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ABSTRACT

Engineering product design requires both technical aptitude and an understanding of the non-technical requirements in the marketplace, economic or otherwise. Engineering education has long focused on the technical side of product design, but there is increasing demand for market-aware engineers in industry. Market-awareness and customer-focus are also associated with entrepreneurship, which has been given increased focus in engineering education. A common tool for gauging customer interest in industry is the focus group. Herein we examine the effect of customer voice as presented in a focus group for influencing engineering product design generated by students as part of the virtual internship and epistemic game Nephrotex. We find that customer exposure is related to decreased product cost without a change in product quality. Therefore, we suggest that the injection of customer voice into the engineering curriculum is a valid method by which to improve engineering design pedagogy.

Key words: Design process, entrepreneurship, games

INTRODUCTION

Success following graduation now requires more than just technical savvy from engineering students (Byers et al., 2013). Adaptability, effective teamwork, creativity, and recognition of current market-based needs and future opportunities are requisite skills in the repertoire of an engineering graduate (Bodnar, Clark, and Besterfield-Sacre, 2015). Though the definition of an entrepreneurial mindset varies to some extent, each of these traits has been identified as an element of such a mindset. Regardless of definition, much focus is being directed toward instilling an entrepreneurial mindset in engineering students (Taks et al., 2014, Byers et al., 2013, Bodnar et al., 2015, Rogy et al., 2014, Schar et al., 2014). Companies require innovative thought, personal initiative, and market awareness from the incoming workforce to stay competitive (Litzinger et al., 2011). And those seeking to venture into new markets require similar personal traits (Kriewall and Mekemson, 2010). Indeed, it is imperative that the entrepreneurial mindset be fostered in the engineering classroom (Ortiz-Medina et al., 2014) for either entrepreneurial or "intrapreneurial" (i.e. the entrepreneurial tendencies of an employee within a company that they do not own) purposes (Damon and Lerner, 2008, Antoncic and Hisrich, 2003). For this reason, it is crucial to gain an understanding of how different pedagogical methods can further the development of an entrepreneurial mindset in students while still in the college environment. Byers et al. (2013) suggest encouraging creativity, flexibility, and technical acumen to foster entrepreneurial tendencies, whereas Kriewall and Mekemson (2010) suggest that acquaintance with business principles including meeting customer needs is essential to developing entrepreneurial engineers. Bodnar, Clark, and Besterfield-Sacre (2015) through a literature review were able to capture an engineering-specific definition of entrepreneurial mindset. Particular to this definition is the notion that engineers must also account for technical aspects in addition to market demands. In the present work, we focus on a method of increasing awareness of customer needs at an early stage of engineering education. By implementing a focus group within a virtual internship for sophomore engineering students we seek to gauge whether exposure to end-customers within the early stages of the design process yields a quantitative change in the final design specifications in terms of product performance in the marketplace and/or quality.

The field of entrepreneurship education, specifically in engineering, is relatively young (Ortiz-Medina et al., 2014, Taks et al., 2014). However, much focus has been given to understanding the customer voice since Akao (2004) first opened the door to that concept nearly 50 years ago (Akao and King, 1990, Woodruff, 1997, Pahl et al., 2013). Producing a technically sound design that meets customer needs is one of the great challenges of engineering product design. Lin and colleagues (2008) have stated, "Understanding customer voice and enhancing design characteristics which meet customer requirements and thus increase product competitiveness are the challenges for designers." Furthermore, it must be understood that the map between a potential user's mental model and the designer's concept have to match in order for quality design to occur (Norman, 1988). The ability to meet this challenge, when fostered in engineering undergraduates, will contribute to a technically savvy engineering workforce with a higher potential for creative and entrepreneurial design, per the definition of Rae (2003). Meeting this challenge requires creative and critical thought and adaptability to the ever-changing needs of the customer base, which are essential components of the entrepreneurial mindset (Gibb 2002, 2010). Therefore, we posit that teaching customer-focused design is necessary for developing entrepreneurial tendencies within the minds of engineering students.

The challenge, then, is understanding how to effectively instill a customer focus in engineering students, a task that requires knowledge of how engineers learn. As it stands, engineering students in our colleges today do not relate well to traditional engineering pedagogy, such as the direct transmission model, which has remained the norm for the past few centuries (Freeman et al., 2014). The current generation of students is looking for a curriculum and educational approach that uses advanced classroom technology and active learning to engage them in the learning process (Freeman et al., 2014, Mina and Gerdes, 2006). A novel approach that can be used to engage students in the engineering product design process in a professional context is the engineering epistemic game (Hatfield and Shaffer, 2006, Svarovsky and Shaffer, 2007).

