Classification of Protocol Complexity and Staffing Needs for MCRU Phase 2: Implementation and Interface with MCRU Scheduling Portal

Final Report

Submitted To:

Ms. Cyndi Bower  
Administrative Program Director, MICHRI Clinical Research Support Services  
Clinical Manager, Michigan Clinical Research Unit

Mr. Luca G. Capicchioni  
Administrative/ Management Engineering Fellow  
Program & Operations Analysis, University of Michigan Health System

Mr. Dale Jackson  
Program & Operations Analysis Associate  
Michigan Quality System, UMHS Michigan Quality System

Dr. Mark Van Oyen  
Professor, Industrial and Operations Engineering

Submitted By:

Charles Oswalt  
Brandon Rosenblum  
Alexa Saplala

IOE 481 Team 10, University of Michigan

Date: December 9, 2014
Table of Contents

Executive Summary ................................................................. 3
Introduction .............................................................................. 6
Background .............................................................................. 6
Key Issues .............................................................................. 6
Goals and Objectives ............................................................. 7
Project Scope ........................................................................... 7
Methodology ............................................................................ 7

Data Collection ........................................................................ 8
  Performed Literature Search .................................................. 8
  Interviewed Key Personnel ...................................................... 8
  Observed MCRU Meetings ...................................................... 8
  Gathered Predicted Visit Requirements .................................. 9
  Organized Results .................................................................. 9

Data Analysis ........................................................................... 10
  Validated Data Collection ..................................................... 10
  Assessed RN Prediction Accuracy .......................................... 10
  Analyzed Over-prediction Frequency ...................................... 10
  Stratified Tool Results by Percent Difference ....................... 11
  Interviewed Key Personnel ................................................... 11

Developed Recommendations ................................................ 11

Findings ..................................................................................... 12
  Validated Data Collection ..................................................... 12
  Assessed RN Prediction Accuracy .......................................... 13
  Analyzed Over-prediction Frequency ...................................... 13
  Stratified Tool Results by Percent Difference ....................... 14
  Interviewed Key Personnel ................................................... 16

Conclusions ............................................................................. 17

Recommendations ................................................................... 17

Expected Impact ....................................................................... 17

Appendices .............................................................................. 18
  A. Flow Chart ..................................................................... 18
  B. Literature Search .............................................................. 19
  C. Time and Events Table ....................................................... 20
  D. Clinic Sheet ..................................................................... 21
  E. MCRU Schedule ............................................................... 22
  F. Screenshot of Tool ............................................................. 23
List of Tables and Figures

Table 1: Database Data Fields and Data Types ................................................................. 9
Table 2: Comparison of Team & Lead Nurse Tool Results ............................................. 12
Table 3: Comparison of Lead Nurse & Team’s Tool Results Without Space Time .......... 12
Table 4: Summary of Prediction Agreement (N=225) .................................................... 13
Table 5: Summary of Four Scenarios in RN Prediction Accuracy (N=225) ...................... 13
Table 6: Most Frequently Inaccurate Protocol Procedures ............................................. 14
Table 7: Over-prediction Frequency Based on Protocol Visit Time Length ..................... 14
Table 8: Accuracy Brand Frequencies .......................................................................... 15
Table 9: Most Frequent Procedures by Accuracy Band .................................................... 15
Table 10: Most Frequent Procedures for x≤10% Protocols ............................................ 15
Table 11: Most Frequent Procedures for 10% < x ≤ 30% Protocols ................................. 16
Table 12: Most Frequent Procedures for 30% < x ≤ 100% Protocols ............................... 16
Executive Summary

The Michigan Clinical Research Unit (MCRU) provides the clinical staff, resources, and infrastructure necessary to facilitate human clinical research protocols. A protocol answers specific questions across individuals, groups, and cohorts. The tool assessed in this project is a Microsoft Excel Workbook created to allocate resources and staffing for protocol visits.

The MCRU is having difficulty predicting necessary staff and resources for complex protocols. In 2010, a tool was created to predict the necessary staffing and resources required for protocol visits. The tool has been updated previously in Phase 1 of the project. However, the tool has never been validated in its predicting ability using active, present protocol data. The Administrative Program Director asked a team of Industrial and Operations Engineering 481 students to assess the tool’s prediction accuracy in protocol resource and staffing, validate the tool against ongoing protocol visits, and recommend where the tool can be immediately implemented for use.

The goal of this project is to optimize scheduling efficiency, improve employee satisfaction, and increase the quality of services to participants through better use of resources.

Methods and Findings

To determine assess and validate the tool, the team completed the following methods for data collection and analysis.

Performed Literature Search
The team performed a literature search to analyze similar studies and draw inferences about their relevance to this project. The team learned about common analytics methods used in Operating Room scheduling analysis.

Interviewed Key Personnel
The IOE 481 team interviewed the MCRU Lead Clerk and Lead Nurse. These interviews helped the team understand how the scheduling process currently works.

Observed MCRU Meetings
The team attended a Huddle Meeting and a Protocol Initiation Meeting. The meetings helped the team to fully understand the current scheduling processes, the documents used in the scheduling process, and the need for this tool to be implemented.

Generated Predicted Visit Requirements
The team obtained data by running the tool on 225 protocol visits covering October 15th through November 6th. The tool outputs served as the predicted data. The team also obtained data by collecting the MCRU schedules to gather protocol visit Total Time for MCRU staffing and resource allocation.
Validated Data Collection
The team validated their tool outputs by comparing 5 protocols to an experienced MCRU employee, the Lead Clerk. The team confirmed that their data was accurate.

