

6-24-2016

# Quality Improvement Initiative in Transplant Diabetes Care: Needs Assessment and Protocol Development

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## Recommended Citation

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Quality Improvement Initiative in Transplant Diabetes Care: Needs Assessment and Protocol

Development

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June 24, 2016

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## Abstract

Over 30,000 people receive a solid organ transplant each year, with 5-30% developing post-transplant diabetes mellitus (PTDM) (United Networking for Organ Sharing, 2015). At a Midwestern transplantation center, over 22% of patients with a history of diabetes were not consulted to endocrinology after kidney and liver transplantation. With poor glycemic control, there is an increased risk of developing PTDM leading to poor outcomes. Utilizing the Donabedian model and the Six Sigma's Define, Measure, Analyze, Improve, and Control (DMAIC) as guides for implementation, the purpose of this project was to address the process measures of increasing appropriate consultations for evaluation and treatment of PTDM patients that would lead to an important quality measure of improved glycemic control for this population. The project involved the implementation of a clinical pathway to address this quality measure. Even though there was not a statistically significant change in number of consultations, there was a clinical meaningful difference because the patients who were consulted after pathway implementation received the benefit of management by endocrinology specialists to improve glycemic control post transplantation. Limitations of the project leading to the reported results include that the sample size was less than 30 and the period of evaluation was only one month. The recommendation is for transplant and endocrinology teams to continue to work together to develop clinical pathways to appropriately consult endocrinology teams that is consistent with the standardized care of other organ transplants. Though this is a small piece to a larger problem, the use of standardized pathways will potentially improve care leading to improved glycemic control in the kidney and liver transplant population. Early consultation immediately after surgery will potentially improve the transitions of care from inpatient to outpatient setting for this patient population.

### Executive Summary

Close to 30,000 people receive a solid organ transplant each year in the United States, 5% - 30% develop post-transplant diabetes mellitus (PTDM) (United Networking for Organ Sharing, 2015). This wide range of incidence is likely due to the inconsistent definition of PTDM. PTDM, formerly called new onset diabetes after transplantation (NODAT), has been recognized as a complication after transplantation since the early 1960's (Stevens, Patel, & Jardine, 2012). In 2014, the International Consensus Guidelines changed the terminology from NODAT to PTDM to address the condition occurring in the post transplantation setting regardless if it was present but undetected prior to transplantation (Sharif et al., 2014). The condition can be diagnosed only 30-45 days after transplantation. These guidelines also recommended the term "pre-diabetes mellitus" to be used for patients with post-transplant hyperglycemia who have not surpassed the threshold values for the diagnosis of PTDM (Sharif et al., 2014).

There are several risk factors for PTDM that include age, obesity, African-American race and Hispanic ethnicity, family history, impaired glucose tolerance, Hepatitis C virus, immunosuppression therapy, underlying kidney disease, HLA mismatches, and induction therapy (Wilkinson et al., 2005). Patients who are diagnosed with PTDM have close to an 80% increase in mortality from any cause and over a 45% increase in mortality from cardiovascular disease (Cosio, Hickson, Griffin, Stegall, & Kudva, 2008). This condition is also linked to a 24% increase risk of graft failure along with acute rejection (Cole, Johnston, Rose, & Gill, 2008).

A midwestern transplantation center, a division of a large academic medical center, has ranked in the top 20% nationally in patient outcomes as well as the number of transplants performed. This center serves as the largest and most successful transplantation program in the midwest (Hospital in Midwest, 2015). Despite the high quality that this center provides for their

patients, PTDM is still a concern, as with almost all transplant centers. Between November 1, 2014 and February 28, 2015, this center performed over 100 transplants. Over 20% of kidney and liver transplant patients with a history of diabetes were not consulted by endocrinology for proper glycemic control. With poor glycemic control ( $BG < 70$  mg/dL,  $BG > 140$  mg/dL), there is an increased risk of these patients developing PTDM.

Currently there is no integration of diabetes management into the primary transplant team decisions causing lack of glycemic control, lack of or delayed endocrinology consultation, and lack of formal diabetes education after transplantation occurs. Heart and lung transplant patients receive endocrinology consultation, whereas the kidney and liver transplant patients do not. The lack of standardized care among these transplant patients has been confusing for nursing staff but has also been part of the health care culture for over a decade.

Effective interventions for this population include identifying patients at risk, performing early and repetitive screening, and aggressively treating patients with PTDM (Rakel & Karelis, 2011). Boerner, Shivaswamy, Goldner, and Larsen (2015) discuss how the collaboration with multidisciplinary teams will result in improved glycemic control and decrease the risk of PTDM in the post-transplant population. Early consultation with the endocrinology team is one example of this phenomenon, which not only improves patient outcomes but eases the burden of the primary transplant team (Boerner et al., 2015). Evidence suggests that with pathways in place to guide appropriate consultation with endocrinology, treatment to control blood sugar is initiated earlier.

The purpose of this project was to address the process measures of increasing appropriate consultations for evaluation and treatment of PTDM patients that would lead to an important quality measure of improved glycemic control for this population. This was addressed by

answering the clinical question: Will appropriate consultations to the endocrinology service occur in patients with abnormal glucose in the post-transplant period after initiation of a nurse driven clinical pathway?

The conceptual frameworks of the Donabedian model and the DMAIC quality improvement processes to guide this quality improvement project involved the implementation of a clinical pathway to address this quality measure. Even though there was not a statistically significant change in the number of consultations, there was a clinical meaningful difference because the patients who were consulted after pathway implementation received the benefit of management by endocrinology specialists to improve glycemic control post transplantation. Limitations of the project leading to the reported results included that the sample size was less than 30 and the period of evaluation was only one month. For project sustainability, it was recommended that a longer evaluation period occur to assess for statistically significant improvement regarding the number of consultations initiated with this pathway. With transplantation highly regulated, these interventions will not only affect patient outcomes and improve patient safety; but could improve the center's approval status with Centers for Medicare and Medicaid Services (CMS) by improving transplantation outcomes (Centers for Medicare & Medicaid Services, 2015).

Cost considerations for this project required human resources and time of the endocrinology team working together to approve a clinical pathway for endocrinology consultation. Additional resources involved the time necessary to train nursing staff on the pathway implementation as well as the financial cost of sustainability, cost of in-services, and the use of conference rooms for the in-services. Furthermore, the cost of time from stakeholders, managers, educators, endocrine service, transplant team, and the Doctor of Nursing Practice (DNP) student to review, approve, and implement the quality improvement project was taken into consideration. Even



with these cost considerations, there is an estimated potential yearly cost savings as high as \$292,864.24 for kidney transplant patients and as high as \$220,704.24 for liver transplant patients if glycemic control could be improved. The recommendation is for transplant and endocrinology teams to continue to work together to develop clinical pathways to appropriately consult endocrinology teams that is consistent with the standardized care of other organ transplants. Though this is a small piece to a larger problem, the use of standardized pathways will potentially improve care leading to improved glycemic control in the kidney and liver transplant population. Early consultation immediately after surgery will potentially improve the transitions of care from inpatient to outpatient setting for this patient population.

## Quality Improvement Initiative in Transplant Diabetes Care: Needs Assessment and Protocol Development

Of the 30,000 people receiving a solid organ transplant each year in the United States, 5% - 30% develop post-transplant diabetes mellitus (PTDM) (United Networking for Organ Sharing, 2015). The wide range of incidence is likely due to the inconsistent definitions of PTDM. PTDM, formerly called new onset diabetes after transplantation (NODAT), has been recognized as a complication after transplantation since the early 1960's (Stevens, Patel, & Jardine, 2012). In 2014, the International Consensus Guidelines changed the terminology from NODAT to PTDM to address the condition occurring in the post transplantation setting regardless if it was present, but undetected prior to transplantation (Sharif et al., 2014).

PTDM is associated with increase cardiovascular morbidity, reduced graft function, and lower survival rates among patients (Midtvedt et al., 2011). From an organizational standpoint, organ transplantation is highly regulated. The Centers for Medicare and Medicaid Services (CMS) and Organ Procurement and Transplant Network (OPTN), serve as regulating bodies for transplant centers (Scientific Registry of Transplant Recipients, 2015). Patient outcomes do not affect reimbursement to an organization, however poor patient outcomes do affect regulatory review, particularly CMS certification (Centers for Medicare & Medicaid Services, 2015).

### **Problem Statement**

Patients who are diagnosed with PTDM have close to an 80% increase in mortality from any cause and over a 45% increase in mortality from cardiovascular disease (Cosio, Hickson, Griffin, Stegall, & Kudva, 2008). This condition is also linked to a 24% increase risk of graft failure along with acute rejection (Cole, Johnston, Rose, & Gill, 2008). At one transplant center, over 20% of kidney and liver transplant patients with a history of diabetes were not consulted by the

endocrinology team for evaluation and treatment of abnormal glucose levels. Of these patients not consulted, 51% of kidney transplant patients recorded having two or more readings of blood glucose (BG) levels less than 60 mg/dL during their hospital stay. Whereas, 67% of liver transplant patients not consulted recorded having two or more readings of blood glucose (BG) levels greater than 200 mg/dL. With poor glycemic control (BG<70 mg/dL, BG>140 mg/dL), there is an increased risk of these patients developing PTDM. Currently, PTDM accounts for roughly over \$21,000 per patient over two years when compared with those patients who did not develop PTDM (Woodward et al., 2003). If this trend continues, health care costs will rise, patient outcomes will decline, and transplant centers will struggle to maintain CMS certification. Appropriate consultation to the endocrinology service for at risk patients is one treatment to improve glycemic control. Looking at this small piece of the puzzle, the clinical question is: Will appropriate consultations to the endocrinology service be initiated in patients with abnormal glucose in the post-transplant period after initiation of a nurse driven clinical pathway? Exploring the current literature of risk factors for PTDM as well as interventions to improve glycemic control will assist in addressing this clinical question.

### **Evidence-Based Initiative**

The 2014 International Consensus Guidelines by Sharif et al. (2014) classify PTDM as:

- Symptoms of hyperglycemia (i.e., polyuria, polydipsia, polyphagia), plus random plasma glucose  $\geq 200$  mg/dL (11.1 mmol/L) and/or
- Fasting plasma glucose  $\geq 126$  mg/dL (7.0 mmol/L) on at least two occasions and/or
- Two hour plasma glucose  $\geq 200$  mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT) and/or
- Hemoglobin A1C (A1C) level  $\geq 6.5\%$ .

