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LCA-based approach to environmental performance of Continuous Ambulatory Peritoneal Dialysis Fluids.

Screening Life Cycle Assessment as a complementary tool for decision making in Gambro AB.

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Classmates, friends and family for their patience, presence and love.

Abstract

Screening LCA has been used to gain further insight into the environmental performance of Gambrosol Trio, a fluid used in Continuous Ambulatory Peritoneal Dialysis (CAPD) as a form of renal therapy. Gambrosol Trio (Trio) is produced and commercialised by Gambro AB, an international company with headquarters in Stockholm and historic roots in Lund, Sweden. The product's distinctive characteristic is its three-in-one compartment bag that allows a patient to use one of three standard glucose concentrations that form the basis of CAPD. This design has logistics and operational advantages compared to similar products packaged in single or dual compartment bags. This thesis was conducted as a first approach to explore whether or not these advantages extend to the product's environmental performance from a cradle-to-grave perspective. The environmental burden of the product is explored from the production and processing of Trio's components, to the manufacturing of the product itself to disposal of generated waste from its use, including transportation in between these stages of the product cycle. The assessment was made based on the construction of the product map, the material requirements for its production and transport and assigning an "Ecoscore" based on the Ecoindicator 99 method as presented in the Ecoindicator Manual for Designers. Results indicate the majority of the product's environmental burden is located at the production stage of its components with PVC based plastics taking the larger share. A quick exploration of Polypropylene and Polyethylene as substitutes did not indicate potential for improved environmental performance. Caution must be exercised as the effects of Phthalate leaking in land-fills or incomplete combustion in incinerators was not available as Ecoscores. Although this approach is based on Life Cycle Assessment, it does not have the validity that a full application of the method would provide; as such, results can only be used within the organisation as a tool to decide whether or not to continue efforts along this track and cannot be used to communicate claims to stakeholders or as the basis for definitive, company-wide decisions such as material substitution in their products.

Executive Summary

Peritoneal Dialysis (PD) is a form of renal therapy for individuals that suffer loss of renal function. A catheter is permanently attached into the abdominal wall and a solution (peritoneal dialysis fluid PDF) is infused into the abdominal cavity where the peritoneal membrane is used as a filter media to replace the filtration function of the kidneys. The dialysis solution is mainly composed of glucose, electrolytes and a buffer that together simulate blood serum conditions to induce filtration through the peritoneum. There are three standard glucose concentrations in the market available to patients. The use of either one has different results as part of the therapy.

There are two types of PD techniques; Continuous Ambulatory Peritoneal Dialysis (CAPD) and Automated Peritoneal Dialysis (APD). CAPD is a self-administered manual procedure in which PDF is infused 4 times per day with each infusion lasting around 4 hours. APD works under the same principle but a machine controls the filtration overnight while the patient sleeps.

Gambro AB is one of the leaders in renal therapy that specialises in the production of hemodialysis and peritoneal dialysis products and systems. One of its latests developments is a CAPD product known as Gambrosol Trio. The product was developed with the aim of improving the function of PD and PDFs. The research conducted at Gambro resulted in a new three-in-one packaging design that can deliver any of the three standard glucose concentrations.

This design has obvious advantages from a logistics and operational point of view since it simplifies transportation and storage both for the company and its customers. Apoteket AB is Gambro's main customer in Sweden and it is the entity responsible to deliver dialysis supplies to patients undergoing renal therapy.

Gambro AB's facilities in Sweden are certified in ISO 14001 as the basis for their environmental management system. The record for the exact number of facilities certified world wide was not available at the time of writing; however, at least manufacturing facilities in Europe do have ISO 14001 certification. The organisation, as part of the healthcare industry as a whole, has been the focus of attention of stakeholders that have expressed concern over some of the materials used in the sector, specifically PolyVinylCholride (PVC) and one of the chemicals commonly used as an additive, phthalates.

These two circumstances have prompted Gambro's Research and Development and Design Validation department to search for suitable approaches that can contribute to gain further insight into the product's environmental performance and that can also be used as systematic tools to contribute in the decision making process, especially during research and development and redesign of the company's products and systems. This is seen as the next step to complement the use of ISO-14001 as the EMS for their routine operations.

This thesis explores the use of a Life Cycle Assessment -based approach to explore the product's performance with a cradle-to-grave perspective and using established environmental 'ready to use' assessment methods. This approach, known as Screening LCA is proposed as an adequate way to begin the exploration and potential adoption of more detailed and robust exercises such as a full-scale Life Cycle Assessment.

Due to time and resource limitations, this thesis cannot provide conclusive evidence in the way that the execution of a full-scale LCA would. However, its aim is to assist Gambro AB in presenting the company with a viable tool to continue their environmental commitments

while providing a qualitative assessment of the product's performance that pursues quantitative insight whenever data availability and usability make it possible.

The results are centered around the determination of an "EcoScore" for the product, taking into account the environmental impacts resulting from the production and processing of its main components (plastics for bags and other items, chemicals for the solution and cardboard for packaging), the assembly of the product itself, the transportation from suppliers to manufacturing, to distribution and delivery to the patients; and finally disposal of waste generated during the use-phase.

An integrated assessment tool, "Ecoindicator 99, Manual for Designers" was used to determine the product's EcoScore. This method was specifically developed for internal discussion in organisations interested in starting to evaluate their products from an environmental perspective but that may not be ready to commit to a large-scale undertaking on the level of a full LCA, or that may wish to find areas of interest to focus their environmental efforts.

The method was applied to Gambrosol Trio under a set of limitations and assumptions that were inevitable due to the scope and limitations of the thesis and the method itself. Crucial amongst them is the use of Region Skåne as the focus of the study, considering the product is sold throughout Europe and parts of Asia. Also important to note is that the method does not cover all the relevant processes involved in the production of Trio and some assumptions had to be made to continue the analysis. An important limitation is the lack of an ecoindicator for a process equivalent to the actual mixing, filling and packaging of the fluid. A compromise was made by approximating with the use of energy consumption rates based on similar processes in the milk industry and by raising those requirements by an order of magnitude to reflect the higher need for hygiene and quality control in the medical sector. Likewise, ecoscores related to disposal of PVC did not include impacts of leaching of Phtalates in landfills or incomplete combustion in incinerators.

Results show that the main contributor to environmental impacts is the production and processing of the product's components (plastics, chemicals, water and packaging) and of those, production of plastics (PVC) contributed the most.

Two alternative materials were explored (Polypropylene and Polyethylene) as substitutes but were not able to reduce the product's Ecoscore (higher points mean higher impacts). It is important to note that this comparison was made on equal grounds in terms of material requirements used for the plastic components. It was not established the extent to which the use of a different material with different properties (density in particular) would involve a change in the shape or weight of the plastic components.

The advantages of Trio in terms of logistics of production and transport due to its three-in-one design did not appear to translate into increased environmental performance. The main reason was the observation that patients under CAPD do not change their glucose concentration on a contingency basis. Therefore, they do not necessarily have all three standard concentrations available at all times which limits the effect of wasted product due to expiration or returns as was originally thought.

Changes in prescription appear to be controlled by continuous and careful observation of each patients renal function and patients usually place orders for CAPD solutions with one or too weeks advance notice. Although no data was available from Apoteket AB on their inventory status and supply protocols, it is reasonable to assume that they would track their

customer demands and react accordingly when placing orders with the CAPD fluid manufacturers.

However, there were some indications of a limited amount of scrapping taking place at Apoteket (even if it is not normally tracked). In the absence of concrete information, a quick calculation was made with a ten percent scrapping rate. Due to the nature of the ecoscoring method and the limitations in data available the product ecoscore was affected in a direct way. A given increase (10%) in manufacturing, transport and disposal because of wasted product led to an equal increase in the product's ecoscore (10% higher).

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1 Introduction

This section covers the general background and reasons that prompted this thesis. The problem formulation, goals and limitations are also included. The outline of the document is presented at the end of the section.

1.1 Background

Environmental awareness has been considerably increased in past decades. Seminal work like that of Rachel Carson's *Silent Spring* in the 1960s paved the way for a heightened level of concern among the general public about our relationship to the environment.

Following on her steps, countless natural scientists, engineers, politicians, artists, institutions, organisations and the public as a whole have contributed to reshape our society's view of the environment. Organic farming, alternative energy technology and pollution accords at the regional and international level are but some of the fruits of these efforts.

Little by little, stakeholders all around the world have been shifting their view of production and consumption systems in order to include the effects of those systems on the environment, moving away from traditional models that only acknowledged simple relationships between producers and consumers; to more holistic approaches that show society's connection to the environment and its role as a limited reservoir of raw materials and as a system that provides numerous services but that is also sensitive to, and can be jeopardised by, inefficient production and careless waste production and disposal practices.

A shift has been noticed: beginning with reactive approaches such as tightening of governmental regulation in the field of pollution emission and control, moving on to shifting attention to more efficient manufacturing lines, the adoption of recycling programs, the development and widespread adoption of environmental management systems and from there to preventive approaches such as design for the environment and sustainable business practices. All of these have marked the way for society's current interactions with our planet's natural systems.

Despite all these advances, society still demands a sometimes seemingly endless number of goods and services, some deemed more essential than others. Some of us might find the switch from incandescent bulbs to fluorescent ones a rather painless transition in the quest of reduced energy consumption while others might shudder at the prospect of abandoning our cars and have them substituted with public transportation systems. Some may question the need to abandon them at all if we were to use an alternative energy source, thus reducing some of the negative impacts associated with their use. Is building lighter and more efficient vehicles, perhaps phasing out a range of materials and substituting them with others, reasonably sufficient efforts when dealing with personal transportation's negative environmental impacts?

These lines of thought resonate in most of society's production sectors, the health care sector being one of them. There are few other sectors that can be considered more essential than this one, a situation that can cause complications when trying to open a dialogue about the industry's environmental performance. It may not be a case of stakeholders and members of the industry not genuinely concerned about the environment but simply a case where a function is considered so essential that other issues do not usually receive the same amount of attention.

One of the pressure points for the medical sector is a heightened awareness of the materials used in plastic products such as gloves, blood and dialysis fluids bags, intravenous and feeding lines and similar connecting elements. Polyvinyl Chloride (PVC) has been the focus of attention due to concern as to the potential toxicity of one of one of the common plasticisers (Di(2-ethylhexyl)phthalate, DEHP) used in the production of this material. Although there is no definitive evidence of the effects of this compound on human health[1], there is pressure on the sector to move away from either PVC containing DEHP or from PVC altogether[2].

As a response to this pressure, a number of health centres around the world have initiated efforts to substitute PVC and/or DEHP for materials like silicon or polyurethane in the case of tubing; ethylene vinyl acetate (EVA) for plastic bags and nitrile in the case of gloves. (HCWH, 2008)[3]. Blood bags are an exception due to the fact that phthalates act as a stabiliser for blood products and the use of PVC/DEHP is still common for this application[4].

In the US, out of a total of 7,569 hospitals registered in 2005[5], a little over 100 (many of them children's hospitals) have started projects to substitute PVC/DEHP. In Europe, there cases reported where hospitals have been actively pursuing substitutes in Austria (18 health care centres), Czech Republic (where in one instance the targeted product was IV bags for hemodialysis), Denmark and Sweden (with one major health centre each in Copenhagen and Stockholm, respectively).

In the case of southern Sweden, MA-Skåne, the entity in charge of material purchasing for the region has purchasing guidelines that recommend the use of PVC-free alternatives whenever feasible and with the restriction that any substitutes should perform as well as the displaced products[6]. As of October, 2007 the efforts and results have been concentrated on the following items: gloves, injection (syringes), infusion (insulin pumps), transfusion, anaesthesia (e.g., epidural sets), enteral nutrition (catheters and tubing), incontinence (drain lines) and office materials[7].

Dialysis products in general and fluid bags in particular have not been addressed to the extent other items have because a switch of this nature represents a major overhaul for producers and distributors as substitutes may not be readily available or only at higher costs[8]. This punctuates the need for producers to have and use systematic tools that aid them in deciding how to better approach product design and redesign to cover issues like human health and environmental impacts.

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1 US Food and Drug Administration (2002). Public Health Notification: PVC Devices containing the plasticizer DEHP. Available online: http://www.fda.gov/cdrh/safety/dehp.html [September 01, 2008]

2 Health Care Without Harm (a2008). Dioxins and Phtalates. Available online: http://www.noharm.org/europe/pvcDehp/dioxin-phthalates [September 01, 2008].

3 Health Care Without Harm (b2008). PVC-free alternatives. Available online: http://www.noharm.org/europe/pvcDehp/pvcFree [September 10, 2008]

4 Health Care Without Harm (2005). Avoiding PVC Use in Hospitals. Available online: http://www.noharm.org/europe [September 1, 2008].

5 US Census Bureau (2005). Available online: http://www.census.gov/Press-Release/www/releases/archives/facts_for_features_special_editions/004491.html [September 10, 2008].

6 MA-Skåne (a2008). PVC-Free Alternatives for Sustainable Health Care in Skåne. Available online: http://www.miljo.skane.se/eng/d/pd3.htm [September 10, 2008]

7 MA-Skåne (b2008). Products wihtouht PVC and PVC products without Phthalates. Available online: *www.miljo.skane.se/eng/d/bilagor/**PVC**-free**_products**.pdf* [September 10, 2008]

8 Medical Device Link (2008). PVC and Phthalates in Medical Devices: A Never Ending Story. Available online: http://www.devicelink.com/mdt/archive/06/04/002.html [August 15, 2008].

This thesis seeks to explore the efforts of Gambro AB, a member of this industrial sector, in addressing environmental issues, similar to the ones described above, by using Life Cycle Assessment-based preventive approaches concerning one of their product systems.

Gambro AB, based in Stockholm, Sweden is one of the major global players in the area of renal care. It currently specialises in hemodialysis products and systems and is actively pursuing a bigger role in other renal therapy options such as peritoneal dialysis[9].

Gambro AB has a long record of research and development and one of their most recently developed products, a peritoneal dialysis fluid commercially known as *Gambrosol Trio*, is one of the available options for patients that experience severe renal deficiencies and that have not been able to receive a transplant. Compared to hemodialysis, peritoneal dialysis can provide a better quality of life and due to its relative simplicity, it frees the patients from constant trips to hospitals and clinics to receive treatment. Furthermore, the design of *Gambrosol Trio* appears to offer a superior performance in its critical role of substituting renal function when compared to traditional peritoneal dialysis fluids developed in the past.

Gambrosol Trio is in essence a glucose solution that contains a number of electrolytes naturally present in blood serum. The fluid is instilled into a patient's abdominal cavity through a catheter that is permanently attached to the abdomen, while instilled, it uses the peritoneal membrane's properties as a filtering medium to remove waste products and fluids from the body, in much the same way a healthy kidney would do.

Patients undergoing peritoneal dialysis may need one or more out of three standard glucose concentration fluids during the course of treatment. Some manufacturers produce this fluid in single concentration bags, thus requiring three separate products to cover a patient's needs. Others do so using dual concentration bags. Gambrosol Trio is currently the only fluid that is produced in a three-in-one concentration bag, meaning a patient will never need to be supplied with a different type of bag if or when their prescription change.

Gambrosol Trio's three-in-one compartment design was originally intended to increase the product's performance as part of a renal therapy system. However, the same characteristics that allow this product to perform its intended function also appear to be responsible for lessening the environmental impacts associated with its manufacture, distribution and use when compared to single and two-in-one compartment design fluids.

The details of this product's design, its relation to the environment, and how to systematically address its environmental performance using a preventive approach are the object of this thesis and will be covered in the following chapters.

1.2 Problem formulation

The aim of this thesis is to critically explore Gambrosol Trio's environmental performance as a peritoneal dialysis fluid using an LCA-based approach. The product's three-in-one concentration design seems to have obvious advantages in reducing material intensity, storage and transportation requirements when compared to products that are also commercially available, that have the same function but a different design.

By exploring Gambrosol Trio's environmental performance, this thesis also aims to contribute to Gambro AB's current efforts to assess and if pertinent, to adopt a framework that assists in the decision making process by including environmental concerns into the organisation's research and development protocols.

[9] Gambro AB (a2008). Available online: http://www.gambro.com [June 01, 2008].

The problem formulation can be summarised in the following primary and secondary research questions:

Are there any qualitative or quantitative indications that provide further insight into Gambrosol Trio's environmental performance, in practice?

How can a framework based on Life Cycle Assessment can be used to initiate a systematic exploration of the product's environmental performance, that could be adopted as part of the organisation's current decision-making tools?

Answers to these questions will provide the means to reach the thesis objectives as stated in the following section.

1.3 Objectives

The main objective of the thesis is to *propose an LCA-based framework that facilitates assessment of the environmental performance* of product systems manufactured and commercialised by Gambro AB, using Gambrosol Trio as the focal point of the study.

A case will be made of *how to use, in practice, such a framework in order to gain further insights into a product's environmental performance* by establishing key components in the manufacturing and distribution chain and by exploring the way they operate so that potential areas of attention can be identified for further work on the topic.

1.4 Limitations

Gambro AB as an organisation and Gambrosol Trio as a product are both part of complex systems. The study of both systems in full is beyond the scope of this thesis due to the relatively short time period allocated to it as well as man-power constrains. Therefore, some limitations must be used to address the objectives stated above within a reasonable time and to a reasonable level of detail.

The selection of an appropriate framework for the assessment of environmental performance will be based on a literature review of current materials. Emphasis will be placed on streamlined approaches that reduce the inherent complexity of this type of assessments when compared to stricter and more complex methods.

The proposed LCA-based framework will be regarded as a first step in terms of the effort within Gambro to develop a systematic way to integrate environmental performance as a criterion for the development of new products and/or redesign of existing ones. As such, it will mainly rely on qualitative assessments; whenever possible, quantitative insight will be pursued.

A full LCA, that is, a quantification of the actual environmental performance of Gambrosol Trio throughout its life cycle is directly related to the availability of relevant data, its usability as well as the time allocated for research and it is not considered as within the scope of this exercise.

As for the product itself and to expedite access to key players in the system, the thesis will be contained to the Swedish market and qualitative and quantitative data gathering will be limited to region Skåne, where Gambro's Headquarters are located. Likewise, in the case of the manufacturing and distribution chain, the scope is limited to the manufacturing of the product itself, excluding its component parts. As such, the conclusions of this document may not be applicable to other parts of the peritoneal dialysis market.

