

The DMVP (Detect, Measure, Valuate, Propose) Method for Evaluating Identified Needs During a Clinical and Technology Transfer Immersion Program

Miss Hannah Lynn Cash, Clemson University

Hannah Cash is pursuing her PhD in Bioengineering with a focus on Engineering and Science Education. Working with students through the engineering design process, Hannah has been encouraged to aid in outreach opportunities to bring Bioengineering and Design to younger students and teachers throughout the Upstate of South Carolina through work with the Perry Initiative and Project Lead the Way. The Perry Initiative works to inspire young women to be leaders in engineering and medicine, while Project Lead the Way works to bring engineering and medicine to teachers and students in K through 12 programs.

Hannah was a four year club sports athlete for the Clemson University Women's Ultimate team. She was captain for two years, which taught her team-centered leadership. Hannah used these skills to lead her senior design capstone team to develop and create a functional sports rehabilitation device. Hannah found her drive for design and engineering education during the development of this device and is working to instill students with the same drive and initiative through experimental learning.

Dr. John D. DesJardins, Clemson University

Dr. DesJardins is an associate professor in Bioengineering at Clemson University and the director of the Frank H. Stelling and C. Dayton Riddle Orthopaedic Education and Research Laboratory at CUBEInC. He has coauthored over 200 peer-reviewed conference or journal publications in the areas of biomechanics, biomaterials tribology, engineering education and implant design. He is active in many professional societies and review panels, including BMES, NCIIA, ORS, NIH and NSF. He is or has been the PI or co-PI on many multi-disciplinary research teams funded through NASA, DoT, NIH, DoD, NSF, the Gates Foundation, and numerous biomedical industry grants and contracts. He was a guest editor with the Annals of Biomedical Engineering, developing a special issue on Design Innovation in Biomedical Engineering. He directs the bioengineering senior capstone design program, the undergraduate bioengineering study abroad programs, and founded the Clemson University Retrieval of Explants Program and Registry in Orthopaedics (CU-REPRO).

Dr. Breanne Przestrzelski, University of San Diego

Bre Przestrzelski, PhD, is a post-doctoral research associate in the General Engineering department in the Shiley-Marcos School of Engineering, where she seeks to innovatively integrate social justice, humanitarian advancement, and peace into the traditional engineering canon.

Before joining USD in August 2017, Bre spent 9 years at Clemson University, where she was a three-time graduate of the bioengineering program (BS, MS, and PhD), founder of The Design & Entrepreneurship Network (DEN), and Division I rower. In her spare time, Bre teaches design thinking workshops for higher education faculty/administrators at the Stanford d.School as a University Innovation Fellow, coaches a global community of learners through IDEO U, and fails miserably at cooking.

The DMVP (Detect, Measure, Valuate, Propose) Method for Evaluating Identified Needs During a Clinical and Technology Transfer Immersion Program

I. Introduction

The process of biomedical device design is a fundamental skillset that students must learn in order to become effective innovators in the biomedical device industry. One of the initial steps in this process, needs-finding, involves the observation of stakeholders and identification of problems in order to determine potential areas for innovation [1]. However, following the identification of these needs, a filtering process is often employed, wherein external influences such as market dynamics, competition, and intellectual property influence the potential for the successful development and commercialization of solutions in these needs area [2]. Oftentimes, these needs are inappropriately filtered for feasibility rather than potential, leaving behind some of the greatest insights for potential innovation [3,4]. This paper proposes and assesses the implementation of a new method of evaluating needs that has been fully integrated in a university clinical immersion program.

The DeFINE (Design Fundamentals in Needs-Finding Experience) Program is a six-week clinical immersion program funded by the National Institute of Health (NIH) and VentureWell [5]. DeFINE allows rising juniors and seniors in Bioengineering to experience, empathize, and observe various clinical specialties with the goal to identify needs and evaluate these needs from a technology valuation perspective [5]. This enables students to learn how to assess the probability of technology commercialization for potential solutions to the identified needs [5].

During years 1 and 2 of the DeFINE program, experts from the university technology transfer office explained to students how to determine which identified needs were “Problems Worth Solving.” The experts shared with students three criteria that the technology transfer office uses to evaluate the potential of a need and potential solution: commercial potential, ease to commercialize, and technology maturity. However, despite these explanations, students felt that “[t]he tech[nology] evaluation form was difficult for certain technologies,” but the students did recognize that “understanding all the barriers to market are key.” Therefore, in years 3 and 4 of the program, a new method called the DMVP (Define, Measure, Valuate, and Propose) method was created and piloted. The DMVP method translates the technology transfer evaluation process into four distinct sections that are used for needs filtering; also loosely summarized as a method to Determine the Most Valuable Problems for which to develop novel solutions. The goal of the DMVP process, unlike the goal of the technology transfer office, was to incorporate market analysis into the needs finding and problem identification phase of the design process to determine the most valuable problem before solutions to these problems are considered.

II. Methods

Student Population

In years 3 and 4, students applied to participate in the DeFINE program through an application that asked students to discuss their interest in the DeFINE program, their previous experience in

design, clinical shadowing, and technology transfer activities, and their future academic and professional goals. In year 3, 8 rising juniors and 6 rising seniors were selected for a total of 14 students. In year 4, 5 rising juniors and 10 rising seniors were selected for a total of 15 students.

Clinical Population

In year 3, there were 10 different specialties and 19 different physicians that the students were able to contact, as seen in **Table 1**. Overall, students in year 3 observed 106 clinicians and 253 total procedures. In year 4, the majority of specialties were the same, but Bone & Joint, Vascular Surgery, Plastic Surgery, and Prosthetics & Orthotics were offered whereas Pediatrics Intensive Care and Pediatric Urology were not offered as seen in **Table 1**. There were still 19 different physicians that the students were able to contact. The year 4 students were able to observe 62 clinicians and 181 total procedures.