The timeframe for diagnosis of PTDM is only 30-45 days after transplantation. These guidelines also recommended the term “pre-diabetes mellitus” to be used for patients with post-transplant hyperglycemia who have not surpassed the threshold values for the diagnosis of PTDM (Sharif et al., 2014).

Several risk factors associated with PTDM have been identified in the literature. Common risk factors among all solid organ transplantations are heredity, obesity, hepatitis C (HCV), cytomegalovirus (CMV) virus, and tacrolimus use (Marchetti, 2005; Mirabella et al., 2005). Specific risk factors for kidney transplantation include age, race/ethnicity, family history of diabetes, immunosuppression therapy, induction therapy, and hyperglycemia before and/or after transplantation. Of these risk factors, Cosio, Pesavento, Osei, Henry, & Ferguson (2001) determined age over 45 in transplant recipients was the strongest and most consistent risk factor for PTDM in kidney transplantation. Obesity, African American and Hispanic descent, and the other common risk factors also contributed to PTDM in this population (Kasiske et al., 2003; Friedman, Miskulin, Rosenberg, & Levey, 2003; Santos et al., 2012; Shah et al., 2006).

Basiliximab (Simulect) induction therapy has proven to be effective in reducing the rate of acute rejections as well as limit the dosages of calcineurin inhibitors and steroids necessary in the early post transplantation period (Vincenti et al., 2006). However, previous studies suggest an increased incidence of PTDM in patients who received basiliximab (Aasebo et al., 2010; Bayes et al., 2007).

Effective interventions for this population include identifying patients at risk, performing early and repetitive screening, and aggressively treating patients with PTDM (Rakel & Karelis, 2011). Boerner, Shivaswamy, Goldner, and Larsen (2015) discuss how the collaboration with multidisciplinary teams will result in improved glycemic control and decrease the risk of PTDM

in the post-transplant population. Early consultation with the endocrinology team is one example of this phenomenon, which not only improves patient outcomes but eases the burden of the primary transplant team (Boerner et al., 2015).

At the Medical University of South Carolina (MUSC), the endocrinology department developed a Diabetes Management Service (DMS) that provides 24/7 concurrent care for the management of hyperglycemia and diabetes-related consults to all adult inpatient units. This organization found that DMS involvement tended to reduce graft failure rates from 20% to 6% in renal transplant patients (Medical University of South Carolina, 2015). From these results, DMS coordinated post-discharge follow up visits to reduce the readmission rates related to poor glycemic control. Currently, at this study organization, all diabetic renal transplant patients are seen by the endocrinology team weekly for the first four weeks post transplantation. This appointment is on the same day as their transplant clinic follow up. MUSC also determined that early consultation of DMS in patients with glycemic control issues resulted in significantly shorter length of stay compared to other patients (Medical University of South Carolina, 2015).

Another organization studied the post-operative glycemic control in heart transplant patients. In this retrospective study, the Glucose Management Service (GMS) implemented inpatient insulin protocols to obtain glycemic control in patients with and without diabetes. The time period from the time the insulin drip was initiated until it was discontinued was defined as the IV insulin protocol time period. The transition protocol consisted of insulin glargine given daily. As part of the protocol, patients were seen daily by a member of the GMS team to determine the insulin response of each patient. Insulin was reduced daily as the reduction in postoperative stress and steroid dosing decreased. Nurse practitioners could deviate from this protocol and individualize care. The results indicated that with the use of these protocols, heart transplant

patients reported postsurgical outcomes at 30 days with adequate control of blood glucose with minimal hypoglycemia events. With the implementation of glycemic control protocols, postsurgical outcomes improved (Wallia et al., 2014).

The same organization that initiated insulin protocols in heart transplant patients analyzed glycemic control by the Glucose Management Service (GMS) and infection rates in liver transplantation. The retrospective study evaluated 73 liver transplant recipients who were treated with insulin infusions, before and after introduction of GMS. The purpose of the study was to analyze patients who were followed by GMS compared to non-GMS management. The results indicated that the number of days in the intensive care unit as well as the length of stay (LOS) in the hospital was greater in the non-GMS group than the GMS group. Also infection rates in the GMS group were lower than for the non-GMS group (Wallia et al., 2011). Based on these outcome measures, within one year post liver transplantation, outcomes of patients followed by the GMS was associated with improved glycemic control and decreased postoperative infections (Wallia et al., 2011).

Since there is an inconsistent definition of PTDM, proper identification of patients at risk of PTDM, and with utilization of the evidence from the current literature, interventions can be implemented to improve glycemic control in a transplant center. Evidence suggests that with pathways in place to guide appropriate consultation with endocrinology, treatment to control blood sugar is initiated. With appropriate glycemic treatment, patient outcomes can be improved.

## **Conceptual Models**

### **The Donabedian Model**

Conceptual models serve as frameworks needed to explain the phenomenon and guide interventions. The Donabedian model is a conceptual model that provides a framework for examining health services and evaluating quality of health care (Donabedian, 1988). Avedis Donabedian, a physician and health services researcher at the University of Michigan, first developed the model in 1966. According to the model, there are three categories: structure, process, and outcomes (See Appendix A). Structure describes the context of the setting in which care is delivered. This can include material resources from the hospital building, staff, methods of reimbursement, and equipment. The process denotes the transactions between patients and providers including pathways and measures to deliver care. Finally, outcomes refer to the effects on the health status of patients and populations in response to structure and process (Donabedian, 1988). This model was developed to be flexible enough for application in diverse healthcare systems and among various levels within a delivery system. The model can be used to modify structures and processes within a healthcare delivery system such as improving glycemic control by developing protocols to guide early consultation with endocrinology. With improved processes and structure established, this model draws connections to improve patient outcomes, which are vital to this phenomenon. The Donabedian model will serve as a framework to guide interventions in this proposal along with another methodology to implement process improvements.

### **Six Sigma**

Six sigma is a method that provides organizations tools to improve processes and increase performance. The decrease in process variation and increase in performance improves outcomes,

employee morale, and quality of services provided (Pande, Neuman, & Cavanagh, 2002). This perspective is data and fact driven, utilizing qualitative and quantitative techniques to drive process improvement (Pande, Neuman, & Cavanagh, 2002). Tools that illustrate this process can be in the form of diagrams, control charts, processing mapping, and failure mode and effects analysis (Pande, Neuman, & Cavanagh, 2002).

Process improvement strategies eliminate the root causes of performance problems in an organization, which is an integral part of six sigma. DMAIC (define, measure, analyze, improve, and control) is an acronym for the five phases used in six sigma methodology (Pande, Neuman, & Cavanagh, 2002) (See Appendix B).

Each step in the DMAIC process is required to ensure the best possible result:

- **Define** the problem, project boundaries, and process to be improved by performing an organizational assessment (Pande, Neuman, & Cavanagh, 2002).
- **Measure** the process performance through data collection from multiple sources (Pande, Neuman, & Cavanagh, 2002).
- **Analyze** the data collected and process map to determine root causes of poor performance and identify gaps between current performance and goal performance (Pande, Neuman, & Cavanagh, 2002).
- **Improve** process performance by developing solutions addressed in the root causes (Pande, Neuman, & Cavanagh, 2002).
- **Control** the improved process and future process performance by implementing continuous monitoring and incentives for quality improvement (Pande, Neuman, & Cavanagh, 2002).



The DMAIC approach is a conceptual framework that guides an organization through process and quality improvements. An organization can employ this methodology to illustrate root causes for poor glycemic control as well as improve the process measures to recognize and intervene on the risk factors associated with PTDM. The organization has successfully used this framework for quality improvement project work in the past and staff are familiar with this process. This was the reason this framework was chosen to guide the project intervention.

### **Need and Feasibility Assessment of the Organization/Population**

A midwestern transplantation center, a division of a large academic medical center, has been providing solid organ transplantations since 1964 (Hospital in Midwest, 2015). Ranking in the top nationally in patient outcomes as well as the number of transplants performed, this center serves as the largest and most successful transplantation program in the midwest (Hospital in Midwest, 2015). With over 200 kidney and 100 liver transplants performed yearly, this center offers five satellite clinics to provide convenient and exceptional patient care while sustaining the mission, values, and vision of the academic medical center.

There is a strong external environment within this organ transplantation center. Centers for Medicare and Medicaid Services (CMS) and Organ Procurement and Transplant Network (OPTN), the regulating bodies for transplant centers, receive data on all solid organ transplants and donations from The Scientific Registry of Transplant Recipients (SRTR) (Scientific Registry of Transplant Recipients, 2015). Transplant centers receive generated reports from SRTR every six months.

In the summer of 2014, three reports were released at once regarding quality measures. The center did not meet quality standards on two of the three reports in patient survival and graft survival resulting in lack of compliance for CMS (G. McNatt, personal communication, October

15, 2015). This resulted in a mitigating factors report to CMS as well as an overhaul within the organization. An organizational assessment plan was developed to ensure that these citations would be resolved.

A nephrologist at the center developed Real-time Analysis and Performance Improvement Dashboard (RAPID) to monitor the performance of patient and graft survival (Hospital in Midwest, 2015). With the one year lag time with SRTR, this dashboard allowed centers to identify performances that may trigger regulatory review by United Network for Organ Sharing (UNOS) or CMS.

The center also analyzed patient outcomes along with patient satisfaction rates. This analysis resulted in each patient being assigned a nephrologist and nurse coordinator before their discharge from the hospital. The nurse coordinator made weekly phone calls to the patients as well as the patient was seen in the clinic more frequently. This intent was not only to improve continuity of care but improve patient satisfaction.

To improve patient outcomes, the center evaluated the types of patients transplanted at the center and decreased the age of recipients they would transplant. They also developed new protocols to assess patients before they were listed for transplantation. This involved utilizing the Montreal Cognitive Assessment (MoCA) and the Timed Up and Go test (TUG) to assess patient's cognitive status and frailty. Depending on these results, patients were either sent to a gerontologist or physical therapy for further evaluation on cognition and frailty.

