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Patient Protection and Affordable Care Act and the Infection Prevention and Control Department of the Roswell Park Cancer Institute

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Abstract

Through the Patient Protection and Affordable Care Act, Prospective Payment System-Exempt Cancer Centers, including the Roswell Park Cancer Institute, will eventually be denied payments by the Centers for Medicare & Medicaid Services' Hospital-Acquired Condition Reduction Program for certain preventable Hospital Acquired Conditions. This study is a participant-observer case study of the Infection Prevention and Control Department of the Roswell Park Cancer Institute. The purpose of this study is to explore the effects that the CMS' Hospital-Acquired Condition Reduction Program may have on the Infection Prevention and Control Department of the Roswell Park Cancer Institute. Data was collected through direct observation over an eight week period, including in-person interviews with department members. This study suggests the primary impact is a perception by the members of the Infection Prevention and Control Department that compliance with the Hospital-Acquired Condition Reduction Program will be hindered due to uncooperativeness by other departments at the RPCI with the implementation of policies, procedures, and programs designed to target infections identified in the regulation.

Table of Contents

Chapter I: Introduction 4
a. Introduction 4
b. Statement of Problem and Purpose of Study 5
c. Significance of Study 6
Chapter II: Review of Related Literature 8
a. Introduction 8
b. Review and Critique of Literature 8
c. Summary 13
Chapter III: Methodology 14
a. Design of Study 14
b. Sample Selection 14
c. Data Collection Methods 15
d. Data Analysis 18
Chapter IV: Discussion 23
Chapter V: Summary, Results, Implications 35
a. Implications of Possible Outcomes 35
b. Limitations of Study 38
c. Future Research 39
References 41
Appendices 46
Appendix A: 46
Appendix B: 47
Appendix C: 50
Appendix D: 52
Appendix E: 54
Tables 57
Table 1: 57
Table 2: 57
Table 3: 58
Table 4: 58

Chapter I: Introduction

a. Introduction

Under the Patient Protection and Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS) will eventually be denying payments to Prospective Payment System-Exempt Cancer Centers through their Hospital-Acquired Condition Reduction Program. The Roswell Park Cancer Institute (RPCI) is a Public Benefit Corporation within New York State and is considered a Prospective Payment System-Exempt Cancer Center. CMS defines the Prospective Payment System as, "a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount," (CMS, 2013). The cancer centers that have been made Prospective Payment System-Exempt receive reimbursement as cost-based instead of a fixed amount due to the historically higher cost of treating cancer patients (Vanchieri, 1991, p. 907). The Hospital-Acquired Condition Reduction Program highlights three types of infections that are deemed reasonably preventable when best practice is in place. These three infections are Catheter Associated Urinary Tract Infections, Vascular Catheter-Associated Blood Stream Infections, and various Surgical Site Infections.

The Infection Prevention and Control (IPC) department of the RPCI conducts surveillance of hospital acquired and hospital associated infections through the analysis of patient charts, lab results, and clinical expertise to compute infection rates, which includes the three types of infections targeted in the Hospital-Acquired Condition Reduction Program. The infection rates that are computed get reported to the National Health Safety Network (NHSN), which belongs to the Center for Disease Control and Prevention (CDC). That information then gets disseminated to CMS, along with the New York State Department of Health. The IPC

department also develops, oversees, and audits programs based on best practices in the field with the goal of preventing infections and reducing overall infection rates throughout the RPCI.