Table 1: The specialties and the number of physicians in each specialty in year 3 and year 4. The physicians were located in 3 local hospitals in year 3 and in 5 local hospitals in year 4.

Year 3		Year 4	
Specialty	Number of Available Physicians	Specialty	Number of Available Physicians
Neurology	1	Neurology	2
Surgical Oncology	1	Surgical Oncology	1
Pediatric Intensive Care	1	Prosthetics & Orthotics	1
Pediatric Urology	1	Plastic Surgery	1
Primary Care and Sports Medicine	4	Primary Care and Sports Medicine	3
Minimally Invasive Surgery	2	Minimally Invasive Surgery	1
Colon and Rectal Surgery	1	Colon and Rectal Surgery	2
Otolaryngology (ENT) Surgery	1	Otolaryngology (ENT) Surgery	1
Orthopaedics & Trauma	2	Orthopaedics & Trauma	3
Obstetrics/Gynecology	1	Obstetrics/Gynecology	1
		Bone & Joint	2
		Vascular Surgery	1

Clinical Shadowing Experience

Each student ranked the different specialties based on the student’s interest and was then matched into groups of two to three based on similar rankings of the specialties. Each group went through two rotations, with two weeks for each rotation. The groups were given the contact information for their specialty and coordinated observation times with their physicians. For each week in the two rotations, students observed their physicians and documented all observed problems. These problems ranged from disorganization and sanitation in the operating room to

total knee replacement failure. Students were encouraged to document all problems regardless of how small they seemed as well as to observe not only the physicians, but also the nurses and operating room staff.

Students documented the number of hours spent in the operating room and in the clinic. In year 3, students spent 792.5 total hours in the operating room and 337.5 total hours in the clinic. Students in year 3 spent 291.5 total hours documenting 610 problems and from those problems, identified 138 total needs. In year 4, students spent more time in the operating room and clinic with 804.5 total hours in the operating room and 550 total hours in the clinic. The year 4 students spent 356.5 total hours documenting 319 problems. From these 319 problems, the students identified 140 needs.

Table 2: The total hours spent by students observing and documenting and the amount of problems and needs identified during years 3 and 4 of the program.

Program Year	Hours in Operating Room	Hours in Clinic	Hours Documenting	Documented Problems	Identified Needs
3	792.5	337.5	291.5	610	138
4	804.5	550	356.5	319	140

“Problems Worth Solving” Selection

At the end of each observation week, students selected their five top-problems from that week, these problems students considered to be “Problems Worth Solving.” Once these problems were selected, students used the DMVP process to evaluate and present each top-problem to their peers and mentors [5].

DMVP Evaluation Process

The DMVP process utilizes four steps to evaluate one problem: I. Detect, II. Measure, III. Valuate, and IV. Propose. Each step was developed from the technology transfer office evaluation form to evaluate potential patentable devices. For each step in the DMVP process, a worksheet was developed in order to describe the four main segments of each step as seen in the following table.

Table 3: The four steps in the DMVP process and the overall goal that each step accomplished. Each step had four main segments that students researched in order to understand what factors contributed to the overall goal of each step.

I. Detect	II. Measure	III. Valuate	IV. Propose
<i>Goal of detect</i>	<i>Goal of measure</i>	<i>Goal of valuate</i>	<i>Goal of propose</i>
People	Incidence	Market	Population
Places	Prevalence	Growth	Outcome
Products	Morbidity	Intellectual Property	Problem
Procedures	Mortality	Competitors	Metric

A sliding scale was developed from the technology transfer office evaluation form and introduced on the Measure and Valuate worksheets. The technology transfer evaluation form used a sliding scale to evaluate the potential of the market opportunity, clinical adoption, and degree of innovation for each technology. The scale on the Measure and Valuate worksheets was similarly developed in order to numerically quantify the qualitative descriptions on each worksheet and then, in the Propose worksheet, students were asked to calculate a score to numerically quantify the importance of the need. Then, after each need was defined, the higher score was considered to be the “Problem Worth Solving.”


During orientation week, the DMVP worksheets were introduced to the students one at a time, and each component of the worksheet was explained and discussed. Each team was given an example clinical problem or disease state and asked to complete the worksheet using internet resources. The teams then discussed their results in a group setting, and instructors provided feedback. Finally, students observed a mock surgery during the last part of orientation week. While observing the surgery, students documented every observed problem and then chose their top problem. Once the problem was chosen, students worked through the 4 worksheets of the DMVP process. Then, students presented and discussed each worksheet to their peers and mentors.

In step 1, Detect, the key observed variables of Problem, Places, People and Procedures (the 4 “P’s”) related to each issue were documented to answer the following questions: What is the Problem? Where (Place) was the problem detected? Who (People) was observed in the situation? What Procedure was being conducted where the problem was observed? **Figure 1** depicts an example of a student’s worksheet for I. Detect.

In the People segment, students indicated all people that were involved in the situation where the problem was identified, including, but not limited to clinician, patient, nurse, technician, medical representative, etc. In the Places segment, students documented the location that the observed problem took place. Students were asked to be as specific as possible regarding the location, and include the shadowed hospitals/clinics, as well as the department and sometimes even down to specific operating room within the location. In the Products segment, all products that were associated with the observed problem were documented, both those directly involved with the surgery and those not. Students were asked to follow up on the products observed in the clinical setting for further evaluation (material type, properties, etc.). Finally, a detailed description of the procedure where the associated problem was observed was explained in the Procedures segment. This section, while documented partially during the procedure, was often complemented with additional student research following conclusion of the procedure.