Other specific limitations that are related to the framework itself are addressed in detail in chapters 4 and 5.

1.5 Key facts and figures

Around 10% of the global population is estimated to suffer some form of kidney deficiency[10].

About 1% of individuals afflicted with kidney disease will require renal replacement therapy[11].

The numbers of those affected are estimated to steadily increase at an annual rate of 5 to 8 in developed countries%[12]

While historically the main causes of renal failure were trauma and non-specific inflammation, the causes are shifting to poorly treated diabetes and hypertension, especially in developed countries[13].

The total global market for renal therapy is estimated to be worth around USD 8.5 billion. Of this, around 70% (~USD 5.97 billion) corresponds to hemodialysis and 26% (~USD 2.25 billion) corresponds to peritoneal dialysis[14].

1.6 Thesis outline

Chapter 1. Introduction.

The first chapter will present background information required to understand the motivation behind this document. Problem definition, goals and limitations are also covered here.

Chapter 2. Methodology and Research Design.

This chapter provides an brief exposition of the methodology used throughout the thesis as well as the selected research strategy to address the research questions that constitute the problem formulation.

Chapter 3. Kidney Function, Failure and Treatment options.

Contextual information is provided in this chapter with regards to the way the human kidneys work, the ways in which they can fail and the currently available treatment options. Emphasis is placed on filtration, one of the kidneys main functions. Likewise, out of the two main treatment options (transplantation and dialysis) a more detailed description is provided in the case of dialysis. Within the category of dialysis, the chapter further explores peritoneal dialysis and the specific product around which the document revolves: a three-in-one glucose concentration fluid commercially known as Gambrosol Trio.

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[10] http://www.worldkidneyday.org/pages/facts.php [June 20, 2008]

[11] Glassock R.J., Winearls Christopher. The Global Burden of Chronic Kidney Disease: How valid are the estimates? Neprhon Clinical Practice 2008;110:c39-c47 . Available online: http://content.karger.com/produktedb/produkte.asp?typ=fulltext&file=000151244 [August 15, 2008].

[12] El Nahas A.M., Bello A.K. (2005). Chronic kidney disease: the global challenge. *Lancet*. 9456 Vol. 365, 331-240

[13] See 10.

[14] Gambro (2005). Annual Report. Available online: http://www.gambro.com/annualreport2007.htm [August 20, 2008].

This chapter, together with chapter 4, provide the required information to understand the connection of the product design to the concept of environmental performance and sets the stage to begin the exploration of suitable methodologies that can be used to assess it.

Chapter 4. Product Map.

This chapter will present the product map, describing its component parts and their origins, the product's manufacturing itself and its product's transportation routes destination until it reaches the end-user.

Chapter 5. Life cycle-based approach to environmental performance.

Concepts like sustainable enterprising, corporation evolution and life cycle thinking, are discussed under the lens of the research questions proposed in chapter 1.

This chapter explores in further detail the main components of the proposed methodology, how it relates to, or has been adapted from, existing frameworks and tools and how it can be used to facilitate assessment of environmental performance and decision making within the organisation.

Chapter 6. Findings and Conclusions.

This chapter provides the results of the use of the proposed methodology to the targeted product system. It will present the findings of the qualitative assessment as well as quantitative insights that were gained during this exercise.

The main conclusions of the thesis are also presented in this chapter.

Chapter 7. Recommendations.

Recommendations based on the items covered in the previous chapter as well as observations made during the mapping of the product system will be provided here. They are indented to cover limitations to the results of this thesis and how to address them in future work and suggestions on how to make use of LCA-based tools as part of the organisation's environmental management efforts.

Note: For those familiar with the concepts of renal function, failure and therapy and with Gambro AB in general, it is recommended to proceed to chapters 6 for a view of the proposed framework and its use and to chapter 7 for the findings of this study and the concussions and recommendations.

2 Methodology and research design

Given the characteristics of the problem defined in chapter 1, it was decided that this exercise would be approached using a case study oriented research strategy. Therefore, in order to answer the main research questions a research process was designed that would provide a reasonable amount of information to:

1. Create a map of *Gambrosol Trio* as part of a product system managed by Gambro.

2. Identify areas of interest in the product map to focus on during subsequent work.

3. Select an appropriate general approach and a more specific method to explore the environmental performance of the product in the areas previously identified.

4. Collect qualitative and whenever possible, quantitative data to verify both the validity of the areas of interest previously identified, and

5. To use the selected methodology to provide answers to the primary and secondary research questions.

2.1 Data collection

Items *1* through 5 were approached through a combination of literature reviews and qualitative and quantitative data collection by means of interviews with key individuals inside and outside of Gambro AB. These reviews and interviews shaped the outline and results of this thesis as shown in fig. 2-1.

A number of experts within the organisation were selected to form a *steering group* that would provide guidance and extended critical discussion conducted through open conversations in order to gain the required level of understanding to map the product system.

The participants in this steering group were:

1. Anders Wieslander. Senior Researcher. Member of the original research group responsible for the development of Gambrosol Trio. Steering group leader.

2. Malin Isaacson. Sales Manager. Peritoneal Dialysis (Product System Mapping)

3. Theodor Sandström. Director of R&D. Materials and Chemistry Development (Product System Mapping).

4. Barbara Musi. Senior Researcher. Toxicology and Biocompatibility / Environmental Management (Background on materials and development protocols used within the organisation. Insight into current status of Gambro's environmental management system).

Three extended sessions with the steering group were allocated during the thesis period. One at the beginning to formulate the problem and goal followed by a midterm one to review the methodology and course of action and finally one prior to submission to discuss findings and conclusions.

Additional interviews were conducted to collect additional qualitative and where possible, quantitative data. The list of interviewees and their relevant role are presented as follows.

1. Mikael Redin. Logistics. Distribution Centre (quantitative data on the product characteristics: weight, manufacturing points, shipment destinations).

2. Tom Lindhal. Product delivery. Responsible for the delivery of dialysis supplies from Apoteket to patients in Malmö (quantitative data on delivery logistics collected during interview and observation of a full delivery day).

3. Lena Krutzen. Head of Peritoneal Dialysis unit. Universitetssjukhuset i Lund (quantitative data on number f patients under PD treatment, qualitative data on treatment option trends)

4. Katalin Kiss. Pharmacist. Apoteket, Universitetssjukhuset i Lund (qualitative data on product delivery to end-users and storage practices at Apoteket).

5. Lena Kempf. Head Pharmacist, dialysis unit. Apoteket, Universitetssjukhuset i Malmö (qualitative data on product delivery to end-users and storage practices at Apoteket).

Once the product map was established, a literature review was conducted to identify and select a suitable framework capable of assessing the product's environmental performance and becoming a complementary tool in the organisation's decision-making process.

The key factors for the selection of an LCA-based approach as a suitable framework for this excercise were:

- Holistic nature. Early on, during discussions with the steering group and while constructing the product map, it became clear that even though the exercise was prompted by a scientific and technological innovation (the three-in-one design of Gambrosol Trio), the effects of this innovation would resonate beyond the boundaries of the organisation itself. Therefore, it was decided that an approach able to go beyond technological solutions and that could frame the product as but a "part of a whole" would be preferable.

- Conducive to objective results. One of the first points of discussion with the steering group was the need to create a systematic approach to include environmental issues as one of the core components in the organisation's decision making process, beyond routine operations. In order to do that, the selected framework would have to be able to offer some measure of objectivity in its results.

- Good ratio of comprehensiveness/expediency. The potential to streamline the frameworks was considered as a positive factor due to the time-related constrains of the study.

Once having a selected framework, literature review continued to identify how this framework could be adapted to assess the product's environmental performance while maintaining the same three criteria stated above.

The main components of the selected framework were applied to the product system itself to gain qualitative insight into its environmental performance. Where data was available or

usable, an effort was made to complement this with quantitative insights. The resulting findings, conclusions and recommendations are contained in chapters 6 and 7.

2.2 Validity, reliability and objectivity

The validity and reliability of the findings presented in this thesis are dependant on the comprehensiveness of the literature review and the accuracy and adequate assessment of qualitative and quantitative collected data.

An effort was made to review and critically compare the broad approaches described above and the resulting framework. These items were presented to the steering group and their function, implications and limitations were subject of discussion to verify their validity as a means to answer the primary and secondary research questions.

The objectivity of the results is liable to be compromised due to the limited amount of quantitative data that was collected, either due to it being not available, usable or because of its sensitive nature.

It is acknowledged that data collection during open conversations and unstructured interviews risks the interviewer to ask leading questions and thus receive skewed qualitative data that may include untested and/or hard to verify observations from the interviewees.

The author made an effort to maintain a critical approach to the results of all interviews and discussions, more so in the case of those with the steering group. Although an effort was made by all participants to remain critical during discussions there is always the risk of a certain degree of bias to enter the conversation. To counteract this, an effort was made to contrast the information obtained in this manner to the established general approach and framework that resulted from the literature review.

As for the application of the framework itself, it must be observed that an strict application of Life Cycle Assessment was considered to be outside the scope of this study. Therefore, the results presented herein do not possess the validity that a full LCA would have. Chapter 6 states in detail the differences from the standard LCA method that were used throughout this exercise.

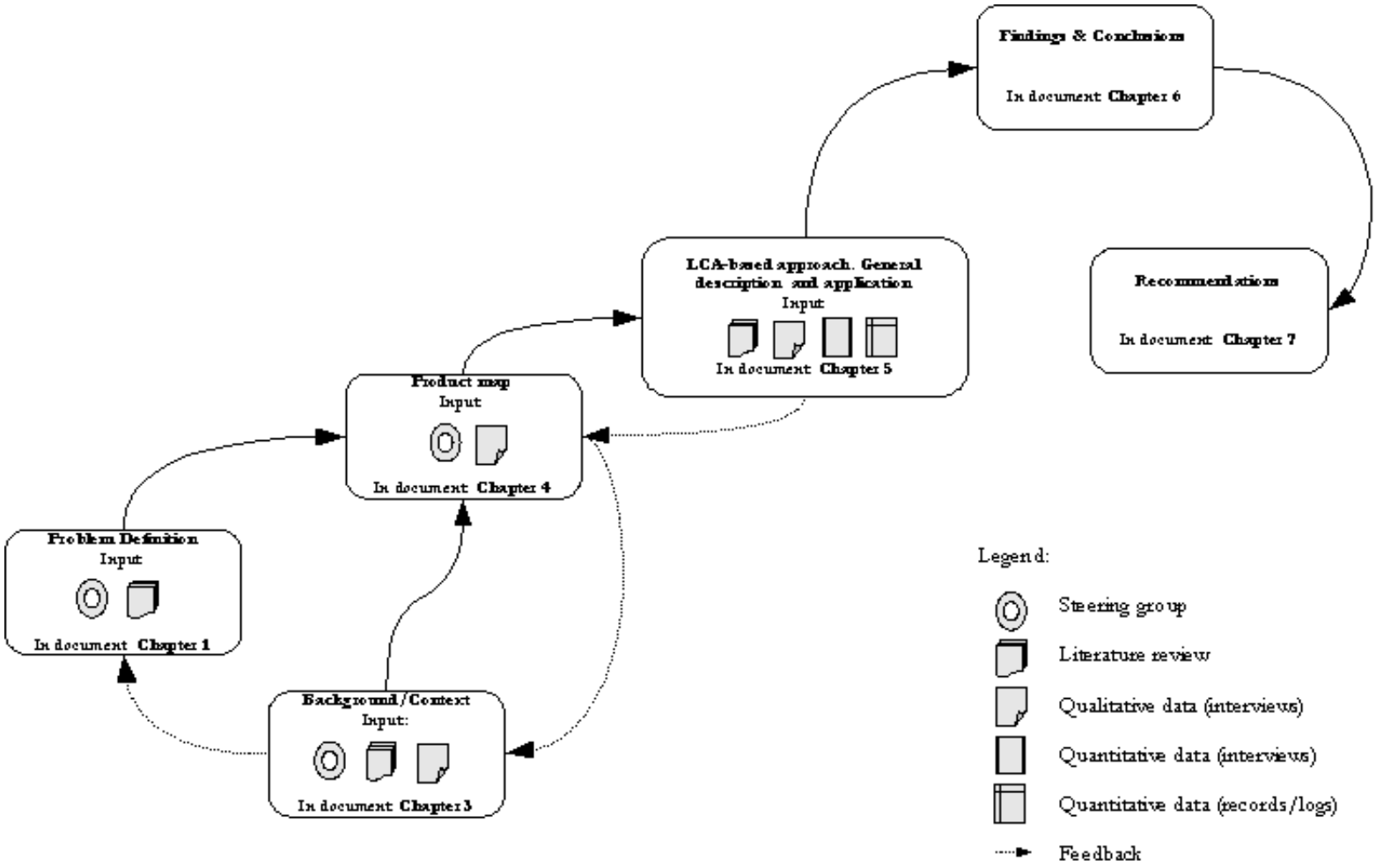

Figure 2-1Research Action Plan & Document Outline

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3 Renal function, renal failure and treatment options

The section begins with a general introduction to renal function, renal failure, its consequences and treatment options. This is followed by a more detailed description of Peritoneal Dialysis (PD), one of the currently available treatment options for this condition, as well as some of the systems and products that deliver it.

Although the purpose of this section is not to provide and exhaustive treatment of the mechanisms and processes that take place in our kidneys, the information presented herein to describe their function will hopefully provide sufficient context as to their importance as a part of a bigger system. Likewise, a description of the ways this sub-system may fail and the therapy options that have been developed to provide a functional substitute are meant to give the context required to understand the connection of this topic to environmental performance through the lens of life cycle thinking and environmental management (chapters 5 and 6).

The descriptions mentioned above provide the basic reasons for conducting this exercise in the context of environmental performance and life cycle thinking. An introduction to these two concepts will also be provided. In a similar manner, the problem definition, purpose and limitations are also addressed in this section.

3.1 Renal function basics

One of the functions commonly associated with kidneys is that of waste removal. In general terms, kidneys are the organs in charge of removing waste products from our blood streams producing urine as the vehicle for their final disposal.

Their function, humble in appearance when compared to other, more illustrious components of the human anatomy is nevertheless considered as one of the key developments that allowed our distant ancestors to take the jump out of our planet's oceans to thrive in dry environments where the extremely risky proposition of an ever changing environment was minimised by the ability to maintain their internal environment in a more or less constant state[15].

A big part of the ability to regulate our internal environment is the domain of the kidneys' filtering functions. Plasma (blood *sans* its suspended elements) is continuously processed in complex substructures called nephrones, microscopic repeating units into which the kidney is divided. (see Fig. 3-1 for an illustration of the working principles of these substructures[16]). These structures and their corresponding components are in charge of the constant filtering and absorption steps that allow our bodies to clean our blood streams while retaining useful substances thus helping to maintain a stable internal state. Under normal conditions, the kidneys of an average healthy adult will filter the equivalent of up to 150[17] litres of fluid each day to produce about 1.5 litres of urine[18,19].

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[15] Sullivan, Lawrence P. (2002).

[16] A human kidney is essentially a collection of about one to one and a half million nephrons. Although not clearly visible in Fig. 1, blood vessels surround the whole structure (dashed line) and water and solutes move back and forth through the nephron's wall. In other words, nephrons operate in a way similar to that a shell and tube, concurrent heat exchanger would do, except that "mass" is exchanged instead. One of the core drivers for the mass transfer that takes place is the difference in tonicity of the plasma-blood solution in both structures. Hypertonic conditions outside of the nephrons at number 3 (a region permeable to water but semi-impermeable to salts) result in water moving out of the nephron and into the blood vessel. Likewise, hypotonic conditions in the area marked as 4 (impermeable to water but permeable to salts) result in the movement of solutes (e.g., sodium) from nephron in the same direction.

[17] This number corresponds to all the absorption and reabsorbtion 'loops' required to clean the bloodstream of an average adult.

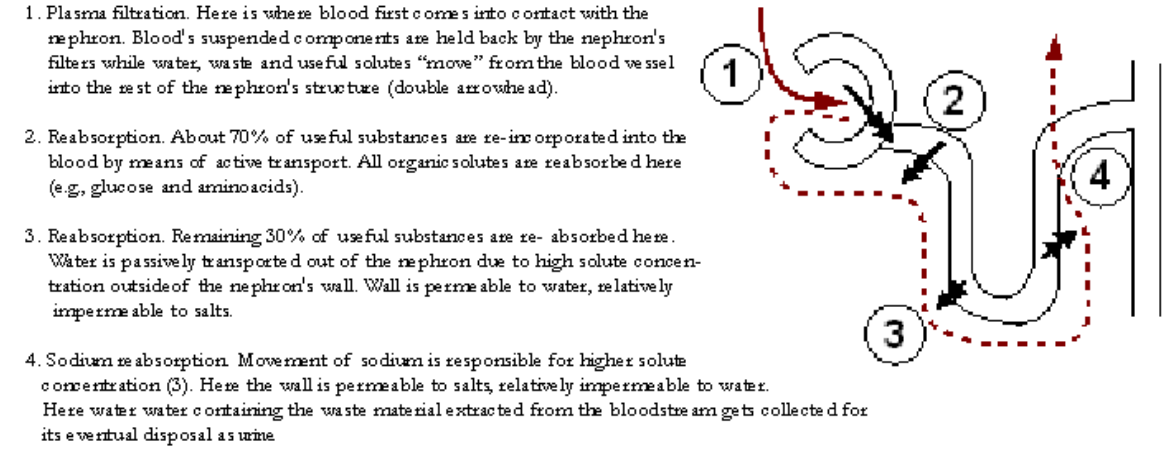

Figure 3-2: Filtration in the kidney's nephrons.

In addition to the intricate hydraulic arrangements that make it possible for kidneys to clean our blood, they are also responsible for regulating blood pressure by producing an enzyme that is part of a complex system (see Fig 3-2.) involving both liver an lungs. The end result is the production of another enzyme that cause salt and water retention in the kidneys, thus increasing blood pressure[20].