Epistemic games are founded on epistemic frame theory (Shaffer, 2004). This theory posits that the formation of "communities of practice" - groups of practitioners with similar problem-solving styles - is essential for learning to solve the most challenging problems in a discipline (Chesler et al., 2013, Shaffer, 2004). Moreover, the concept that every community of practice has its own culture with unique skills, knowledge, values, identity, and epistemology that constitute its epistemic frame is the basis of the "epistemic frame hypothesis" (Chesler et al., 2013, Rohde and Shaffer, 2003, Shaffer, 2006).

Epistemic games are simulations that allow students to act as practitioners in a simulated real-world environment while gathering data on students' development as practitioners within a given epistemic frame (Chesler et al., 2013). In engineering epistemic games, students role play as interns for a virtual company and are tasked with a real-world design problem to engage them in the engineering design process. Within the engineering epistemic game Nephrotex (Chesler et al., 2013), students are tasked with designing a dialysis membrane for therapeutic blood ultrafiltration. The design process involves the participation of multiple students (i.e., design teammates) and a design mentor as students progress through design activities. These activities occur in stages referred to as "rooms" in which the students play through a specific task. The interns are advised by virtual employees in the company's research and development team (either simulated or played by student volunteers) during each of these activities. The internship and product design culminate in the selection of a final design, written justification for the selection of that design, and an oral or poster presentation of the design to other teams and the course instructor.

The implementation of Nephrotex has been shown to increase student engagement (Chesler et al., 2013) and positively impact the intent of women in first-year engineering programs to persist in an engineering discipline (Arastoopour, et al., 2013). Its utility in fostering entrepreneurial mindset and encouraging customer-focused design was previously investigated (Rogy et al., 2014). Taking this further, we evaluate in this work the effect of the implementation of a focus group within Nephrotex for its possible effects on final product performance with an emphasis on end customer desired attributes. Customers can add their voice to the design process through the focus group, one of the most widely employed tools in market analysis (Langford and McDonagh, 2003). In the context of epistemic game research, the focus group also provides a controlled environment in which to probe initial student interest in terms of focus group participant selection from a pool of customer types and ultimate student response to both internal and external stakeholder requests. We find that even though students may not specifically focus on reducing cost to meet customer needs, decreased final product cost is associated with the exposure to external stakeholders in the focus group.

Research Questions

The following three research questions were investigated through this study:

1. Is there a direct relationship between information sought by students relevant to final design specifications during an external customer focus group and the attributes of the final design in the virtual internship Nephrotex?
2. Does the incorporation of an external customer focus group within Nephrotex influence any specific attribute of the final designs generated by student groups?
3. Does the incorporation of an external customer focus group within Nephrotex raise or lower the overall quality of student designs?

METHODS

Study Design

Nephrotex was implemented at the University of Pittsburgh in two sections of a required Sophomore-level Chemical Engineering course during the spring semester of 2014. One section had a version of Nephrotex that incorporated two additional activities pertaining to a focus group that provided those students with external stakeholder (i.e. end-customer) insight. The Nephrotex game allows for the customization of four components of each membrane design: membrane polymer, polymerization process, processing surfactant, and carbon nanotube percentage (see Chesler *et al.* (2013), Figure 3 for a complete description of the design space). The selections made for each of these four components are taken as inputs to the design process, and the resulting outputs are five quantified metrics of design performance: marketability (in anticipated units sold), cost (in $), and three technical metrics – flux ($m^3/m^2/day$), blood cell reactivity (BCR, ng/mL), and reliability (hours). These output values for each final design were compared between the focus group (FG) and non-focus group (NFG) sections. Cost was considered to be a non-technical attribute, and marketability was considered as both technical and non-technical because economic and ergonomic considerations are vital for the production of a marketable product.

Each section had 57 students enrolled. Lecture periods for the course utilized both direct transmission and active learning methods. The Nephrotex virtual internship took place over the course of 10 consecutive weeks in a 15-week semester. Play-through of the virtual internship occurred during the scheduled class period for one hour per week where students were assigned to one of 10 teams composed of either 5 or 6 students. Tasks assigned to the students within the internship that were not completed in the allotted time were completed outside of classroom hours. The internship culminated in the presentation of each student-group's final membrane design in poster format. Proper human subjects approval was obtained prior to the conduct of this study.