The CMS's Hospital-Acquired Condition Reduction Program has potential in the coming future to alter reimbursements to the RPCI dramatically from what are currently being reimbursed, based on infection rates. The program has not yet gone into effect for the Prospective Payment System-Exempt Cancer Centers which leaves many questions unanswered regarding how this government regulation will be implemented and enforced, and what impact it will have on the institutions involved in the months and years to come. This is an issue that needs to be studied and explored for the Prospective Payment System-Exempt Cancer Centers to gain a better understanding of how to ensure they have everything in place to be in compliance with the new regulation.

b. Statement of Problem and Purpose of Study

Since infection rates at the RPCI are computed by the IPC department, there is inherently a connection between how the Hospital-Acquired Condition Reduction Program will be implemented and the IPC department's role in the RPCI's compliance. The ambiguity of how the Hospital-Acquired Condition Reduction Program will be implemented in Prospective Payment System-Exempt Cancer Centers is leading to institutions and individuals using their interpretations of the regulation and their perspectives as a guide for preparation for the upcoming changes. With each individual having a unique perspective, this makes the administrative practices of evaluating preparedness and compliance to the regulation difficult. Due to the lack of uniformity amongst the Prospective Payment System-Exempt Cancer Centers, there will be obstacles in establishing accurate baseline data to compare amongst each other for quality improvement initiatives.

The purpose of this participant observer case study will be to explore the impact that the CMS' Hospital-Acquired Condition Reduction Program may have on the IPC department of the RPCI. This will be done by observing and interviewing the individual members of the IPC department to gain a better understanding of their perspective and perception of administration practices, internal policy making, financial implications, overall focus and goals of the department, communication and interaction amongst other departments and external entities, internal communication and interaction, and how all of these may or may not be impacted by the Hospital-Acquired Condition Reduction Program.

It is hypothesized by the researcher that the IPC department members perceive an increase in the amount of infection surveillance they conduct based on the forthcoming Hospital-Acquired Condition Reduction Program. It is also hypothesized by the researcher that IPC department members perceive uncooperativeness from other departments in the RPCI with the implementation of new programs put in place to help lower infection rates based on the forthcoming Hospital-Acquired Condition Reduction Program.

c. Significance of Study

This study is important because it is highlighting the significance of how a regulation made at the Federal level affects a Public Benefit Corporation at the State level through the lens of a single department. The Public Administration practices that are implemented at the individual department level is important to be studied as a way to see how the Federal regulation gets interpreted and implemented by the end user. Since the Hospital-Acquired Condition Reduction Program has not yet been implemented within Prospective Payment System-Exempt Cancer Centers, it is important to start addressing the questions and concerns that the end users

might have, in this case the IPC department of the RPCI, to develop a discussion that can provide guidance for a smooth transition once the regulation is put in place.

Chapter II: Review of Related Literature

a. Introduction

Hospital Acquired Conditions and Hospital Acquired Infections have been topics in Congress for many years. Different regulations have been put in place through the years around their prevention, which has resulted in much literature on the topic.

The different themes of literature that will be discussed include how the current regulations regarding prevention of Hospital Acquired Infections have progressed over the years, how these regulations are being interpreted and implemented, how these infections are being defined in the regulations, what type of guidance there is for institutions and professionals affected by the regulations, what is the perceived impact to the institutions and professionals affected, and what are the perceived financial implications.

b. Review and Critique of Literature

Throughout the last ten years Congress has enacted several laws to reduce Hospital Acquired Conditions (HAC), which are preventable conditions that are acquired during a patient's stay in the hospital. Included within these HACs are Hospital Acquired Infections (HAI), which are preventable infections that manifest during a patient's stay in the hospital. Congress has felt that overall there have been too many HAIs and has used its budgetary authority in federal healthcare programs, the Centers for Medicare & Medicaid Services (CMS), as an attempt to lower HAIs and reduce the costs associated with them (42nd United States Congress, 2006, 2010; Department of Health and Human Services, 2012, 2013).

The Deficit Reduction Act of 2005 established that as of October 1, 2008, CMS would stop payment on certain HACs through Inpatient Prospective Payment System regulations,

although certain cancer centers were considered Prospective Payment System exempt, and this did not apply to them. The HACs identified included three HAIs which were Catheter-Associated Urinary Tract Infection (CAUTI), Vascular Catheter-Associated Infection, and the Surgical Site Infection of Mediastinitis after coronary bypass graft surgery (Mattie & Webster, 2008; Medicare Learning Network, 2012; The Nurse Practitioner, 2008).