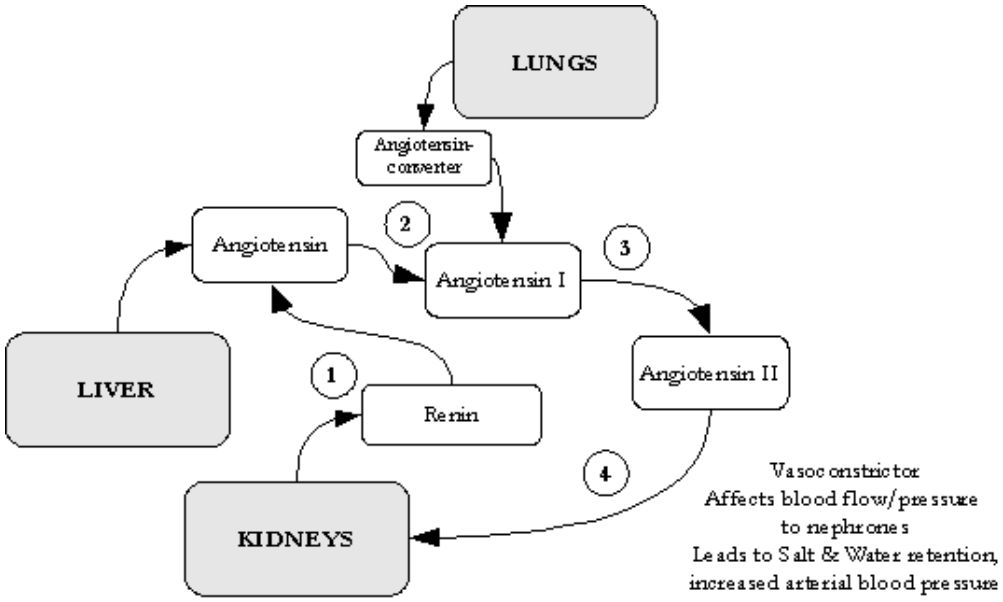

Figure 3-3: Blood pressure control in the kidneys.

The kidneys are also part of another complex system that regulates calcium levels in our bodies resulting in bone mineralisation. In another instance of systematic cooperation, a

[18] Ginsburg, J.M., Borke, J. L. (1999). Essentials of Human Physiology. Ch. 7. Renal Physiology. Ed. By Thomas M. Nosek. Available online: http://www.lib.mcg.edu/edu/eshuphysio/program/default.htm [August 25, 2008]

[19] A comprehensive, yet easy to understand walkthrough of kidney's filtering function can be found at http://pcwww.liv.ac.uk/~petesmif/petesmif/why%20do%20we%20need%20kidneys/index.htm#3

[20] National Library of Medicine. 2008. The Renin-Angiotensin System. Available online: http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi?mode=&term=Renin-Angiotensin+System [2008, August 10]

precursor of Vitamin D is modified in the skin by exposure to sunlight. The resulting molecule is then further modified in the liver. The kidney then makes the final modification and produces the active form of Vitamin D. This final step is also applicable to Vitamin D ingested as part of our diets as it also requires modification by the kidneys to become active. A Vitamin D deficiency results in bone deformities commonly known as *rickets*. While adequate exposure to sunlight and a balanced diet are enough to prevent the condition this is dependent on the kidneys condition as they are ultimately in control of the production of the vitamin's active form[21].

Finally, the kidneys are also major contributors in the oxygen transport system in our bodies This is accomplished by the production of erythropoietin (EPO), a hormone that stimulates the red blood cell production in our bone marrow[22]. Whenever low levels of oxygen are detected in the kidneys, they release EPO which is a detonator for the conversion of 'multi-purpose' stem cells that are located in bone cavities. Contact with EPO results in these stem cells developing into red blood cells[23].

This last feature has received some attention in media and sports circles in the past 30 years due to the practice of some athletes of using a synthetic form of EPO to stimulate red blood cell production thus enhancing oxygen transport potential and consequently improving their endurance. EPO was banned by the International Olympic Committee in the early 1990s and the first comprehensive detection test was introduced in the 2000 Summer Olympic Games in Sidney, Australia[24].

3.2 Renal failure: Description and relevance

Renal failure is said to occur when the kidneys lose their ability to perform their natural functions. This means the kidneys may no longer be able to filter waste products out of the blood stream, to keep the appropriate levels of electrolytes in our bodies, to control blood pressure and to stimulate production of red blood cells as needed[25]

Renal failure is classified into two categories: Acute Renal Failure (ARF) and Chronic Kidney Disease (CKD). Both types of failure represent a loss of renal function and vary in how quickly this function is lost. CKD involves reduced renal function during a time period of three months or longer while ARF stands for a rapid loss occurring in an interval of days or weeks[26].

In general terms, AKF develops when blood flow to the kidneys is abnormal. This may come as a result of blood loss, severe dehydration or obstructions in the renal artery or vein.

[21] Bowen, R.A., et al. (2006). Patophysiology of the endocrine system. Available online: http://www.vivo.colostate.edu/hbooks/pathphys/endocrine/otherendo/vitamind.html [August 05, 2008]

[22] Medicinenet (a2008). Erythropoeitin (EPO) and EPO test. Available online: http://www.medicinenet.com/erythropoietin/article.htm [July 25, 2008]

http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/B/Blood.html#formation][September 10, 2008]

[23] A number of triggers such as EPO are responsible for the creation of white cells (part of the immune system and platelets (partly responsible for blood coagulation).

[24] World Anti-doping Agency (2008). Available online: http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=527 [June 15, 2008]

[25] Medicinenet (b2008) Kidney Failure. Available at http://www.medicinenet.com/kidney_failure/article.htm [May 04, 2008]

[26] U.S. National Kidney Fundation (2008). How your kidneys work. Available online: http://www.kidney.org/kidneydisease/howkidneyswrk.cfm#what [May 15, 2008].

Another cause of AKF is direct injury to the kidneys. Examples are damage caused by inflammation in the event of severe infection[27], intake of medications that are toxic to the kidneys, overload of the kidney's filtering capacity as a result of crushing injuries that breakdown muscle tissue[28]. Finally, obstructions that alter urine flow downstream from the kidneys may also result in renal failure as pressure increases while the kidneys continue their filtering function until they eventually shut down. Kidney stones, tumors and prosthate cancer are amongst the responsible causal agents of these obstructions[29].

Even though CKD is also triggered by abnormal blood flow, in this case this is most commonly caused by poorly treated pre-existing conditions such as diabetes, chronic high blood pressure, or chronic gromerulonephritis –an inflammation of the kidney's filtering subsystems (illustrated in Fig. 3.1).

According to the International Society of Nephrology[30] and the International Federation of Kidney Foundations[31] through their joint project "World Kidney Day", about 500 million individuals world-wide are affected with some form of renal failure. In Europe, the number of cases is estimated to be around 4.5 million. Furthermore, mortality rates amongst those suffering renal failure is estimated to be around 20%[32]. Other estimations have placed the incidence of CKD in Taiwan at around 12% of the country's population whereas that of Australia, Japan and Europe ranges from 6 to 11%[33].

Loss of renal function in individuals suffering from CKD can reach a point where renal replacement therapy is required (see the following section for a description of therapy options). This is referred to as end stage renal disease (ESRD). Estimates for developed countries show that the number of ESRD cases is expected to increase at an annual rate of around 5 to 8%. The estimates for developing countries anticipate the number of ESRD cases to triple from 99 million in 2005 to around 286 million in 2025[34].

In monetary terms, around USD 28 billion[35] are devoted to ESRD to cover about 26 million cases in the U.S.[36] while in Europe this condition takes up to 2% of the health care budget for the 4.5 million currently receiving treatment.

It is important to note that some studies have provided indication that not all CKD cases will necessarily reach a stage where renal replacement therapy is required1. In Europe for example, only around 1% of individuals with CKD will see a loss of renal function that requires replacement therapy.

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[27] Only in the case of sepsis, a general infection that causes an overreaction of the immune system that is ultimately responsible for inflammation and shut down of the kidneys.

[28] In this instance, the products of muscle fiber breakdown are carried in the bloodstream and may eventually 'clog' the kidney's filtering system.

[29] See 14.

[30] http://www.nature.com/isn/index.html [June 20, 2008]

[31] http://www.ifkf.net/ [June 20, 2008]

[32] European Renal Genome Project (2008). Available at: http://www.euregene.org/euregene/pages/public_science_info_e.htm [June 20, 2008]

[33] El Nahas A.M., Bello A.K. (2005). Chronic kidney disease: the global challenge. *Lancet*. 9456 Vol. 365, 331-240

[34] Ibid

[35] Ibid

[36] National Kidney Foundation (2008).Available online: http://www.kidney.org/kidneydisease/ckd/index.cfm [June 20, 2008).

3.3 Treatment options

Regardless of the nature of the condition, i.e., AKF or CKD, part of the treatment consists of renal function replacement, either by undergoing kidney transplantation or by means of a procedure known as dialysis. Two types of dialysis are available: hemodialysis (HD) – in which the blood of the patient is pumped through an external filtering media and returned to the body; and peritoneal dialysis (PD) in which a solution of minerals and glucose is instilled into the peritoneal cavity through a catheter in in order to use the patient's peritoneal membrane as the filtering media. This membrane replaces the filtering function illustrated in Fig. 3-1.

Hemodialysis as a renal replacement therapy begun development in the late nineteenth century but it would take almost fifty years to see the first recorded recovery of a patient suffering from ARF in 1943. In a similar way, the principles behind peritoneal dialysis were first observed in the late eighteenth century but reliable therapy methods would have to wait until the mid twentieth century when catheters had been developed to prevent infection and to reduce the need of repeated incisions each time the treatment was required[37].

Hemodialysis is most commonly carried out at health centres (although recent developments have made possible to receive treatment at home) that have the required equipment and usually takes place in single 4 to 6 hour sessions, three times per week.

Peritoneal dialysis requires a surgical procedure to insert a catheter through which a glucose solution is pumped into the patient's abdominal cavity. Once the procedure is completed, equipment requirements are considerably lower than hemodialysis and the treatment can be conducted at home.

3.4 Hemodialysis & peritoneal dialysis

Although the use of peritoneal dialysis as a treatment is considerably smaller when compared to hemodialysis (see section 3.4) , a trend has been observed for a slow but sustained switch from hemodialysis to peritoneal dialysis as a first treatment option[38].

There are two main reasons for this shift. The first is that continuous use of hemodialysis can have a significant negative impact on patients' vascular access (the connection point into the circulatory system used to perform hemodialysis, similar in principle, to the catheter used in peritoneal dialysis) during the course of the treatment that leads to a reduction in the effectiveness of hemodialysis as a renal replacement therapy. Additionally, hemodialysis has been observed to cause a reduction in the production of urine (urine is still produced in patients suffering from loss of renal function) which in turn has been observed to negatively affect patients quality of life and survival rates[39].

Loss of vascular access may be caused by complications such as inflammation of the access point, infiltration and reduced flow amongst others. Complications associated with vascular access have been estimated to account for up to 20% of hospital admissions among patients with advanced degrees of chronic kidney malfunction.

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[37] Fresenius (2008). History of Peritoneal Dialysis. Available online: http://www.fmc-ag.com/internet/fmc/fmcag/neu/fmcpub.nsf/Content/Dialysis_Compact_2005_0 [June 15, 2008]

[38] Personal communication. Lena Krutzen. Head nurse, dialysis unit at Universitetssjukhuset i Lund

[39] US National Kidney Foundation (2006). Clinical Practice Guidelines and Clinical Practice Recommendations. Hemodialysis adequacy, peritoneal dialysis adequacy, vascular access. Available online: http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm [August 25, 2008]

To understand the cause for the loss of urine production due to hemodialysis it is important to remember that blood filtration, and therefore urine production is dependent of blood pressure levels (as illustrated in fig. 3-1). In simple terms, when undergoing hemodialysis, large volumes of blood are removed from the body, creating a pressure drop that eventually reduces the amount of urine produced.

3.5 Peritoneal Dialysis

There are two different treatment options within PD: Continuous Ambulatory Peritoneal Dialysis (CAPD) in which short dialysis sessions (each lasting 4 to 5 hours) are conducted 4 times per day (see Fig. 3.3) and Automated Peritoneal Dialysis (APD) in which a machine, commonly known as a dialyser, that automatically pumps the dialysis fluid in and out while the patient sleeps.

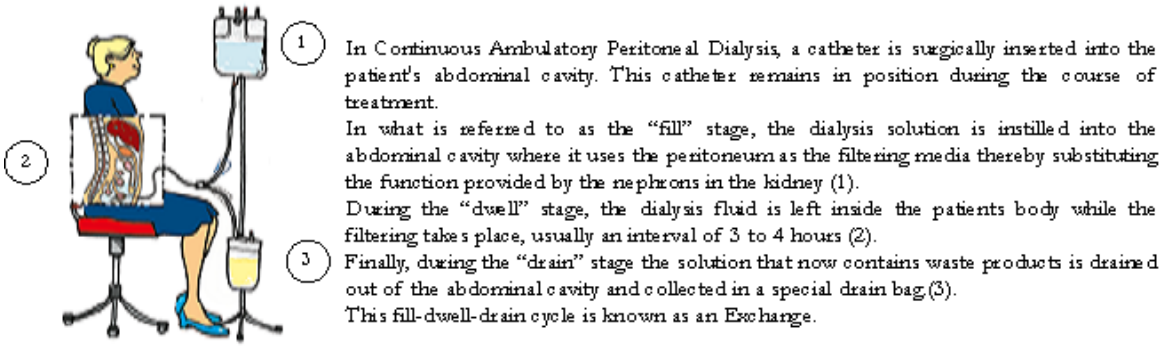

Figure 3-4: Continuous Ambulatory Peritoneal Dialysis (CAPD) basics.

Patients using PD as a renal function replacement therapy require a number of items as part of the treatment. These items are:

- Dialysis fluid
- Catheter
- Connecting lines (fluid bag to catheter and catheter to drain bag)Drain bag
- Disposable aseptic towels
- Catheter adapter
- Dialyser (for Automated Peritoneal Dialysis only).

As can be seen from the list above, due to the relative simplicity of the PD technique, material requirements are limited, a fact that greatly facilitates the ability of patients to conduct their treatment on their own. Furthermore, dialysis fluids have been developed to reduce discomfort during the dwell phase so that patients are able to continue their daily routines as close to normal as possible[40].

While the catheter is a very important component of PD treatment (enabling a permanent connection for the fluid exchange process, thus reducing stress by repeated incisions to the abdominal cavity) the core of the treatment resides in the PD fluid. Table 2 shows the typical

[40] Personal communication. Anders Wieslander. Gambro Lundia AB.

composition of a standard PD fluid unit as well as their function. These PD fluid units or bags hold 2 liters of fluid when used in CAPD (one per exchange) and 5 liters when used in APD (where two bags of 5 L each are used overnight).

Drain bags and connecting lines are supplied to patients along and they hold the dialysis product, known as dialysate. Disposable, aseptic towels are often supplied to patients in order to help with cleaning of the area surrounding the catheter. Hygiene is always stressed as an important factor for the continued performance of PD treatment as lack of proper care may result in infection and complications for the PD patient[41].

Finally, catheter adapters are sometimes supplied so that patients may use PD fluids produced by different manufacturers that posses incompatible connections to the catheter.

Table 1: CAPD main components and their function

Component	Function
Electrolytes (Sodium, Chloride, Calcium and Magnesium).	To create an isotonic (equal concentrations of solutes) environment on both sides of the peritoneum to match those of normal plasma.
Buffers (Lactate).	To regulate acidity in the bloodstream.
Glucose.	Osmotic agent. Regulates diffusion through the peritoneum (higher concentrations stimulate removal of liquids from the body).

Perhaps the most distinctive feature of the dialysis fluid is its glucose concentration. Glucose concentration affects the amount of water that is drained from the body during any given exchange. With greater concentrations of glucose, a higher amount of water is diffused through the peritoneal membrane, leaving the body to be collected in the drain bag. Although concentration options vary depending on the manufacturer of the PD fluid, there are always three of them available to patients. They range from 1.5 to 5% with the medium concentration around 2.3%

Each PD patient is assessed by their physician and prescribed the concentration that better suits their treatment needs. For example, if a patient has been retaining liquids as a consequence of either illness or the treatment itself, a higher concentration will be preferred in order to stimulate diffusion of water through the peritoneum and eventually into the drain bag[42].

PD fluids are commercially available in one of three presentations, either as single, double or triple concentration bags. Single concentration designs are bags with 2 liters of fluid in either low, medium of high glucose concentration.

Double concentration bags keep glucose at low pH (glucose naturally degrades at close to neutral pH) in one compartment while the second compartment rises the fluid's pH

[41] Personal communication. Lena Krutzen. Dialysis Unit. Universitetssjukhuset i Lund.

[42] Ibidem.

immediately before infusion into the peritoneum. A line takes fluid from each of the two pouches and takes it to a valve with preset positions that is intended to simplify the dialysis procedure by removing clamps and pins as is the case in the three-in-one design.

Finally, three-in-one designs consist of a three compartment bag that delivers any of the three glucose concentrations depending on the number of compartments used. Two compartments contain concentrated glucose at low pH. By breaking the pins in one or both of these compartments the bag reaches either of the three glucose concentrations required. (see fig. 3-4 for an illustration of each of these designs).

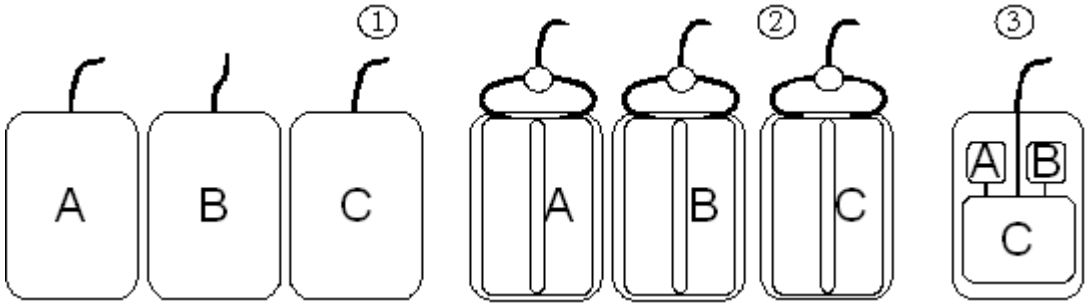

Figure 3-5: Schematic of commercially available PD fluids packaging design

3.6 Gambro AB

Gambro AB is an international company headquartered in Lund, Sweden with market presence in 40 countries. The company is specialised in medical technology, developing and delivering products, therapies and services for hemodialysis, peritoneal dialysis, renal intensive care, hepatic care and water purification.