Assessment of Final Membrane Designs

Assessments were made on the performance metrics of each final design according to the design of the Nephrotex software, and comparisons were made between those of the section with the added focus group and the non-focus group section, referred to as FG and NFG, respectively.

We also assessed the quality of the final design relative to thresholds for each of the five output categories based on the framework developed by Arastoopour and colleagues (Arastoopour et al., 2015). Four graduated thresholds per output were used. These were described to the students in uniform detail as either suggested or required performance levels according to requests from internal Nephrotex "employees," henceforth referred to as "internal consultants." The designs were given a point for each threshold - minimum, medium low, medium high, and maximum - with minimum receiving one point and maximum receiving four points. Thus, a "perfect" design that met the maximum threshold (given in Table 1) in every output category would receive a 20 point quality score. However, the maximum possible score for any actual design in the design space was 18 due to design space constraints. Students were unaware of this quality framework during the design process, so while design requests were made by the internal consultants, the design process by which they arrived at a final design was open-ended.

Table 1. Thresholds for design outputs.

Threshold	BCR	Flux	Cost ($)	Marketability (Units)	Reliability (hr)
Minimum	110	10	165	250,000	1.5
Medium low	90	12	150	350,000	3
Medium high	55	13.5	100	550,000	4.7
Maximum	45	16	75	650,000	5.5

Design of Focus Group

The focus group was implemented to determine whether design input from stakeholders external to Nephrotex could be mapped to a resulting design output. To that end, the focus group was designed to work in concert with the existing play-through structure of the internship to ensure an otherwise equivalent (in terms of information conveyed and time required) gameplay experience for both sections. The focus group "room" of play was designed to elicit input from five simulated external stakeholders otherwise referred to as end customers for the product: a dialysis patient, a nephrologist, a hospital administrator, a Medicare assistant, and an industry thought leader. The questions that students could ask of each stakeholder and the subsequent stakeholder responses were pre-established within the game framework by the authors of this work. These questions and responses were sent to a practicing nephrologist independent of this work for review. The full set of questions and answers available to students in the focus group section is provided in Appendix A.

Students in the FG section were told to select two of the five external stakeholders (i.e., end customers) to participate in their focus group and were allowed to strategize prior to the focus group within their team as to who and what questions would be best to ask. They were then allowed to ask each stakeholder three questions from a bank of ten about their opinion relating to the design of dialysis membranes (see Figure 1). Students discussed the focus group responses to question findings with their team members. At the completion of the virtual internship, we sorted all the questions that students asked of external customers into the performance relevant categories (i.e., BCR,

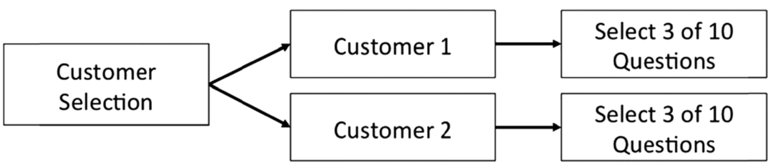

Figure 1. Schematic of stakeholder/customer and question selection process for the focus group interview.

reliability, flux and cost). Marketability was excluded from this analysis due to its inherent crossover into both the technical and economic aspects of design.

Statistical Analysis

Statistical analyses were performed in Matlab (© 2013 The MathWorks Inc., Natick, MA) using either the *ttest* (a Student's or matched t-test), *ranksum* (Wilcoxon rank-sum), or *corr* (determination of either the Spearman or Pearson correlation statistic) functions, using an alpha level of 0.05 for statistical significance in all cases. Due to small sample sizes, we used both the Pearson and Spearman correlation coefficients as well as the t-test and Wilcoxon rank-sum test.

RESULTS

In this section, we present our results relating to customer input in the virtual internship Nephrotex based upon each of our research questions.

RQ1: Is there a direct relationship between information relevant to final design specifications obtained from an external customer focus group and the attributes of the final design in the virtual internship Nephrotex?

Figure 2 shows the box-plot of the number of questions asked by each student group pertaining to each output parameter. Students asked more cost-related questions than other question-types with some overlap in the upper tail of both the flux and BCR categories.