Within a year, the center noticed remarkable improvement with patient satisfaction as well as patient outcomes. However, patients were still seen in the clinic with abnormal glucose levels and the staff believed this was out of their scope of practice. There was concern about glycemic control within the first 30 days post-transplantation. In August 2015, members of the transplant

quality team reached out to the endocrinology team at the academic center requesting their assistance on this problem.

At the Glycemic Control Committee (GCC) meeting held in August 2015, assessment data and key stakeholders were identified. With the current health care culture at CTC, the endocrinology team explored how many endocrinology consultations were initiated by the transplant team with kidney and liver transplant patients. The GCC recognized that this has been a constant issue over the years because several members of the endocrinology team as well as transplant team have opposing views of glycemic control in post-transplant patients. Attendees at the meeting agreed to follow up in October 2015 after gathering data to determine if there was a need for endocrinology consultation with transplant patients.

An organizational assessment was performed as well as a SWOT analysis, illustrating potential barriers, challenges, and threats that could cause problems for implementation of a proposed project of improving glycemic control (See Appendix C). This organizational assessment also assessed the current practices for glycemic control among all transplant patients. The heart and lung transplant patients receive endocrinology consultation, whereas the kidney and liver transplant patients on the same unit do not. The lack of standardized care among these transplant patients has been confusing for nursing staff but has also been part of the health care culture for over a decade. From the organizational assessment, a fishbone diagram was developed that determined reasons for poor glycemic control (See Appendix D). As part of the organizational assessment, information was gathered that determined that over 20% of patients with a history of diabetes were not consulted by endocrinology (See Appendix E). Of these patients not consulted, 51% of kidney transplant patients recorded having two or more readings of blood glucose (BG) levels less than 60 mg/dL during their hospital stay. Whereas, 67% of

liver transplant patients not consulted recorded having two or more readings of blood glucose (BG) levels greater than 200 mg/dL (See Appendix F). The organizational assessment also noted that several of the patients transplanted had many risk factors associated with PTDM (See Appendix G). Since glycemic control affects patient outcomes and from the information collected during the organizational assessment, the director of CTC and the transplant surgeons agreed that this was a concern that needed to be addressed.

## **Project Plan**

### **Purpose of the Project**

The purpose of this project was to address the process measures of increasing appropriate consultations for evaluation and treatment of PTDM patients that would lead to an important quality measure of improved glycemic control for this population. This was addressed by answering the clinical question: Will appropriate consultations to the endocrinology team occur in patients with abnormal glucose in the post-transplant period after initiation of a nurse driven clinical pathway?

### **Objectives**

Efforts to improve glycemic control in post-transplant patients was evaluated by developing a quality improvement process that:

- Created and implemented a nurse driven clinical pathway that established criteria for endocrinology consultation in kidney and liver transplantation on May 2, 2016.
- Evaluated knowledge of nursing staff after in-service and implementation of nurse driven clinical pathway on May 2, 2016.
- Analyzed data on the number of consultations that were obtained after pathway implementation on June 7, 2016.

- Evaluated if appropriate consultations to endocrinology were initiated on June 7, 2016.

### **Type of Project**

The project was a quality improvement (QI) initiative. QI “consists of systemic and continuous actions that lead to measureable improvement in health care services and the health status of targeted patient groups” (HRSA, 2011, p. 2). QI is directly linked to the delivery approach and systems of care within an organization. To improve quality, the current system of care requires change within an organization. This is obtained following four key principles: QI in systems and processes, focus on patients, focus on team approach, and focus on use of data (HRSA, 2011).

Within in this project, the systems and processes as well as the focus of a team approach was evaluated during an organizational assessment (see Appendix C). Utilizing data that determined poor glycemic control in this population and how patient outcomes were affected, members of the transplant and endocrinology teams initiated actions to develop ways to improve glycemic control.

### **Setting and Needed Resources**

The setting for implementation of this project occurred on the cardiac transplant intensive care unit (CTICU) and the step down floor for transplant patients at the academic medical center. The resources needed to complete this project included physicians from transplant surgery, endocrinology team, pharmacy, quality leaders from transplant, project coordinator from the endocrinology service, nurse practitioners from endocrinology and transplant services, and nurses from CTICU and the step down unit. Other resources included agreement from members of the endocrinology service to agree upon a pathway, set time aside to educate all staff on the implementation of this pathway, and finally after implementation was completed, utilized the

quality teams to gather data to determine if consultations to the endocrinology service increased and were appropriate. Other resources considered were the support from the unit managers as well as the additional time within the current work day for staff to attend the in-service to learn about the clinical pathway implementation.

### **Design for the Evidence-based Initiative**

DMAIC was the conceptual model used to guide the interventions for this project (See Appendix B) (Pande et al., 2002).

- **Define the problem:** Patients who are diagnosed with PTDM have close to an 80% increase in mortality from any cause and over a 45% increase in mortality from cardiovascular disease (Cosio, Hickson, Griffin, Stegall, & Kudva, 2008). This condition is also linked to a 24% increase risk of graft failure along with acute rejection (Cole, Johnston, Rose, & Gill, 2008). Currently the organization does not have protocols in place to screen patients for diabetes or process measures to improve appropriate consultations to the endocrinology service. Increasing appropriate consultations for evaluation and treatment of PTDM patients would lead to an important quality measure of improved glycemic control for this population. From the organizational assessment, there was evidence that poor glycemic control exists in this patient population.
- **Measure:** Over 20% of patients with history of diabetes were not consulted to the endocrinology service. Of these patients not consulted, 51% of kidney transplant patients recorded having two or more readings of blood glucose (BG) levels less than 60 mg/dL during their hospital stay. Whereas, 67% of liver transplant patients not consulted recorded having two or more readings of blood glucose (BG) levels greater than 200

mg/dL. Several of the patients transplanted had many risk factors associated with PTDM. These risk factors are associated with poor outcomes in this patient population.

- **Analyze:** Analyze the data from the organizational assessment. A fishbone diagram was developed concluding that poor glycemic control in this organization was multifactorial.
- **Improve process performance:** Utilizing evidence from the literature as well as the information gathered from the organizational assessment, members of the endocrinology team met to discuss quality improvements. This team worked together to develop criteria for consulting the endocrinology service within this patient population as well as discussed ways to implement a pathway for sustainability.
- **Control:** Once pathway was implemented, data was measured and analyzed to determine if the pathway improved consultations as well as determined if the consultations were appropriate. Once information was gathered, data was disseminated to endocrinology and transplant teams. This information can then be used to develop pathways for the outpatient setting. Based on the current literature, over time appropriate consultations to endocrinology will support the transition plan to primary care for improve glycemic control in the outpatient setting.

### **Participants**

The participants included any patient who received a kidney or liver transplant, nursing staff caring for this population, the GMS service, and transplant quality leaders. The nursing staff was responsible to recognize which transplant patients met criteria for consultation while the quality leader was responsible for providing data to determine if consultation occurred.

**Measurement: Sources of Data and Tools**

Data was collected by the DNP student and quality leaders one month after the pathway was implemented. All information was protected through the academic center and data was not replicated for outside use. The data collected was from documentation from the surgical list of the number of patients who received a kidney and liver transplantation. Other data collected was derived from the charts of patients who received a kidney or liver transplantation and the number of patients meeting criteria for consultation (See Appendix L). This data was utilized to determine the percent of appropriate consultations after pathway implementation.

**Steps for Implementation of Project, including Timeline**

During the implementation of the project, the DNP student (See Appendix H):

- Gathered data and best practices from the literature, collected data (risk factors for PTDM) from the organizational assessment which guided in developing the pathway.
- Developed a nurse driven clinical pathway for endocrinology consultation utilizing the data from the organization and current literature (See Appendix I).
- Presented pathway to the endocrinology team for review and recommendations.
- Elicited recommendations from endocrinology team and made corrections.
- Obtained approval of new clinical pathway from GMS service.
- Obtained clinical pathway approval from Glycemic Control Committee (GCC).
- Obtained approval from nurse managers and education coordinators on CTICU and the step down unit.
- Presented clinical pathway for approval to Nursing Policy and Procedure Subcommittee and Nursing Professional Practice Committee.



- Educated all nursing staff on CTICU and the step down unit, through several sessions of in-service education (See Appendix I, J). Staff understanding of new pathway was determined by a sign off sheet and post survey that stated staff understood new criteria and clinical pathway, when implementation would occur, and their responsibilities (See Appendix K).
- Implemented clinical pathway on CTICU and the step down unit.
- After one month of implementation, evaluated clinical pathway using an evaluation tool. This tool evaluated how many patients were transplanted, how many met the criteria, and how many were consulted appropriately (See Appendix L).
- Compared before and after consultation rates by utilizing the evaluation tool (See Appendix L).
- Discussed results with the endocrinology team at the Glycemic Control Committee (GCC) and quality meetings.
- Evaluated current clinical pathway and made recommendations for further changes and possible implementation of expanding the pathway for outpatient setting in this transplant population.
- Disseminated results of the final project at Grand Valley State University Kirkhof College of Nursing during the final defense of the project.

### **Ethical and Human Subjects Protection**

With the QI initiative, no contact of human subjects occurred during this project intervention. Data was collected but protected under the protocols regarding de-identification under the academic medical center. An application was submitted and approved through Grand Valley State University (GVSU) Human Research Review Committee's (HRRC) for Institutional

Review Board (IRB) determination. The IRB found that the project was quality improvement and not research. There was already an exempt status granted by the IRB at the academic medical center, for a larger project that the DNP student was working on with other members at the organization (See Appendix M).

### **Budget**

Cost considerations for this project required human resources and time of the endocrinology team working together to approve a clinical pathway for endocrinology consultation. Additional resources involved the time necessary to train nursing staff on the pathway implementation as well as the financial cost of sustainability, cost of staff in service education, and the use of conference rooms for educational sessions. Furthermore, the cost of time from stakeholders, managers, educators, endocrine service, transplant team, and the DNP student to review, approve, and implement the quality improvement project was taken into consideration.

Based on the average wages of an endocrinologist, a nurse practitioner, a nurse, and a project coordinator along with the time utilized to implement this project (in hours), a monetary value on the time spent implementing this project was calculated (Hospital in Midwest, 2016; Payscale.com, 2016; Salary.com, 2016). Other expenses included the education materials and laminated documents that were placed in each patient room on CTICU and the step down unit for project implementation. The total expenses were \$3981.97 for this project implementation (See Appendix N).