Up until 2006, the entity known today as Gambro AB was part of a publicly traded company that had three main business areas: Gambro Renal Products (GRP), Gambro Healthcare and Blood Component Technology (BCT). In July 2006, Gambro was acquired by Investor AB[43], an industrial holding group based in Sweden. Gambro was subsequently removed from the Stockholm Stock Exchange and divested itself of Gambro Healthcare and BCT.

According to the last full Annual Report published by Gambro in 2005[44] before the change of ownership that occurred the following year, the total renal products market was estimated to be worth USD 8.5 billion, out of which Gambro had a share of 17%. The two other main players were U.S. Based Baxter and Fresenius Medical Care with 23 and 29% market share respectively.

With regards to hemodialysis, the total market was estimated to be worth around USD 6 billion out of which Gambro had the second largest market share (20%), behind Fresenius Medical Care (34%) and well ahead of Baxter (7%) with the remaining 39% distributed among other players.

In the peritoneal dialysis category, the total market was estimated to be worth USD 2.25 billion or just over 26% of the total renal market. Of this, Gambro held a share of 2% with Baxter well ahead (69%) and Fresenius trailing behind (19%). In 2008, the market share of

[43] www.investorab.com

[44] Gambro (2005). Annual Report. Available online: http://www.gambro.com/annualreport2007.htm [August 20, 2008].

Gambro in the peritoneal dialysis sector is estimated to be around 30% in the Nordic countries with no data available for the total market[45].

The company is currently using a certified environmental management system based on ISO 14001 for its routine operations. At the time of writing restructuring was taking place with the addition of a new environmental manager to coordinate environmental affairs.The facilities in Sweden are all ISO 14001 certified but the extent of certification world-wide was not available. It was indicated that at least all manufacturing facilities in Europe have received certification. Furthermore, as part of the work in the Research and Development and Design Validation department a new project was been started to explore the potential of integratation of ISO-1400 EMS criteria into project development operations protocols[46].

3.7 Gambrosol Trio

Gambrosol Trio is one of the PD fluids currently manufactured by Gambro AB and available in the European and Asian markets. A distinctive feature of this product is the three-compartment design that allows a patient to receive any of the three standard concentrations of glucose in the dialysis fluid. The packaging design of Gambrosol Trio (see fig. 3-5) allows the patient to configure the use of the product for one of three concentrations in a single pack: using only large compartment "C" the user receives a solution of glucose 1.5%. By combining "B" and "C" (by breaking a seal connecting them, see orange tips in fig.1) the user receives a solution of glucose 2.5%. By combining all three compartments, the user receives a solution of glucose 3.9%.

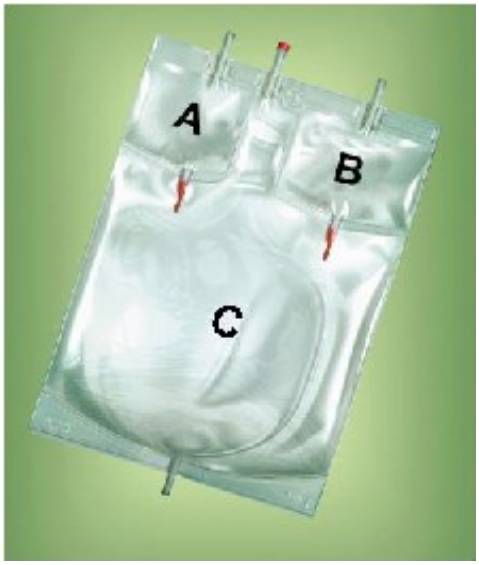

Figure 3-6: Three-in-one bag design of Gambrosol Trio

Conventional PD fluids are produced in single concentration bags while some manufacturers have opted for dual concentration designs. Fig. 3-6 shows the two-in-one design currently used by Fresenius Medical Care and Gambro's Gambrosol 10L.

[45] Personal communication. Malin Isacsson. PD Sales Manager, Gambro AB.

[46] Personal communication. Barbara Musi. Senior Scientist, Research and Development and Design Validation, Gambro AB.

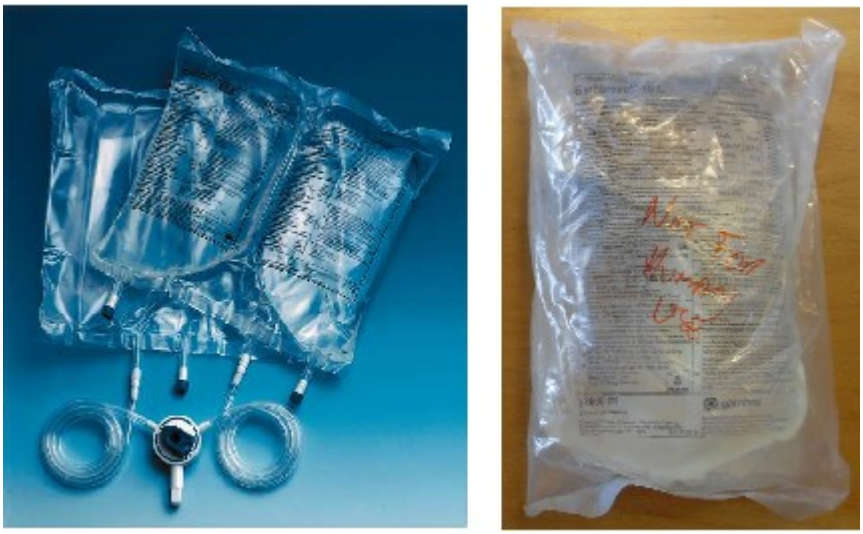

Figure 3-7: Dual and single concentration PD fluid bags
Sources: Fresenius Medical Care (2008), Gambro AB (2008).

Gambrosol Trio's three-in-one design was developed to address a problem with PD fluids first identified by researchers at Gambro's cell toxicology laboratory in Lund, Sweden. In a series of studies that date back to the early 1990s[47], it was discovered that PD fluids had a toxic effect on cultured cells. The research led to the identification of so-called *Glucose Degradation Products (GDPs)*, a group of highly reactive aldehyde compounds that are formed when glucose is exposed to high temperatures, especially during sterilisation but also during storage if temperatures reach 25°C. The same research identified GDP formation increasing in strong relation to higher temperatures with two-fold increases at 40°C and three-fold at 60°C.

The chemicals collectively known as GDPs include fructose, acetaldehyde, formaldehyde, methylglycoxal, glyoxal, 3-Deoxyglucosone (3-DG) and 3,4-dideoxyglucosone-3-ene (3,4-DGE). Of these, 3-4 DGE has been identifiedas one of the most biologically active[48] compounds in PD fluids exposed to high temperatures as mentioned in the paragraph above.

GDPs are a cause of concern in PD therapy because these molecules have been observed, both in in-vitro and in-vivo studies, to contribute to the deterioration of the peritoneal membrane in patients undergoing CAPD treatment[49]. Some of the effects of GDPs have been observed to manifest as inflow pain and reduced filtration rates in patients exposed to these chemicals[50].

In general terms, GDPs are present in all PD fluids as a consequence of high temperature sterilisation but the effects of temperature during transportation and storage can be controlled by maintaining glucose in a concentrated form (in compartments A and B in the case of Gambrosol Trio) at low pH levels (~3.1) and low temperatures (~20°C) right until the

[47] Gambro (c2008). Glucose Degradation Products (GDPs). An underestimated factor in peritoneal dialysis. Available online: http://www.gambro.com/int/Treatment-offerings/Peritoneal-Dialysis/Products/Peritoneal-Dialysis-Fluids/ [June 10, 2008]

[48] Musi B. (2003). Biocompatibility of Peritoneal Dialysis Fluids: Impact of glucose degradation products, pH and buffer choice on peritoneal transport and morphology in the rat. Doctoral Dissertation. p. 17. Faculty of Medicine, Lund University.

[49] Idem.

[50] Jorrës A. (2003). Glucose Degradation Products in Peritoneal Dialysis: from bench to bedside. Available online: http://content.karger.com/ProdukteDB/produkte.asp?Doi=70993 [September 10, 2008].

moment where it needs to be used when pH reaches less acidic levels (~6.6) by the combination of any two concentration compartments and temperature is increased by heating up the bag until it approaches normal body temperature (~35°C)[51].

While Gambrosol Trio's design ensures that the fluid is not negatively affected by exposure to high temperatures during storage, this is not applicable to conventional designs. Especially those with single concentration bags. Although Gambro has phased out conventional PD bags in the Nordic countries, they are still commercially available in the European and Asian market in addition to those offered by other manufacturers.[52] A study conducted in 2003 discovered some peaks in temperature (~35°C) at different stages during the transportation chain of Gambro's conventional PD fluids at the time[53]. This is an indication of the risk of GDPs occurring in single and double concentration PD fluid design, dependent on the amount of temperature control exerted by each manufacturer along the distribution chain.

[51] Personal communication. Anders Wieslander. Gambro AB.

[52] Personal communication. Malin Isacsson. PD Sales Manager. Gambro AB.

[53] Nilsson L., Wallergård M. (2004) Distribution of Dialysis Fluid. Department of Design Sciences. Lund University.

4 Product system map

The main sources of input used in mapping Gambrosol Trio as part of a product system were the interviews with the members of the thesis steering group and with health professionals in direct contact with dialysis patients (dialysis unit at Universitetssjukhuset i Lund) and those in charge of supplying them with the items required for PD treatment (pharmacists working within the same health centres and delivery company in Lund and Malmö).

See fig. 4-1 for an overview of the processes involved in the production, use and disposal of Gambrosol Trio. The numbers in brackets in correspond to the locations where each process takes place as presented in fig. 4-2 (manufacturing and distribution) and 4-3 (delivery and disposal).

Several assumptions have been made due to the sensitivity nature of information connected to the location and logistics involved with Gambro's supply chain. While these do not correspond to the actual location of suppliers in the manufacturing chain, they are required for the continuation of the exercise. A decision was made to place all suppliers in Europe as it was assumed better quality control would be possible within the Euro-zone compared to overseas suppliers. The results would naturally be significantly impacted if components are brought from outside Europe particularly in the case of transport by air. The assumptions are as follows:

- Glucose anhydrous manufactured in Sas-van-Gent, the Netherlands. This reflects the presence of a large glucose producer. Formerly known as Cerestar Pharma, the company was bought by the US food group Cargill in 2002. Of the many Cerestar-Cargill plants in Europe, Sas-van-Gent was identified as one of the main starch and glucose production points and was therefore selected for this exercise[54].

- PVC bag and Polypropylene components are manufactured in Meyzieu, southern France. Meyzieu hosts one of Gambro's facilities in France. Although this facility not responsible for the manufacturing of the bags themselves there were indications that Gambro's main supplier is located in southern France[55].

- Buffer, electrolytes, HCl are manufactured in Sondalo, northern Italy. Similar to PVC and PP components, the actual supplier was not available. Since none of the chemicals used in the solution are specialty substances it was deemed sufficient to use the location of one of Gambro's facilities as a place holder for this instance.

- Packaging (cardboard) is manufactured in Ovaro, northeast Italy. This refelcts the location of one of Italy's largest cardboard producers located in relative close proximity to Gambrosol Trio assembly point in Canosa Sannita, Italy.

As shown in fig. 4-1, each of the process steps has accompanying inputs in the form of energy and material consumption (electricity and fuel use, materials for maintenance office operations). Likewise, each step produces outputs in the form of waste streams (air pollution, waste water and solid waste).

To illustrate the previous point, we may consider that in general, glucose production requires starch and the enzyme glucoamylase as the raw materials. Furthermore, the process is conducted in batches at around 85ºC with durations of up to 72 hours. After a filtration

[54] http://www.foodnavigator.com/Financial-Industry/Cargill-VP-explains-reasons-behind-Cerestar-purchase
http://www.neth-water.nl/cms/page4.asp?active_page_id=112

[55] Personal communication. Theodor Sandström. Director of R&D. Materials and Chemistry Development. Gambro AB.

stepis used to remove impurities created during enzymatic conversion, evaporation is used to concentrate the resulting glucose in order to ship it in solid form[56]. Waste streams include waste water from filtration, condensates and cleaning operations; solid waste from filtration and cleaning operations; air emissions as an indirect stream associated to the source of energy used throughout the production process.

Although a detailed description of all unit operations in each of Gambrosol Trio's process stages is out of the scope of this thesis, their environmental impacts are addressed in a simplified form in chapter 5 as part of this exercise.

For a detailed breakdown of the components in one unit of Gambrosol Trio please see section 4.1.

[56] London South Bank University (2008). Production of glucose syrup. Available online: http://www.lsbu.ac.uk/biology/enztech/glucose.html [September 05, 2008]

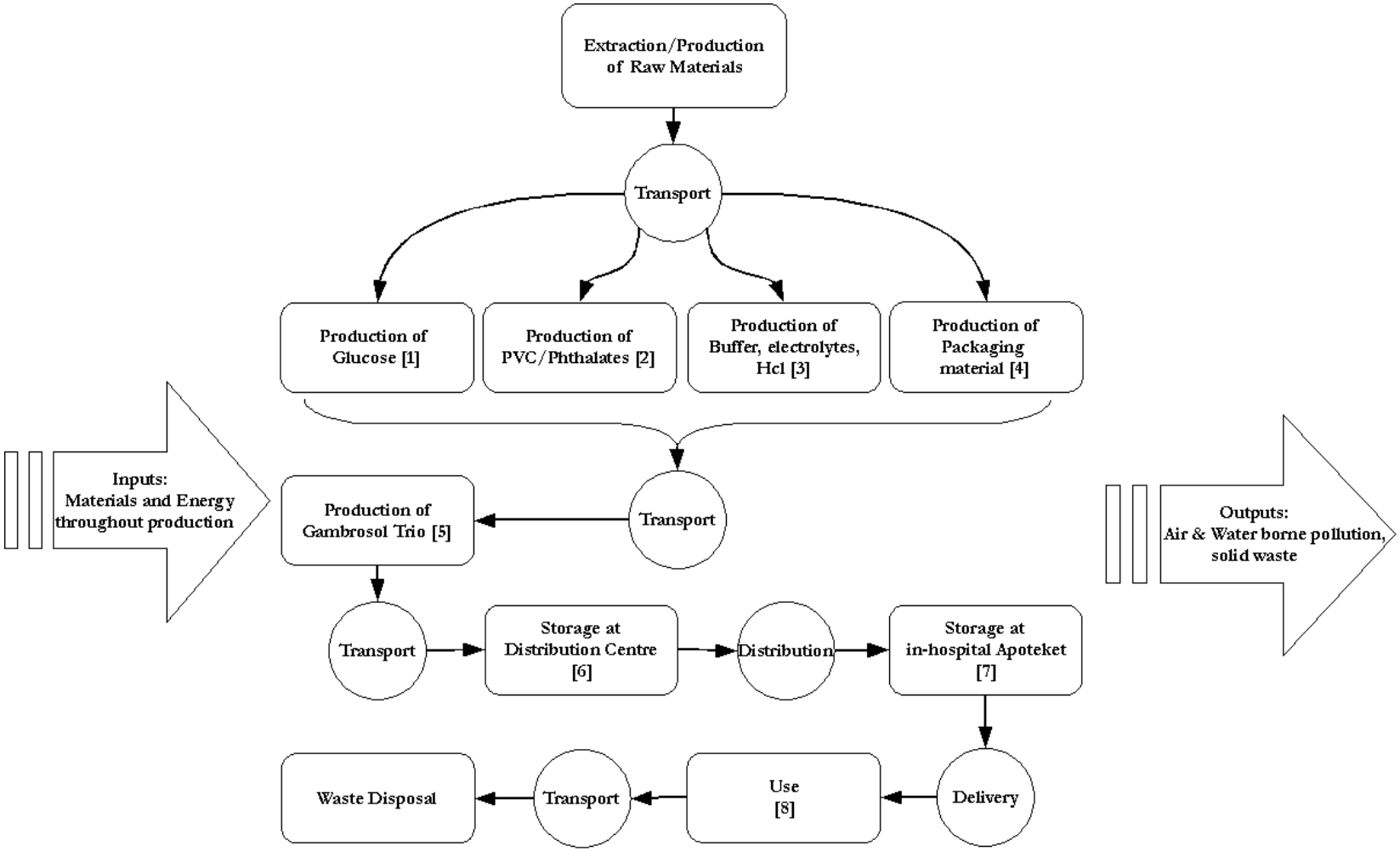

Figure 4-8: Gambrosol Trio System Map

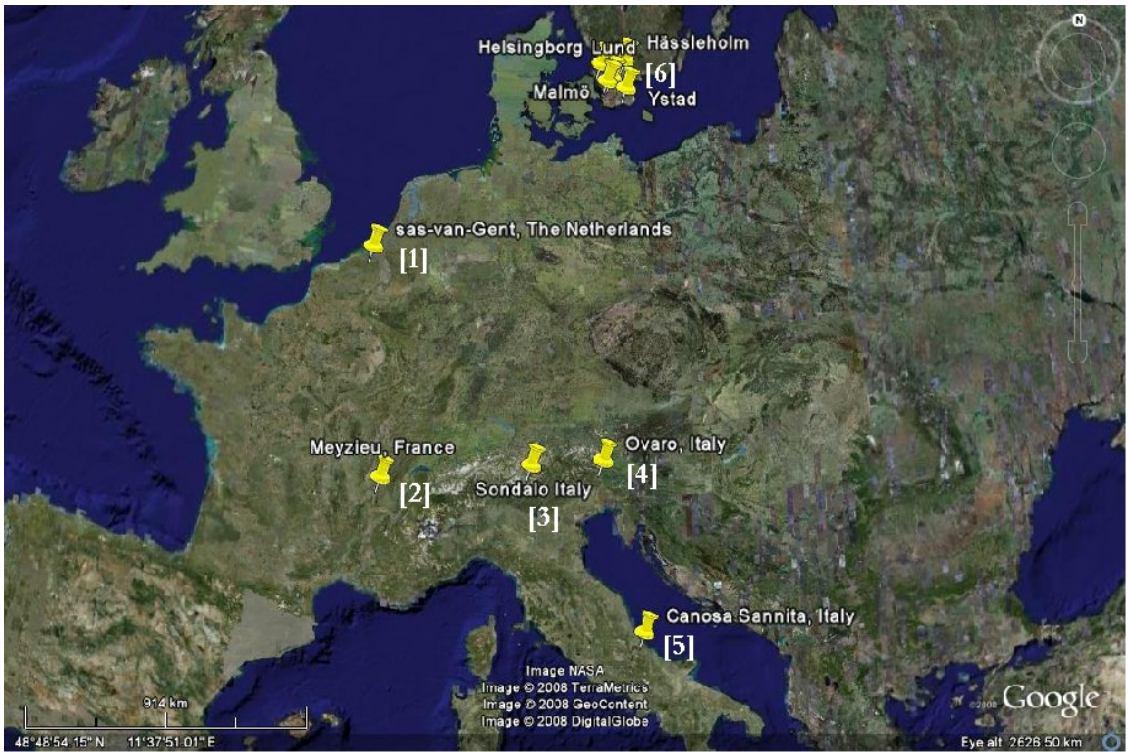

Figure 4-9: Gambrosol Trio system map.
[Glucose production: the Netherlands, PVC & PP production: France. Packaging production: Italy. Product Assembly: Italy. Distribution: Lund, Sweden. Consumption: Lund, Malmö, Ystad, Helsingborg, Hässleholm, Sweden] Source: Google Earth 2008.