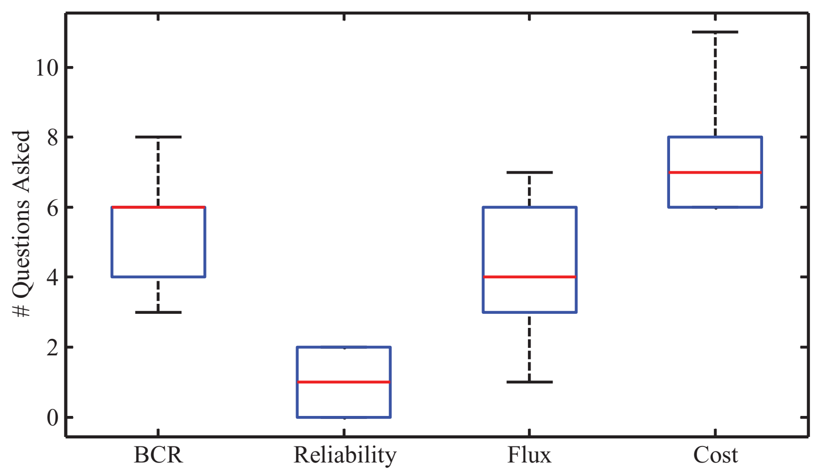

Figure 2. Number of cost, BCR, reliability, and flux-related questions asked by each group in FG section.

Table 2. Correlations for each of the four metrics of the final design versus the number of questions asked.

Value vs. #Questions	BCR	Reliability	Flux	Cost
R^2	0.0402	0.0192	0.0281	0.0039
p-value (Pearson)	0.579	0.703	0.643	0.863
p-value (Spearman)	0.553	0.621	0.794	0.788

Additionally, averaging the number of questions asked in each category over all the groups demonstrated that students ask significantly more cost-related questions versus any one technical-related question ($p<0.05$). This may indicate that cost was a highly-valued metric in the minds of students.

To determine if apparent interest had a direct relationship to design output values, we investigated the relationship between questions asked during the focus group and achievement/performance on the final design. We calculated correlation coefficients between the number of questions asked per metric and the corresponding final design metric (e.g. BCR) value. These results are given in Table 2 and showed no significant correlations. This indicates that there was no correlation between the number of questions asked for any of the metrics and their associated performance level in the final team design.

RQ2: Does the incorporation of an external customer focus group within Nephrotex influence any specific attribute of the final designs generated by student groups?

Adding the data from the NFG section to our analysis and comparing final design metrics, including marketability, between the NFG and FG sections allowed us to investigate whether the external customer focus group within the Nephrotex virtual internship influenced any specific attribute of the final designs generated by the student groups, such as reliability or flux. The results of this comparison are given in Table 3.

We determined that the cost of the final design was significantly less in the section with the focus group even after adjusting for multiple comparisons using Bonferroni's correction, and was the only metric that demonstrated any significant difference ($p<0.05/5$). In terms of effect sizes, there was

Table 3. Comparison of final design metrics between FG and NFG sections.

	Marketability		Cost		Reliability		Flux		BCR	
	NFG	FG	NFG	FG	NFG	FG	NFG	FG	NFG	FG
average	7.50E+05	6.40E+05	135	114	10.7	9.7	15.6	16	42.2	47.77
std. dev.	1.35E+05	2.37E+05	10.8	15.1	2.5	1.7	1.3	1.4	16.1	14.1
p-value	0.222		0.002		0.305		0.526		0.421	

a large decrease in marketability due to the focus group (Cohen's d = 1.15), but the impact on cost was even larger (d = 2.45) (Sullivan and Fein, 2012).

RQ3: Does the incorporation of an external customer focus group within Nephrotex raise or lower the overall quality of student designs?

We calculated an overall quality score as described in the Methods by summing the number of stakeholder thresholds met for each design. The resulting score had a possible range from 0 to 18. Across all groups who produced devices, the mean overall quality score was 14.95, with a minimum of 13 and maximum of 17.

An independent samples t-test showed no significant difference ($p > .277$, $t(28) = -1.415$) in overall quality scores for devices chosen by the FG section (mean = 15.3, SD = 1.77) versus the NFG section (mean = 14.6, SD = 0.84).

DISCUSSION

These results suggest the following:

There was not a direct relationship between questions asked in the focus group and students' priorities in device design, where priority was established according to the quantitative value of a given aspect of the final design. That is, students did not focus more on the outcomes that they asked more questions about. However, they did ask about cost more than any other issue.

Teams that were exposed to a focus group made lower cost devices than those that were not. Since there was no correlation between student interest and value of device design criteria, it may be that exposing students to customer voice is responsible, at least in part, for this difference.