Assessed RN Prediction Accuracy
The team then performed an agreement analysis by comparing two binary variables: whether the tool predicted an RN was necessary for a protocol visit and if an RN was scheduled for the same protocol visit. The team learned the tool was in agreement 85% of the time compared to the actual MCRU schedule. The team also identified a potential source of error, which occurs when the MCRU schedules an RN despite an RN not being necessary for a specific visit.

Analyzed Over-prediction Frequency
The team found that 32 of the total 225 analyzed protocol visits were over predicted by the tool. Skin biopsy procedures were over-predicted at the highest frequency of 60% of the time and by an average of 30 minutes. The tool’s over-prediction frequency was determined to be independent of protocol visit time length.

Stratified Tool Outputs by Percent Difference
The team then analyzed the other protocol visits in the dataset that weren’t considered in the analysis described in the previous section. This excluded protocol visits having Tool Total Time greater than the MCRU Schedule Total Time. The team then calculated the Tool Total Time percent difference from the MCRU Schedule Total Time. The team stratified the protocol visits by procedures most frequently occurring in three accuracy bands: $x \leq 10\%$, $10\% < x \leq 30\%$, and $30\% < x \leq 100\%$, where $x$ is the Tool Total Time. The team and the Administrative Program Director categorized the protocol bands as: accurate, neither accurate nor inaccurate, and inaccurate. The team found that the IV Insertion was the most frequently occurring procedure in protocol visits in the accurate band. Because the procedure was occurring at a low frequency it not an accurate predictor of the tool, but it is the most accurately predicted procedure the tool contains. The team also found the Questionnaires, Other Procedures, and Consenting were the most frequently occurring procedures in the $10\% < x \leq 30\%$ band. From these findings, the team was able to convey that these procedures, all contained within the Space Time component of the tool, were inaccurate predictors of the tool.

Interviewed Key Personnel
The team interviewed the MCRU Lead Clerk and Lead Nurse on the robustness of the tool. The team also interviewed a Study Team Coordinator about the Space Time component of the tool. Both interviews provided the team with qualitative analysis to support the quantitative analysis.

Conclusions
The team found that the tool inaccurately predicted 131 of the 225 protocol visits. Therefore, the team concluded that the tool currently is not valid in its ability to predict protocol visit time lengths.
Recommendations
The team recommends making a few adjustments to the tool to increase its protocol visit time prediction accuracy. These changes include adding a vitals section, allowing for up 2 hours in the “other procedures” section, and setting the minimum predicted time to 30 minutes. The team also recommends that the tool can be implemented as an RN necessity predictor.
Introduction

The Michigan Clinical Research Unit (MCRU) provides the clinical staff, resources, and infrastructure necessary to facilitate human clinical research protocols at the University of Michigan. A protocol is the robust scientific validity and operational feasibility of the implementation of science in humans that answers specific questions across individuals, groups, and cohorts. The tool is a workbook that allocates resources and staffing for individual protocol visits.

The MCRU is having difficulty predicting the resources and staffing necessary for protocols due to variable protocol complexity. In 2010, a draft tool was created to predict necessary resources based on protocol complexity, but the tool was never implemented for use. The MCRU would like to know if the information outputted by the tool is valid, and if valid, would like to identify where the tool is found to be an accurate predictor for protocols the MCRU is currently supporting. The Administrative Program Director asked a University of Michigan Industrial and Operations Engineering (IOE) 481 team to assess the accuracy of the tool, validate the tool again ongoing protocols, and to identify where the tool can be implemented immediately. This report presents the methods, findings and recommendations for the validating the tool and identifying its applications.

Background

The MCRU currently hosts 289 active protocols. Active protocols are protocols that are approved and supported by the MCRU and are seeing at least one participant. The unit is open 8 a.m. – 8 p.m. for outpatient clinical trials, but also provides opportunities for extended stays and/ or weekends.

In 2010, a nursing student developed a draft tool as a Workbook in Microsoft Excel to estimate staffing and resources necessary for protocol visits. The tool asked a series of basic questions about the protocol and used the answers provided to output a score that defined the protocol’s complexity. The score indicated the staff and resources required for the specified protocol visit. The tool’s functionality was never validated and it was left unused.

In the spring of 2014, the tool was revisited in what is referred to as Phase 1 of this project. An IOE 481 team from the University of Michigan was asked to update the tool. The Phase 1 team updated the tool to predict staffing and resources of 10 protocol visits that occurred in the past. The tool was updated using only historical data and was never implemented.

The MCRU still does not have a standardized process to allocate daily resources and staffing. Employee dissatisfaction and idle worker time are resulting from inefficient scheduling and inconsistent resource allocation. Currently, the MCRU Lead Nurse assigns staff and resources manually. In addition, the MCRU has two daily Huddle Meetings (at 7:55 am and 3:15 pm every day) and relies on evidence reported by staff at these meetings to determine the effectiveness of staffing schedules. The MCRU would like to use the updated tool at Protocol Initiation Meetings, which are held to orient new protocols or revisit outdated protocols. The MCRU asked the student team to run the tool on ongoing (live) protocols to validate its ability to
predict resources and staffing and to develop recommendations on where the tool can be implemented currently and where it needs to be updated.

The project is a continuation of the work done in Phase 1 and will be referred to as Phase 2.

**Key Issues**

The Phase 1 tool has not been:
- Assessed in its accuracy to predict a protocol visit’s allocated resources and staffing
- Validated against ongoing protocol visits
- Implemented for use in the MCRU scheduling process

**Goals and Objectives**

The goal of the project is to validate the tool’s accuracy to predict ongoing protocol visits, assess where the tool most accurately predicts resources and staffing allocation, and identify where the tool can be immediately implemented for use in the scheduling process.