4.1 Product components

Table 4-1 shows the components of one unit of Gambrosol Trio, the quantities used and their distances to production point in Italy and to distribution in Lund, Sweden. Distances between all the process sites were estimated based on land routes using a mapping and route planner freely available online[57].

Table 2: List of Gambrosol Trio components with distances to production facility and to Gambro Distribution Centre.

Component Name [Origin]	Function	Qt. [Kg]	Approx. Distance to Assembly [Km]	Approx. Distance to Distribution [Km)]
Gambrosol Trio 40 [Canosa Sannita, Italy]	Packaged Fluid for Continuous Ambulatory Peritoneal Dialysis.	2.49	NA	**2079**

57 Www.googleearth.com

Component Name [Origin]	Function	Qt. [Kg]	Approx. Distance to Assembly [Km]	Approx. Distance to Distribution [Km)]
Plastic PVC-Phthalate bag (inc. cover bag)	Fluid Packaging	0.300	1013	NA
Polypropylene (PP) pins and caps	Breakable connecting pins between glucose compartments & Connection line caps.	3 x 0.000106 2 x 0.000996 1 x 0.001098 0.0022+		
PVC-Phthalate connecting lines	Connection between fluid bag and catheter and catheter and drain bag.	0.049++		
Polypropylene clamps	To secure bag and connecting lines during dialysis.	2 x 0.005 Kg 0.01+++		
Glucose	Osmotic agent (affects fluid removal during dialysis).	0.07800*	1596	NA
Sodium Lactate	Buffer	0.00472	735	NA
Sodium Chloride	Electrolyte	0.01614		
Calcium Chloride	Electrolyte	0.000209		
Magnesium Chloride	Electrolyte	0.000054		
Hydrochloric Acid	pH	0.044403 **		
Cardboard	Trio Packaging (1 box per 4 units of Trio)	0.14***	654	NA
Water	Dialysis Vehicle	2.00	NA	NA

+Based on rough estimates of volume of each piece and HDPE density of 0.96 g/cm3. ++ Based on rough estimate of volume of a 200 cm long PVC tube int Ø = 0.3mm and PVC density of 1.15 g/cm3. +++ Estimate based on size comparison versus breaking pins and line caps. *Equal to 3.9% w/w glucose concentration. ** Difference of Unit – Solution weight, exc. Hcl (2.350 – 3.394403 Kg) Although a rough approximation, it is considered sufficient in the absence of the exact concentration and amount of HCl required for pH at time of use. *** Assuming density of 900 g/m2 and box of 0.5x0.3x0.12m, 4 units packaged per box.

4.2 Product Manufacturing

As shown in figs. 4-2, production of Gambrosol Trio takes place at Biosol S.p.A., one of Gambro suppliers, located in Canosa Sannita, Italy. Biosol receives the rest of the PD fluid components sent from suppliers (chemicals, packaging and tubing/clamps/caps) that then proceed to an assembly line dedicated to mixing, filling and packaging the finished product.

From Biosol-Canosa, the finished product is sent by truck to Gambro's Distribution Centre (DC) for Europe, located in Lund, Sweden. This journey covers an approximate 1925 Km including a 154 Km section by ferry from Rostock, Germany to Trelleborg, Sweden(see fig. 4-3).

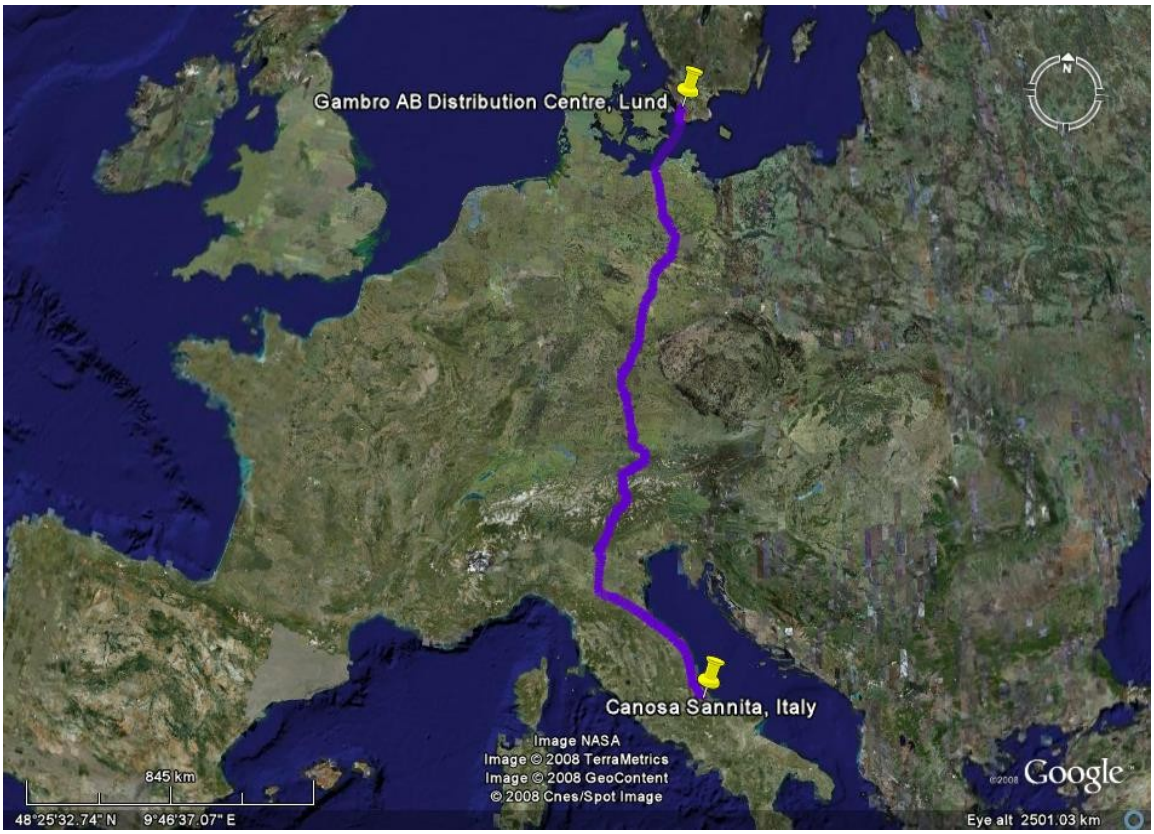

Figure 4-10: From Manufacturing to Distribution Centre.
Source: Google Earth (2008).

4.3 Distribution

Gambro's distribution centre in Lund controls shipments to the European market and therefore, only a fraction of the shipments managed at this DC are destined to the Swedish market. In the case of Sweden, Gambrosol Trio is sold and shipped to state-owned Apoteket AB thus ending Gambro AB's traditional product chain from the point of view of commercial operations.

Apoteket AB is the entity exclusively responsible for the commercialisation of pharmaceuticals. In 2007, Apoteket reported net sales of approximately USD 6 billion, with operating earnings close to USD 89 million and earnings after taxes of close to USD 65 million (Apoteket, 2008)[58].

Apoteket delivers peritoneal dialysis products to patients within the Swedish health care system. Due to the nature of renal disease, patients usually post orders to Apoteket either by telephone or email. In major Swedish urban centres, Apoteket maintains a dedicated store within city hospitals in addition to the regular stores that are available to the general public. It is in these hospital-pharmacies that PD fluids are stored prior to delivery to PD patients.

[58] Apoteket AB (2008). Annual Report 2007. Available online: http://www2.apoteket.se/Apoteket/om/Hem/default.htm [September 01, 2008]

Five of these specialised Apoteket stores cover the needs of PD patients in Region Skåne (southern Sweden). They are located inside hospitals (like Lund and Malmö University Hospitals) or in smaller health clinics where equipment and medical staff necessary for dialysis treatment are available. The location of the cities that host these stores are shown in figure 4-3 and their distances from Gambro's Distribution Centre are shown in table 4-2.

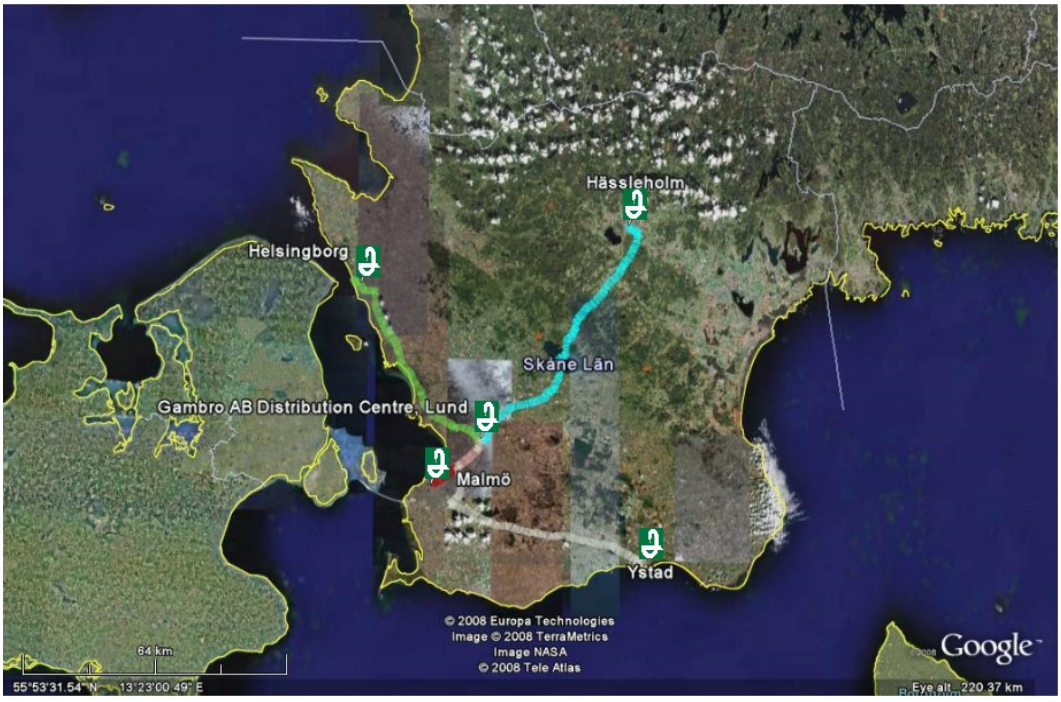

Figure 4-11: Location of Apoteket stores that deliver PD products to patients in Skåne, Sweden. Source: Google Earth (2008).

Table 3: Location of in-hospital Apoteket stores and distance to Gambro's Distribution Centre in Lund

Location	Distance to Gambro Distribution Center
Hässleholm	~73 Km
Helsingborg	~56 Km
Malmö	~17 Km
Lund	~3 Km
Ystad	~71 Km

Of these five locations, those in Lund and Malmö were approached via interviews with pharmacists in an attempt to establish the number of patients currently under PD treatment and those using Gambrosol Trio as well as those using similar products. Requests for information (see appendix A) were made to the in-hospital Apotek stores in both cases in order to establish the figures stated above as well as wastage rates (due to returns and/or losses during routine handling) and safety inventory levels.

Of these figures, ***wastage rate was of particular importance*** *due to the suspected occurrence of patients changing their glucose concentration prescription while still having a stock of PD fluids in their houses*[59]*. In this case, that stock will usually not be used and must be discarded.*

The financial implications in terms of direct cost incurred by Apoteket stores when fluids are returned and have to be destroyed as well as the environmental impacts associated to wasted production were the reason why the scrapping rate at Apoteket was investigated.

Unfortunately, due to confidentiality limitations, not all of these figures were available. Table 4-3 summarises the data that was made available for this study.

CAPD patients in Sweden receive treatment at very low cost. They are required to pay a fee by the Swedish health care system of SEK 1,800 per year that covers the supply of PD fluids, accessories and medication that may be required. The cost of one box of CAPD fluids, required for one day of treatment is estimated to be around SEK 800[60]

Patients usually place orders to cover their needs for one to two weeks worth of dialysis fluid. This is due to the space they have available at home to store the product.

Table 4: Summary of data available from Apoteket stores in Malmö and Lund

Health Center	Number of CAPD Patients	Patients using Gambrosol Trio+	Number of PD bags sold to patients per producer	Wastage rate (returns, in-house/delivery losses)	Safety Inventory
Malmö	~45	~ 60%	NA (confidentiality)	NA (not tracked)	Minimum 1 week
Lund	42	~75%	NA (confidentiality)	NA (not tracked)	Minimum 1 week

4.4 Product Delivery

As for the final stage in the transportation of PD fluids, Gambro's Forwarding Agency (Cullins Transporter AB) in Malmö was contacted to observe the delivery system that takes the product from the Apoteket to the patients. This Agency delivers all PD products and medication to the Apoteket customers.

Although the delivery service is independent from Gambro (it bills Region Skåne through Apoteket) it is coordinated from there and as such, all trips begin in Gambro AB's facilities in Lund, from there, the delivery truck goes to the in-hospital Apoteket in Malmö, it is loaded with the day's worth of PD products and medication and proceeds to deliver house by house.

On the return trip the delivery truck also collects cardboard boxes, empty bags and full drain bags for those patients with limited access to waste collection (either because waste separation is not implemented in their housing units or because of their physical condition prevents them from doing it themselves) and returns the waste to Gambro in Lund where it is aggregated to the facilities' similar waste production and eventually disposed of in bulk.

A 7.5 Ton diesel truck (see fig. 4-4) is used for deliveries and the delivery routes are optimised to some extent based on proximity of the patient's location and the estimated time that it

[59] This was corroborated during interviews with all external contacts. See Chapter 2 for the full list of interviewees.

[60] Personal communication. Malin Isacsson. PD Sales Manager. Gambro AB.

takes for one person to load, unload and deliver the fluids to the patient's storage. Delivery trips are made 4 times per week with six to 12 patients attended per day.

Figure 4-12: 7.5 Ton diesel truck used for delivery of PD fluids in Malmö.

Truck load is variable on the orders placed for any given day and can range from an estimated 5% up to around 60% by volume (see fig 4-6 for observed final load). Table 4-4 summarises the observations made during one delivery trip to patients in and around Malmö.

Figure 4-13: Truck load to supply 8 PD patients in Malmö.
(Approx. 30% load by weight and 20% by volume)

Table 5: Observations regarding product delivery.

Type of Vehicle used for delivery	7.5 ton Diesel truck
Type of fuel	
Number of delivery trips	4 per week
Number of patients per trip	6 to 12

Type of Vehicle used for delivery	7.5 ton Diesel truck
Truck load (by weight)	25 to 50%* (1044 Kg to 2088 Kg for 6 to 12 patients per trip, respectively).
Distance traveled	99 Km-patient / year**

*Based on 4.1 maximum load as per manufacturer specifications. **Estimate based on total mileage observed on board, for the period August 2006 – August 2007.

4.5 Use and disposal

In the case of patients in Malmö, patients can dispose of used dialysis and full drain bags as municipal waste by themselves. Full drain bags are emptied into the toilet and then both bags and other plastic components are placed into municipal waste bins. Separation of cardboard for recycling is dependent on cardboard bins close to their homes and this varies throughout the city. The option is provided by Gambro to take all waste materials back to one of its hemodialysis manufacturing units in Lund where it is incorporated into the site's waste stream. The alternatives for final disposal of bags and other plastic items are incineration or landfilling.

5 Life Cycle Assessment-based approach: Why, how and how far?

This chapter makes use of the contextual information presented in chapter 3, the insight gained by the information presented in chapter 4 and a brief revision of Life Cycle Assessment as a viable tool that can answer the research questions stated in chapter 1. The chapter begins by looking at the context and product map to provide justification for the suitability of this approach, then describes the method itself, its components, advantages and disadvantages and explores how it can be adapted in order to further explore the environmental performance of Gambro AB' dialysis product, given the resources and time constraints inherent to this thesis.

5.1 Why? A holistic approach

Although at first glance Gambro AB and their activities as a producer in the medical sector may be explained in the context of traditional business models like the one illustrated in fig. 5-1, the reality is that the interactions of Gambro with both society and the environment go beyond acquisition of raw materials from suppliers and distribution of their products to their customers.