Endocrinology consultations are a surrogate measure to potentially result in improved outcomes of glycemic control. Appropriate consultations to address glycemic control have the potential to decrease readmissions driven by poor glycemic control which then leads to cost savings. The readmission rates at this academic medical center within 30 days post-transplant

range from 16% for liver transplant patients to 31% for kidney transplant patients, averaging two patients readmitted per quarter (K. Thomas, personal communication, June 6, 2016). The average length of stay (LOS) for these patients once they are readmitted range from 7.7 days for liver transplants to 9.9 days for kidney transplant patients. The reasons for readmission are potentially driven by poor glycemic control: infection, acute rejection, or hyperglycemia (K. Thomas, personal communication, June 6, 2016).

The fixed cost for 24 hours for a patient in the CTICU is \$4100.00 compared to \$1889.00 on the step down unit (Hospital in Midwest, 2016). Analyzing this data along with the LOS for readmissions for kidney and liver transplantations, the expense of one kidney transplant patient readmitted ranges from \$18,701.00-\$40,590.00. Whereas, the expense of one liver transplant patient readmitted ranges from \$14,545.30-\$31,570.00 (See Appendix O). Therefore evaluating the cost of the project implementation compared to the cost of one patient readmitted, there is a potential savings of \$14,719.03-\$36,608.03 for preventing readmission in the kidney transplant population. Whereas the potential savings for liver transplantation is \$10,563.33-27,588.03 (See Appendix P). From this data, estimated quarterly savings can range from \$29,438.06-\$73,216.06 for kidney transplant patients and \$21,126.66-\$55,176.06 for liver transplant patients. Therefore, there is an estimated potential yearly cost savings as high as \$292,864.24 for kidney transplant patients and as high as \$220,704.24 for liver transplant patients if eight readmissions per year were prevented (See Appendix Q).

### **Project Outcomes**

One month after project implementation, the DNP student collaborated with the transplant quality leader and collected data on the number of kidney and liver transplantations that occurred from May 2-May 31, 2016. Other data collected consisted of the number of patients meeting

criteria for consultation per the new pathway, and how many appropriate endocrinology consultations actually occurred. This data will then be disseminated to the endocrinology and transplant team during the July quality meetings in the form of charts that list how many transplants occurred during this time, how many transplants met criteria (percentage), and how many patients meeting the criteria were actually consulted (percentage). Another chart will show the comparison of appropriate consultations before and after pathway implementation. As a result of this quality improvement project, the following outcomes were realized:

- A nurse driven clinical pathway was created that established criteria for endocrinology consultation in kidney and liver transplantation on May 2, 2016.

Outcome measure: Transplant nurse practitioners, surgical intensive care unit (SICU) physicians, endocrinology team, transplant pharmacists, nurse managers, education coordinators, quality teams on CTICU and the step down unit, and nursing committees approved criteria and the clinical pathway based on current literature and organizational needs (See Appendix I). Approval was met prior to the May 2, 2016 project implementation.

- Nursing staff knowledge was evaluated after in-service and implementation of nurse driven clinical pathway on May 2, 2016.

Outcome measure: The majority of nursing staff (97% on CTICU and 85% on the step down unit) completed in-service education (Appendix J) and a post survey (Appendix K). The majority of nurses (92%) felt the clinical pathway pertained to their job, 90% stated that they understood the purpose and criteria needed to consult the endocrinology service, and 80% understood their responsibilities pertaining to the clinical pathway. However only 60% of nurses felt the pathway would improve their work load, whereas, only 4%

felt the pathway would create more work for them. Nurses felt the potential barriers that would prevent them from consulting endocrinology were remembering to page, weekend/night shift coverage would not be responsive, receptive, or kind; increased glucose checks obtained by nursing, and there was a concern of pushback from the transplant team for when nursing would place the order (See Appendix R).

- Data was analyzed on the number of consultations that were obtained after pathway implementation on June 7, 2016.

Outcome measure: Data was assessed and evaluated regarding a change in appropriate consultation rates with the new pathway. Normally over 30 transplants occur per month. However, in the month of implementation, 21 transplantations occurred (16 kidney and 5 liver). Of the patients consulted to endocrinology, 100% of those consultations were appropriate. However, 19% of patients were not consulted according to the criteria of the pathway (See Appendix S). The barriers to consultation were:

- Nurses on units failed to place order for consult (underlying reason unknown)
  - Transplant team failed to place order for consult when the patient was on an insulin drip in the operating room. The team stated they felt the order/consult was unnecessary.
  - Nurses on step down unit failed to obtain glucose checks per the guidelines of the pathway. Hyperglycemia was noted from the labs obtained daily.
- The appropriate number of consultations to the endocrinology service were evaluated on June 7, 2016.

Outcome measure: From the data collected after a month after project implementation, appropriate consultations occurred. Comparing the data before the pathway

implementation to after implementation, there has been a 4% reduction in missed consultations in kidney transplantation and a 2% reduction in missed consultations with liver transplantations (See Appendix S). When performing the Chi-square test, there was not statistically significant evidence ( $p = 0.948$ ) to conclude that appropriate consultation to the endocrinology service and abnormal glucose in the post-transplant period were related (See Appendix S). However, a larger sample could have affected statistical significance ( $N = 21$ ). Even though there was not a statistically significant change in number of consultations, there was a clinical meaningful difference because the patients who were consulted after pathway implementation received the benefit of management by endocrinology specialists to improve glycemic control post transplantation. Therefore the recommendation for future study would be a longer evaluation period to determine true significance level. Project results will be disseminated during the July quality meetings to the transplant and endocrinology teams regarding the number of appropriate consultations with new clinical pathway implementation to serve as a guide for a longer implementation period of current pathway as well as possible expanded pathways to include the outpatient setting in this transplant population.

### **Implications for Practice**

Up to 30% of all patients with solid organ transplantation will develop PTDM (United Networking for Organ Sharing, 2015). Since there is an inconsistent definition of PTDM, proper identification of patients at risk of PTDM, and with utilization of the evidence from the current literature, interventions can be implemented to improve glycemic control in a transplant center. Utilizing the Donabedian model that guides quality improvement efforts to improve outcomes, evidence suggests that with pathways in place to guide appropriate consultation with

endocrinology teams, treatment to control blood sugar is initiated. The process of improved glycemic control along with proper education and resources on the nursing units, patient outcomes could potentially lead to improved control that results in a decreased risk of cardiovascular morbidity, reduced graft function, and mortality (Midtvedt et al., 2011). The recommendation is for transplant and endocrinology teams to continue to work together to develop clinical pathways to appropriately consult endocrinology teams that is consistent with the standardized care of other organ transplants. Though this is a small piece to a larger problem, the use of standardized pathways will potentially improve care leading to improved glycemic control in the kidney and liver transplant population. Early consultation immediately after surgery will potentially improve the transitions of care from inpatient to outpatient setting for this patient population. Further implications for determining the effects of appropriate consultation beyond this study should be formally determined as a recommendation following this QI intervention. Based on this project implementation, there were important successes/difficulties encountered, project strengths, opportunities for improvement, and sustainability factors addressed, limitations to the quality improvement project, and the period after the project. Also a reflection of the Essentials of DNP education were utilized during this QI intervention (American Association of Colleges of Nursing, 2006).

### **Successes of Project**

Throughout the development and implementation of this project, several members of the transplant team, surgical intensive care unit (SICU) team, endocrinology team, pharmacy team, nursing, and quality team stated that there was a better working relationship and communication among the disciplines. These disciplines worked together on a project and collaborated on establishing a pathway for an issue that has been a topic of discussion for years with no

resolution. A theme of empowerment emerged during the in service educational sessions where the nurses stated they “felt they had direction on an issue and felt they could do something to improve patient outcomes.” Nurses also felt empowered after the DNP student presented at nursing committees and the nurses stated this project could be implemented in other departments to improve patient outcomes. This project ultimately empowered disciplines, especially nursing, about the importance of glycemic control in transplantation which can then be utilized in other departments in the hospital.

### **Difficulties of Project**

There were many difficulties to overcome with this project implementation. Many of these difficulties were associated with the structure and processes within the organization. First of all empowering multiple disciplines with the concept of change and the positive outcomes that can occur when change is present was more difficult to overcome because of the organizational barriers that occurred in this large medical center. One organizational barrier was managing differences in opinions among transplant and endocrinology providers. Another example of an organizational barrier was understanding the stakeholders’ level of support for quality improvement. These stakeholders (i.e. members of the transplant team) would collaborate on the project but then they would refuse to place orders for nurses to obtain glucose monitoring on their patients. These same stakeholders stated they supported the pathway but would not take responsibility for the process changes that occurred in the transplant patient population. Another difficulty was understanding the staffing barriers and processes on the nursing units and how the level of autonomy was different among team members on the various units. Staff on the step down unit had a culture where the nurses are driven by tasks and they would not monitor a glucose level despite the pathway guidelines unless an order was placed. In contrast, the CTICU



nurses would monitor glucose levels regardless of the order status. This difference was significant and was illustrated during the evaluation process of the project when reasons for not monitoring glucose levels was determined by provider order status.

### **Strengths of Project**

The strengths of the project were the collaboration of leaders and clinicians in the field of endocrinology and transplant teams working together to improve the quality measures of glycemic control in the transplant population. Also there was support for the clinical pathway and project implementation from multiple disciplines including nursing committees as illustrated by their approval at several presentations and meetings. Another strength to the project was the DNP student has worked at the large academic center for nearly eight years and has developed positive working relationships with multiple disciplines. These supportive relationships allowed meetings with stakeholders to occur in a timely fashion since the meetings may not have occurred if the DNP had not already established these professional connections. From this networking, there was support for this project which allowed implementation of pathway that standardized the care among all transplant patients.

### **Weaknesses of Project**

Weaknesses in the project was lack of collaboration with all of the endocrinology team (i.e. fellows) when creating the guidelines for the clinical pathway. This was a strategic move to avoid potential opposition from these members. However, these same members were the physicians taking call on nights and weekends where the nurses already felt these people would be a barrier to endocrinology consultation. Preventing these key stakeholders from collaborating in the development of the pathway still caused confusion and opposition once the pathway was implemented. This avoidance could have potentially affected the sustainability of the pathway.

