** EPO E/week: recalculated in case of Aranesp application (correction factor 200)

Eprex	3
Recormon	8
Aranesp	6
Sum	17

Annex 7B

Monthly reporting sheet of hemodialysis patients

Hemodialysis Centre Y *Code* 2

Month November *Year* 2005

Patient	Sex	Age Range *	Attendance in %**	Hb (g/dl)	EPO Dose***(units)	EPO/KG	BMI (kg/m2)	Ca x PO4 (mmol2/l2)	PTH (pmol/l)	kt/V single pool	URR (%)	nPCR (g/kg/day)	Albumin (g/l)	Predialysis syst. BP (mmHg)	Predialysis diast. BP (mmHg)	Postdialysis syst. BP (mmHg)	Postdialysis diast. BP (mmHg)
1	m	6	100	13.3	2'000	25.0	27	3.99	14.8	1.2	66.0	0.73	38	154	79	153	85
2	f	5	100	13.5	12'000	203.0	22	4.66	1.4	1.39	70.0	0.99	39	212	85	171	79
3	f	6	100	12.3	6'000	118.0	19	2.94	1.3	1.33	69.0	0.67	30	144	77	196	91
4	m	5	100	12.4	4'000	60.0	24	3.15	39.9	1.1	60.0	1.24	37	186	99	148	83
5	m	5	100	13.6	4'000	74.0	20	4.93	1.2	1.57	77.0	1.67	34	175	63	138	61
6	m	5	100	12.7	6'000	120.0	18	2.34	-	1.57	75.0	1.18	31	109	69	115	71
7	m	6	100	14.3	-	-	27	5.39	147.9	1.43	71.0	1.34	39	132	76	113	59
8	m	5	100	12.6	-	-	23	4.34	52.1	1.47	71.0	1.3	38	235	112	190	101
9	m	5	100	11.8	6'000	86.0	22	5.16	12.6	1.37	69.0	1.2	42	158	73	171	78
10	f	5	100	15.1	6'000	136.0	19	4.21	1.0	2.1	83.0	1.46	36	84	49	86	55
11	f	3	100	11.4	6'000	115.0	18	4.42	6.4	1.62	75.0	1.12	38	164	89	151	86
12	m	2	100	10.9	12'000	162.0	24	5.36	18.7	1.04	57.0	1.08	42	190	101	148	80
13	m	5	100	13.2	4'000	56.0	26	4.72	96.3	1.44	71.0	1.36	40	131	74	113	68
14	m	5	100	11.2	6'000	92.0	21	3.37	21.9	1.14	64.0	0.99	36	169	73	137	60
15	m	5	100	11.6	9'000	120.0	21	3.51	13.3	1.1	63.0	0.78	37	152	79	202	95
16	f	5	100	11.8	6'000	92.0	23	6.16	-	1.93	81.0	1.54	-	179	84	142	81
17	f	5	100	12.2	9'000	180.0	21	4.98	-	-	-	-	-	164	103	156	97
mean		**4.9**	**100**	**12.6**	**6'533**	**109.3**	**22.1**	**4.33**	**30.6**	**1.43**	**70.1**	**1.17**	**37.1**	**161**	**81**	**149**	**78**
STD		**1.0**	**0**	**1.1**	**2850**	**48.1**	**2.9**	**1.01**	**42.7**	**0.29**	**7.1**	**0.29**	**3.4**	**36**	**16**	**31**	**14**
median		**5.0**	**100**	**12.4**	**6'000**	**115.0**	**22.0**	**4.42**	**14.1**	**1.41**	**70.5**	**1.19**	**38.0**	**164**	**79**	**148**	**80**

*Age range

1 - <18 **2** - 18 - 44 **3** - 45 - 59 **4** - 60 - 69 **5** - 70 - 79 **6** - ≥ 80

**Attendance

attendended hemodialysis treatments/planned hemodialysis treatments

*** EPO E/week: recalculated in case of Aranesp application (correction factor 200)

Eprex	1
Recormon	15
Aranesp	1
Sum	17