The team’s objectives are to:
- Optimize scheduling efficiency to minimize underutilization and overutilization of staff
- Improve employee satisfaction
- Increase quality of services to participants through better use of resources

**Project Scope**

This project included the scheduling process of research protocols. The process begins during the initial protocol meeting where a protocol complexity rating is assigned and ends when the protocol has terminated. The team analyzed 225 protocols spanning over a time period from October 15th – November 6th. This project examined only outpatient protocols within the University of Michigan MCRU. The entire tool created in Phase 1 was tested. The team had access to all existing protocol information.

The project excluded personal patient information. The team did not contact any patients directly and gathered necessary information only through interviews and meetings. Additionally, this project did not focus on protocol visit research performed outside the MCRU. This project did not include overnight protocols or protocols containing DEXA Bone Density Scans, Nutritional Counseling, and Metabolic Cart procedures due to their varying complexity.

**Methodology**

The team of IOE students worked alongside the MCRU. The MCRU staff involved included the Administrative Program Director, the Lead Clerk, the Lead Nurse, and Study Team Coordinators. The operating entities included the Programs and Operations Analysis Coordinators and the IOE 481 teaching staff.
Data Collection

Data collection was scheduled from October 15th – November 6th. Data analysis began October 27th and occurred simultaneously with data collection. The team conducted data collection as follows: performed literature search, interviewed key personnel, observed MCRU meetings, generated predicted visit requirements, and organized results. A flowchart detailing the entire data collection process is shown in Appendix A.

Performed Literature Search
The team conducted a literature search to identify similar projects and methods conducted. The literature search provided the team with guidelines and ideas for this project. The article identified through this search is titled Operator Room Scheduling: Factors to Consider by the Association of periOperative Registered Nurses (AORN). This article outlines factors to consider while scheduling an operator room (OR) for surgery, in addition to recommended methodologies. This article also analyzes various OR scheduling systems and provides the pros and cons of each. This literature search helped the team understand the analysis process of a scheduling system. Finally, the article highlighted that resource and staff allocation optimization is an ongoing area for improvement across the Medical Field. The article is referenced in Appendix B of this report.

Interviewed Key Personnel
The team interviewed the MCRU Lead Clerk and Lead Nurse on October 15th. During this meeting, the two employees explained how to interpret the Time & Events Tables, the Clinic Sheets, and the MCRU Schedule. The team requested to receive the tables, sheets, and schedule on a daily basis beginning October 15th. The team learned that the Time & Events Table is provided by the study team at the Protocol Initiation Meeting. This table contains the protocol information that will appear in the upcoming week’s schedule and details each step of the protocol performed by the MCRU or independently by the study team. Appendix C shows a Time & Events Table. The Clinic Sheets are created by the MCRU and list the protocol activities only performed by the MCRU staff. Appendix D shows a Clinic Sheet. The MCRU schedule lists the daily resource and staffing allocations for each protocol. Appendix E shows a MCRU Schedule.

Observed MCRU Meetings
The team attended a Huddle Meeting on November 3rd. The Huddle Meetings happen twice daily. During the meetings, MCRU staff analyzes that day’s schedule and determine if the workload is appropriate. The team attended the huddle meetings to understand what the MCRU staff thinks about the current scheduling process.

The team attended a Protocol Initiation Meeting on November 3rd. These meetings occur between the protocol study team and the MCRU. During these meetings the logistics and requested resources and staffing are planned for the entirety of the protocol. The team attended the meetings to better understand the needs of the study teams.
Generated Predicted Visit Requirements
The team received the Time & Events Tables, the Clinic Sheets, and the MCRU Schedule on a daily basis. The team organized the Time & Events Tables and the Clinic Sheets to configure the tool inputs for each protocol visit. Any protocol that included activities not conducted by MCRU staff was disregarded when organizing protocol information. First, the team received a copy of the Time and Events Tables and Clinic Sheets from the Lead Clerk. The tool’s inputs were extracted from both the tables and the sheets. Lastly, the team received a copy of the MCRU Schedule from the Lead Nurse. This included the protocols scheduled for the following day and the resources and staff assigned to perform the required protocol activities. The team used the schedule during the analysis process as a comparison to the tool’s outputs.

The tool organized the protocol input information into the following categories: Specimen Collection, Drug Administration, Monitoring During Procedure, Monitoring Post Procedure, Tests, Invasive Preparation, Other Services, and Space Requirements. A screenshot of the tool is included in Appendix F.

The team ran the tool on 225 protocol visits covering October 15th through November 6th. The team entered each protocol visit into the tool. The tool’s totals table displayed the tool’s outputs for that protocol visit and is displayed in Appendix F. The outputs included the protocol’s total time, the time required by a registered nurse, the time required by a medical assistant, the time a room will be occupied (Space Time), and the protocol complexity score.

Organized Results
The team organized the tool’s results into a Microsoft Excel Spreadsheet. The data fields and corresponding data types are shown in Table 1.

<table>
<thead>
<tr>
<th>Data Field</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Date (MM/DD/YYYY)</td>
</tr>
<tr>
<td>Protocol Number</td>
<td>Numeric (integer)</td>
</tr>
<tr>
<td>Visit Number</td>
<td>Numeric (integer)</td>
</tr>
<tr>
<td>Tool Outputs</td>
<td>Numeric (integer)</td>
</tr>
<tr>
<td>MCRU Scheduled Time</td>
<td>Numeric (integer)</td>
</tr>
<tr>
<td>MCRU Scheduled RN</td>
<td>Binary (1=Yes, 0=No)</td>
</tr>
<tr>
<td>Protocol Specifics</td>
<td>Binary (1=Yes, 0=No; Multiple Columns)</td>
</tr>
</tbody>
</table>

The organized database with the specified data fields enabled the team to easily stratify, interpret, and compare the results for analysis.