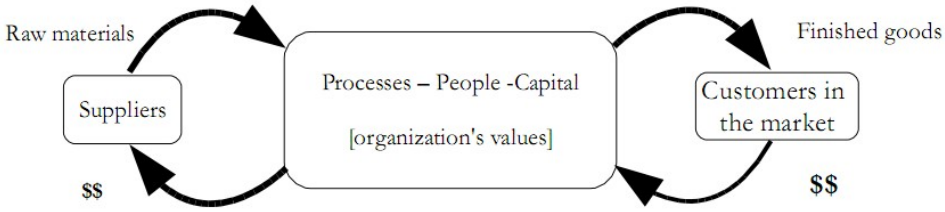

Figure 5-14: Traditional Business Model.
Source: Adapted from Anderson (1998)

A more holistic approach is required to visualise the number and nature of the actual interactions of an organisation like Gambro. The interface model proposed by Anderson (1998) is a good first step in this process. It shows how any organisation is linked to society and the environment in more ways than simple raw material acquisition and delivery of finished goods. It punctuates how producers, through the use that their customers make of products, are also linked to environmental impacts due to disposal, use of alternative energy sources and technological improvements that may reduce material intensity, thus increasing their organisation's overall environmental performance. Fig 5-2 summarises the expanded version of this interface model.

The relevant components of the expanded model as pertains to this study are the inclusion of indirect "customers" in Gambro's business model. That is, Gambro's products in general, and Gambrosol Trio in particular, do not end their relationship with the company as a producer at the time they are sold to the Apoteket which act as their direct customer, that is, the one engaged in the direct physical and monetary transaction.

The above is exemplified by the fact that due to Gambrosol Trio's three-in-one design (technological innovation) users that for whatever reason must change their fluid's glucose concentration while still having a stock of conventional fluids will not require additional fluids delivered to cover their new needs and will therefore not scrap their existing, now unusable fluid stock thus reducing the amount of "wasted" product and with that the amount of materials that must be discharged as waste water (the fluid itself), landfilled and/or incinerated

(packaging material and the bag itself), avoid unnecessary raw material extraction and use as well as the impacts associated to the manufacturing of chemicals and assembly of the fluids themselves (see dashed lines in fig. 5-2).

Another important aspect of the model is the pressure exerted on the company's action by the stakeholders within the community, exemplified in this case by the recent and constant efforts of several pressure groups to phase-out the use of PVC and some of its associated materials in products like Gambrosol Trio that are used in the medical sector[61].

All of the effects mentioned above are in this case driven by a technological innovation that did not have as its main goal the improvement of the product's environmental performance. However, by illustrating the indirect effects of the science and technology behind the product's design this thesis seeks to bring attention to the potential of using similar development processes to actively seek environmental improvements whenever possible.

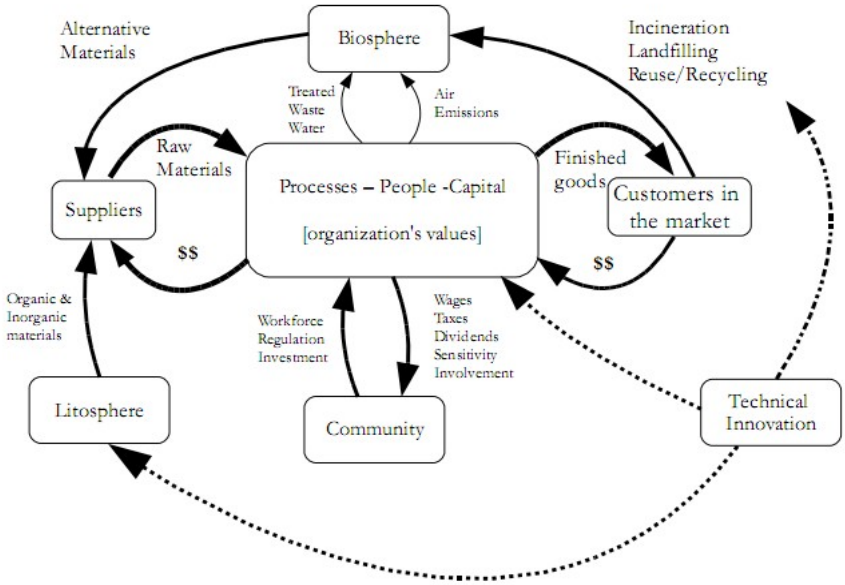

Figure 5-15: Expanded Interface business model.
Source: Adapted from Anderson (1998).

As can be inferred from fig. 5-3, the actual environmental behaviour of Gambrosol Trio depends on the actions not just of the company itself but of all of its suppliers upstream in the manufacturing chain as well as that of end-users beyond the company's direct customers.

The visualisation of an expanded business cycle serves as an adequate first step in addressing a product's environmental performance. However, in order to provide with more objective and goal oriented assessments, it is necessary to attempt a quantification of this performance all along the business cycle.

This quantitative "cradle-to-grave" approach is one of the basic tenets of Life Cycle Assessment and is covered in the next section.

[61] USFDA (2002). See footnote 1.

HCWH (2008). See footnote 4

Medical Device Link (2006). See footnote 8.

5.2 How?[62]

5.2.1 Life Cycle Thinking

Life cycle thinking is conceptual framework that takes on ideas and process visualisation similar to those presented using the interface model in the preceding section. It is one of the frameworks that were developed as a consequence of heightened environmental awareness which in turn, spurred the creation and use of concepts like sustainable development and the triple bottom line during the late 1990s and the early 2000s.

The concepts like sustainable development and the triple bottom line stress the importance of the interactions between Social, Economic and Environmental factors in the global production and consumption systems of today. Life cycle management is a particular type of business strategy that takes into account these concepts, combined with others like Corporate Social Responsibility in order to develop a cohesive and systematic way to achieve sustainability in the industrial sector and to communicate it to the relevant stakeholders. By doing so, competitive advantage may be established by the inclusion of environmental concerns that drive eco-innovation and eco-design.

The central concept behind life cycle thinking is the reduction of resource use and pollution throughout the life cycle stages of a given product. However, product design is another crucial component that is meant to increase the extent to which a product can be reused, recycled or repaired.

The framework acknowledges the fact that environmental impacts must begin to be quantified, assessed and addressed as far back in the manufacturing chain as possible. Likewise, impacts must be tracked during the use and disposal phases that are part of a product's lifetime. In order to do so, it makes use of specific tools, one of which is what is known as Life Cycle Assessment.

5.2.2 Life Cycle Assessment

The are several definitions of what LCA is and all reflect on the original one that was developed by the International Standards Organisation in 1997 that classifies LCA as a "tool that allows to assess the potential environmental impacts from a product or system from raw material extraction to final disposal" (ISO, 1997 in Kørnøv et al. Eds., 2007).

The process of conducting an LCA can be summarised by the following steps (illustrated in fig. 5-3a and 5-4):

- Definition of Goal and Scope.
- Inventory Assessment.
- Life Cycle Impact Assessment (LCIA).

[62] This section is based on the work presented in the following sources and draws extensively from them unless otherwise noted:

Baumann, H. Tillman, A. (2004). The Hitchhikers Guide to LCA. An orientation in life cycle assessment methodology and application. Ch. 1, 2. Studentlitteratur, Sweden.

--- (2007). Tools for Sustainable Development. Eds., Kørnøv L., Thrane M., Remmen A., Lund H. Ch. 11, 12. Aalborg Universitetsforlag.

USEPA (2006). Life Cycle Assessment: principles and practice [online]. Available at: http://www.epa.gov/NRMRL/lcaccess/pdfs/600r06060.pdf[2008, August 10]

- Interpretation.

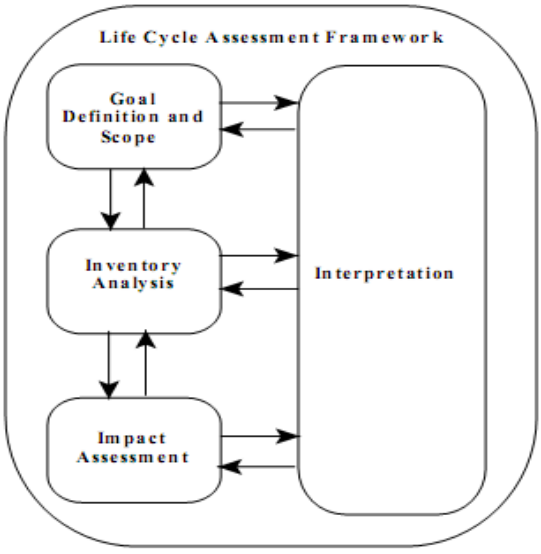

Figure 5-16: LCA stages.
Source: USEPA (2006)

When defining the goal and scope of any given LCA several key factors must be clearly addressed. For example, the purpose of the study may vary from the need to document processes and material and energy flows within the organisation or it may be part of a systematic marketing strategy focused on environmental concerns expressed by consumers. It is important to clearly define the target audience in order to provide adequate context and to prevent misuse of the results by non-intended audiences.

The scope of the study is related to the determination of what is known as functional unit. The functional unit is a quantitative expression of the function a given product offers to the user. As such, it should accurately describe the function of the product, the duration of the provided function and qualitative aspects of the product. The "number of coffee servings during a 10 day conference" would describe the function of ceramic and paper coffee cups during a well defined time horizon. Using servings instead of litres served reflects the fact that coffee does not only function as a stimulant but also as an element of social interaction.

It's important to keep in mind that the question is how do the two products compare when their whole life cycle is taken into account. It might be the case that the water used during washing of ceramic cups represents considerably smaller impacts than the use of natural resources (paper production) and waste disposal (collection, recycling, land filling or incineration) involved in the production of paper cups when both products are analysed identically from cradle to grave.

In this logic, the definition of a product's functional unit in LCA is very important because it leads to a reference flow. The reference flow is the basis for the calculations done in later stages of the method. Using the example above, by using ceramic cups it would stand to reason that a certain amount of water would be consumed during the conference for washing whereas paper cups would only involve water consumption during their manufacture. The reference flow will indicate that, among many others, "x" tons of raw materials, "y" tons of water and "z" MW of electricity are required for the manufacture of the required number of paper cups. Different amounts will correspond to ceramic cups but their use at the conference will also involve the consumption of a given amount of water for cleaning and they will only require a fraction of resources when it comes to disposal.

Another crucial part of this stage is the definition of system boundaries, that is, what will be the geographical (based on where the market for the product is), systematic (what processes and sub processes will be included) and temporal (validity of the study based on the status of technology and production practices and techniques) limits.

The goal and scope will also determine the nature of the study itself. It may mean that a single product is being internally assessed by an organisation or that a comparison will be made with competing products that have similar functions and are available in the market. Single-product LCA allows for a first screening of life-cycle stages of importance and can facilitate the selection of for example, alternative materials, suppliers or manufacturing lines.

The inventory analysis stage consists of the description of processes and collection of quantitative and qualitative data on the inputs and outputs throughout the products life cycle (see fig 5-3). This means inputs and outputs must be defined for raw materials, energy carriers, the product itself and solid waste and water and air emissions. An important consideration during this stage is that of allocation. Allocation occurs when a component used in the product's life cycle is also used in different production systems. An example is in shared transportation of bulky materials. If two or more different materials are transported in the same truck, the air pollution emitted will be distributed among the transported materials as it is volume that determines truck loading. This guarantees that the material of interest will only be assigned its relative emissions and not those of other materials that share the transport trip.

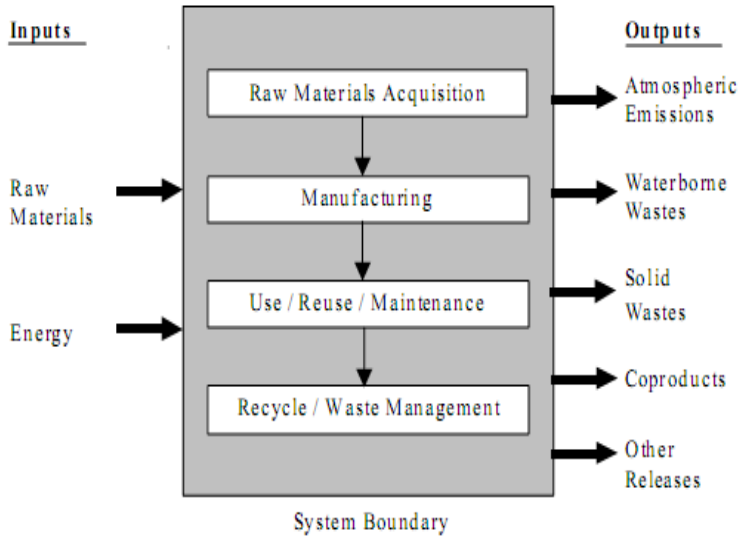

Figure 5-17: LCA fundamental components: Boundaries, Processes, Input and outputs.
Source: USEPA (2006)

Stage 3 or LCIA uses the inventory developed in the preceding stage in order to assess potential environmental impacts. Causal links have been established between inputs and outputs (e.g., emitted CO_2 and NO_2 due to fuel combustion, discharged P04) and effects such as global warming, eutrophication or acidification. All the inputs and outputs are categorised and aggregated based on their causal relation to specific environmental impacts as mentioned above. In this way, the total emissions of global warming agents are expressed as a single figure like number of Kg CO_2 equivalents or SO_2 equivalents in the case of acidification.

Optional steps in the LCIA stage are normalisation and weighting. Normalisation refers to the expression of figures such as Kg. CO_2 equivalents in terms of something that the audience can more easily relate to. For example, the annual contribution to global warming of an average individual can be used as a reference. In this way, "x" product can be said to contribute to this average individual's global warming effect by 0.5%. This is easier for the audience to understand than telling it that the product has a total effect equal to the emission of "x" number of Kg. CO_2 equivalents.

Weighting is a way to assign priorities to the different environmental impacts associated with a product's life cycle by means of weighting factors. Weighting may be made based on regulatory targets (such as governmental imposed emission reductions of SO_2) or on the levels of available non-renewable resources. Monetary weighting, based on willingness to pay can also be used. Finally, groups of experts can be approached in what is known as panel weighting to discuss and reach consensus on the priority of the impact categories (e.g., the effects of acidification may be deemed more important that global warming in a sensitive or relatively isolated marine micro-region).

Finally, during the interpretation stage, key inventory and impact assessment results are presented in order to identify the salient environmental issues concerning the product under study. A case must be made for the sensitivity (how the results are affected by variations in the inventory for example), completeness (whether all available information has been included or not) and consistency (if the methods used throughout the study follow a coherent and logical pattern) of the LCA as a whole. In the case of recommendations, perhaps the most crucial consideration is to explicitly address the assumptions that form the basis for any recommendations as per the results of the Assessment.

5.2.3 How far? Screening LCA as a compromise

The execution of a full Life Cycle Assessment would involve the development of a full inventory database for all the process stages involved in the manufacturing, distribution, use and disposal of Gambrosol Trio as presented in chapter 4, followed by a full impact assessment of all identified input and output streams. Impacts would then be grouped into categories and a final score would have to be assigned to the product as a whole based on the selected weighting criteria. The same procedure would then have to be followed for a similar product delivering the same function in order to be able to assess Trio's performance against a benchmark. An endeavor of this magnitude is out of scope for this thesis so a compromise was sought that would be able to make use of the general method as developed for LCA but that could be limited and usable to pursue further insight into the product's environmental performance.

Shortly after the formalisation of LCA as a tool for decision making, analysts discovered the risk associated with attempting to use unreasonable amounts and quality levels of data in their assessment as an over-extended attempt can hinder the decision making process itself, both due to the time it takes to complete it and the amount of financial resources required. As a result, may options have been explored to simplify its application to reasonable levels. Still within the scope of the original method, analysts have often tried to simplify, or 'streamline' the method by reducing the amount and difficulty involved in data collection by reduction of boundaries, using qualitative and quantitative data, limiting impact categories and impact assessment (Curren, 1996).

The two basic alternatives to full-scale life cycle Assessment are known as conceptual and screening LCA. Conceptual LCA is a strictly qualitative approach and as such can only be

considered during the very early stages of any serious evaluation effort. It requires basic knowledge of the product system and its interactions with the environment.

Screening LCA is based on the traditional LCA method but it allows for simplification beyond streamlining as described above by allowing qualitative or surrogate data (e.g., estimates and equivalent data available in databases) or by focusing only on one or a few data and impact categories (e.g., screening only for energy use and addressing global warming).

It is important to note that, according to International Standard that sets the guidelines for LCA, neither conceptual nor screening LCAs should be considered equal to full LCA in terms of their implementation and results. Instead, they are approaches that use and adapt LCA-based technique.

The main criteria encountered in the literature (Thrane, Schmidt in Thrane et al. 2007) that relates to the use of either conceptual, screening or full approaches basically revolves around the purpose behind the use of LCA technique itself.

When the purpose is to evaluate environmental policies at company-wide levels or to develop new guidelines for product developments then the full approach is suggested as the results of the exercise may have a long-term impact not only on the organisation itself but potentially on the whole production-consumption system as well. The same holds true when the results of the assessment will be communicated to stakeholders outside of the organisation's direct area of influence since this requires a greater level of attention to accuracy, comprehensiveness and transparency.

If the purpose is internal identification of areas of concern in terms of environmental impacts (i.e, stages along the product chain where impacts might be critical) or as a documented response to stakeholder pressure then a combination of streamlined LCA and conceptual or screening LCA might be used instead.

As part of this thesis, the screening LCA approach was selected based on the following reasons:

- The purpose is to gain further insight into whether or not the product's packaging design, developed exclusively to increase its functional performance, could also result in better environmental performance when compared to similar products.

- Gambro is now facing increasing pressure from stakeholders when it comes to the use of PVC and phthalates in their products. Although there is no conclusive evidence of the negative effects of either chemical on human health it has been identified as a potentially toxic compound for other species[63].

- Although the health care sector has experienced some success in phasing out PVC from certain products, alternative materials are not yet available at an equal cost when it comes to peritoneal dialysis bags. Thus a decision to switch to a different material can not be based on costing alone[64].

- Although the organisation has an environmental management system based on the ISO-14001 standard for their day to day operations, for part of the organisation (represented by the steering group as defined in chapter 2) is actively seeking for

[63] See chapter 1

[64] Ibid

alternatives to extend their environmental efforts beyond their traditional EMS. As such, the purpose of this exercise is to use a screening approach as an introduction to the full LCA approach.

5.2.4 Applied Screening LCA for Gambrosol Trio

This section is based on the core components of the full LCA approach as presented in section 5.3 and it includes the limitations that were encountered for each of them.

Goals.