Another weakness to the project was lack of consideration of the culture of nursing regarding clinical decision making. Nurses on the step down unit stated they did not feel comfortable monitoring glucose levels without an order despite the guidelines of the pathway. The status of the transplant order sets and the lack of an order to monitor glucose levels was not discussed as a potential concern of project implementation.

Another weakness of this project was lack of consideration that the pathway may not be appropriate for all transplant patients (i.e. readmissions). This pathway purposely had a low threshold of criteria for endocrinology consultation. Whereas transplant patients who are readmitted may or may not fit the same criteria as immediate post-transplant patients, causing inappropriate consultations. Even though this project did not evaluate transplants patient who were readmitted, this weakness could cause opposition for further pathway implementation.

As much as this was a strength, the DNP student working at the organization of implementation also served as a weakness. There were boundaries crossed when the student was in her working role compared to when she was in her student role. Many disciplines often referred to this pathway as the “DNP student’s pathway” even though the pathway was approved by nursing committees and other interdisciplinary committees. This weakness was also compounded with the kidney and liver transplant team having opposing views of glycemic control which often was discussed with the DNP student even during her working hours. Finally a weakness of this project was not having the appropriate staff to manage the influx of patients who were consulted to the endocrinology service. The management of these additional patients were discussed but no solid plan was developed to fully handle the patient load caused from the project.

**Limitations of Project**

Limitations to this study included lack of a pre and posttest for the nursing staff as well as limited content questions on the survey during the in-service. This occurred because there was a lack of time for the in-service and the pretest was in a form of open discussion with the nursing staff regarding their current knowledge of glycemic control. However for future project implementations, a pre and posttest along with more content questions on the survey would be encouraged. There was also a short evaluation period after implementation. The data collected prior to implementation occurred over three months. Whereas, the evaluation period was only one month. Additionally, the project implementation occurred during a time of low volume of transplantations (n=21). Normally, over 30 transplantations occur each month. Therefore the true significance of this project was not completely accurate to determine the full implications of practice moving forward. Finally, the project only evaluated patients who were immediately post-transplant. The implications of practice for all transplant patients on these nursing units was not addressed in the evaluation of the pathway.

**Sustainability**

Prior to the project implementation, no interventions to address glycemic control post-transplant for kidney and liver patients had been trialed before at this organization. For years, glycemic control improvement among transplant patients has been a topic of discussion with no resolution. In the past, members of both endocrinology and transplant teams had opposing views of glycemic control, resulting in no previous pathway implementation. Therefore, strategic pathway revisions are key to stakeholder support and sustainability. With transplantation highly regulated, these interventions will not only affect patient outcomes and improve patient safety; but could improve the centers approval status with Centers for Medicare and Medicaid Services

(CMS) by improving transplantation outcomes (Centers for Medicare & Medicaid Services, 2015). Moving forward, recommendations for clinical pathway sustainability consist of:

- Evaluating the pathway after three months or until there is a sample size greater than 30. The current evaluation period was too short with a small sample size (n=21) to provide data to show statistical significance for or against the pathway.
- Re-evaluating the pathway criteria that would initiate consultation. This evaluation would determine if the criteria encompasses all of the transplant population, not just immediate post-transplant patients as well as determine if the pathway's criteria threshold is too low for all of the transplant patients.
- Designating a member from the GCC team to take over the pathway implementation after the DNP student has completed the project to continue the quality process improvement measures that the revisions of the pathway would allow.
- Working with quality leaders to have glucose monitoring part of the transplant order sets. A weakness in this study was determining that nurses were not monitoring glucose levels because there was not an order placed. For project sustainability, establishing glucose monitoring in the order sets may encourage nurses to be compliant with the pathway guidelines.
- Empowering the transplant team to have accountability for the glycemic control of their patient population. The current culture at this center focuses more on immediate transplantation outcomes instead of long term glycemic control in this patient population.
- Establishing a business plan to monitor and evaluate the current staff who would manage the influx of patients who are consulted to endocrinology. This project study illustrated an influx of patients for the endocrinology service that over time could be difficult to

manage with their current staff. This business plan would include the use of full time employees to manage the pathway, triage acute needs for this patient population, allocate resources, and provide clinical decision support.

- Considering the cost of a future project implementation and potential cost savings of the QI improvement project. Including the cost considerations, there is an estimated potential yearly cost savings as high as \$292,864.24 for kidney transplant patients and as high as \$220,704.24 for liver transplant patients if glycemic control could be improved.

### **Essentials of DNP Education**

The DNP prepared nurse strived to delineate the doctor of nursing practice (DNP) Essential competencies along with theory to guide practice during this project implementation (American Association of Colleges of Nursing, 2006). These competencies, served as a foundation, provided the leadership principles that ensured quality improvement in the organization, and analyzed clinical scholarship to implement evidence based practice. Several of the DNP essentials were utilized during this project.

**Essential I: Scientific Underpinning for Practice.** This Essential provides the scientific basis necessary for advanced nursing practice (AACN, 2006). This Essential was enacted by the DNP student obtaining an extensive organizational assessment and literature review for this quality improvement project. This Essential was delineated in the frequent meetings with the mentor and members of endocrinology at the organization, in the evaluation of the pathway and in making changes based on knowledge from other disciplines before project implementation.

**Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking.** This Essential describes the preparation needed in the organizational and systems leadership that affects the delivery in health care and patient outcomes (AACN, 2006).

This Essential was delineated in this project by the DNP student working and collaborating with the transplant quality leader on the process improvement measures, dashboards, and metrics used at the transplant center. The DNP student also attended several kidney and liver quality meetings, shadowed the medical quality leader, and incorporated the existing DMAIC QI framework of the organization to improve successful implementation.

**Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice.**

Essential III describes the evaluation, integration, translation, and application of evidence-based practices (AACN, 2006). The competency for this Essential was met with the implementation and evaluation of the QI project. The utilization of evidence based practices guided the implementation to analyze, predict, and disseminate findings to improve healthcare outcomes. The DNP student also collaborated with quality leaders, project coordinators, and multiple disciplines in identifying the gaps in evidence based practice at this organization.

**Essential VI: Interprofessional Collaboration for Improving Patient and Population**

**Health Outcomes.** This Essential concentrates on the importance of expanding interprofessional collaboration, ensuring that the DNP student will develop the expertise needed to assume leadership roles as well as participate in the work environment alongside collaborating teams (AACN, 2006). This Essential was met by the DNP student providing effective communication and collaboration developing the pathway with the mentor and members of the endocrinology team. The Essential was also delineated with one on one meetings with key stakeholders (i.e. SICU team, members of transplant team), the DNP student's presentation of pathway to the step down unit's quality meetings, nursing committees, and transplant pharmacy staff meetings. The DNP student also performed educational in-services to over a 100 nurses, as

well as, collaborated with nurses, pharmacy, transplant, and endocrinology teams to discuss solutions to potential barriers of project implementation.

**Essential VIII: Advanced Nursing Practice.** This Essential describes the clinical specialization content of the advanced nursing practice through the development of therapeutic relationships with patients and providers, utilization of advanced clinical decision making, and mentoring others in the nursing profession (AACN, 2006). This Essential was delineated in this project by the DNP student presenting at the organization's outcomes research collaborative meeting with the discussion consisting of the enactment of the DNP as well as the clinical pathway implementation. The DNP student also guided and mentored nurses on the project implementation as well as developed and sustained therapeutic relationships with multiple disciplinary teams for optimal patient outcomes.

#### **Dissemination of Outcomes**

Dissemination of results will first occur with the stakeholders at the organization where project implementation occurred. The DNP student will present at the July, 2016 quality meetings. The final presentation will be to the DNP student's committee at the scholarly project defense. Final project results will be disseminated in the future at the organization's research committees, in future poster presentations at conferences, and possible journal publications.

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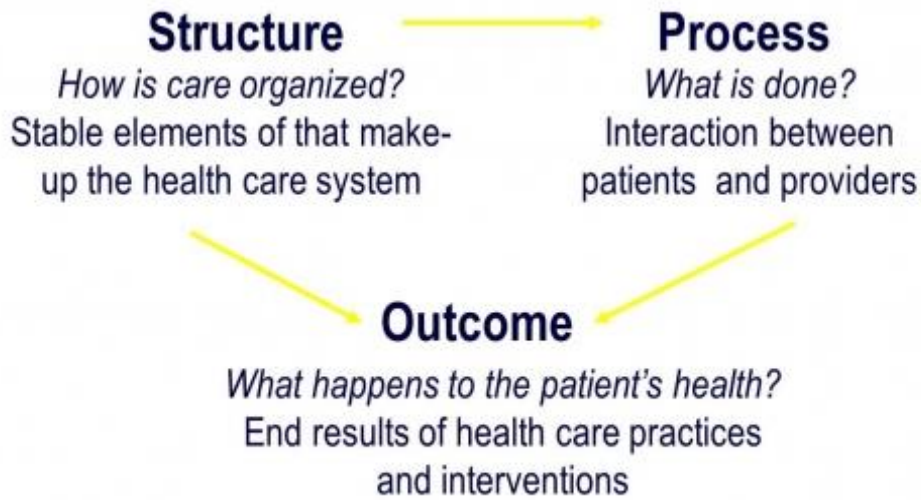
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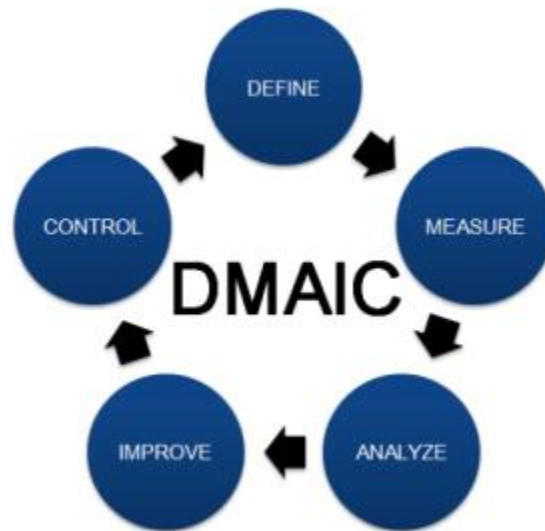
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**Appendices**

**Appendix A: The Donabedian Model**



*Figure A.* The Donabedian Model. Reprinted from “Evaluating the quality of medical care,” by A. Donabedian, 1966, *Milbank Memorial Fund Quarterly*, 44, p. 166-206. Copyright 2004 by [jasn.asnjournals.org](http://jasn.asnjournals.org). Reprinted with permission.