Data Analysis
The team began data analysis on October 27th. The team analyzed data as follows: validated data collection, analyzed over-prediction frequency, assessed RN prediction accuracy, stratified tool outputs by percent different, and interviewed key personnel. The analysis identified where the tool most accurately predicts protocol visit information.
Validated Data Collection
The first step in the data analysis process was data collection validation. The team wanted to validate that the resource and staffing allocation predictions produced by the team through the tool were similar to that of a knowledgeable, experienced MCRU employee. The team decided that the Lead Nurse was a good basis for comparison due to her experience with both resource and staff scheduling and general MCRU terminology.

To validate the data collection, the team and the Lead Nurse ran the tool on five protocol visits that occurred on October 15th, 2014. The protocol numbers were 2592, 3143, 3007, 2704, and 2021. The team then recorded the Tool Total Time outputted for the team and the Lead Nurse, for each of the five protocols. The team compared the difference in Tool Total Time minutes between the team and the Lead Nurse. The team and the Administrative Program Director decided that an average tolerance range within 10 minutes would indicate that the team’s data collection methods were valid.

Assessed RN Prediction Accuracy
The team conducted an analysis on the tool’s ability to predict whether a Registered Nurse (RN) was necessary for the protocol visit or not. For this analysis, a comparison was conducted between two binary variables:

- **RN Required on MCRU Schedule (1=Yes, 0=No)**: This variable was obtained from the daily MCRU schedules in column “RN”. If there was an RN named, the variable equaled 1. If the cell was blank, the variable equaled 0.
- **RN Predicted Necessary by Tool (1=Yes, 0=No)**: This variable was obtained from the tool output from the “RN Time” predicted. If the “RN Time” predicted was greater than 0 minutes, the variable equaled 1. If the “RN Time” predicted had a value equal to 0 minutes, the variable equaled 0.

First, the team calculated the percentage of RN predictions in agreement with the actual schedule. The team created a binary variable “Agreement” that is true if “RN Required on MCRU Schedule” and “RN Predicted Necessary by Tool” had the same values for a given protocol visit. The total in agreement was divided by the total number of protocols ran, 225. The team used this value as an estimate of the tool’s RN predicting ability. Analyzed the four scenarios that were produced by the variables: Tool-Yes, Schedule-Yes, Tool-Yes, Schedule-No; Tool-No, Schedule-Yes; and Tool-No, Schedule-No.

Analyzed Over-prediction Frequency
The team calculated how accurately the tool predicted the total times of the protocols. The Administrative Program Director requested that the team consider the tool inaccurate if the tool predicted a total time greater than the scheduled time. Once all the protocol data was collected, the team selected these inaccurate protocols visits and stratified the data by procedure type and MCRU scheduled time to identify trends between the inaccurate data points. To analyze trends based on the amount of time the MCRU scheduled, the team stratified the tool results by protocols scheduled for less than 60 minutes, from 60 to 119 minutes, 120 to 179 minutes, and 180 to 240 minutes. This helped the team identify any procedures or length of procedures that caused the tool to be inaccurate.
**Stratified Tool Outputs by Percent Difference**

The team stratified the Tool’s Total Time into three accuracy bands: within 10%, within 10-30%, and within 30-100% of the MCRU Schedule’s Total Time. The team excluded protocol visits with Tool Total Time greater than the MCRU Schedule Total Time. The team and the Administrative Program Director agreed on the percentages and their ability to interpret the tool’s results. Additionally, the team and Administrative Program Director agreed that the 0-x≤10% band represents accurately predicted protocols, the 10%<x≤30% band represents protocols that are neither accurate nor inaccurate, and the 30%<x≤100% band represents protocols inaccurately predicted by the tool.

For each of the three accuracy bands, the team stratified the most frequently occurring procedures in each of the accuracy bands. This helped the team recommend where the tool accurately predicts protocol information and where the tool should be updated.

**Interviewed Key Personnel**

The team selected one Team Coordinators at random and met with her on November 24th. The team asked the Study Team Coordinator specifically about protocol visit Space Time. Space Time is a section of the tool that encompasses all of the activities performed by the study team, and therefore does not require the MCRU staff. Appendix F contains a screenshot of the tool, which includes the Space Time activities. The team asked questions about:

- Activities missing from the Space Time section of the tool
- Time frames available to choose from for each Space Time activity
- Improvements to the Space Time section of the tool

These questions helped the team make recommendations on how to update the tool’s ability to predict the Space Time. The responses from these questions also provided recommendations on how to better monitor study team activities unaccounted for by the tool.

The team met with the MCRU Lead Nurse on November 19th. During this time, the team interviewed the Lead Nurse on the robustness of the tool. The team and the Administrative Program Director chose the Lead Nurse to interview because they currently allocate the resources and staffing for each protocol, manually. The team asked questions about:

- How easy it is to navigate the tool
- What is missing from the tool
- Where the tool can be improved

This helped the team recommend where the tool should be updated. Also, this analysis will show the team how comfortable the Lead Nurse is with using the tool.

**Developed Recommendations**

The team developed recommendations to identify where the tool is an accurate predictor of resource and staffing allocations. This allowed the team to detect where the tool can be immediately used by the MCRU. Additionally, the team recommended ideas for further tool development.
Findings

The team’s findings are organized as follows: validated data collection, assessed RN prediction accuracy, analyzed over-prediction frequency, and stratified tool outputs by percent different. The findings helped the team assess the validity and accuracy of the tool and identify where the tool can be implemented.

Validated Data Collection

Based on the data validation methods, the team confirmed that the team’s tool outputs are consistently similar to the results of an experienced MCRU employee, the Lead Nurse. The results for comparison are summarized in Table 2.