DETECT D

Problem: _____

<p>People</p> <p>Dr. Culumovic / Dr. Rex Evan Bledsoe (Mesh Rep)</p> <p>Patients undergoing Hernia repair</p>	<p>Places</p> <p style="text-align: center;">GHS Memorial Hospital OR Room D8</p>
<p>Products</p> <p>Hernia Surgical Mesh</p> <ul style="list-style-type: none">• Polypropylene 	<p>Procedures</p> <p>Surgical mesh is a medical device that is used to provide additional support to weakened or damaged tissue. The majority of surgical mesh devices currently available for use are constructed from synthetic materials</p> <ul style="list-style-type: none">• Laparoscopic - The surgeon makes several small incisions in the abdomen that allow surgical tools into the openings to repair the hernia. Laparoscopic surgery can be performed with or without surgical mesh.• Open Repair - The surgeon makes an incision near the hernia and the weak muscle area is repaired. Open repair can be done with or without surgical mesh. Open repair that uses sutures without mesh is referred to as primary closure. Primary closure is used to repair inguinal hernias in infants, small hernias, strangulated or infected hernias.

Recorded by: _____

Figure 1: Example of the I. Detect worksheet students used to evaluate the 4 “P’s.”

In step 2, Measure, students were tasked with the collection of the clinical significance and societal impact of the problem. This was determined through the assessment of the Incidence, Prevalence, Morbidity and Mortality associated with the problem, all of which were researched outside of the clinical setting using tools introduced to the students by the university librarian, the DeFINE program instructor, and graduate mentors. Students were shown how to search for this information online through the university research website. The university librarian demonstrated how to search for reputable journals and papers that contains the necessary information a student needed to Measure the problem. **Figure 2** is an example of the worksheet used for the II. Measure assessment. The Incidence was first established by determining the rate of occurrence of the observed problem. Next, the Prevalence of the observed problem was researched to determine the proportion of past cases or its associated outcomes that were currently in the population. Then, the Morbidity associated with the observed problem was explained by quantifying the prevalence and impact of diseases and unhealthy states associated with the problem. The final variable associated with II. Measure, was Mortality, which was determined by researching the number of deaths associated with the observed problem.

MEASURE
M

Problem: _____

<p>⚠ Incidence</p> <p>More than 1 million abdominal wall hernia repairs are performed each year in the United States, with inguinal hernia repairs constituting nearly 770,000 of these cases; approximately 90% of all inguinal hernia repairs are performed on males.</p> <p style="text-align: right;">40%</p>	5 4 3 2 1 ①	<p>👥 Prevalence</p> <p>About 25% of males and 2% of females develop inguinal hernias; this is the most common hernia in males and females.</p> <p style="text-align: right;">20%</p>	5 4 3 ② 1
<p>⚡ Morbidity</p> <p>The most common adverse events following hernia repair with mesh are pain, infection, hernia recurrence, adhesion, and bowel obstruction. Some other potential adverse events that can occur following hernia repair with mesh are mesh migration and mesh shrinkage (contraction).</p> <p style="text-align: right;">25%</p>	5 4 3 2 1 ①	<p>👤 Mortality</p> <p>Contraction rates are 31.5% and 26.4% based on fixation methods</p> <p style="text-align: right;">15%</p>	5 4 3 2 ①

Recorded by: _____ Final Score: 1.2

Figure 2: Example of the II. Measure worksheet students used to evaluate clinical significance and impact of the problem. The number columns represent the scale developed from the technology transfer office.

In step 3, Valuate, the students researched and identified the economic impact of the interested clinical area of innovation. To determine this impact, students quantified the key marketability variables of Market Size and Growth and then initially identified key Intellectual Property and Competitors within the market. This worksheet was specifically adapted from the form used by the technology transfer office for evaluating technology, which used variables such as target market size, market trends, barriers to entry, and patent analysis to triage potential technology for this determination. The Valuate step focused on quantifying the market size as the Market, the market trends as the Growth, and barriers to entry and patent analysis as Intellectual Property and Competitors. **Figure 3** shows an example of the third worksheet students used to determine the growth and market of the area as well as to identify the market competitors and evaluate the intellectual property landscape. First, students identified the size of the Market and the Growth of the market online using journals and published data as well as market reports. Students were taught how to find accurate and up to date reports by technology transfer experts from the university technology transfer office as well as the university librarian. Students then identified any key intellectual property and patents that were attempting to solve the problem, and any key competitors within the market to determine how crowded the market landscape may be for solutions in this space. This was important in initially determining the ease to market for a solution, which helped to determine if the observed problem was worth pursuing.

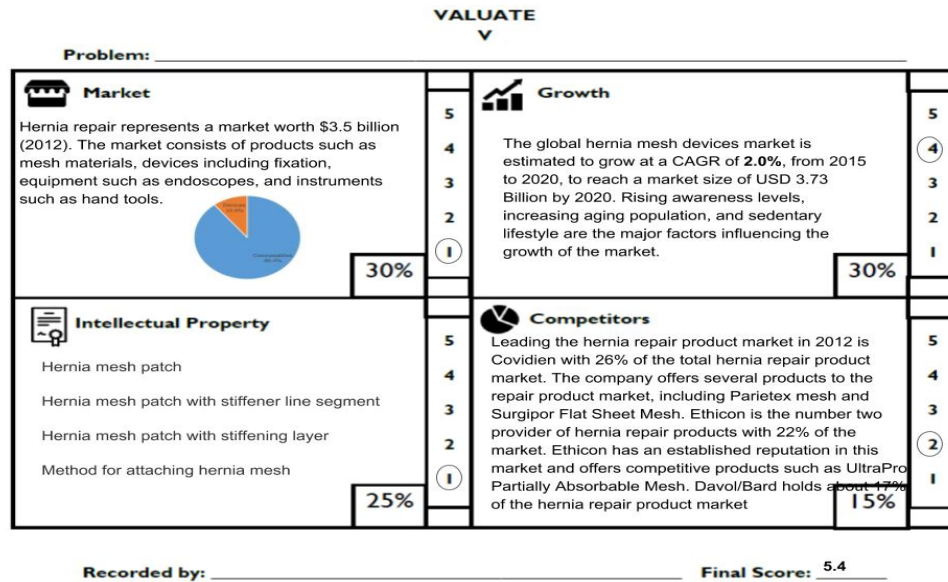


Figure 3: Example of the III. Valuate worksheet students used to quantify key marketability variables.