The Patient Protection and Affordable Care Act 2010 (ACA), Sec. 3008, mandates that CMS would stop payment to the Prospective Payment System-Exempt Cancer Centers for the same HAIs that were established in the Deficit Reduction Act of 2005. This was scheduled to take effect on October 1, 2014. The CMS' final rule for Fiscal Year (FY) 2014 put into writing how they would implement what was established in the ACA, "Section 3008 of Public Law 111-148, which establishes the Hospital-Acquired Condition (HAC) Reduction Program and requires that applicable hospital's payments be adjusted, effective for discharges beginning on October 1, 2014, and for subsequent program years" (Department of Health and Human Services, 2013). The rationale was explained as follows, "We believe that our continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality while simultaneously decreasing costs" (2013, p. 50708). Part of the rationale for why cancer centers were now being included was explained as, "these commenters urged CMS to work with cancer centers to establish an effective quality reporting program that will lead to meaningful improvements in cancer centers" (2013, p. 50838).

There has been much response to this legislation from organizations representing Infection Prevention and Control professionals such as the Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA) (APIC, 2005; Farber & Patterson, 2012; Grant & Diekema, 2013; Hailpern,

2013; Tomlinson & Young, 2013). APIC and SHEA have expressed many concerns about how the legislation will be interpreted. Regarding the Deficit Reduction Act of 2005, "another concern voiced by the provider community is their assertion that not all conditions on the list are preventable all the time. For example, catheter-associated UTI in a patient with chronic indwelling catheter poses a big challenge" (White, 2008, p. 41).

How an infection is defined in these documents has also been up for debate by APIC and SHEA, "APIC and SHEA note that the National Health Safety Network (NHSN) has recognized the current CLABSI definition may be overly sensitive in certain oncology patient populations, detecting bloodstream infections (BSIs) that occur in patients with central lines but are not primarily due to the presence of the central line" (Farber & Patterson, 2012, p. 9). Vascular Catheter-Associated Infections are also referred to as Central Line Associated Blood Stream Infections (CLABSI) in much of the current literature as "central line" is in reference to "vascular catheter". There have also been recommendations as how to phase in these new regulations, "APIC supports a phased-in approach of expansion with CLABSI and CAUTI beyond the ICUs, specifically recommending that CLABSI expansion be transitioned first, followed by CAUTI after surveillance definitions have been updated and implemented" (Hailpern, 2013, p. 3).

Due to the length of the legislative documents and all of the changes that have been made over time, APIC and SHEA have expressed a need for guidance on how the professionals working in hospitals should interpret and work with the new requirements. Fact sheets and info-graphs have been provided by CMS, the Medicare Learning Network, and APIC in order to clarify the information (APIC, 2013; CMS, 2012; Medicare Learning Network, 2012). Information and interpretations have been made by professionals in the field to provide guidance

to working professionals (Cardo et al., 2010; Chinn et al., 2013; Jarett, Holt, & LaBresh, 2013). Preparation and the proper infrastructure needs to be in place for goals to be reached, "It is the consensus of the working group that in order to achieve the intended goals of public reporting of HAIs, which are, to improve the quality of healthcare delivery by preventing infections and provide credible information to the consumer, states must ensure that essential components are in place before enacting legislation," (Chinn et al., 2013, p. 1). There have been guidelines established to explain what will be examined, "Through collaboration with the Centers for Disease Control and Prevention (CDC) and extensive input, CMS identified 11 HACs as being reasonably preventable based on the application of published, evidence-based guidelines, and thus targeted these HACs for program payment reductions (Jarett et al., 2013, p. 3).