Table 2: Comparison of Team & Tool Results

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Visit</th>
<th>Lead Nurse's Total Time (minutes)</th>
<th>Team's Total Time (minutes)</th>
<th>Difference (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2592</td>
<td>2</td>
<td>116</td>
<td>86</td>
<td>30</td>
</tr>
<tr>
<td>3143</td>
<td>1</td>
<td>155</td>
<td>155</td>
<td>0</td>
</tr>
<tr>
<td>3007</td>
<td>4</td>
<td>35</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>2704</td>
<td>84</td>
<td>45</td>
<td>55</td>
<td>10</td>
</tr>
<tr>
<td>2021</td>
<td>1</td>
<td>80</td>
<td>80</td>
<td>0</td>
</tr>
</tbody>
</table>

Average: 10

As seen by Table 2, the largest difference seen between the team and the Lead Nurse’s predictions was 30 minutes. The analysis showed an average difference of 10 minutes. Although the average is within the specified range of differences allowed (10 minutes), protocol 2592 had a difference of 30 minutes that well exceeded the boundaries. Further analysis indicated that protocol 2592 visit 2 was composed of mostly space time minutes. By removing the space time minutes predicted from both the Lead Nurse’s predictions and the team’s tool outputs, the following results are displayed in Table 3.

Table 3: Comparison of Lead Nurse & Team’s Tool Results Without Space Time

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Visit</th>
<th>Lead Nurse's Total Time (minutes)</th>
<th>Team's Total Time (minutes)</th>
<th>Difference (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2592</td>
<td>2</td>
<td>26</td>
<td>26</td>
<td>0</td>
</tr>
<tr>
<td>3143</td>
<td>1</td>
<td>155</td>
<td>155</td>
<td>0</td>
</tr>
<tr>
<td>3007</td>
<td>4</td>
<td>35</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>2704</td>
<td>84</td>
<td>45</td>
<td>55</td>
<td>10</td>
</tr>
<tr>
<td>2021</td>
<td>1</td>
<td>80</td>
<td>80</td>
<td>0</td>
</tr>
</tbody>
</table>

Average: 4

This table indicates an average difference of 4 minutes. This is within the average difference allowable by the team’s specified methods. By both including and excluding Space Time, the team’s tool outputs are within range of being accurate. However, removing Space Time produced results with a higher consistency.
Assessed RN Prediction Accuracy

Based on the RN Prediction Accuracy analyses, the team concluded that the tool is an accurate predictor of whether or not an RN is needed for the protocol visit. Table 4 provides summary statistics based on the percentage of the tool’s RN predictions in agreement with the actual MCRU schedule.

Table 4: Summary of Prediction Agreement (N=225)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tool Predicted RN Required</td>
<td>66/225</td>
</tr>
<tr>
<td>MCRU Schedule RN Required</td>
<td>67/225</td>
</tr>
<tr>
<td>Match (Agreement)</td>
<td>192/225</td>
</tr>
</tbody>
</table>

Table 4 displays that there was a match percentage of 85.33% between the tool’s prediction and the MCRU’s actual schedule. The team determined that the agreement percentage of 85.33% indicated that the tool was moderately accurate during RN prediction.

The team then analyzed the four possible outcomes from the two variables being analyzed. The results are summarized in Table 5.

Table 5: Summary of Four Scenarios in RN Prediction Accuracy (N=225)

<table>
<thead>
<tr>
<th>RN Required?</th>
<th>Tool Prediction</th>
<th>Total Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCRU Schedule</td>
<td>Yes</td>
<td>48 (21.33%)</td>
<td>19 (8.44%)</td>
</tr>
<tr>
<td>No</td>
<td>17 (7.56%)</td>
<td>144 (63.11%)</td>
<td></td>
</tr>
</tbody>
</table>

In Table 5, the two variables are in agreement when both are ‘Yes’ or both are ‘No’. By speaking with the Administrative Program Director, the team identified a potential source of inaccuracy in this analysis. The team learned that on occasion, the MCRU would schedule an RN despite an RN not being required for the specific visit. This happens for various reasons, of which two examples are as follows:

- An RN has been working on the majority of the protocol and is extremely familiar with the work and patient.
- AN RN is in the room prior and the next visit is a short, simple task. To optimize staffing, the RN occasionally stays in the room for the next, short visit.

The team has identified this situation (MCRU Schedule = Yes, Tool Prediction = No) as a place where further analysis can distinguish whether the MCRU Scheduled RN was necessary. It is believed that further analysis will increase the agreement percentage.

Analyzed Over-prediction Frequency

The team and the Administrative Managing Director determined that if the tool’s total time output was greater than the corresponding MCRU scheduled total time, it would be considered inaccurate. The team found that the tool predicted more protocol visit time than scheduled time for 32/255 (14.2%) of the protocols. The team isolated each procedure to pinpoint what caused
the tool to be most inaccurate. The team only considered procedures occurring in 10 or more protocol visits to avoid skewed results. The team found that the tool predicted the protocol visit times the most incorrectly with the 5 procedures shown in Table 6.