Finally, in step 4, Propose, students summarized the Problem, Population, and Outcome that the potential solutions should solve, and a Metric to measure potential solutions. All of this was completed and then compiled to create a more clearly defined need statement to then assist in determining the critical elements in a potential solution to the problem (innovation). An example of the Propose worksheet students used in the final step of the DMVP process is seen in **Figure 4**. Students specified a critical Population that the observed problem affected, this population was not necessarily the same people identified in I. Detect, but rather a larger population to which this innovation could be applied. Then, students reexamined the problem and translated the problem into a defined critical Outcome that a solution should influence. After defining the Population and Outcome, students redefined the Problem that was initially observed based on the content compiled from steps DMV and then listed clearly defined Metrics that could be used to measure potential solutions.

PROPOSE
P

Recorded by: _____

<p>Population</p> <p>Patients in need of Hernia repair</p>	<p>Outcome</p> <p>Recurrence rates will decrease and patients will have successfully undergo one repair procedure</p>
<p>Problem</p> <p>Often following hernia repair with mesh are mesh migration and mesh shrinkage (contraction). This can lead to recurrence.</p>	<p>Metric</p> <p>Increased Fixation</p> <p>Decreased Contraction</p> <p>Increase Support to Damaged Tissue</p> <p>Recurrence rates will decrease</p>

There is a need for: _____ (40%) + _____ (60%) = _____
M V FINAL

Need Statement:
There is a need to improve the efficacy of hernia mesh material to prevent migration and contraction rates, which would reduce the rate of recurrent operations.

Figure 4: Example of the IV. Propose worksheet students used to identify specific variables the solution should solve.

Using the defined Population, Outcome, Problem, and Metric, students developed a well-defined need statement that incorporated these four segments in the Propose step. Once the need statement was developed, students wrote out the need statement on the bottom of the worksheet as seen in **Figure 4**. The 40% and 60% split between M and V respectively was a weight factor used to determine a quantitative score for the problem. V was weighted higher due to V representing the market and intellectual landscape that a potential solution would enter. The problem with the highest final score was then considered the “Problem Worth Solving.” These need statements were then collected for a final program database that was passed on to future senior design courses that followed the summer clinical immersion.

Data Analysis

In year 2 of the DeFINE program, students (n = 18) used a technique called MindMeister to mind map observed problems in order to visualize, share, and present these problems to their peers⁶. To evaluate the effectiveness of this technique, students were given a survey using a Likert scale from “Not Useful” to “Highly Useful.” The year 2 survey asked students to comment on the usefulness of the MindMeister introduction, the usefulness of the MindMeister for documentation of observed problems, and the usefulness of the 4 “P’s” structure.

At the end of years 3 and 4, students (n = 14 and n = 15) were given a survey about the DeFINE program. In year 3, the survey utilized a Likert scale from “Not Useful” to “Highly Useful” as well as a comment section. The year 3 survey asked students about the usefulness of the introduction to each of the steps in the DMVP process, the DMVP worksheet practice of the observed surgery, and the DMVP worksheets overall. Finally, students were asked to comment on the tools and techniques that they used as well as those they wished they could have used. In year 4, a more extensive survey was developed to determine the effectiveness of the DMVP process. Students were still asked to comment on the usefulness of the introduction of each step

in the DMVP process using the same Likert scale, but the survey evolved to include a section specific to commenting on the DMVP process and technique. In this section, students were asked to rank on a Likert scale of “Strongly Disagree” to “Strongly Agree” how effective the DMVP process was in allowing students to better understand important considerations when assessing problems and how well the DMVP process broke down the process into discrete, easy to follow steps. This section also asked students to rate on the same Likert scale, how well each step of the DMVP process allowed the students to assess the segments within each step. The last questions in this section asked students to comment, using the same Likert scale, on how well the DMVP process allowed them to more intelligently discuss observed problems with peers and objectively assess the relevance and importance of the observed problems.

III. Results and Discussions

Year 2 (n = 18)

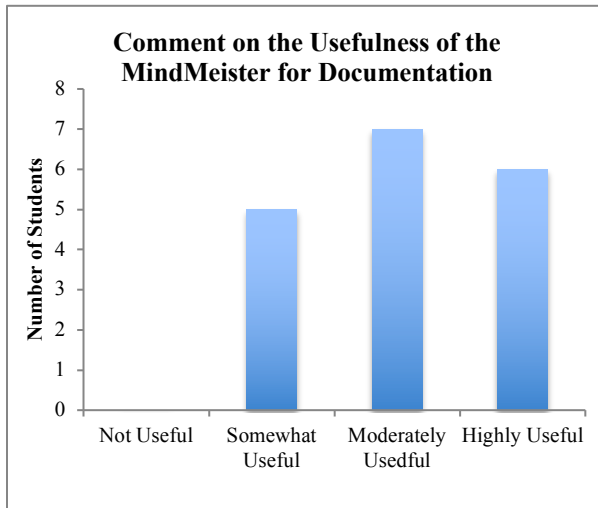


Figure 5: The DeFINE year 2 survey results for the usefulness of the MindMeister technique introduction.