The quality of devices was not different when comparing focus group and non-focus group teams. Thus, we found that on average, students in both sections produced equally viable designs. Given the decreased cost of designs by focus group teams, and that decreased cost meets a consumer need, the focus group may have achieved these ends by increased attunement to customer voice. Therefore, the exposure of students to customer needs via a focus group may improve the design process by preserving design quality while decreasing cost.

Our results thus preliminarily show that customer exposure through a focus group can encourage a high-quality, lower-cost design within an epistemic game environment. This result has implications for structuring engineering pedagogy to develop the entrepreneurial mindset of students at an early stage of education. As Pahl and colleagues (2013) noted, "The market price and operating costs are the most important criteria for a customer when selecting between competing products and processes." Thus, the lower cost associated with the designs in the focus group section suggests that simulating interactions with external stakeholders in an educational context may help with encouraging the development of an entrepreneurial mindset. The prospect of enhancing an aspect of entrepreneurial mindset through the incorporation of end customer exposure within design experiences in the classroom is important for the future if we are to attain our goals of creating more entrepreneurially minded engineers.

Study Limitations

Unfortunately, the class-size of each section was small with only 57 students each. Since the students worked in teams to complete Nephrotex, our statistical analyses could only be based on a sample size of ten teams per section. However, we employed both parametric and non-parametric statistical analyses in this work, and their results were in general agreement.

Another limitation to this work relates to the pre-constructed questions and responses built into the focus group design. The space from which students could draw questions relevant to their design was constrained in a manner that may not be reflective of what they might ask in a true industrial setting. This could be remedied by an open question format; however, this is difficult to regulate within an epistemic game environment. It would be possible to further determine student valuation of the design metrics through qualitative analysis of the notebook logs students maintained during these activities. This work is currently underway and should serve as useful feedback for future iterations of the customer focus group design as well as additional insight into the students' design processes.

CONCLUSIONS

We have demonstrated that while students who participate as interviewers in a customer focus group show interest in both the technical and cost attributes of a product design, there is at this preliminary stage no evidence of a direct relationship between their interest level and the performance of the design in various areas, including cost and reliability, possibly because students may not ask about matters in which they already have a knowledge-base, a hypothesis that we intend to examine qualitatively in future work. However, students in the focus group section produced final designs that were less expensive than the designs produced in the section without a focus group. Based on this, exposing design students to end customer input processes may yield increased awareness towards customer needs, including cost. It appears this does not sacrifice the technical performance of the final product based on our analysis. This suggests the need for including elements or activities leading to increased customer focus within the design process while not sacrificing on design quality, both of which may help develop amongst students' traits inherent to an entrepreneurial mindset.

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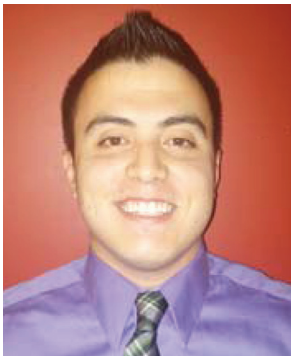

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David W. Shaffer is a Professor at the University of Wisconsin-Madison in the Department of Educational Psychology and a Game Scientist at the Wisconsin Center for Education Research. Before coming to the University of Wisconsin, he was a teacher, teacher-trainer, curriculum developer, and game designer. Dr. Shaffer studies how new technologies change the way people think and learn, and his most recent book is *How Computer Games Help Children Learn*.

Cheryl A. Bodnar, PhD, CTDP, is an Assistant Professor in Experiential Engineering Education at Rowan University although she was working as an Assistant Professor (Teaching Track) in the Department of Chemical and Petroleum Engineering at the Swanson School of Engineering at the University of Pittsburgh when this study was conducted. Dr. Bodnar's research interests relate to the incorporation of active learning techniques in undergraduate classes (problem based learning, games and simulations, etc.) as well as integration of innovation and entrepreneurship into engineering curriculum. More specifically, she is focused on evaluating the effectiveness of games for increasing student motivation and learning within the classroom environment.

APPENDIX A. EXTERNAL STAKEHOLDER QUESTIONS, RESPONSES, AND CATEGORIZATIONS

IN-HOME PATIENT

I have recently been diagnosed with end-stage kidney disease and my nephrologist said that I only have twelve percent kidney function. After several weeks of training, I am legally allowed to have in-home dialysis. I am glad to be able to do this in my own home because I can do it more frequently and for less time each time, plus I'm more comfortable than in a clinic. All of this is important because my nephrologist said I will be doing hemodialysis for the *rest of my life*.