The goals of this exercise reflect the purpose of the thesis as a whole as described both in chapter 1 and in the preceding section as part of LCA methodology. They are:

- To gain further insight into the environmental performance of a three compartment glucose PDF (Trio).
- To explore the implications of 3-in-1 design in the distribution and use phase of the product.
- To introduce/reinforce knowledge and approaches based on LCA thinking within the organisation.

Functional unit and reference flow

The functional unit is important whenever quantitative insight is to be pursued as it forms the basis for calculations involving input and output inventories.

The first step to define the functional unit of Gambrosol Trio is to consider its function. This is important due to the importance that is placed in the product's packaging design as the source of potential environmental benefits.

Strictly speaking, a CAPD patient is only interested in the fluid contained in the package as a means to substitute renal function. In that sense, they are buying the fluid not the bag itself. Thus, the function of the product can be summarised as follows:

"To substitute a patient's renal function by means of a peritoneum-based fluid exchange-"

The product's bag comes into play when referring to the quality of the provided function. As was described in chapter 3, Gambrosol Trio reduces the amount of Glucose Degradation Products present in the dialysis fluid and there are indications that this can lead to preserving the peritoneum for longer periods when compared with fluids that contain higher concentrations of GDPs.

The duration of PD as a treatment option depends on many variables. The extent of renal failure, infection, associated illnesses, transplant availability and death can all influence the duration of treatment. Although there have been cases of patients being on CAPD for over 5 years[65], some studies have shown that there is a marked increase in risk of death after the second year of CAPD therapy[66]. No definitive data on treatment duration was found for

[65] Personal communication. Lena Krutzen. Dialysis Unit. Universitetssjukhuset i Lund

[66] http://www.medscape.com/viewarticle/538757

CAPD but 2 years was considered as a reasonable approximation based on the information available and the estimates provided by the steering group.

As for qualitative aspects, a patient's choice of Gambrosol Trio over a similar product appears to be related to the ease of use of the product, both for training of medical staff at health centres and for patients at home[67]. This is due to the fact that patients have to "break" one or two of the plastic pins within the bag in order to get the required glucose concentration in every exchange. A competing product uses a different design that is actively marketed as a simpler alternative to Gambrosol Trio[68]. Finally, a degree of hand strength is required to break the pins and elderly patients might encounter difficulties with Trio's design.

Taking into account the factors mentioned above, the proposed functional unit for Gambrosol Trio as a CAPD fluid is:

"Number of PD exchanges during the course of an average PD patient's treatment"

CAPD involves 4 exchanges per day; using 2 years as the duration of an average CAPD patient means 2192 exchanges will be conducted during that period of time. At 2 litres per exchange, that means that 5824 litres of CAPD fluid be required by the average treatment patient. Although the number of litres serves well to represent the reference flow of this product, it was decided to use the number of exchanges instead since all the product components are referred to in terms of a single 2-L bag.

Therefore, for this exercise, the **reference flow is equal to 2192 exchanges using packaged CAPD fluid.**

Boundaries

The first set of boundaries are those that deal with the product system itself. During the initial rounds of discussion with the steering group at Gambro AB it was suggested to focus the work on the distribution stage in the product system with especial regard to transportation during distribution and delivery. However, the author considered it important to touch on the production and manufacturing of components as well, especially because of the attention that is being currently placed on the use of PVC and phthalates (as PVC plasticisers) by different stakeholders in the health care sector (see chapter 1).

The initial focus on distribution and delivery was due to an initial assumption that Apoteket stores would have to have all three concentration solutions (for products other than Trio) available for the total number of CAPD patients in the event of them switching prescription on a contingency basis. If this were the case, it would be reasonable to think that the use of Gambrosol Trio would have significant advantages due to reduced manufacturing, storage, transport and wastage of unused bags. However, during interviews with pharmacists and health care professionals it was observed that this was reckoned to be a limited occurrence.

Changes in glucose concentration appear to be a more or less regulated instance, mediated by continuous monitoring of patients' renal functions and liquid retention. Patients do not necessarily have to have all three concentrations available at home in the sense that a different concentration is not required on a day-to-day basis. This means that patients usually store a single concentration for extended periods of time and only if their concentration needs

http://www.nature.com/ki/journal/v73/n108s/abs/5002606a.html

[67] Personal communication. Malin Isaacson. PD Sales manafer. Gambro AB.

[68] Product information on Fresenius Medical Care's Stay Safe system. Available online: http://www.fmc-ag.com/internet/fmc/fmcag/neu/fmcpub.nsf/Content/Continuous_ambulatory_PD

change they will order new product even if they still have bags with the previously required concentration. In this case bags no longer required are returned to Apoteket where they must be destroyed as it can not re-enter the market once it has been delivered[69].

These observations resulted in the inclusion of component production and manufacturing as illustrated in fig. 4-1.

The next set of boundaries is that related to the geographical delimitation of the study. This set of boundaries is particularly important when conducting full-scale LCA as it is related to the spatial extension of environmental impacts.

In the case of Gambrosol Trio, although manufacturing of components and the product itself is located over many European borders, the geographical focus of the study is on Region Skåne, southern Sweden. The reason for this is two-fold. Gambro is head quartered in Lund, Sweden and a good deal of research, development and takes place at this location. In this sense, the author hopes that the results of efforts within the environmental field such as this study will have a greater chance of disseminating to the rest of the organisation and its manufacturing sites and suppliers. Gambrosol Trio is sold in Europe and Asia under different arrangements depending on the health care system in each country; the inclusion of such a widespread use-phase base was deemed to be out of scope for the purposes of this study.

The last set of boundaries addressed in this thesis is that related to a time-horizon. According to the steering group, production of Gambrosol Trio has not experimented major technological modifications since it was first initiated in the early part of this decade. Likewise, the steady increase in the number of individuals that will require CAPD as a form of renal treatment is not expected to drive major modifications in the system. Pressure to substitute PVC and/or phthalates seems to be the main potential driver for change in the near future. However, change ofmaterials in this regard is not expected to occur at least within the next five years. This period is therefore considered as a reasonable time boundary for this exercise.

Inventory Analysis and Impact assessment

Inventory analysis and impact assessment are based on the components presented in table 4-1. In a strict application of full-scale LCA, every material and energy input and output that would result from the production and transport of each of those items would have to be quantified to create the product's inventory. For example, inputs and outputs associated to the production of vegetable matter as a precursor of glucose production would have to be included and the same would apply to the production of each of the chemicals used in Trio's formulation.

This list of materials (considering energy converted to mass as per the fuel combusted to generate it) would then have to be characterised and aggregated according to a predefined list of environmental impact categories as was described in section 5.2.2

Several methods have been developed to simplify the use of LCA-technique when it comes to impact assessment as the subsequent step after inventory analysis. In general, some of these methods are intended to provide a single score or index that conveys the environmental burden associated to a given process unit. It is important to note that simplicity here means that a considerable number of scores for a variety of processes are currently available and can be applied directly to the input/output inventory. However, each score contains the

[69] Personal communication. Katalin Kiss. Pharmacist, Universitetssjukhuset i Lund in-house Apoteket.

Personal communication. Lena Kempf. Head Pharmacist for dialysis. Universitetssjukhuset i Malmö in-house Apoteket.

evaluation of the environmental impact of each process based on a natural science approach that is complemented by a set of predefined environmental impact categories and impact weighting criteria. Simplification then, in strict terms, comes from the criteria, assumptions and estimated data used by each method to provide each environmental index or score.

One of these methods, "Ecoindicator 99 (Eco99)" was selected for use in this exercise due to the general availability of usable scores for the processes that form part of Gambrosol Trio's product system. Originally commissioned by the Netherland's Ministry of Housing Spatial Planning and the Environment it is one of a series of LCIA methods recommended in the literature for screening LCA (Kørnøv et al, eds. 2007).

This method was developed as a complementary tool in the evaluation of environmentally preferable designs. As such, it can only be used to initiate the exploration of life cycle concerns and considerations and cannot be used as a marketing tool or as a means to prove or disprove claims to the general public. However, the method was developed as a tool to facilitate decision making early on in the design process[70].

Eco99 scores are available for material production, process operations, transportation and disposal. They are built around three impact categories: human health, ecosystem quality and resource depletion. The method originally used a panel approach (a group of 365 LCA practitioners in Switzerland) to assign priorities to the impact categories mentioned above[71].

Throughout the analysis, a higher ecopoint count means higer environmental impacts. The calculations log is included as a spreadsheet file in Appendix 2. The original document used as the basis for the application of this method is included in Appendix 3. Also included is the Methodology Annex of the method that contains all the background information originally used by the developers of Ecoindicator '99 to arrive at the ecoscores per material requirement that were used in this exercise.

Material and transportation requirements

Table 5-1 shows the total amount of materials required to deliver 2192 exchanges during an average CAPD patient's treatment and the distances they are transported as part of the product's system. This material amounts will be the basis for the use of Ecoindicator 99 to generate Eco99 scores for transportation, component manufacturing and processing, manufacturing of the product itself and disposal.

Table 6: Total material requirements per Reference Flow

[70] Ministry of Housing, Spatial Planning and the Environment (2000). Eco-indicator 99 Manual for Designers. A damage oriented method for Life Cycle Impact Assessment. Available online: http://www.pre.nl/eco-indicator99/ei99-reports.htm [September 01, 2008]

[71] Idem.

	Mass requirements KG/unit	Total required per RF [Kg/unit x RF]	Considerations – Transportation	Distances [Km]	Ton * Km
Gambrosol Trio 40 2L PDF bag	2.050000	5969.6000	Italy-Lund-Apoteket-Patients	2321.1	13856.04
Plastic PVC-Phthalate bag (inc. cover bag)	0.300000	873.6000	France-Italy	1013	884.96
PVC-Phthalate connecting lines	0.049000	142.6880	France-Italy	1015	144.83
Polypropylene (PP) pins and caps	0.002200	6.4064	France-Italy	1014	6.5
Polypropylene clamps	0.010000	29.1200	France-Italy	1016	29.59
Glucose	0.078000	227.1360	Netherlands-Italy	1596	362.51
Sodium Lactate	0.004720	13.7446	Italy (Sondalo-Canosa Sannita)	735	10.1
Sodium Chloride	0.016140	46.9997	Italy (Sondalo-Canosa Sannita)	736	34.59
Calcium Chloride	0.000209	0.6086	Italy (Sondalo-Canosa Sannita)	737	0.45
Magnesium Chloride	0.000054	0.1572	Italy (Sondalo-Canosa Sannita)	738	0.12
Hydrochloric Acid	0.044403	129.3015	Italy (Sondalo-Canosa Sannita)	739	95.55
Water	2.000000	5824.0000	NA	0	0
Cardboard	0.140000	407.6800	Italy (Ovaro-Canosa Sannita)	654	266.62

Ecopoints in Gambrosol Trio's life cycle

The following series of tables show the results obtained when applying ecoindicators to the material and transportation requirements in table 5-1. Table 5-2 shows the scores for the production and processing of the product's components. Tables 5-3 and 5-4 show the scores for transportation and disposal, respectively.

Ecoscores are adimensional in principle as they reflect all the considerations for impact assessment that are inherent to the method. However, they were developed in such a way that 1 ecopoint is roughly equivalent to one thousandth of the environmental burden that corresponds to the average European resident[72].

Table 7: Ecopoint score for production and processing of Gambrosol Trio's component

PRODUCTION AND PROCESSING		
Components	**Total requirement [Kg]**	**Ecopoints**
Plastic PVC-Phthalate bag (inc. cover bag)	873.6000	248.1024
PVC-Phthalate connecting lines	142.6880	40.5234
Polypropylene (PP) pins	6.4064	2.2486
Polypropylene clamps	29.1200	10.2211
Glucose	227.1360	22.4865
Sodium Lactate	13.7446	1.3607
Sodium Chloride	46.9997	0.3102
Calcium Chloride	0.6086	0.0323
Magnesium Chloride	0.1572	0.0083
Hydrochloric Acid	129.3015	5.0428
Water	5824.0000	1.5142
Cardboard	407.6800	28.1299
Total	**7701.4421**	**359.98**

[72] Ibid.

It is important to note that although Ecoindicator 99 has values for some of the components (e.g., Sodium Chloride and Chlorhydric Acid) others are absent and reasonable subsititute ecoindicators had to be used. For example, there is no indicator for the production of glucose and the entry for "organic chemicals, average" was used instead.

This is particularly important in the case of water processing. Gambrosol Trio as well as other dialysis fluids must use water of a high purity level, assumed to be achieved by ultrafiltration. Ecoindicator 99 has indicators for production of decarbonised and demineralised water. The latter with a score higher by one order of magnitude. The score for demineralised water was used after raising it one order of magnitude further. This attempts to reflect and include the use of ultrafiltration in the case of the finished product.

Likewise, there is no score that can be used for operations similar to those that take place at Gambro's facility in Canosa Sannita (Italy) where all the components are mixed, filled in to the dialysis bags and packaged for distribution. In this case a simplification was made by attempting to estimate an energy consumption rate to represent these operations. To do this, energy consumption values for packaged milk production were used in order to reflect similar quality and hygiene requirements. A value of 1.66 MJ / Kg of packaged Gambrosol Trio was used[73].

As for disposal, an assumption was made that all the waste enters the municipal waste stream except for cardboard which can be recycled. Plastic items were assigned a 50-50% destination in either landfills or incineration. Negative values in this instance correspond to the avoidance of manufacturing of new products due to recycling and electricity or thermal power generated due to incineration. Furthermore, it was assumed that 90% of the solid waste stream ends up in incinerators and only 10% goes to landfills.

Table 8: Ecopoint score for transportation, distribution and delivery of Gambrosol Trio

Transport of components to Trio Manufacturing (using 40 ton truck)	**Ton*Km**		**Ecopoints**
Plastics (PVC & PP)	1065.87		15.99
Glucose	362.51		5.44
Electrolytes, Buffer and Hcl	407.77		6.12
Cardboard	266.62		4
Semi-total	2102.77		**31.54**
Transport of Gambrosol Trio to Distribution Centre (W/16 ton truck)	**Km**	**Ton*Km**	
Manufacturing to Distribution (land)	1925	13173.16	197.6
Manufacturing to Distribution (sea)	154	1053.85	5.37
Semi-total	2079		**202.97**
Transport of Gambrosol Trio to Patients			
Distribution to Apoteket	44.1	301.79	10.26
Apoteket to Patients	198	172.97	5.88
Semi-total	4400.1		16.14
TOTAL			**250.66**

[73] Foster, C., Green, K., Bleda, M. Dewick, P., Evans, B., Flynn A., Mylan, J. (2006). Environmental Impacts of Food Production and Consumption: A report to the Department for Environment, Food and Rural Affairs. Manchester Business School. Defra, London. Available online: *www.defra.gov.uk/science/Project_Data/DocumentLibrary/EV02007/EV02007_4601_FRP.pdf* [September 10, 2008]

Table 9: Ecopoint score for waste disposal.

	Waste produced [Kg]	Ecopoints [50% incineration, 50% landfilling, 100% cardboard recycling]
PVC Items (bag and lines)	1016.29	20.22
Polypropylene Items (pins, caps and clamps)	35.53	-0.17
Cardboard	407.68	-3.38
Total	1459.49	**16.67**

Figure 5-5 shows the ecoscores for Gambrosol Trio from production and processing of its components to the disposal of the waste generated after its use. Fig. 5-6 shows the difference in impacts coming from a theoretical switch from truck-based transport to rail. As per the Ecoindicator '99, this assumes a mix of 80% electrical and 20% diesel-based rail.

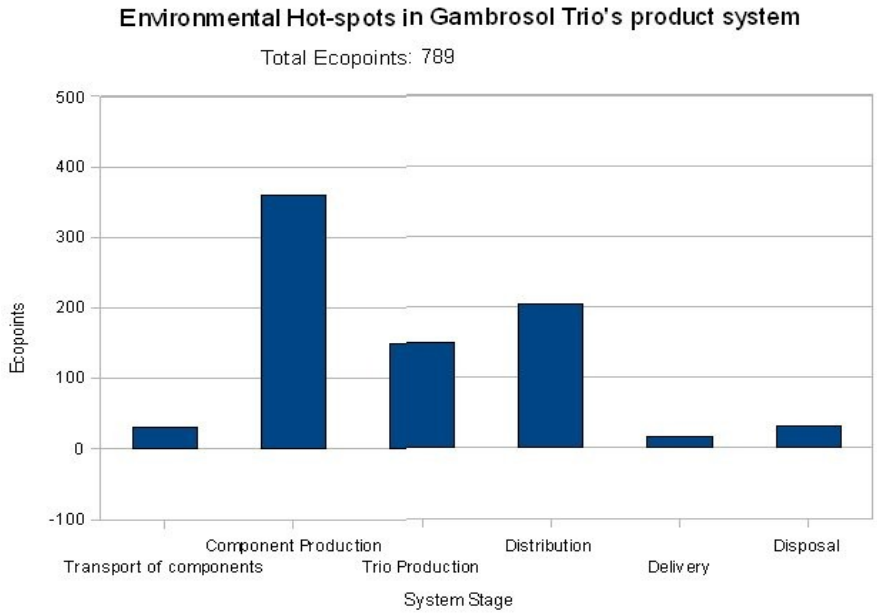

Figure 5-18: Ecopoint score throughout Gambrosol Trio's life cycle

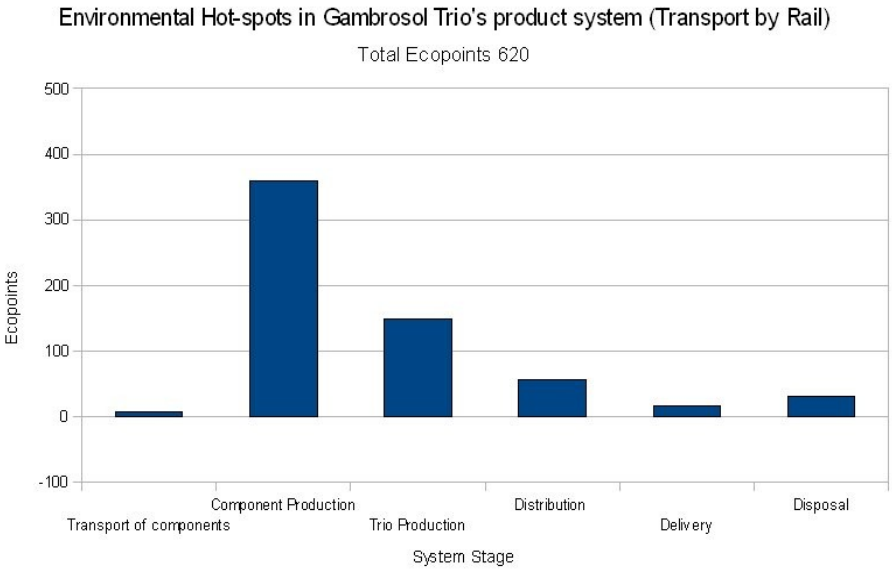

Figure 5-19: Ecopoint score throughout Gambrosol Trio's life cycle (rail).

