NxStage Purification Pack Efficiency and Lifespan Enhancement

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Abstract
According to the U.S. Department of Health, around one in ten Americans suffer from some sort of kidney failure of which 400,000 are end stage renal disease (ESRD) patients who are being treated with some form of dialysis. NxStage Medical, Inc. is currently leading a renal treatment revolution with their innovative hemodialysis system, the NxStage System One™. Hemodialysis cannot be done without an essential component of the process, the dialysate, therefore the System One has to be used in conjunction with either pre-mixed dialysate fluids or the PureFlow™ SL Dialysate Preparation System (PFSL). The PFSL consists of two key components: the Purification Packs (PAK) and the Dialysate Sacks (SAK). After thorough analysis, an opportunity for improvement has been identified in the configuration and utilization of the PAK system. As NxStage continues to expand its operations and the number of patients using the System One, it is gaining additional experience with the PAK in a variety of regions. In some cases, the lifespan of the PAK is being affected by the varied water quality in certain regions within the United States by exhausting the filtering system prematurely, making the current overall replenishment rate higher than anticipated during development. The purpose of this project is to use multiple Industrial and Mechanical Engineering tools in order to define and design an optimal and efficient complementary system that will extend the lifespan of the PAK. After careful analysis of different solution alternatives, the team has determined that the best solution is to create and implement what is now called a pre-PAK, containing deionization resins able to filter water impurities and output ultra-pure water. This pre-PAK is to be used in conjunction with the PAK in order to increase its lifespan, which will present cost-saving opportunities. This project will also serve to minimize waste in the form of excess unused components.

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*For proprietary reasons, certain details of the process and outcomes have been redacted or withheld.
The Need for Project

NxStage Medical, Inc. distributes their PFSL throughout the United States and is currently expanding worldwide. It has been identified that the water quality varies significantly across the regions served and this variation has been affecting the lifespan of a key component in the PFSL, the PAK, under certain conditions.

However, the water impurities identified only accelerate the exhaustion of one component in the PAK, which constitutes 70% of the PAK. As a result, the remaining parts of the PAK are being discarded without being fully utilized.

Therefore, the PAK having a variable and irregular consumption rate not only increases the number of PAKs being replenished, but also increases wastes from unutilized or underutilized components being discarded. In addition, having to replace the PAK more frequently than expected could create a burden on NxStage’s patients. The ability to control and standardize the rate at which the PAK exhausts will play a key role in achieving significant goals.

The Design Project Objectives and Requirements

The objective of this project is to define and design a complementary system with the capability of standardizing the replenishment rate of the PAK, following the design requirements set by the Capstone team and NxStage.

Design Objectives

The objective of this project is to define and design a system with the capability of simultaneously reducing and standardizing the replenishment rate of the PAK. This consists of providing a final recommendation that can increase the lifespan of the PAK in geographical areas that are affected by compromised or poor water quality, decrease the amount of waste originated by discarding the PAK before full exhaustion, increase patient satisfaction, and decrease costs.

In addition, this must have minimal disruption or alteration to the current manufacturing processes. The solution was conceived using multiple Industrial and Mechanical Engineering tools.
Design Requirements

For this project to be feasible, the Capstone team developed a set of criteria that should be considered in the final design solution. The design should not require any changes to the current PFSL system. It should have the ability to decrease costs through shipping and/or manufacturing, as well as have a high ease of implementation. Finally, the design should aim to increase the lifespan of the PAK.

Design Concepts Considered

The Capstone team developed three primary solution alternatives and used strategic decision criteria to select the best solution.

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<th>Matrix of Solutions Considered</th>
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<td>Improve Current Processes Associated with PAK</td>
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<td>Decrease Materials and Cut Costs</td>
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When discussing process improvement for this initiative, the two main areas of focus are the manufacturing process and the new patient training process. There are a few reasons why this alternative was eliminated from contention. First, the modified manufacturing process will require approval and detailed examination from high-level management, which would incur additional manufacturing costs. Certain steps of the manufacturing process are being outsourced and fall outside the team’s scope. In addition, by making changes to how the everyday production activities are carried out, the Capstone team foresees certain levels of resistance to change. As a result, this would increase the difficulty of implementation. Finally, this design alternative does not have the ability to increase the lifespan of the PAK.

Decrease Materials and Cut Costs

Material expenses make up a majority of the total standard cost to manufacture a PAK. By changing and/or reducing materials within the PAK, not only can material costs be reduced, but the manufacturing costs as well. While this design alternative may change/reduce materials within the PAK, it does not require any change to the PFSL system itself. When it comes to medical device components, operations must be performed according to certain procedures. This would potentially jeopardize the implementation of this design alternative. In addition, this design alternative does not have the ability to increase the lifespan of the PAK.

Design and Develop a Supplementary Filtering Option

This design alternative proposes adding a supplementary filtering system before the current PAK. Its purpose would be to “pre-treat” the source water in order to increase the lifespan of the PAK. The supplementary system will not interfere with the current PFSL system.
This feature will make the supplementary system easy to implement. The Capstone team believes that adding a supplementary system will increase the PAK’s lifespan to the ideal length of twelve weeks. As a result, there will be an appreciable decrease in both shipping and manufacturing costs.