1. How much time do you set aside for your treatment on your dialysis days?
    1.1. I spend two to three hours in each of my dialysis sessions, six times per week. FLUX
2. Other than your actual dialysis sessions, how many hours a week do you set aside for your kidney disease?
    2.1. I have routine check-ups once a month, which last about four hours each time including meeting with my nephrologist, the nurse and the dietician. On average, I would say that I spend about 13 hours per week for my kidney disease. N/A
3. What values did you have in mind when considering the flux of the membrane you use for dialysis?
    3.1. I'm not sure what you mean. I am not familiar with the flux of a membrane. Therefore, I do not have any values in mind. N/A

4. Are you willing to spend over $100 on a hemodialysis membrane?
    4.1. It doesn't matter to me how much it costs. Medicare and my secondary insurance pay for all of it. COST
5. How often do you plan to specifically purchase membranes for your dialyzer?
    5.1. My center just supplies them to me. But, membranes that don't work properly definitely cost me time and effort. RELIABILITY
6. Are you willing to sacrifice an efficient membrane for a membrane that reduces blood cell reactivity?
    6.1. I am not sure what blood cell reactivity is so I cannot answer this question. N/A
7. What is your pain threshold (how tolerant are you to pain)?
    7.1. I feel as if I can tolerate a high amount of discomfort. BCR
8. Have you seen any commercials or magazine ads for dialyzer membranes?
    8.1. Yes – on TV. I saw one that seemed to use really advanced technology and told my nephrologist about it. I'm not sure if we're using that one or not. MARKETABILITY
9. Would you be willing to pay more for a high-flux membrane?
    9.1. Like I said, I don't pay for it but if high-flux means less time for me, the answer is yes! N/A
10. For your treatment, are you performing daily (3 sessions per week), short-daily (5–7 sessions per week) or nocturnal dialysis (3-6 night sessions per week)?
    10.1. I am currently on a short-daily dialysis regimen about 6 times per week. N/A

NEPHROLOGIST

In my practice, I care for a lot of patients with end stage renal disease. Many of them use hemodialysis. I want the most effective treatment for these patients in the shortest amount of time. I have 15 hemodialysis machines available at my clinic that are in use 8 hours a day, six days a week. These machines must be replaced after 25,000 to 40,000 hours of use and with constant monitoring. I would like to purchase membranes that are as efficient as possible and also reliable to avoid downtime.

1. Would your practice be able to use a medium-high flux through the membrane if it saved you money?
    1.1. As long as the membrane is able to provide the patient with the best care possible and save us money, then it would definitely be used. COST
2. Is your practice willing to purchase membranes in bulk (greater than 50 units at a time)?
    2.1. My clinic typically would like to purchase materials in bulk to get a volume pricing discount if possible since we have a very consistent, predictable and ongoing need. COST

3. How many patients, on average, do you have monthly?
    3.1. My practice has about 50 patients per month that come in for hemodialysis. N/A
4. Are you willing to use a membrane with lower flux if it means your patients will be in dialysis longer?
    4.1. No. We are not interested in doing so since our practice sees a lot of patients and if the treatment takes longer we would have to reduce the number of patients that we can treat. FLUX
5. Have you seen any magazine advertisements for our hemodialyzer membranes?
    5.1. I have seen a few membrane ads in medical magazines, but I have not seen any of yours specifically. MARKETABILITY
6. How many dialysis machines do you currently own and how many have you had to replace since your practice originally opened?
    6.1. My practice has 15 dialysis machines that are currently in use. I have had to replace three of them since my practice opened. N/A
7. How closely do you monitor blood cell reactivity?
    7.1. We try our best to minimize blood cell reactivity, as we do not want to impose any more discomfort than necessary on our patients. While we maintain the minimum legal requirement, we do not solely base our practice on the blood cell reactivity rate. BCR
8. Are you willing to pay more for a high-flux dialyzer?
    8.1 The dialysis clinic is paid a set amount per treatment, and we have to provide care within that budget. Therefore, the cost of the membranes is very important to us. We would consider a higher cost membrane if it really improved patient care, but I'd want to really know how it improves patient outcomes. COST
9. Have you heard about any of our membranes through any other clinics or during any seminars?
    9.1. To be honest, I have not heard about your membranes or anything related to your company before. MARKETABILITY
10. How much is your clinic willing to pay for a membrane that has a suitable reliability?
    10.1. Though the membrane may have good reliability, we are still on a budget and would like to spend no more than $80 on the membranes that we use. COST

HOSPITAL ADMINISTRATOR

Nearly 175 acute and chronic kidney disease patients come into my hospital *every month*. My job is to control costs while providing the best possible care. With that said, I would like to purchase membranes that satisfy the minimal legal requirements (reliability, flux and blood cell reactivity) in bulk from you. As with all of my bulk orders, I do expect the overall price to be significantly lower than what a normal order would be due to volume discounts. I also tend to be less concerned with the reliability of the membrane since I have a large quantity in stock at the hospital.