Figs. 5-5 ad 5-6 give indication as to how the environmental impacts of Gambrosol Trio are spread all along its life cycle. As was stated above, there is uncertainty in this results in terms of the true scale of the impacts associated to the production of Trio itself.

In order to gain further insight into the potential consequences of a material shift from PVC and phtalates to the use of alternative plastics, ecoscores were recalculated based on company information about potential substitutes. The assumption was made that the dialysis bag, connecting lines and other plastic items would be made of:

- Polypropylene.
- A combination of Polyethylene (bag and components) and Polypropylene (connecting lines)

Theoretical ecoscores using these two combinations are presented in figures 5-6 and 5-7, respectively. Figure 5-8 shows a comparison of the total ecoscores for Trio as it is now and with alternative materials.

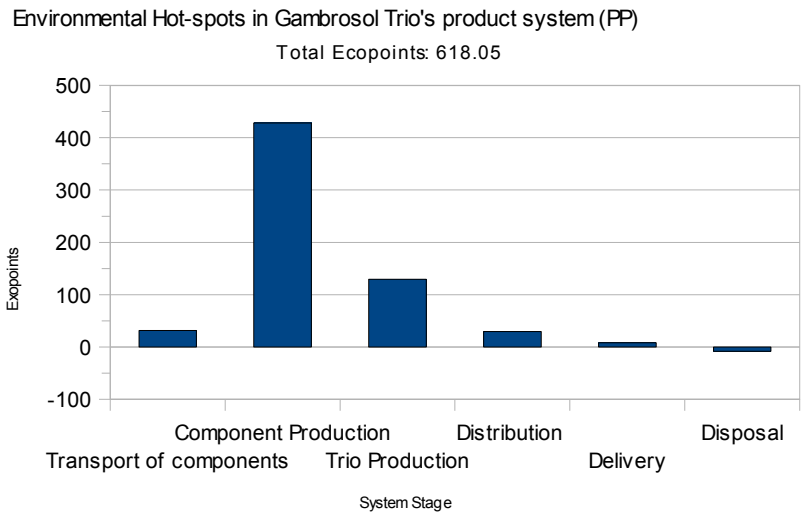

Figure 5-20: Ecoscores after substitution of PVC with Polypropylene

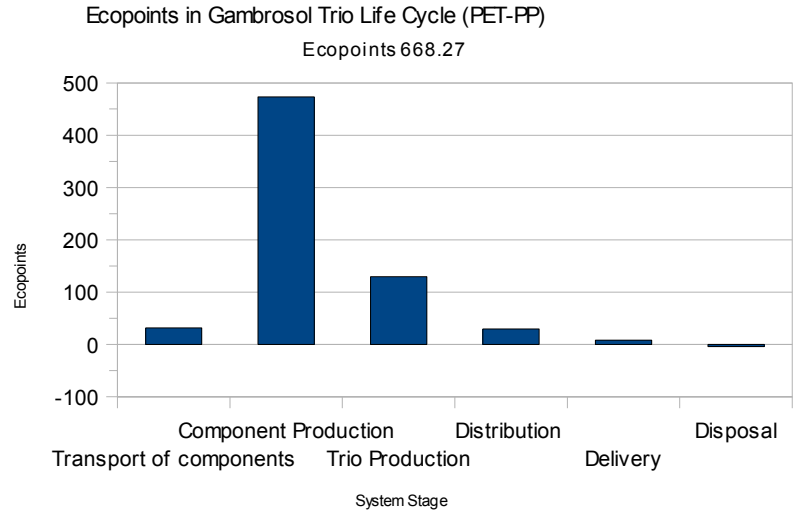

Figure 5-21: Ecoscores after substitution of PVC with PET-PP

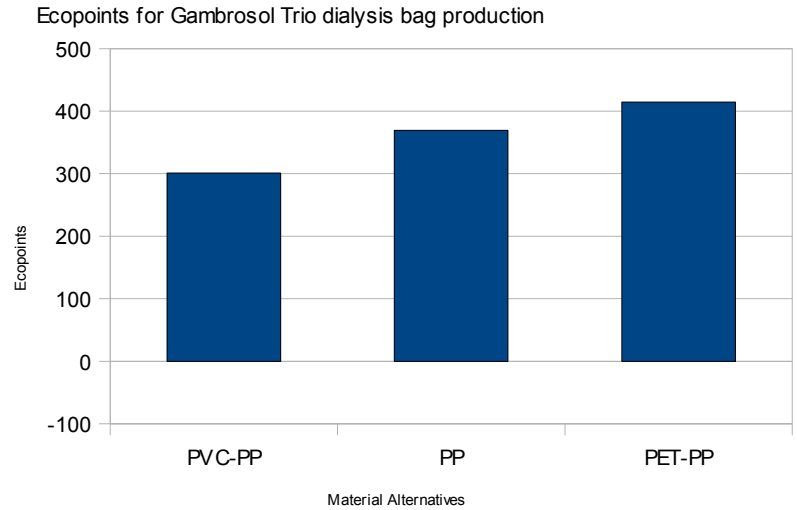

Figure 5-22: Ecoscore for bag production depending on material alternative.

Finally, the scrapping rate was included in the analysis in order to gain insight into the extent of the advantage of Trio's design compared to one and two-in-one concentration designs.

Due to the fact that data was not available for products from competing producers, ecoscores were calculated based on the material and energy requirements as presented in Table 5-2 and adding an extra 10 percent. This is meant to represent that patients using a competing product would scrap up to 10% of their supplies due to changes in prescription. Unfortunately, data on actual scrapping at Apoteket was not available as it is not tracked by the stores that were approached during this study. The figure also aims to represent the infrequent nature of the prescription changes as was observed during the interviewieng period.

It is important to note that, all else equal, the fact that Ecoindicator 99 uses mass as the base for its indicators means that it was possible to add the scrapping rate directly to the ordinary Ecoscore for Trio. This means changes in prescription would only stimulate production of one bag of the demanded new concentration so that the patients needs as expressed in the functional unit can still be covered during treatment.

Using a 10% scrapping rate resulted in an increase in the total ecoscore for Gambrosol Trio from 575 to 633.

6 Findings and conclusions

The screening LCA approach used in this study shows that the majority of the environmental burden associated with the production and use of Gambrosol Trio as a fluid for Continuous Ambulatory Peritoneal Dialysis appear to be concentrated in the production stage of its different components and of these, the production and processing of the bag and other plastic items are the greater contributors.

These findings cannot be regarded as conclusive due to the limitations of the approach itself and to the assumptions used during the Assessment. Of particular importance is the lack of indicators for the manufacturing of the finished product at Gambro's facility in Italy. An estimate of energy consumption was the criteria used to assign a score, disregarding air and water borne pollution.

In spite of the limitations, the results shed some light into the performance of the product througout its life cycle, and were particularly useful in bringing attention to the fact that, considering the limitations of this exercise, the product design does not appear to have significant environmental effects in the distribution, delivery and use phase.

The main reasons for this were the observations that pointed to the fact that CAPD patients do not seem to change their glucose concentration prescription on a contingency basis. The prescription appears to depend on continuous monitoring of the patient's renal function and changes do not happen suddenly. Furthermore, patients usually place orders for CAPD fluids in intervals of 1 to 2 weeks, depending on space available for storage and the Apoteket uses these orders as the basis for their inventory stock. It is reasonable to conclude from these observations that orders placed from Apoteket stores to manufacturers of CAPD solutions also follow this pattern and therefore, production of all three concentrations for every patient does not take place to a larger extent.

It is important to note that this exercise does not compare Trio's performance to its direct competitors. Therefore, it is not possible to clearly distinguish the advantages of Trio transport versus that of its competitors even though it is reasonable to expect that the reduced volume of Trio would mean lesser impacts in distributer-to-patient transport. As a counter-point, a next step would be the assessment of the impacts related to wasted glucose occurring with Trio (when using lower concentrations) use as compared to 100% use of glucose in other designs.

There were some indications of wasted fluid but unfortunately they are not formally tracked by the Apoteket stores that were approached during this study (see Appendix 1). Ecoscores were calculated using an assumed scrapping rate of 10%. Results show that the scrapping rate has an additive character in its effect on the products' ecoscore. Although no data was available to calculate ecoscores for competing products, the result provides some insight into the extent of the environmental advantage of Trio with regards to scrapping.

A measure of insight was also gained into the decision that the company is currently facing on whether or not to substitute PVC and phtalates as the bag and other components material of choice. The results show that in terms of material production, processing and final disposal, alternative materials such as Polypropylene and Polyethylene do not necessarily improve the environmental performance of the product.

It is important to note that the comparison of plastics use was done assuming an equal amount of material is required to produce all plastic components. This does not take into account any reductions that may be achieved due to differences in PP and PET density.

The use of recycled polypropylene and polyethylene in plastic manufacturing would lower the environmental burden of their production stages. Unfortunately this would present the risk of having a number of unknown additives in the recycled mix, a situation that would not be acceptable in the production of medical devices due to the same toxicity concerns that drive the issue of PVC replacement.

Insight into the environmental characteristics of the materials for the dialysis bag is important since so far the debate has revolved around the potential toxicity to human health of PVC and phtalates. This type of exercise adds a new dimension to the debate by including a broader look at the environmental implications that come with choice of materials. Unfortunately, no data was found as to the effects of phtalates released into the environment, either as a result of leakages in landfills or incomplete combustion in incinerators.

The results also mark the need to open and maintain a constant dialogue with suppliers, both to maintain an up to date and easily accessible inventory database as well as to track opportunities for actions such as material replacement or eco-efficiency improvement programs.

7 Recommendations

This thesis was conducted as a first approach to Gambrosol Trio's environmental performance and cannot provide conclusive evidence that may be used for marketing purposes or for official communication with stakeholders. However, it does provide insight into the environmental performance of the product throughout its lifecycle and is intended to present Life Cycle Approaches as a tool that, if applied to the full extent and rigor of the method, can provide more conclusive findings into the true measure of the product performance.

A full-scale Life Cycle Assessment is therefore recommended should the organisation decide to pursue the use of this tool to complement the decision making process in order to include environmental criteria, especially during the research and development stages of product development and in particular as a central decision making tool in the topic of PVC and/or phthalate substitution.

At the time of writing, the organisation's environmental management system (EMS), based on the ISO 14001 standard, was being re-structured. This can be a crucial opportunity to include comprehensive approaches like life cycle assessment to become one of the instruments with which to execute the organisations environmental policy. In turn, due to the hierarchy of this policy, it would be expected that its effect would trickle down to the research and development and production areas of the company.

The complexity and resource intensity of full-scale assessments run the risk of transforming the tool into a barrier for the decision making process they are meant to assist. To counter this, it is strongly recommended to continue the practice of creating "steering" groups as was the case for the duration of this study. The interaction of relevant players from different areas within the organisation can greatly facilitate exercises of this nature.

Should these approaches be used in the future, it is recommended to also include production and logistics managers located both at home and abroad as they can greatly assist in complementing the information required for analysis.

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Isaacson, Malin. Sales Manager. Peritoneal Dialysis (Product System Mapping).

Kempf, Lena. Head Pharmacist, dialysis unit. Apoteket, Universitetssjukhuset i Malmö (qualitative data on product delivery to end-users and storage practices at Apoteket).

Kiss, Katalin. Pharmacist. Apoteket, Universitetssjukhuset i Lund (qualitative data on product delivery to end-users and storage practices at Apoteket).

Krutzen, Lena. Head of Peritoneal Dialysis unit. Universitetssjukhuset i Lund (quantitative data on number f patients under PD treatment, qualitative data on treatment option trends).

Lindhal, Tom. Product delivery. Responsible for the delivery of dialysis supplies from Apoteket to patients in Malmö (quantitative data on delivery logistics collected during interview and observation of a full delivery day).

Musi, Barbara. Senior Researcher. Toxicology and Biocompatibility / Environmental Management (Background on materials and development protocols used within the organisation. Insight into current status of Gambro's environmental management system).

Redin, Mikael. Logistics. Distribution Centre (quantitative data on the product characteristics: weight, manufacturing points, shipment destinations).

Sandström, Theodor. Director of R&D. Materials and Chemistry Development (Product System Mapping).

Wieslander, Anders. Senior Researcher. Member of the original research group responsible for the development of Gambrosol Trio. Steering group leader.

Appendix 1

Request for information, Lund:

Request for Information. Apoteket, Lund. 18082008
Contact Persons / Apoteket Lund: Annelie Lundgren / Katalin Kiss
Topic: Thesis on environmental performance of Peritoneal Dialysis (PD) Fluids. Internationella Miljöinstitutet at Lund University.

Dear Annelie and Katalin,

As I mentioned to you in previous communications, I'm working on my Master's Thesis on the environmental performance of PD fluids. I'm looking at three-bag design and how it compares to single concentration bag design, especially when it comes to transportation, storage and waste generation, handling and disposal.

I visited the Apotek in Lund a few weeks ago and I have a series of follow-up questions that would help me in continuing my work. I would be immensely grateful if you could answer them.

1. **Total number of patients that are placing orders for PD fluids** (Example: in 2007 a total of 90 patients were registered as ordering PD fluids irrespective of type of bag or concentration).
2. **Number of patients per PD fluid design** (Example: in 2007 30 patients were prescribed and were buying Gambrosol Trio, 25 using Baxter, 20 using Fresenius).
3. **Number of PD fluid bags sold to patients per product manufacturer** (Example: in 2007 43,000 Gambrosol Trio bags were sold to patients, 20,000 bags in the case of Baxter, and 10,000 each for Fresenius three different concentrations, etc.)
4. **'Safety' Inventory of PD bags in Apoteket's warehouse** (Example: At all times there should be 20 boxes containing 10 bags each of Gambrosol Trio, 15 boxes containing 10 bags of Fresenius 1.5%, 10 boxes of Fresenius 2.5%, 5 boxes of Fresenius 4.5%, etc.).
5. **Wastage or scrapping rate per product** (Example: in 2007, a total of 500 bags of Gambrosol Trio were disposed of/destroyed at Apoteket. The same for 200 bags of Baxter's and Fresenius, etc.). If these data do not exist, I can infer it from the **Total number of PD fluid units purchased by Apoteket** from each manufacturer.

I'm trying to explore if the three-bag design does lower transportation and storage compared to single bag fluids. In general terms, the assumption is that a three-bag fluid should lower the need to manufacture/transport and store by two thirds. However, if due to the way renal failure operates and standard practices in health care, a patients does not require to have all three concentrations available at all times, then the positive effects of the three-bag design may not be as large as expected.

Therefore, I'm seeking a number that will tell me, on a per-patient basis, how many PD fluid bags are kept in store by Apoteket and how many of them are purchased and therefore, moved around, depending on the bag design. All of this as much to satisfy the patients' demands as to maintain a safety stock in Apoteket's warehouse.

The wastage rate is a similar case. I am trying to find out the extent of the effect a three-bag design has on the number of bags that are returned to Apoteket (that are in the end, disposed of/destroyed there) by patients or that are lost in-house due to normal operations (punctures, leaks, bags that reach their shelf-life, if at all, etc.).

Request for Information. Apoteket, Lund. 18082008
Contact Persons / Apoteket Lund: Annelie Lundgren / Katalin Kiss
Topic: Thesis on environmental performance of Peritoneal Dialysis (PD) Fluids. Internationella Miljöinstitutet at Lund University.

Finally, I'm hoping to do a similar effort with Apoteket in Malmö, with the aim of comparing the data here in Lund and to gain insight into a more general trend of use of PD fluids in Skåne.

With best regards,

Alfredo Rodriguez, Chem.Eng.
Candidate for MSc in Environmental Management and Policy
LU Internationella Mijöinstitutet (IIIEE) Tegnérsplatsen 4, Lund
www.iiiee.lu.se
Mobile: 0761108324

Response, Lund:

APOTEKET FARMACI

SJUKHUSAPOTEKET
UNIVERSITETSSJUKHUSET I LUND

Lund 2008-08-22

Dear Mr Rodriguez,

Thank you for your questions. I have discussed them with the Manager of the Hospital Pharmacy, Bengt Åke Peterson. According to the policy of our company and our professional secrecy we can't give you any complete answer to all your questions. This is the information we may give you.

2008-07-31 we had 53 patients ordering PD fluids. This is an average of patients ordering fluids each month. For the moment we have 11 patients needing night dialysis (bags with large volumes) and rest of the patients are dialysing daytime (smaller volumes) The patients need 4-5 bags/day for their treatment. For patients using bags with large volumes I haven't got the data about how many bags they need/night. You better ask Lena Krutzen about that.

The question concerning the number of fluid bags sold per product and manufacturer, I suggest you get in contact with each manufacturer and I hope they may handle you the figures of how many bags they have purchased.

We deliver PD fluids to patients dialysing at home as well as to the clinics. I have no possibility to specify how many bags of each product the different patients are ordering.

We don't keep any statistics concerning wastage.

Best regards

Camilla Hoffer

The same request was made in Malmö. A response from the Apoteket there was delivered in person by Lena Kempf, Head Pharmacist for dialysis, and was virtually identical to that received from Lund.

Appendix 2

The log with the calculations performed for the Assessment is available as an electronic spreadsheet.

Appendix 3

Ecoindicator '99 Manual for Designers.

Ecoindicator '99 Methodology Annex.

See in references:

Ministry of Housing, Spatial Planning and the Environment (2000). Eco-indicator 99 Manual for Designers. A damage oriented method for Life Cycle Impact Assessment. Available online: http://www.pre.nl/eco-indicator99/ei99-reports.htm [September 01, 2008].