Table 6: Most Frequently Inaccurate Protocol Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Frequency of Total Time Over Predicted</th>
<th>Percentage of Total Time Over Predicted</th>
<th>Average Over Prediction Time Amount (Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Biopsy</td>
<td>6/10</td>
<td>60.00%</td>
<td>30.0</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>11/43</td>
<td>25.58%</td>
<td>39.5</td>
</tr>
<tr>
<td>EKG/ECG</td>
<td>12/47</td>
<td>25.53%</td>
<td>37.5</td>
</tr>
<tr>
<td>IV Insertion</td>
<td>5/27</td>
<td>18.52%</td>
<td>23.0</td>
</tr>
<tr>
<td>Pregnancy Urine Test</td>
<td>12/73</td>
<td>16.44%</td>
<td>28.3</td>
</tr>
</tbody>
</table>

Table 6 displays that out of the 225 total protocol visits, a Skin Biopsy procedure occurred 10 times and was over-predicted by the tool 6 times. Skin Biopsies were over-predicted by the tool by an average of 30 minutes. This implies that the time allocated for skin biopsies is too large and needs to be updated. Protocol Visits including Physical Exams, EKG/ECGs, IV Insertions, and Pregnancy Urine Tests had a total time predicted too large by the tool less than 30% of the time. The team concluded that these procedures’ allotted time in the tool need to be reevaluated, but can be addressed with less urgency than skin biopsies.

The team also stratified the data by the amount of time the MCRU scheduled each protocol visit for. The frequency that the tool predicted more time than was allocated by the Lead Nurse for different protocol time lengths is shown in Table 7.

Table 7: Over-prediction Frequency Based on Protocol Visit Time Length

<table>
<thead>
<tr>
<th>MCRU Schedule Time (Minutes)</th>
<th>Frequency of Total Time Over Predicted</th>
<th>Percentage of Time Tool Over Predicted</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60</td>
<td>7/51</td>
<td>13.73%</td>
</tr>
<tr>
<td>60+</td>
<td>25/174</td>
<td>14.37%</td>
</tr>
<tr>
<td>60-119</td>
<td>17/75</td>
<td>22.67%</td>
</tr>
<tr>
<td>120-179</td>
<td>1/32</td>
<td>3.13%</td>
</tr>
<tr>
<td>180-239</td>
<td>5/42</td>
<td>11.90%</td>
</tr>
<tr>
<td>240+</td>
<td>2/25</td>
<td>8.00%</td>
</tr>
</tbody>
</table>

Table 7 shows that out of the 225 total protocol visits, 51 of them were scheduled by the MCRU for under 60 minutes, and 174 of them were scheduled for greater than 60 minutes. The over-prediction frequency was about the same for procedures under 60 minutes, and those greater than 60 minutes at 14% of the time. Based on this analysis, the team concluded that the tool’s over prediction frequency is independent of protocol visit time length.
Stratified Tool Outputs by Percent Difference

The team then analyzed the findings of the remaining protocol visits that weren’t considered in the findings described in the previous section. The team found that 193 of the 225 protocol visits (86%) had a Tool Total Time less than or equal to the MCRU Schedule’s Total Time. The team excluded the remaining 32 protocol visits from this portion of the analysis. Table 8 displays the frequencies of each accuracy band.

Table 8: Accuracy Brand Frequencies

<table>
<thead>
<tr>
<th>Accuracy Band</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>x&lt;10%</td>
<td>53/193</td>
<td>27%</td>
</tr>
<tr>
<td>10%&lt;x&lt;30%</td>
<td>41/193</td>
<td>21%</td>
</tr>
<tr>
<td>30%&lt;x&lt;100%</td>
<td>99/193</td>
<td>51%</td>
</tr>
</tbody>
</table>

The team then stratified protocols by most frequently occurring procedures in each of the accuracy bands. The team only considered procedures occurring in 10 or more protocol visits to avoid skewed results. Table 9 organizes the procedures by frequency for each accuracy band.

Table 9: Most Frequent Procedures by Accuracy Band

<table>
<thead>
<tr>
<th>Procedure</th>
<th>N</th>
<th>Tool Time (Minutes)</th>
<th>x&lt;10%</th>
<th>10%&lt;x&lt;30%</th>
<th>30%&lt;x&lt;100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire</td>
<td>53/193</td>
<td>30</td>
<td>7 (13%)</td>
<td>10 (19%)</td>
<td>36 (68%)</td>
</tr>
<tr>
<td>Other Procedures</td>
<td>18/193</td>
<td>0-5</td>
<td>1 (6%)</td>
<td>5 (28%)</td>
<td>12 (67%)</td>
</tr>
<tr>
<td>Consenting</td>
<td>40/193</td>
<td>15 or 30</td>
<td>10 (25%)</td>
<td>10 (25%)</td>
<td>20 (50%)</td>
</tr>
<tr>
<td>Blood</td>
<td>158/193</td>
<td>15</td>
<td>43 (27%)</td>
<td>38 (24%)</td>
<td>77 (49%)</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>32/193</td>
<td>30</td>
<td>8 (25%)</td>
<td>9 (28%)</td>
<td>15 (47%)</td>
</tr>
<tr>
<td>EKG/ECG</td>
<td>35/193</td>
<td>15</td>
<td>8 (23%)</td>
<td>11 (31%)</td>
<td>16 (46%)</td>
</tr>
<tr>
<td>Pregnancy Urine Test</td>
<td>58/193</td>
<td>5</td>
<td>12 (21%)</td>
<td>24 (41%)</td>
<td>22 (38%)</td>
</tr>
<tr>
<td>Urine</td>
<td>92/193</td>
<td>5</td>
<td>40 (43%)</td>
<td>21 (23%)</td>
<td>31 (34%)</td>
</tr>
<tr>
<td>IV Insertion</td>
<td>22/193</td>
<td>15</td>
<td>11 (50%)</td>
<td>6 (27%)</td>
<td>5 (23%)</td>
</tr>
</tbody>
</table>

The first row of Table 9 conveys that 53 protocol visits out of the 193 protocol visits analyzed contained a Questionnaire. The row also conveys that a Questionnaire has a 30-minute duration and is most frequently occurring in the inaccurate protocol band. The team organized the dataset by the 3 most frequently occurring procedures in each of the accuracy bands. Table 10 displays the accurate protocol visit procedures.