**Appendix B: The Define Measure Analyze Improve Control (DMAIC) Process**

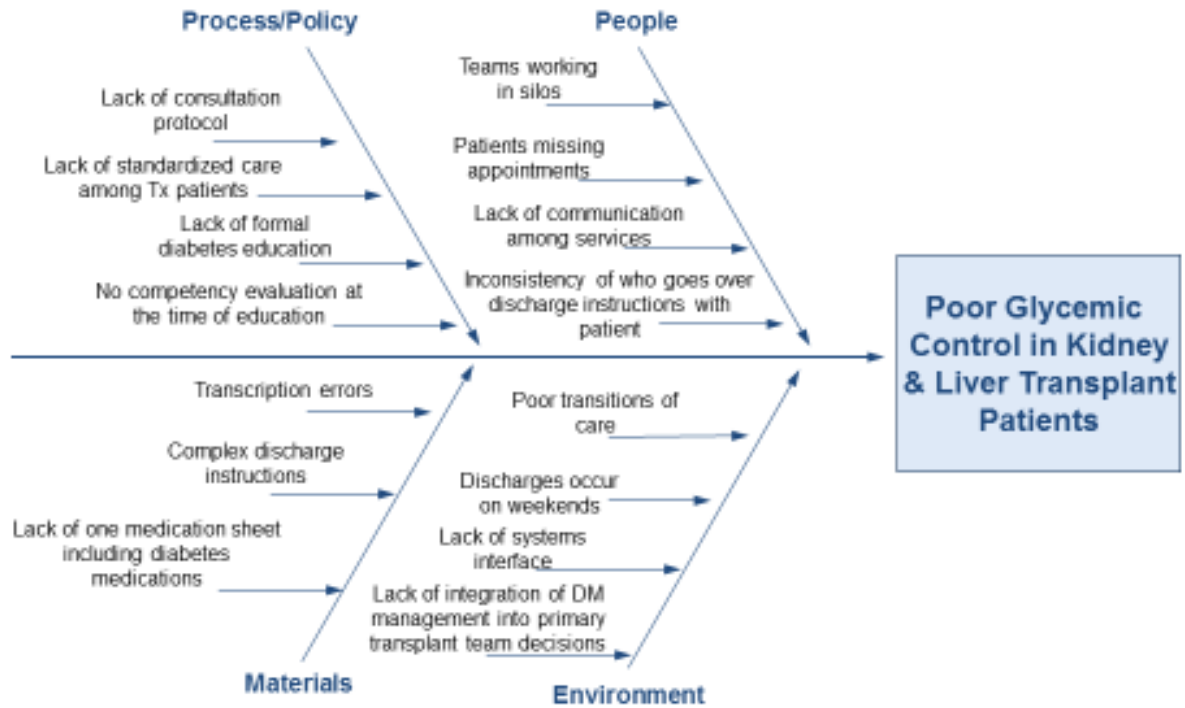
*Figure B. DMAIC Model. Reprinted from Villanova University by University Alliance, 2016, Retrieved from <http://www.villanovau.com/resources/six-sigma/six-sigma-methodology-dmaic/#>. VxL7XvkrLX4. Copyright 2016 by University Alliance. Reprinted with permission.*

**Appendix C: SWOT Analysis for Academic Medical Center**

<b>Strengths</b>	<b>Opportunities</b>
<ul style="list-style-type: none"> <li>• Leading hospital in Midwest for education, research, and patient care</li> <li>• Magnet certified</li> <li>• Transplant center serves as the largest and most successful transplantation program in Illinois</li> <li>• Transplant center ranked top nationally in patient outcomes and transplant performed</li> <li>• Over 200 kidney transplants yearly</li> <li>• Over 100 liver transplants yearly</li> <li>• Several satellite clinics</li> <li>• Developed Real-time Analysis and Performance Improvement Dashboard (RAPID) for quality improvement</li> <li>• Committed to our patients</li> <li>• Strong leadership</li> </ul>	<ul style="list-style-type: none"> <li>• Improve wait times for organ transplantation</li> <li>• Change in allocation system for organ transplantation</li> <li>• Heavy regulation to ensure safe and effect transplant system</li> <li>• No change in reimbursement with Affordable Care Act</li> <li>• United Network for Organ Sharing (UNOS) has changed criteria for who is listed</li> <li>• RAPID software to improve quality assurance</li> <li>• Improve patient satisfaction with improved discharge planning</li> <li>• Improve patient follow up with appropriate consultations</li> </ul>
<b>Weaknesses</b>	<b>Threats</b>
<ul style="list-style-type: none"> <li>• Lack of communication among staff members</li> <li>• High turnover rates among staff</li> <li>• Divided health care culture</li> <li>• Divided viewpoints among surgeons</li> <li>• Poor follow up with patients</li> <li>• Overbooked clinic days</li> <li>• Poor patient satisfaction</li> <li>• Poor discharge teaching</li> </ul>	<ul style="list-style-type: none"> <li>• Changing electronic health record systems</li> <li>• Possible probationary period from regulating bodies from poor patient outcomes from Scientific Registry of Transplant Recipients (SRTR) reports</li> <li>• Complete closure of transplant program</li> <li>• Government regulations</li> </ul>

**Appendix D: Fishbone diagram of Poor Glycemic Control**

**Poor Glycemic Control in Kidney and Liver Transplant Patients**





**Appendix E: Non-Glucose Management Service Consults and Status  
11/1/2014-2/28/2015**

	<b>Patients</b>	<b>Patients with History of DM (%)</b>
<b>Kidney</b>	43	10 (23%)
<b>Liver</b>	18	4 (22%)

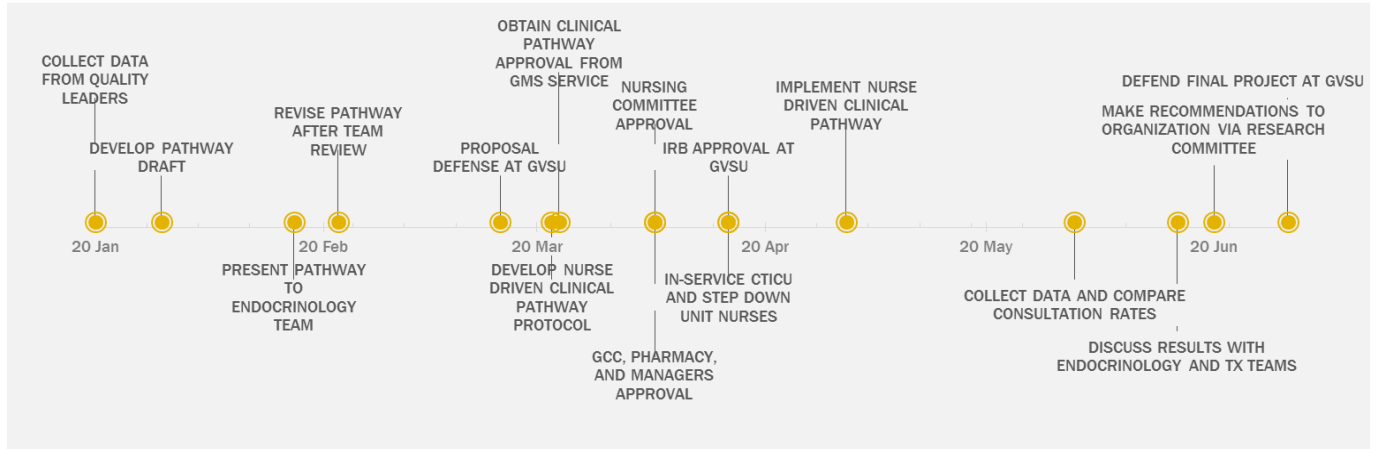
**Appendix F: Non-Glucose Management Service Consults and Glucose Outcomes  
11/1/2014-2/28/2015**

	<b>Patients</b>	<b>≥2 BG values &lt;60 mgdl</b>	<b>≥2 BG values BG&gt;200mgdl</b>	<b>Both Hypo and Hyper</b>
<b>Kidney</b>	43	22 (51%)	5 (11%)	7
<b>Liver</b>	18	0	12 (67%)	3
<b>Total</b>	61	22	17	10