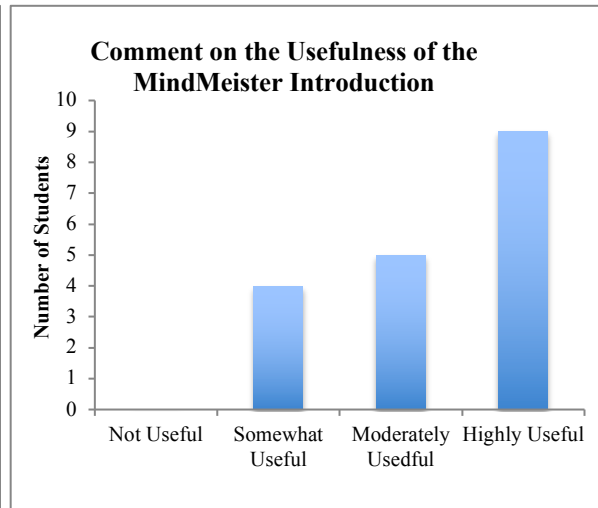


Figure 6: The DeFINE year 2 survey results for the usefulness of the MindMeister for documentation of the identified problems.

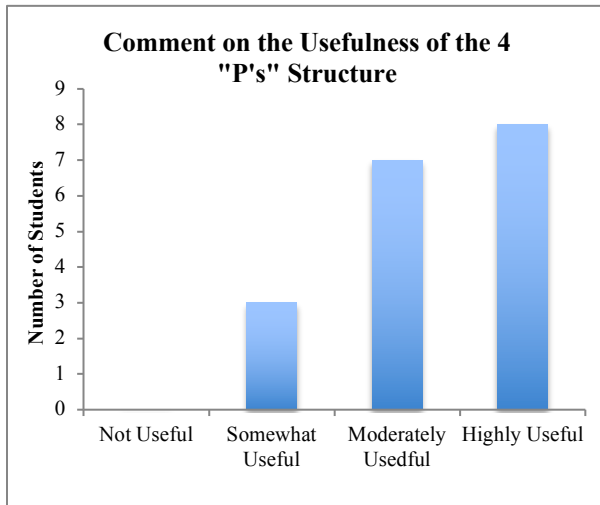


Figure 7: The DeFINE year 2 survey results for the usefulness of the 4 “P’s” structure.

Years 3 and 4 (n = 14 and n = 15)

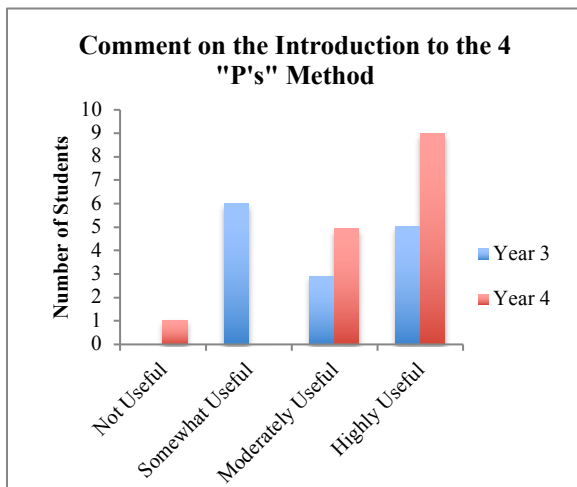


Figure 8: The DeFINE year 3 and 4 survey Results for the usefulness of the introduction to the 4 “P’s” Method.

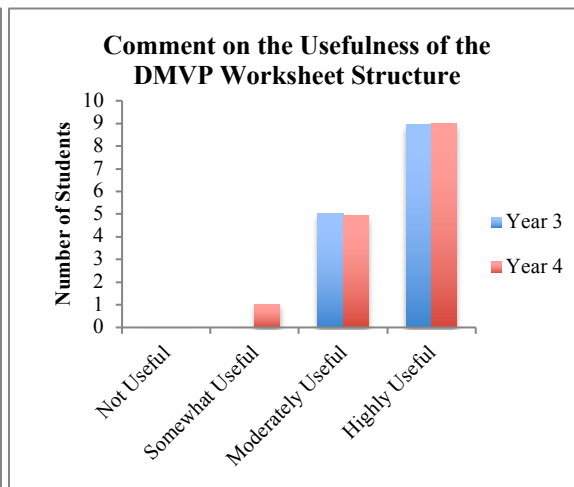


Figure 9: The DeFINE year 3 and 4 survey results for the usefulness of the DMVP worksheet structure.

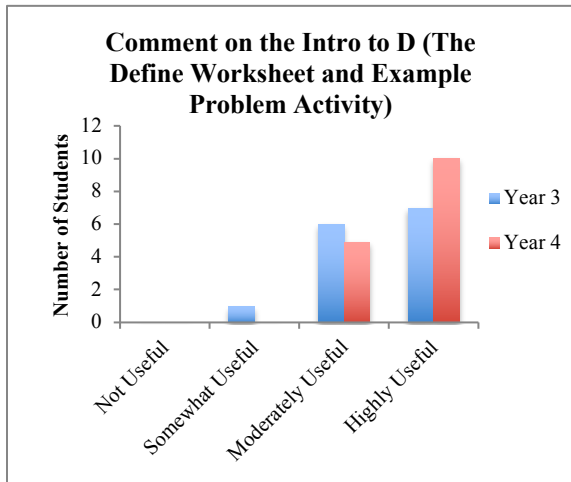


Figure 10: The DeFINE year 3 and 4 survey results for the usefulness of the intro to Define and example problem.

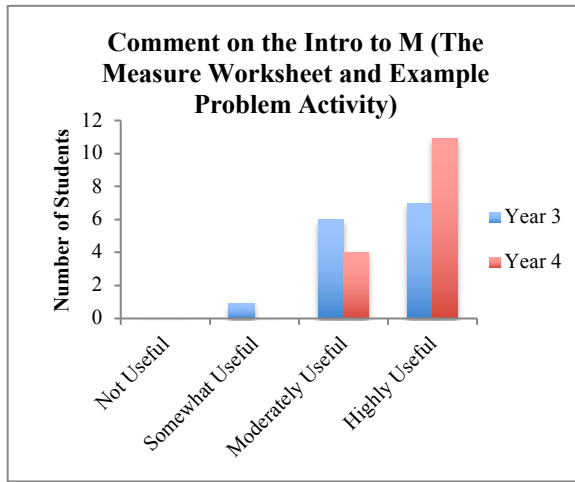


Figure 11: The DeFINE year 3 and 4 survey results for the usefulness of the intro to Measure and example problem.