Table 10: Most Frequent Procedures for x≤10% Protocols

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Frequency of Procedures</th>
<th>Percentage of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV Insertion</td>
<td>11/22</td>
<td>50%</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>40/92</td>
<td>43%</td>
</tr>
<tr>
<td>Blood Draw</td>
<td>43/158</td>
<td>27%</td>
</tr>
</tbody>
</table>
Table 10 illustrates that IV Insertion procedures were most occurring in the accurate band at a frequency of 50%. The team found that this is the tool’s most accurately predicted procedure, but because it does not occur at a significant frequency it is not an accurate predictor of the tool.

Table 11 displays the most frequently occurring neither accurate nor inaccurate protocol visit procedures.

**Table 11: Most Frequent Procedures for 10% < x ≤ 30% Protocols**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Frequency of Procedures</th>
<th>Percentage of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy Urine Test</td>
<td>24/58</td>
<td>41%</td>
</tr>
<tr>
<td>EKG/ECG</td>
<td>11/35</td>
<td>31%</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>9/32</td>
<td>28%</td>
</tr>
</tbody>
</table>

Table 11 illustrates that no procedures in the neither accurate nor inaccurate band occurred at a frequency greater than 50%. The team found none of these procedures to be neither accurate nor inaccurate predictors of the tool.

Table 12 displays the most frequently occurring inaccurate protocol visit procedures.

**Table 12: Most Frequent Procedures for 30% < x ≤ 100% Protocols**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Frequency of Procedures</th>
<th>Percentage of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire</td>
<td>36/53</td>
<td>68%</td>
</tr>
<tr>
<td>Other Procedures</td>
<td>12/18</td>
<td>67%</td>
</tr>
<tr>
<td>Consenting</td>
<td>20/40</td>
<td>50%</td>
</tr>
</tbody>
</table>

Table 12 illustrates that Questionnaires, Other Procedures, and Consenting procedures are the most inaccurate predictors of the tool, all occurring at significant frequencies over 50%. The team found that these procedures are all located in the Space Time component of the tool.

**Interviewed Key Personnel**

The team received positive feedback about the ease of use of the tool from the Lead Nurse. After going through 3 protocol visits with the tool the Lead Nurse felt comfortable about using it and stated that it would make her job much easier. The team found that the Lead Nurse’s two comments regarded adding two sections to the tool. The Lead Nurse recommended adding a vitals section, and PK Samples as a subsection of Blood Draw.

After interviewing a study team coordinator, the team found many potential adjustments to the Space Time section of the tool. The study team coordinator first mentioned that consenting typically only occurs for baseline visits. This was something that was not clear on many of the MCRU Clinic Sheets. The study team coordinator recommended more time options in the Other Procedures section. This would allow for procedures that the study team may perform, such as a 45-minute ultrasound, to be accounted for in the other procedures section.
Conclusions

The team concludes that the tool, in its current state, is not valid in its ability to predict protocol visit time lengths. 131 out of the total 225 protocol visits were inaccurately predicted by the tool. This includes 32 that were over-predicted and 99 that had greater than a 30% difference (under-predicted) from the MCRU schedule's time.

The team also concludes that the tool can be used as an RN necessity predictor, and the specific outputted RN time length could be used as a guideline. This is important because currently the MCRU schedule only shows whether or not an RN is needed, but not for how long. The team believes that using the tool for RN necessity can reduce staffing errors and nurse idle time.

Recommendations

After running the time allocation prediction tool 225 times and analyzing the results, the team has a few different types of recommendations for the client. The categories are adjustments to the tool, ideas for further analysis, and applications of the tool.

There are a few adjustments to the tool that the team believes will make it a more comprehensive predictor of protocol visit time. The first is that there is no option for vitals in the tool. Although vitals may only take between 5-10 minutes, this time necessity may be the difference between the tool being accurate and inaccurate. In addition, the “Other Procedure” option only allows for a procedure lasting under 5 minutes. Allowing for up to 2 hours in the “Other Procedure” section will enable it to encompass many of the procedures that the study team performs. The team also suggests including a feature that would set the minimum predicted time to 30 minutes. Currently there is no minimum prediction time, even though the hospital schedules protocol visits for no less than 30 minutes.

The team recommends that the tool can be used to assess RN necessity. This is important because the tool outputs a specific RN required time, which can be used to help staffing allocations.

Expected Impact

In conducting this study, the team will use quantitative data analysis and statistical quality assurance methods to analyze the results. Additionally, the team will deliver insights on the validity of the tool. If the team finds the tool to provide valid, consistent predictions across the MCRU, this project will also:

- Standardize the scheduling process
- Decrease time spent scheduling resources
- Optimize the available resources for protocols
- Reduce staffing errors and confusions
Appendix A: Flowchart

*Actual Resource Allocation: total amount of time allotted for per protocol visit, this total time is compared directly to the tool’s outputted “Total Time”, also indicates if the protocol requires a Registered Nurse
Appendix B: Literature Search