**Appendix G: Kidney Transplantations with Risk Factors  
11/1/2014-2/28/2015**

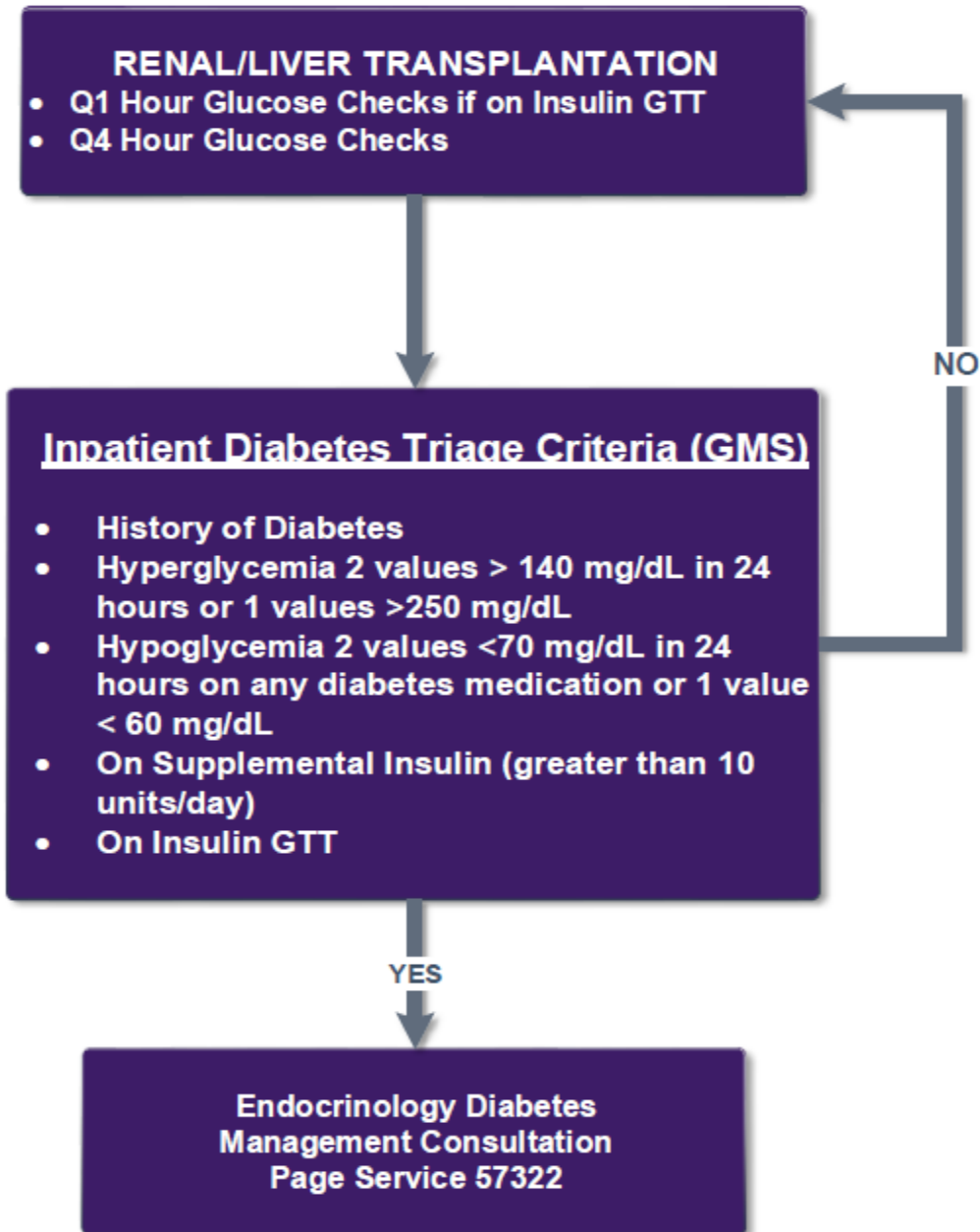
	<b>Total Transplants</b>	<b>Age&gt;45</b>	<b>BMI&gt;25 kg/m<sup>2</sup></b>	<b>History of DM</b>	<b>African American/Hispanic</b>	<b>Hyperglycemia BG&gt;140</b>
<b>Kidney</b>	61	36 (60%)	30 (49%)	27 (44%)	23 (38%)	20 (33%)

### Appendix H: Implementation of Project Timeline



**Appendix I: Criteria for Nurse Driven Diabetes Clinical Pathway in Kidney/ Liver Transplantation**

**Criteria for Nurse Driven/ Pharm D Diabetes Clinical Pathway in Kidney and or Liver Transplantation**



**Appendix I: Abbreviations Key for Clinical Pathway**

GMS = Glucose Management Service

gtt = drip

Q = every

**Appendix J: Education Materials**

**Endocrinology Consultation in  
Kidney and Liver Transplantation**

**PURPOSE:**  
**Appropriate consultations for evaluation and treatment of hyperglycemia in post-transplant patient population**

- Inpatient Glucose Management Goals**
- **Target Glucose 110-140 mg/dL\***
  - **Blood Glucose > 180mg/dL is considered uncontrolled**

<b>Upper Limit for Glycemic Targets</b>		
<b>Intensive Care units</b>	<b>Non Critical care Units</b>	
	<b>Pre - Prandial</b>	<b>Maximum Glucose</b>
<b>110 - 140 mg/dL*</b>	<b>&lt;140 mg/dL</b>	<b>180 mg/dL</b>

\*140-180mg/dl acceptable via guidelines above

<b>Guideline for Non-Critically Ill Patients</b>	
<b>Pre – meal Glucose Target</b>	<b>&lt;140 mg/dL</b>
<b>Random Blood Glucose</b>	<b>&lt;180 mg/dL</b>

- Hyperglycemia (BG>140 mg/dL)**
- **Risk factor for PTDM**
  - **Associated with acute rejection**
  - **Increase post-operative infections**

- Risk Factors for Hyperglycemia Post-Transplant**
- **Age>45**
  - **African American/Hispanic**
  - **Obesity (BMI>25)**
  - **HCV/CMV viruses**
  - **Immunosuppression therapy (Calcineurin Inhibitors)**
  - **Induction therapy: Simulect**
  - **Family history of diabetes/history of diabetes**
  - **Hyperglycemia before and/or after transplant surgery**

- Hospital in Midwest and Hyperglycemia Post-Transplant**
- **Over 20% of transplant patients with a history of diabetes are not consulted by Endocrinology Diabetes Service and over 50% of these non-consulted patients have two or more BG readings of <60 mg/dL or >200 mg/dL.**
  - **Goal: Reduce the number of patients experiencing hypo- and hyperglycemia.**

Umpierrez, G.E., et al., *Management of hyperglycemia in hospitalized patients in non-critical care setting: an endocrine society clinical practice guideline.* J Clin Endocrinol Metab, 2012. 97(1): p. 16-36.  
Moghissi, E.S., et al., *American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control.* Endocr Pract, 2009. 15(4): p. 353-69.

**Appendix K: Nurse Driven Clinical Pathway Survey**

**Nurse Driven Clinical Pathway Survey**

For each of the statements below, circle the response that best characterizes how you feel about the statement, where 1= Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, and 5=Strongly Agree

	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
The in-service pertains to my job	1	2	3	4	5
I understand the purpose and criteria needed to consult endocrinology	1	2	3	4	5
I understand my responsibilities pertaining to the clinical pathway	1	2	3	4	5
I feel the clinical pathway will improve my work load	1	2	3	4	5
I feel the clinical pathway will cause more work for me	1	2	3	4	5

Please list potential barriers that would prevent you from consulting endocrinology?

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**Appendix L: Evaluation Tools**

<b>TX #</b>	<b>Hx of DM</b>	<b>Hyperglycemia 2X&gt;140 or 1X &gt;250</b>	<b>Hypoglycemia 1X&lt;60 or 2X&lt;70</b>	<b>Insulin gtt Y or N</b>	<b>Supplemental Insulin Y or N</b>	<b>Was Pt consulted Y or N</b>	<b>Did pt meet criteria</b>	<b>Barriers to consultation</b>
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

<b>Total Transplants</b>	<b>Total Consulted Appropriately (%)</b>	<b>Should have been Consulted (%)</b>

<b>Type of Transplant</b>	<b>Consults Missed before Pathway Implementation (%)</b>	<b>Consults Missed after Pathway Implementation (%)</b>
<b>Kidney</b>		
<b>Liver</b>		

**Appendix M: IRB Letters**

**Institutional Review Board Office  
Northwestern University**

Biomedical IRB  
750 North Lake Shore Drive  
Rubloff Building, Suite 700  
Chicago, Illinois 60611  
312-503-9338

Social and Behavioral Sciences IRB  
600 Foster Street  
Chambers Hall, Second Floor  
Evanston, Illinois 60208  
847-467-1723



**APPROVAL OF MODIFICATION**

**DATE:** August 6, 2015  
**TO:** Dr. Amisha Wallia  
**FROM:** Office of the IRB  
**DETERMINATION DATE:** 8/6/2015  
**APPROVAL DATE:** 8/6/2015  
**EFFECTIVE DATE:** 8/6/2015  
**EXPIRATION DATE:** 5/26/2016

The Northwestern University IRB has reviewed and approved the submission described below:

Type of Submission:	Modification
Review Level:	Expedited
Expedited Category:	- (mm) Minor modification
Title of Study:	Evaluating the Process of Identification and Treatment of Hyperglycemia and Diabetes in Liver Transplant
Principal Investigator:	Amisha Wallia
IRB ID:	STU00090319-MOD0009
Funding Source:	American Diabetes Association, Funding Source ID: 1-13-JF-54
Grant ID:	
IND, IDE, or HDE:	None
Documents Reviewed:	
Special Determinations:	Students / Employees; Waiver of HIPAA authorization; Waiver/alteration of the consent process; Waiver of consent documentation;

Description of the modification:

- Dawn Korson to be added as Research Personnel.

In conducting this study, you are required to follow the requirements listed in the Northwestern University (NU) Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the eIRB+ system.



DATE: April 20, 2016

TO: Dawn Korson  
FROM: Grand Valley State University Human Research Review Committee  
STUDY TITLE: [898200-1] Quality Improvement Initiative in Transplant Diabetes Care: Needs Assessment and Protocol Development

REFERENCE #:  
SUBMISSION TYPE: New Project

ACTION: NOT RESEARCH  
EFFECTIVE DATE: April 20, 2016  
REVIEW TYPE: Administrative Review

Thank you for your submission of materials for your planned research study. It has been determined that this project:

*DOES NOT* meet the definition of covered human subjects research\* according to current federal regulations. The project, therefore, *DOES NOT* require further review and approval by the HRRC.

If you have any questions, please contact the Research Protections Program at (616) 331-3197 or [rpp@gvsu.edu](mailto:rpp@gvsu.edu). The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.

\*Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information (45 CFR 46.102 (f)).

Scholarly activities that are not covered under the Code of Federal Regulations should not be described or referred to as *research* in materials to participants, sponsors or in dissemination of findings.