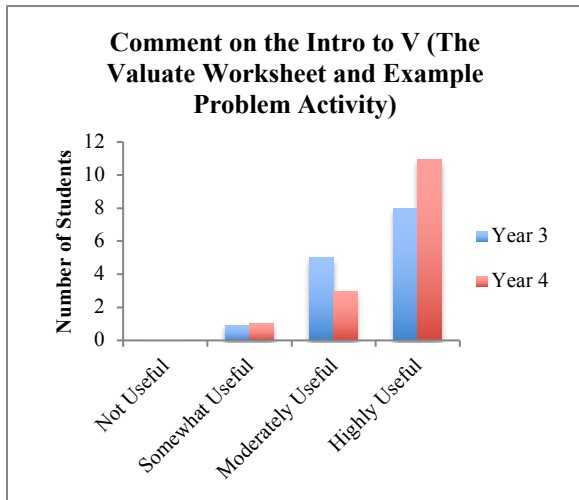


Figure 12: The DeFINE year 3 and 4 survey results for the usefulness of the intro to Valuate and example problem.

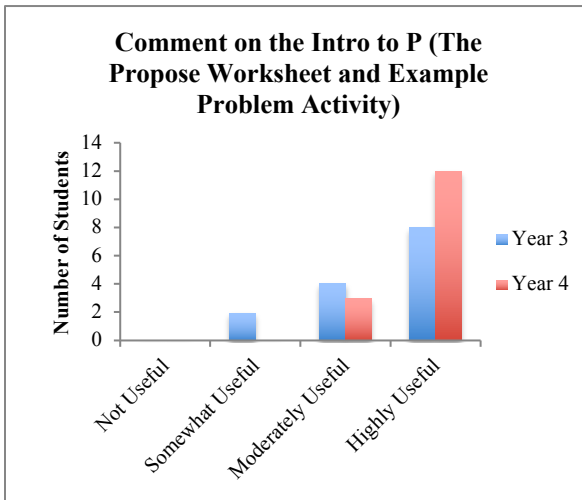


Figure 13: The DeFINE year 3 and 4 survey results for the usefulness of the intro to Propose and example problem.

Year 4 ($n = 15$)

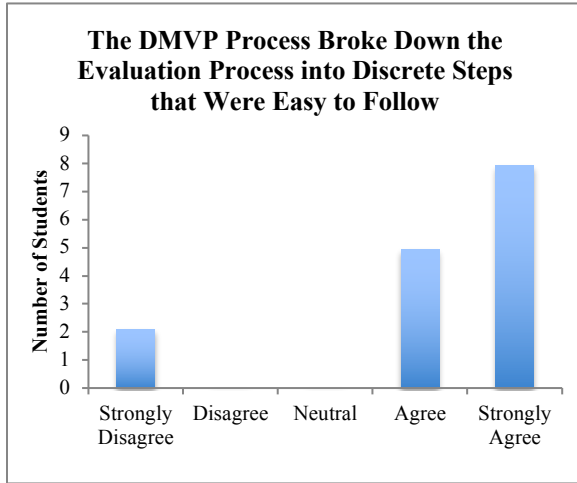


Figure 14: The DeFINE year 4 survey results for how well the DMVP process broke down the evaluation process of each problem into easy to follow steps.

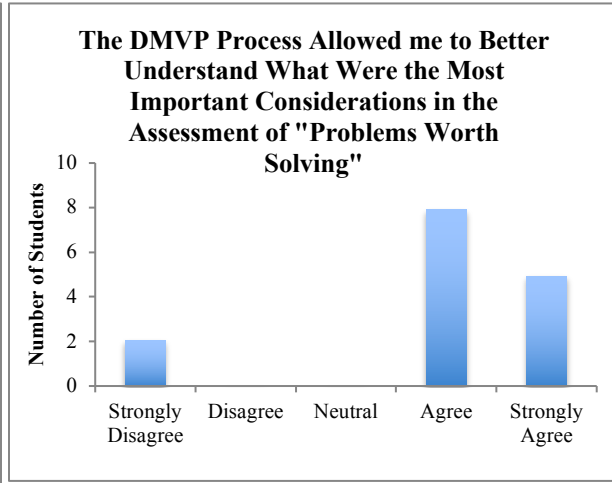


Figure 15: The DeFINE year 4 survey results for how well the DMVP process allowed each student to understand the most important considerations in assessing which problems were worth solving.

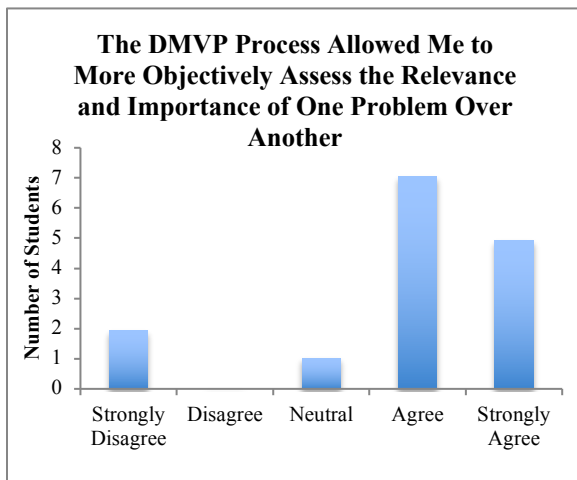


Figure 16: The DeFINE year 4 survey results for how well the DMVP process allowed students to objectively assess the relevance and importance of one problem over another.