Scholars have suggested that infection prevention and control programs are in need of reorganization and in some cases, additional resources, in order to accommodate these regulations (Conway, Pogorzelska, Larson, & Stone, 2012; Palmer, Lee, Dutta-Linn, Wroe, & Hartmann, 2013; Stone et al., 2011; The Nurse Practitioner, 2008; Wald, Richard, Dickson, & Capezuti, 2012). In some instances, the current infection control programs have a need for improvement. For example, Conway, Pogorzelska, Larson, & Stone (2012, p. 1) suggest that, "little attention is currently placed on CAUTI prevention in ICUs in the United States. Further research is needed to elucidate relationships between adherence to CAUTI prevention recommendations and CAUTI incidence rates." Indeed, Palmer, Lee, Dutta-Linn, Wroe, & Hartmann (2013, 15) argue that, "Despite the pervasiveness of CAUTI and the existing clinical guidelines to prevent the condition, it has traditionally ranked as a relatively low priority in hospital infection control programs." Additional resources were noted as being necessary in order to meet the guidelines for the new requirements, "Mandatory reporting subthemes included

frustration with increased workload, frustration with current reporting requirement between state and federal policies, and positively an increased awareness and priority of infection prevention at the administrative level" (Stone et al., 2011, p. 5).

Hospital administrators and IPC professionals have shown that the cost hospitals have or will incur is of main concern to them when discussing these regulations. While there have been some preliminary studies looking to predict what the financial impact may be, these are preliminary and it may take years to collect the data in order to accurately assess the financial impact on health care providers (Healy & Cromwell, 2012; Kandilov, Dalton, & Coomer, 2012; Teufack et al., 2010). The financial impact can even go beyond the hospitals themselves as discussed, "From a social perspective, the costs of preventable HACs include not only the value of resources consumed for HAC-attributable health care services (regardless of who is paying for the care) but also the value of lost productivity for patients and their informal caregivers," (Kandilov et al., 2012, p. 9). There is also the idea that there may be a positive impact financially, "We expect the increased provider awareness of the incidence and costs of HACs to lead to improved hospital protocols and reductions in the number of reasonably preventable events across all patients," (Healy & Cromwell, 2012, p. 1). The potential payments that will be lost can be seen as an incentive for hospitals to decrease their HAIs (Arias, 2008; Lavine, 2008). The incentive to decrease HAIs can hold great results, "Many infections can be prevented by improving the health care system to promote a culture of zero tolerance for HAIs and to demand adherence to evidence-based infection prevention practices" (Arias, 2008, p. 757).

The overall goal of these regulations is to decrease HACs, with the included HAIs. It is undetermined if these regulations will in fact decrease the targeted HAIs as it will take many years to collect the appropriate data. Data collection techniques have been discussed for what

would be appropriate measures, but work is still being done to identified what would be best practice (Morgan et al., 2012; Stone et al., 2010). There have been some research in this area to see if there has been any impact on HAI rates, however more research on this topic needs to be conducted (Lee et al., 2012; Stone et al., 2011).

c. Summary

As the government regulations pertaining to Hospital Acquired Infections have progressed over the years, there continues to be more and more hospitals and institutions affected by them. This is true for the RPCI as the Hospital-Acquired Condition Reduction Program will eventually be put in place for Prospective Payment System-Exempt Cancer Centers. There continues to be discussion in the literature on how to define and interpret the regulations, including defining specific conditions and infections when dealing with different patient populations. Not every infection that develops can be defined in a clear cut "one size fits all" manner, which can cause confusion for what can be deemed preventable and non-preventable. IPC professionals are seeking guidance with how to deal with the new regulations and all of the work that comes along with them including administrative practices, policy making, and quality improvement measures. This entails allocating the proper time and resources to ensure compliance is met. It is still too early to gather enough data that could accurately show the financial impact that these regulations will have on the hospitals and institutions involved, and it may be years before this data becomes available.