**Appendix N: Expense Report for Project Implementation**

<b>Expenses</b>	<b>Average Salary/Wage</b>	<b>Hours (Time in meetings/education)</b>	<b>Total Cost</b>
<b>2 Endocrinologists</b>	\$101.00 per hour (\$211,000 per year based on 40 hour work week)	5	\$1,010.00
<b>1 Project Coordinator</b>	\$21.90 per hour (\$45,560 per year based on 40 hour work week)	5	\$109.50
<b>1 Nurse Practitioner</b>	\$50.20 per hour (\$104,379 per year based on 40 hour work week)	5	\$250.00
<b>DNP Student</b>	\$40.00 per hour	30	\$1200.00
<b>106 Nurses</b>	\$40.00 per hour	26.5	\$1,060.00
<b>Education Materials/ Laminated Documents</b>			\$352.47
<b>Total</b>			<b>\$3,981.97</b>

**Appendix O: Readmission Expenses for one Kidney and Liver Transplant Patient**

**Readmission Expenses for a Kidney Transplant Patient**

<b>Unit</b>	<b>Fixed Room Rate for 24 hours (\$)</b>	<b>Average Length of Stay (LOS)</b>	<b>Total</b>
<b>CTICU</b>	\$4100.00	9.9	\$40,590.00
<b>Step Down Unit</b>	\$1889.00	9.9	\$18,701.10

**Readmission Expenses for a Liver Transplant Patient**

<b>Unit</b>	<b>Fixed Room Rate for 24 hours (\$)</b>	<b>Average Length of Stay (LOS)</b>	<b>Total</b>
<b>CTICU</b>	\$4100.00	7.7	\$31,570.00
<b>Step Down Unit</b>	\$1889.00	7.7	\$14,545.30

**Appendix P: Cost Savings for Kidney and Liver Transplantation**

**Cost Savings for Kidney Transplantation**

	<b>CTICU</b>	<b>Step Down Unit</b>
<b>Readmission Expenses (one Patient)</b>	\$40,590.00	\$18,701.00
<b>Project Implementation Expenses</b>	\$3,981.97	\$3,981.97
<b>Total Cost Savings</b>	<b>\$36,608.03</b>	<b>\$14,719.03</b>

**Cost Savings for Liver Transplantation**

	<b>CTICU</b>	<b>Step Down Unit</b>
<b>Readmission Expenses (one Patient)</b>	\$31,570.00	\$14,545.30
<b>Project Implementation Expenses</b>	\$3,981.97	\$3,981.97
<b>Total Cost Savings</b>	<b>\$27,588.03</b>	<b>\$10,563.33</b>

**Appendix Q: Estimated Quarterly and Yearly Cost Savings for Kidney and Liver Transplantation**

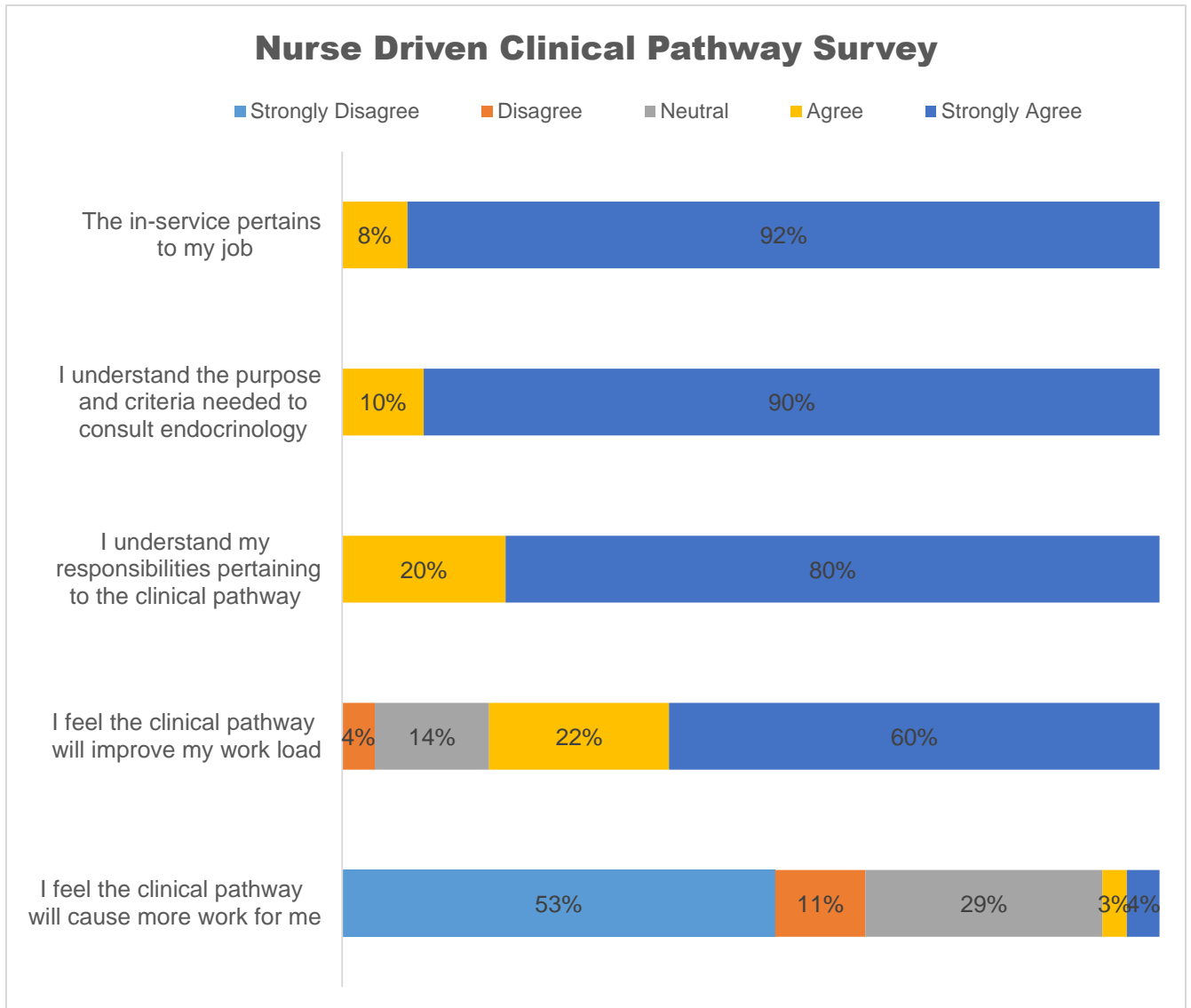
**Estimated Cost Savings for Kidney Transplantation**

	<b>Quarterly (based on 2 readmissions per quarter)</b>	<b>Yearly</b>
<b>CTICU</b>	\$73,216.06	\$292,864.24
<b>Step Down Unit</b>	\$29,438.06	\$117,752.24

**Estimated Cost Savings for Liver Transplantation**

	<b>Quarterly (based on 2 readmissions per quarter)</b>	<b>Yearly</b>
<b>CTICU</b>	\$55,176.06	\$220,704.24
<b>Step Down Unit</b>	\$21,126.66	\$84,506.64

**Appendix R: Nurse Driven Clinical Pathway Survey Results**



**Please list potential barriers that would prevent you from consulting endocrinology?**

- Remembering to page Endocrinology
- Weekend/night shift coverage not responsive, receptive, or kind
- More frequent glucose checks obtained by nursing
- Concern of pushback from transplant team for placing order



**Appendix S: Evaluation of Project**

<b>TX #</b>	<b>Hx of DM</b>	<b>Hyperglycemia 2X&gt;140 or 1X &gt;250</b>	<b>Hypoglycemia 1X&lt;60 or 2X&lt;70</b>	<b>Insulin gtt Y or N</b>	<b>Supplemental Insulin Y or N</b>	<b>Was Pt consulted Y or N</b>	<b>Did pt meet criteria</b>	<b>Barriers to consultation</b>
<b>1 DD Kidney</b>	No	Yes	No	No	No	Yes	Yes	
<b>2 DD Kidney</b>	No	Yes	No	Yes	No	No	Yes	Tx team failed to place order for consult. Patient was on Insulin gtt in the OR.
<b>3 DD Kidney</b>	No	Yes	No	No	No	Yes	Yes	
<b>4 LD Kidney</b>	Yes	Yes	Yes	No	Yes	Yes	Yes	
<b>5 DD Kidney</b>	No	Yes	No	No	Yes	Yes	Yes	
<b>6 DD Kidney</b>	No	Yes	No	No	No	Yes	Yes	
<b>7 LD Kidney</b>	No	Yes	No	Yes	Yes	Yes	Yes	
<b>8 LD Kidney</b>	No	Yes	No	No	Yes	Yes	Yes	
<b>9 DD Kidney</b>	No	Yes	No	Yes	No	Yes	Yes	
<b>10 LD Kidney</b>	No	Yes	No	No	No	Yes	Yes	
<b>11 DD Kidney</b>	Yes	Yes	No	No	Yes	Yes	Yes	
<b>12 LD Kidney</b>	No	Yes	No	No	No	No	Yes	Nurses on step down unit failed to check glucose levels per guidelines of pathway
<b>13 LD Kidney</b>	No	Yes	No	No	Yes	Yes	Yes	
<b>14 DD Kidney</b>	Yes	Yes	No	Yes	No	Yes	Yes	

<b>15</b> DD Kidney	No	Yes	No	Yes	No	Yes	Yes	
<b>16</b> LD Kidney	No	Yes	No	No	Yes	No	Yes	Nurses failed to place order for consult
<b>17</b> LD Liver	No	Yes	No	Yes	Yes	Yes	Yes	
<b>18</b> DD Liver	No	Yes	Yes	Yes	No	Yes	Yes	
<b>19</b> DD Liver	No	Yes	No	Yes	Yes	Yes	Yes	
<b>20</b> DD Liver	No	Yes	No	Yes	No	No	Yes	Nurses failed to place order for consult
<b>21</b> DD Liver	Yes	Yes	No	Yes	Yes	Yes	Yes	

Total Transplants	Total Consulted Appropriately (%)	Should have been Consulted (%)
21 transplants (16 Kidney, 5 Liver)	100%	19% (N= 3) (19% Kidney, 20% Liver)

Type of Transplant	Consults Missed before Pathway Implementation (%)	Consults Missed after Pathway Implementation (%)
<b>Kidney</b>	23% (N=10)	19% (N=3)
<b>Liver</b>	22% (N=4)	20% (N=1)

**Chi-Square Test for Significance of Appropriate Consultation to Endocrinology and Abnormal Glucose for Post-Transplantation**

Observed Values

	Yes	No	Total
Kidney Transplants	13	3	16
Liver Transplants	4	1	5
Total	17	4	21

Expected Values

	Yes	No	Total
Kidney Transplants	12.95	3.05	16
Liver Transplants	4.05	0.95	5
Total	17	4	21

p- value = 0.948 (p<0.05 shows significance)