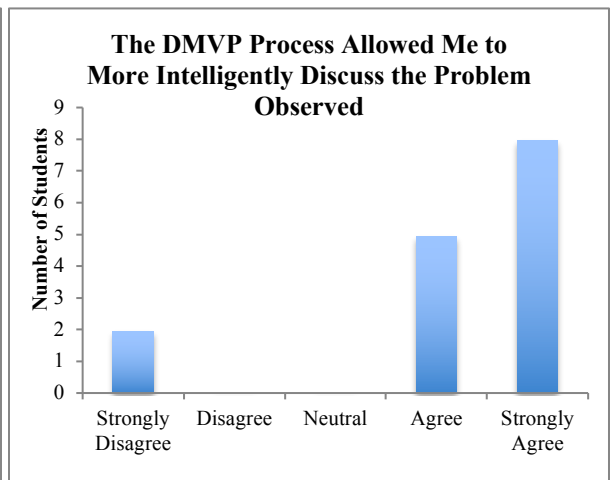


Figure 17: The DeFINE year 4 survey results for how well the DMVP process allowed students to intelligently discuss observed problems.

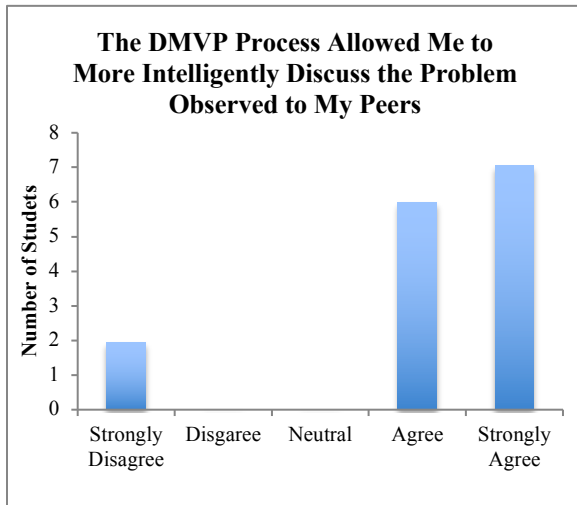


Figure 18: The DeFINE year 4 survey results for how well the DMVP process allowed students to intelligently discuss observed problems to their peers.

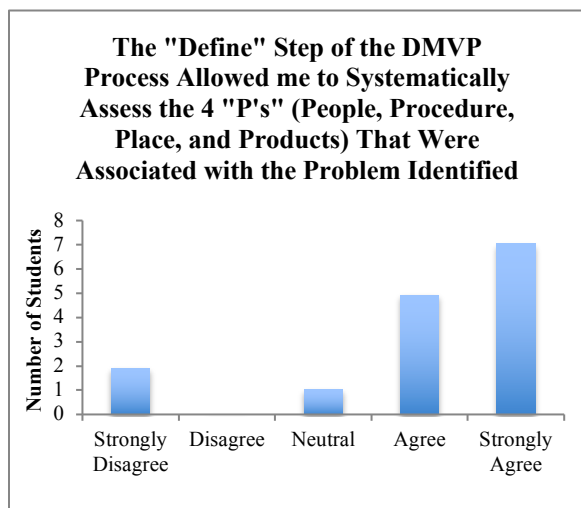


Figure 19: The DeFINE year 4 survey results for how well the “Define” step of the DMVP process allowed students to systematically assess the 4 “P’s.”

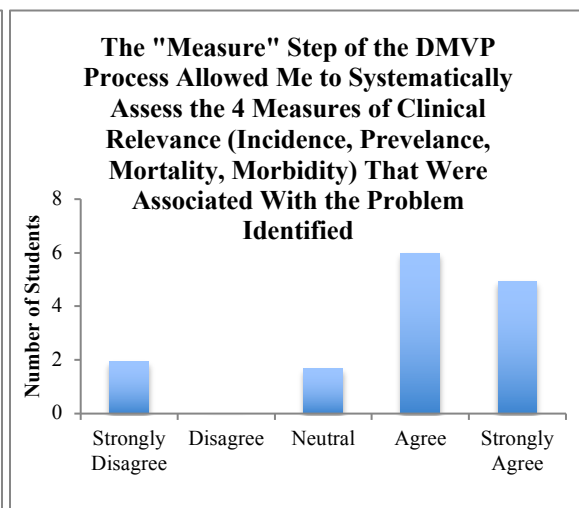


Figure 20: The DeFINE year 4 survey results for how well the “Measure” step of the DMVP process allowed students to systematically assess the 4 measure of clinical relevance.

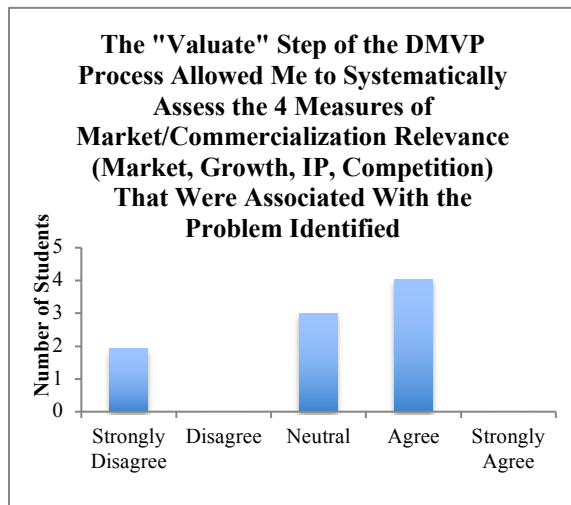


Figure 21: The DeFINE year 4 survey results for how well the “Valuate” step of the DMVP process allowed students to systematically assess the 4 measure of market and commercialization relevance.