Chapter III: Methodology

a. Design of Study

This study utilized a qualitative methods research design as a case study of the IPC department within the RPCI using a participant-observer approach, where the role of the researcher was known, and the observer role was secondary to the participant role. Each member of the IPC department participated in a baseline one-on-one interview facilitated by the researcher, who is also the IPC department's Data Manager. The IPC department within the RPCI was then observed over an eight week time period, during the IPC department's operational hours of 8am-4pm, Monday through Friday. Once observation of the IPC department within the RPCI was completed, each member of the IPC department participated in a follow-up interview facilitated by the researcher; one being a one-on-one interview and the other two being telephone interviews. The baseline interviews, observations, and follow-up interviews all took place in the IPC department office, which is located in room 4919 in the Gratwick Basic Science Building on the RPCI campus.

b. Sample Selection

The IPC department of the RPCI was chosen for study because the researcher has worked in the department as the Data Manager since November, 2012. The sample selection for this participant-observer case study used the non-probability convenience method. The sample selected was drawn from current staff members of the IPC department of the RPCI. The IPC department of the RPCI consists of one Senior Infection Control Coordinator, two Infection Control Coordinators, and one Data Manager. The recruitment of subjects was from face-to-face solicitation.

The sample that has been selected is not intended to be representative of all IPC departments within Prospective Payment System-Exempt Cancer Centers. The sample has been selected as a means to assist the RPCI to evaluate the effects that the CMS' Hospital-Acquired Condition Reduction Program may or may not have on their IPC department. Due to the researcher's role as the Data Manager of the IPC department, it was more efficient financially and less time consuming to have him undertake intensive and deep observations for this study concurrently with his normal work activities.

c. Data Collection Methods

The IPC department administrator was asked in person to sign a site agreement form allowing the researcher to conduct research within the IPC department of the RPCI. The IPC department administrator signed the site agreement form after it was reviewed. The site agreement form can be found in Appendix A. The researcher went over an informed consent form with each member of the IPC department, addressed any questions or concerns, and had them sign the forms before research was started. The informed consent form can be found in Appendix B. Each member of the IPC department was assigned a respondent number to be used throughout the study that was separate from the participant's name to ensure the data would remain confidential. Only the respondent number was used as a means to identify the collected data.

Baseline semi-structured open-ended, one-on-one qualitative interviews with the IPC department's Senior Infection Control Coordinator and two Infection Control Coordinators were conducted first by the researcher. The one-on-one interviews were conducted during times that were convenient for the interviewee and were done in a private room in the IPC department's office, with only the researcher and interviewee present, in order to ensure confidentiality of

answers given. The researcher took hand written notes of all answers that were given by the interviewee, which were later typed up by the researcher to be used for data analysis.

The baseline interview questions were developed by the researcher to gain a better understanding of individual perspective pertaining to new regulation in the workplace, more specifically the CMS's Hospital-Acquired Condition Reduction Program. Questions were asked regarding individual perspective pertaining to administration practices, internal policy making, financial implications, overall focus and goals of the department, communication and interaction amongst other departments and external entities, and internal communication and interaction. The baseline interview questions that were asked can be found in Appendix C.

Observational data was then collected by the researcher over an eight week period where the role of the researcher was known, and the observant role was secondary to the participant role. Qualitative observations of the IPC department's daily activities were collected in a field journal through the form of hand written field notes during the entire eight week observational period. The field journal was located on the researcher's desk to allow for ease of accessibility during the IPC department's normal hours of operation. The field journal was locked in a filing cabinet, for which the researcher only had the key, during the IPC department's non-operational hours. The observations consisted of the activities and interactions involving the members of the IPC department that were relevant to the day-to-day operations of the IPC department, and excluded any personal, non-work-related, or protected health information. Each observation recorded include the date, time, who was involved, and a description of the observation. The researcher only included observations that were made from within the physical location of the IPC department, and did not include any observations from activities or interactions held outside of the physical location of the IPC department such as meetings, trainings, or inspections. Once

the eight weeks of observations were completed, the hand written field notes were then typed into a spreadsheet by the researcher to be used for data analysis.

After the observational data was collected, follow-up semi-structured open-ended, qualitative interviews with the IPC department's Senior Infection Control Coordinator and two Infection Control Coordinators were conducted by the researcher. The interviews were conducted during times that were convenient for the interviewees. One of the interviews was a one-on-one interview that was conducted in a private room in the IPC department's office, with only the researcher and interviewee present, in order to ensure confidentiality of answers given. Due to scheduling conflicts, the other two interviews were conducted over the telephone. The researcher conducted the telephone interviews in a private room in the IPC department's office in order to ensure confidentiality of answers given, while the interviewees participated in a safe and private place, while not driving a vehicle, to ensure confidentiality and safety. The researcher again took hand written notes of all answers that were given by the interviewees. These hand written notes were later typed up by the researcher to be used for data analysis.