1. Have you seen our ads for hemodialyzer membranes in any medical magazines or advertisements?
    1.1 What magazine did you advertise in? I have not seen any advertisements from your company before. MARKETABILITY
2. Would you be willing to have smaller, more frequent orders rather than one large bulk order?
    2.1. I would much rather buy the membranes in a bulk order as we go through many of them quickly. Frequent orders would mean I have to monitor membrane use much more closely and spend time ordering this item more often. Also, if I order smaller quantities, any reliability problems could really affect the treatment of our patients. RELIABILITY
3. Many patients tolerate different levels of pain. Are you willing to purchase membranes with different blood cell reactivity rates associated with the membrane in order to accommodate your patients?
    3.1. I am not willing to order membranes based on different blood cell reactivity rates. I am interested in ordering membranes that meet the minimum legal requirements for blood cell reactivity. BCR
4. How many dialysis machines does your hospital currently have in use?
    4.1. I currently have 15 dialysis machines in use in my hospital. N/A
5. Is your hospital willing to spend more money on a high-flux dialyzer for your patients?
    5.1. As of right now, my hospital is not willing to spend more money in this area. We tend to use the minimum legally required membranes within our hospital, which is generally cheaper for us. COST
6. Would you ever consider making an exclusive sales contract with one company who could supply all of your dialysis membrane needs?
    6.1. I would need to know more details before I could make this type of decision. The good part of having a large selection of vendors is that it is a competitive market which enables our hospital to get the best product at a great price point. COST
7. How important is it for your hospital to provide your patients with a comfortable setting?
    7.1. We want our hospital to be known for patient care and overall well-being. We want our hospital to provide the maximum care for all patients and have them feel that they are comfortable. BCR
8. How does your hospital deal with the blood cell reactivity involved with the hemodialysis patients?
    8.1. My hospital typically purchases membranes that have blood cell reactivity rates at the minimum legal requirement. BCR

9. Are you familiar with the use of carbon nanotubes within membranes?
    9.1. I have heard of carbon nanotubes within dialysis membranes, and I do know that it makes the membrane significantly stronger. However, I do not know much more about them, or any details about the effects they have during dialysis. N/A
10. How long is a typical dialysis session at your hospital and would you be willing to accept longer or shorter sessions?
    10.1. A typical dialysis session in my hospital lasts for about four hours. Although shorter sessions could be advantageous if the overall treatment efficacy were the same, we wouldn't want the sessions to last any longer because it would limit the number of patients we could treat on a daily basis. FLUX

Industry Thought Leader

I have been working in the field of hemodialysis for the majority of my career (greater than 30 years). My current position is Chief Medical Officer (CMO) for one of the large medical technology companies that work in the hemodialysis field. Recently, I was asked to compile my thoughts and reflections on dialysis and all the transitions the field has gone through over the course of my work in the field. Working together with other leading scientists, we have published a book that documents the history of dialysis, the changes in this field and the latest state of the art advances that we believe will lead this field into the next century.

1. Have you ever worked on the design of hemodialysis membranes?
    1.1. I have not specifically designed membranes although I have worked closely with biomedical engineers within my organization that have been involved in the design of these membranes. N/A
2. What specifications do you feel are most important to consider when making a hemodialysis membrane?
    2.1. From a pure technical standpoint, I believe that the blood cell reactivity and the flux you can achieve through the membrane are important to focus upon. FLUX and BCR
3. At your company does cost play a significant issue in design?
    3.1. Cost always plays an issue but it is not the sole criterion. It is important that you balance cost with the overall quality of the design to create a product that customers will value. N/A
4. Have you ever seen any television or magazine ads for Nephrotex membranes?
    4.1. I am aware of Nephrotex and their hemodialysis membranes. As an industry leader, it is important to be aware of your competitors and what they are working on. MARKETABILITY