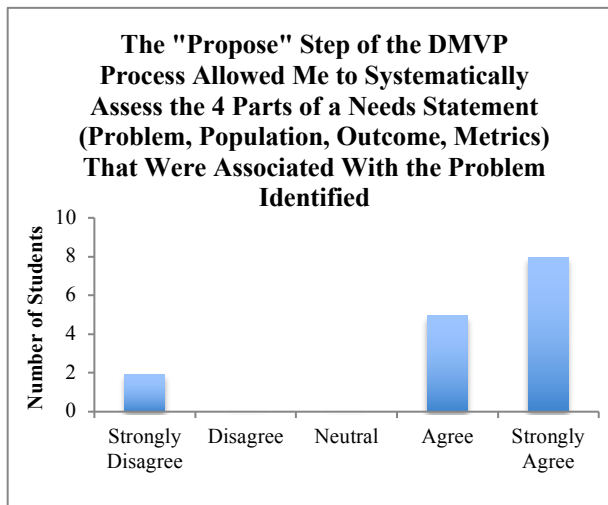


Figure 22: The DeFINE year 4 survey results for how well the “Propose” step of the DMVP process allowed students to systematically assess the parts of a need statement.

IV. Discussion

In year 2, students were introduced to the MindMeister technique. At the end of the immersion program, 7 of the 18 students agreed that the MindMeister technique was moderately useful and 6 of the 18 agreed that it was highly useful for documenting observed problems, **Figure 5**. Despite the majority of students agreeing that it was a useful technique, most students agreed that the “MindMeister mapping was difficult to navigate in a beneficial and essential manner” and asked if there was a better program available for documenting observed problems. These comments and results informed the decision to utilize the DMVP method in years 3 and 4 instead of utilizing the MindMeister technique. Students in year 2 also agreed that the 4 “P’s” structure was a useful tool in defining observed problems, **Figure 7**. Therefore, this technique was incorporated into the DMVP method.

In years 3 and 4, students agreed that the 4 “P’s” method introduction was still highly useful, but the number of students that agreed it was highly useful increased from year 3 to year 4, **Figure 8**. Since students in year 3 agreed that the structure of the DMVP worksheet was highly useful, the structure was not changed for year 4 and the same number of students agreed that the structure was highly useful, **Figure 9**. There was a dramatic increase during year 4 in how many students agreed that the introductions and example problem activities for each of the four steps were highly useful, **Figures 10-13**. This suggests that the more in-depth explanation and demonstration using an example problem were very useful and aided in showing how to evaluate each step.

In the year 4 survey, there was a section in the survey devoted to evaluating how effective the DMVP process was for each student. Students were first asked if the DMVP process broke down the evaluation process into discrete and easy to follow steps. The majority of students strongly agreed that the DMVP process did break the evaluation process into easy to follow steps, **Figure**

14. Students were then asked how well the DMVP process allowed them to better understand the important considerations in the assessment of “Problems Worth Solving.” The majority of students agreed that the process did allow them to better understand what to consider in assessing “Problems Worth Solving,” which suggests that there could be more emphasis placed on how important each step of the DMVP process is when assessing “Problems Worth Solving,” **Figure 15**. Students were then asked how well the DMVP process allowed them to objectively assess the relevance and importance of one problem over another and the majority of students agreed that the DMVP process allowed them to objectively assess problems, **Figure 16**. Then, the students were asked how well the DMVP process allowed them to intelligently discuss observed problems in general and with their peers. The majority of students strongly agreed that the DMVP gave them the ability to intelligently discuss observed problems and to communicate effectively, **Figure 17** and **Figure 18**. Finally, students were asked how well the DMVP process allowed them to systematically assess the four steps of the DMVP process. Overall, students strongly agreed that each step allowed them to systematically assess the four components of each step, **Figures 19-22**. However, students were more neutral in how well the “Valuate” step allowed them to systematically assess the four measures of market and commercialization, **Figure 21**. The “Valuate” step was the most challenging step of the process potentially due to students not being exposed to analyzing market analysis, market growth, intellectual property, and competitors within a market before the DeFINE program.

Between years 3 and 4, there was an increase in student satisfaction of the usefulness of the DMVP process. Students agreed “the DMVP template was very useful to present and evaluate each problem” and the “the DMVP process was easy to use” and “very useful in formulating a problem.” The DMVP process increased how effectively students were able to determine “Problems Worth Solving” as well as how effectively students communicated the “Problems Worth Solving.”

Overall, student comments on the use of the DMVP process were positive. When asked to “comment on what worked well,” students remarked, “the DMVP template was very useful to present and evaluate each problem” and that “overall the DMVP slides were very useful in formulating a problem and taught how to look at problems in general.” Students also agreed that they “learned a lot about effective question asking based on the DMVP method.” Some articulated that “[t]he DMVP process was easy to use” and “really liked the DMVP format.” Students agreed that “the DMVP process worked well” and was a good tool for assessing identified needs.

V. Future Work

Despite the increase in success in the DMVP process from year 3 to year 4, there was still difficulty in explaining the sliding scale shown on the worksheets in **Figure 3** and **Figure 4**. In years 3 and 4, this scale was not clearly defined and students were unable to use it effectively. Students commented in year 4 that “the numerical ranking system on the DMVP slides was not helpful.” Therefore, in year 5 the meaning and importance of the scale in quantitatively determining if a problem is a “Problem Worth Solving” will be more clearly defined and communicated. There also needs to be a section of the program devoted to adequately explaining how to determine the market an observed problem is in and a more effective way of explaining

to students how to locate the market analysis, intellectual property, and competitors within a market so that students can better utilize the “Valuate” step of the DMVP process. Even though the majority of students either agreed or strongly agreed that the worksheets allowed students to systematically assess the 4 segments in each step, there were consistently two students who strongly disagreed. This suggests that more demonstrations and explanations of how to determine each segment may be necessary.

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