### Time and Events Table (schedule of visits and procedures)

<table>
<thead>
<tr>
<th>Types of Test/Procedure</th>
<th>Day 0</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent screen</td>
<td>Blood Draw 24hr</td>
<td>Blood Draw 48hr</td>
<td>Blood Draw 72hr</td>
<td>Blood Draw 96hr</td>
<td>Blood Draw 120hr</td>
<td>Blood Draw 144hr</td>
<td>Blood Draw 168hr</td>
</tr>
<tr>
<td>Study Drug</td>
<td>Blood Draw time 6hr</td>
<td>Blood Draw time 18hr</td>
<td>Blood Draw time 24hr</td>
<td>Blood Draw time 30hr</td>
<td>Blood Draw time 36hr</td>
<td>Blood Draw time 42hr</td>
<td>Blood Draw time 48hr</td>
</tr>
<tr>
<td>Blood Draw time 3hr</td>
<td>Blood Draw time 9hr</td>
<td>Blood Draw time 15hr</td>
<td>Blood Draw time 21hr</td>
<td>Blood Draw time 27hr</td>
<td>Blood Draw time 33hr</td>
<td>Blood Draw time 39hr</td>
<td>Blood Draw time 45hr</td>
</tr>
<tr>
<td>Blood Draw time 2hr</td>
<td>Blood Draw time 4hr</td>
<td>Blood Draw time 10hr</td>
<td>Blood Draw time 16hr</td>
<td>Blood Draw time 22hr</td>
<td>Blood Draw time 28hr</td>
<td>Blood Draw time 34hr</td>
<td>Blood Draw time 40hr</td>
</tr>
<tr>
<td>Blood Draw time 1hr</td>
<td>Blood Draw time 3hr</td>
<td>Blood Draw time 9hr</td>
<td>Blood Draw time 15hr</td>
<td>Blood Draw time 21hr</td>
<td>Blood Draw time 27hr</td>
<td>Blood Draw time 33hr</td>
<td>Blood Draw time 39hr</td>
</tr>
<tr>
<td>Blood Draw time 8hr</td>
<td>Blood Draw time 4hr</td>
<td>Blood Draw time 10hr</td>
<td>Blood Draw time 16hr</td>
<td>Blood Draw time 22hr</td>
<td>Blood Draw time 28hr</td>
<td>Blood Draw time 34hr</td>
<td>Blood Draw time 40hr</td>
</tr>
<tr>
<td>Blood Draw time 5hr</td>
<td>Blood Draw time 3hr</td>
<td>Blood Draw time 9hr</td>
<td>Blood Draw time 15hr</td>
<td>Blood Draw time 21hr</td>
<td>Blood Draw time 27hr</td>
<td>Blood Draw time 33hr</td>
<td>Blood Draw time 39hr</td>
</tr>
</tbody>
</table>

**Notes:**
- *pH:
  - 3ml plasma
  - 2 aspirant
  - no drink*
- Genetic Lab.
- Yellow lab
- on 1st visit only
Appendix D: Clinic Sheet
Michigan Clinical Research Unit
#3129 Pharmacokinetic Study of Bupropion Hydrochloride Products with Different Release Patterns (HUM00081894)

☐ Mylan IR 75 ☐ 100 mg ☐ SR 100 ☐ 150 mg ☐ XL 150 ☐ 300 mg

Confirm Informed Consent and verify participant identification
- Check for allergies
- Urine pregnancy test with a Sure-Vue to be done on all females of child bearing age
- Vital signs. Height & Weight on baseline visits.
- Confirm fasting status, minimum of 10 hours (if participant has had something to eat in am notify PI)
- Line placement and draw pre-sample
- 8.5 ml ACD for genetics to MCRU lab, will be drawn on the first visit (if it was not drawn Study Coordinator will let us know and it will be obtained on a subsequent visit)
- Participant to remain fasting for 4 hours after drug, (cannot have H20 1 hour pre and 1 hour post drug) except with drug
- PK samples to be drawn at the following time points (3 ml EDTA plasma)
  - 0 hour pre drug
  - Administer study drug with 240 H20 Document Time in MiChart __________
    - 30 minutes post drug
    - 1 hour post drug
    - 2 hours post drug
    - 3 hours post drug
    - 4 hours post drug Standard lunch (per Bionutrition) Record meal time
    - 6 hours post drug
    - 8 hours post drug Standard dinner (per Bionutrition) if participating in the 12 hr PK study. Record meal time
    - 12 hours post dose for XL formulations only

MCRU lab to process-see below
Follow-up PKs to be done at CVC, Domino’s Farms or RU J (may be done by the study team)
- 3ml EDTA plasma for PK at the following time points
  - 24 hours post drug
  - 48 hours post drug
  - 72 hours post drug
  - 96 hours post drug
  (Study Team will process PKs at RUJ)
- Per study team, it is okay for participants to leave the unit after the lunch meal at 4 hours post as long as participant is back on time for timed blood draws.

Processing the PKs
Spin for 10 minutes @ 2000g, aliquot the plasma into 2.0 cryovial tubes and store at -80 9/9/
Appendix E: MCRU Schedule
*Names hidden in this portion of the report are to respect the privacy of the MCRU staff and study participants in compliance with HIPAA
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Complexity</th>
<th>Tool requires MCRU to perform</th>
<th>Length of Time</th>
<th>Qty, (if &gt;1)</th>
<th>Total Time</th>
<th>Study team performs</th>
<th>Length of Time</th>
<th>Qty, (if &gt;1)</th>
<th>Total Time</th>
<th>Space Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specimen Collection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Space Requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Blood</td>
<td></td>
<td></td>
<td>15 min.</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Pregnancy urine Test</td>
<td></td>
<td></td>
<td>5 min.</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Urine</td>
<td></td>
<td></td>
<td>5 min.</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Drug Administration</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Infusion</td>
<td></td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Injection</td>
<td></td>
<td></td>
<td>45 min.</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Oral</td>
<td></td>
<td></td>
<td>30 min.</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monitoring During Procedure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Space Requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check if MCRU performs procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 &lt; 10 min</td>
<td></td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 10 - 30 min</td>
<td></td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 30 min - 1 hr</td>
<td></td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 &gt;1 hr</td>
<td></td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Monitoring Post Procedure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Procedure requires on RN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tx</strong></td>
<td></td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Time**

**RN Time**

**MA Time**

**Save score information**