5. In the book on dialysis that you were recently involved with can you share what design parameters for membranes were discussed?
    5.1. We discussed all the key design parameters: membrane flux, blood cell reactivity, reliability and cost. N/A
6. In your expert position, do you feel that patients' pain threshold is an important factor in the design of hemodialysis membranes?
    6.1. I believe that this is a factor that needs to be considered when designing a device. However, this is not the sole criterion that needs to be accounted for. BCR
7. What are some of the state of the art advances that were discussed in the dialysis book?
    7.1. We discussed developments in the field overall but didn't examine specifically innovations related to the design of hemodialysis membranes, so unfortunately I cannot help you in this regard. N/A
8. As an industry leader, what compromises do you observe being made in the design of hemodialysis membranes?
    8.1. I believe that each company makes its own decisions; I wouldn't necessarily call these compromises, in order to provide the best possible product to their target customer. N/A
9. When deciding on the target flux for a membrane, are there any specific questions you seek answers for?
    9.1. We seek to determine what is important for our target customer and then utilize that information in the design of our membranes. N/A
10. What are your thoughts on the use of carbon nanotubes in a hemodialysis membrane?
    10.1. I have read that they have extremely smooth walls which will allow for increased flow of fluids and gases through them. I believe that for this reason, they are an interesting possibility to consider in hemodialysis membrane design. FLUX

MEDICARE GOVERNMENT ASSISTANT

As of 1972, the United States government extended Medicare coverage to all people of any age with end-stage renal disease. We cover up to 80 percent of the costs for the treatment of end-stage renal diseases, which includes both in-home and on-site patients. However, over the past few years, we have seen an increase in the average cost of treatment per individual with kidney disease. As of 2012, the average cost of treatment, dialysis, supplies and aide per person was roughly $88,000. While we want every one of our customers to have the best treatment possible, we recognize that we do need to cut down on some areas of coverage for our customers due to the increasing costs. Our analysts have decided that one area we can cut down on costs is through limiting the selection of membranes used during the hemodialysis process for which we will cover costs. We would like to limit our coverage to a lower cost membrane while still providing our customers the best possible care.

1. What is the maximum price range you will cover for customers' membranes?
   - 1.1. Medicare will cover up to $80.00 for customers' membranes. COST
2. What percent of the total costs will you cover if your customers do in fact use a high priced membrane?
   - 2.1. After the $80.00 coverage, the customer will have to cover the cost. This is most often through a secondary insurance company but could be as an individual co-pay. COST
3. How important is it to you for your customers to be comfortable during the hemodialysis process?
   - 3.1. We want our customers to be as comfortable as possible throughout their hemodialysis treatment. Additional pain and suffering would likely increase patient care costs long-term. BCR
4. How important is blood cell reactivity to the Medicare program?
   - 4.1. I will have to double check with our analysts before I can answer this question. Medicare wants to provide the most efficacious, efficient and comfortable treatment for each patient that we can finically support in a responsible, sustainable way. BCR
5. Are you willing to cover a membrane that is shown to be successful in waste removal in a smaller amount of time for the customer?
   - 5.1. Medicare would like to cover as efficient a membrane as possible for our customers; that is, one that reduces treatment times the most. As long as the membrane falls within our coverage limit, Medicare will cover the cost of a more efficient membrane. FLUX
6. Are you willing to cover a membrane that is associated with a small amount blood cell reactivity during a hemodialysis session?
   - 6.1. I will have to check my resources before I can answer any questions regarding blood cell reactivity. N/A

7. Will you cover more expensive membranes if it is proven that lower priced membranes did not sufficiently remove enough waste from the patients?
    7.1. I have to check my resources before I answer any questions about the waste removal rate. I do know that up until now, the membranes that Medicare has covered meet the minimum legal requirements for all aspects of dialyzers. N/A
8. How often do you see our membrane advertisements in medical magazines?
    8.1. As an agent for Medicare, I have not personally read or seen any magazines related to hemodialysis membranes. Medicare analysts are always up to date, however, so I would have to double check with them for this question. MARKETABILITY
9. Does your coverage fluctuate for the in-home or on-site patients?
    9.1. Medicare's coverage does not fluctuate between in-home and on-site patients. There is an 80 percent coverage for approved fees for customers. A private insurance company or a co-pay is required for the other 20 percent of the fees. N/A
10. How efficient of a membrane will Medicare cover?
    10.1. Medicare will cover up to $80.00 for any membrane that meets the minimal legal requirements. The efficiency of the membrane is not a consideration. COST