The baseline interviews and eight week observations were analyzed by the researcher and common themes were developed. The follow-up interview questions were developed by the researcher as a way to gain a better understanding of individual perspective pertaining to what was observed over the eight week observational period and as a way to extrapolate the themes that were developed. Questions were again asked regarding individual perspective pertaining to administration practices, internal policy making, financial implications, overall focus and goals of the department, communication and interaction amongst other departments and external entities, and internal communication and interaction. The follow-up interview questions that were asked can be found in Appendix D.

d. Data Analysis

The hand written notes that were taken by the researcher from both the baseline interviews and follow-up interviews were typed into separate Microsoft Excel spreadsheets respectively. The spreadsheets contained a column for the questions that were asked in the interviews, and columns for the individual responses to these questions from each of the respondents. This was done so all three interviewee's responses could be compared and analyzed side-by-side. The responses to the interview questions were analyzed by looking at each individual respondent's opinions and perspectives on the questions that were asked, and by comparing the respondent's answers to each other.

The baseline interviews that were conducted by the researcher with the members of the IPC department yielded information based on individual perspective and perception. This information signifies that although all members who were interviewed share the same office environment and similar work responsibilities, the different personalities and experiences of the individuals resulted in some different perspectives and perceptions of the same issues.

All of the members of the IPC department agreed on some of the topics that were brought up in the baseline interviews. There was a common consensus that the general focus and goals of the IPC department includes the prevention of hospital transmitted infections, and all had agreed that the proper policies and procedures are in place to help reach this goal. All had mentioned they felt that the potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by CMS will have an impact on the focus and goals for the IPC department at the RPCI in the future. The issue of "backsliding" in regards to implementation of policies and interventions was mentioned by all interviewees when asked about what they felt were some of the greatest challenges to the IPC

department. The term "backsliding" was first used by one of the respondents in the baseline interview and for the purpose of this research it refers to instances where training and education were put in place, only to result in individuals reverting to old and out of compliant practices. The general interaction and communication amongst the IPC staff was considered good by everyone. It was agreed that the dependence on other departments within the RPCI to complete their work has an impact on the ability for the IPC department to reach its goals.

Some questions that were asked to the interviewees resulted in answers that had differing viewpoints from individual to individual. When asked to rank the top three goals of the IPC department, each member gave a different list. Only two out of three who were interviewed believed that the goals of the IPC department are known by other departments within the RPCI. There was no unanimity to the answers regarding the perception of other departments within the RPCI recognizing the challenges facing the IPC department or their impact on the ability of the IPC department to reach its goals. Each individual described a different daily and monthly workload that they partake in, and each had a different perception of how much of their work is dependent on other members of the IPC department and other departments within the RPCI. There was a variation in the descriptions of the general interaction and communication between the IPC department and other departments within the RPCI.

A codebook was developed by the researcher using the technique of predetermined codes described by Creswell as a way to consistently code the observations that were collected during the eight week observational period (Creswell, 2014, p. 199). This allowed for a clear understanding of the definition for each code, and for when each code should be used. The researcher developed seventeen unique codes that were used for coding the observational data that was collected. Not all of the codes were mutually exclusive as explained by the definitions

in the codebook, which allowed for a diverse insight into the data that was collected. Please see Appendix E to reference the codebook used for data analysis.

The observational data that was collected by the researcher in the field journal was typed into a Microsoft Excel spreadsheet for data analysis. Each week of observations were then typed into separate tabs, and were broken down into sections by individual day. Each unique observation was given its own line in the spreadsheet, and was individually coded by the researcher. The codes that were developed were each given a column in the spreadsheet. Each individual observation was analyzed by the researcher and received a "1" in each corresponding code-column for which the observation corresponded. More than one code could be assigned to each observation if applicable. After all of the observations were coded, each code-column was added up to get totals for the week. These eight weekly totals were then compiled on a separate tab to analyze the entire eight weeks of observations together.