**Recommended Design Concept**

The Capstone team designed and developed a supplementary filtering system called the pre-PAK. The pre-PAK contains ion exchange resins capable of combating the factors affecting the current PAK’s lifespan.

The team used a feasibility matrix and strategic decision criteria to determine the best solution from the previously discussed alternatives. Results indicated that designing and developing a supplementary filtering system to be added between the water source and the current PAK would be the most cost-effective and feasible option. The team named the supplementary filtering system the ‘pre-PAK’.

**Design Description**

The pre-PAK will consist of four canisters containing mixed-bed ion exchange resins that in conjunction will act as an additional filtration system for the source water going into the PFSL. Its main purpose will be to extend the life of the current PAK. Through this design innovation, the user will be able to visually detect when the pre-PAK is exhausted and needs to be replaced; thus, the team determined that the ion exchange resins will include a color-changing mechanism. However, since the filters exhaust in series, only the last filter will need to contain a color-indicating ion exchange resin. Therefore, the first three canisters will be made of a non-transparent plastic material and filled with an ion-exchange resin called MBD-15; the last canister will be made of a transparent plastic material and filled with another resin, MBD-30, a color-indicating resin. By using only one transparent canister filled with a color-changing resin, the team will eliminate a great deal of the costs associated with manufacturing the newly designed pre-PAK.

**Measures of Success**

For this design to be a success, the pre-PAK must meet a set of design requirements developed by the Capstone team and NxStage. Most importantly, NxStage would like to see a minimum increase in PAK lifespan of 1 month. Keeping the comfort of patients in mind, the pre-PAK must be small, lightweight, ergonomic, aesthetically pleasing, and intuitive to use. In order for the patient to know when to replace the pre-PAK, there must be a mechanism to signal resin exhaustion. For
delivery to be cost effective, NxStage would like to use USPS flat rate shipping for distribution, so the pre-PAK must be able to fit within a standard USPS shipping box (inside dimensions: 11 7/8” x 3 3/8” x 13 5/8”). Finally, the manufacturing of the pre-PAK must cause minimal disruption or alteration to the current manufacturing processes of NxStage’s products.

**Analytical and Experimental Investigations**

The team performed extensive research, as well as developed and applied a variety of mathematical computations to determine the optimal pre-PAK design. First, all factors that could potentially affect the design and distribution of the pre-PAK were examined: home hemodialysis patient population, the total dissolved solids (TDS) in the water, the hardness of the water, and alkalinity of the water. Through metrics developed by the team to properly weight each factor’s effect on pre-PAK lifespan, the team determined that using a standardized pre-PAK design for the entire United States would be the most cost effective and reliable distribution method, as opposed to introducing minor customization features.

Once the pre-PAK design and its distribution approach were established, the team went on to perform a resin exhaustion analysis to determine the top-performing resin combination. The team’s results combined with subject matter expert’s input led to the selection of mixed bed resins MDB-15 and MBD-30.

The team then applied throughput calculations to compute how many liters of water could theoretically go through the pre-PAK before exhaustion. These calculations allowed the team to determine that the pre-PAK concept is a cost-effective solution for NxStage and therefore should be implemented.

**Key Advantages of Recommended Concept**

Given that the pre-PAK will be smaller, lighter, and more ergonomic than the current PAK, patients could have a reduction in the burden while using the PFSL system in conjunction with the pre-PAK. In addition, the pre-PAK will provide patients with a clear visual indication of resin exhaustion, making it easier for the patient to detect when the pre-PAK needs to be replaced. Finally, implementing the pre-PAK concept may result in significant cost savings to NxStage.
Financial Issues

Throughout the project, there was approximately $300 in travel and material expenses incurred by Northeastern University. The cost of the prototype was estimated to be $100 and incurred by NxStage’s vendor.

The team used the pre-PAK throughput by state, the material and shipping costs of a single pre-PAK, and the cost savings associated with reducing the number of PAKs per patient per year in order to perform a cost benefit analysis. The total material costs for each pre-PAK will be $36.62 and the total shipping costs for each pre-PAK will be $12.35.

With the implementation of the pre-PAK, the team expects an average reduction of approximately 5 PAKs per year per patient with the potential to further reduce total PAK manufacturing costs per year per patient. The pre-PAK will initially be rolled out to patients with source water containing a TDS value between 55-120 mg/L, resulting in the pre-PAK being distributed to a percentage of the total patients using the PFSL system. Therefore, during the initial pre-PAK rollout phase, there may be meaningful cost savings that make the project feasible and implementable.

Recommended Improvements

After the pre-PAK concept has been implemented successfully, the Capstone team recommends that NxStage create a database with the water quality information collected from each of the patients to explore the capability of implementing multiple pre-PAKs to tackle each specific concentration type of water quality. In addition, based on our analysis we believe optimizing the shipping and logistical infrastructure to support the distribution of the pre-PAK(s) may have a meaningful associated cost-benefit ratio. The Capstone team also recommends that NxStage continue reviewing methods for further waste reduction, such as recycling the resins being used in the pre-PAK through resin regeneration.

This project opens doors to many opportunities that are worth exploring.