When all of the observational data was inputted and coded it was found that there were a total of 596 unique observations that were documented throughout the entire eight week observational period. Data was compiled into multiple bar graphs for data analysis. Table 1 shows the percentage of total observations during the entire case study broken down by type of communication. Table 2 shows the total observations by week broken down by the type of communication. Table 3 shows the percentage of total observations during the entire case study broken down by observation category. Table 4 shows the total observations by week broken down by observation category.

The follow-up interviews that were conducted by the researcher were administered as a way to gain insight into individual perspective and perception pertaining to what was observed

over the eight week observational period. The information that was collected showed similarities to the baseline interviews in regard to the different personalities and experiences of the individuals resulting in some different perspectives and perceptions of the same topics.

All members of the IPC department had mentioned that answering questions from other departments at the RPCI was a top area of work that they spend the most time on. The potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by CMS was cited as having impacted the answering of questions from other departments at the RPCI by increasing the number of questions received regarding specifics of the regulation, and how that involves the other departments and their relationships with the IPC department . It was also mentioned by all respondents that an impact is felt on the greatest challenges that each individual faces in their current position due to the time it takes to address the questions and concerns from other departments regarding the regulation. Everyone who was interviewed expressed that there were projects they would like to work on, but do not have the time or resources to complete. Each individual felt comfortable with reaching out to other members of the IPC department, other departments at the RPCI, and entities outside of the RPCI for help with meeting the goals of the IPC department.

The theme of lack of strong leadership and accountability, especially in the Nursing department, was identified by each interviewee as a reason for why “backsliding” was occurring in certain interventions, policies, and education. No one believed that the IPC department has the resources to resolve the problem of “backsliding” on its own. This was identified by all respondents as an obstacle that needs to be overcome in order for IPC departments to become successful.

There were different opinions expressed regarding if the goals of the IPC department are being met and if the process of creating and updating policies in the IPC department is sufficient to help reach these goals. All three members of the IPC department that were interviewed had different perceptions of what their top three greatest challenges and top three greatest accomplishments in their current position are. The was no unanimity to the potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by CMS having an impact on the three greatest accomplishments in the IPC department member's current positions. Only one out of three interviewees felt that they had adequate time and resources to complete all of the work required of them. Each IPC member had a different perception of where they felt the issue of "backsliding" was originating from.

Chapter IV: Discussion

The purpose of this study is to explore the impact that the CMS' Hospital-Acquired Condition Reduction Program may or may not have on the IPC department of the RPCI. The observations made and interviews with the individual members of the IPC department were done to gain a better understanding of their individual perspective and perception on the topics of administration practices, internal policy making, financial implications, overall focus and goals of the department, communication and interaction amongst other departments and external entities, internal communication and interaction, and how all of these may or may not be impacted by the Hospital-Acquired Condition Reduction Program.

During the baseline interviews, administration practices were talked about by all three respondents. A common theme was the administration of the policies and procedures relevant to the IPC department and problems that are perceived with the enforcement and compliance of them with other departments. It was also discussed how there is difficulty with implementing interventions for certain targeted types of infections. It requires the cooperation and involvement of other departments in order for these interventions to work and become successful. Only one respondent described administrative practices as part of their daily and monthly workload, which included making sure the department stays on task, meeting with other departments, and staying on top of regulatory requirements that the IPC department is responsible for.

The topic of administration practices was observed 18 times, which was 3.0% of all observations. Only one observation of administration practices was relevant to the Hospital-Acquired Condition Reduction Program. This observation dealt with the approval of a modification to a project that is in place to help lower CAUTIs.

The follow-up interviews again showed a common theme from all respondents of a perceived problem of getting other departments to adhere to the IPC department's policies and procedures. One respondent explained there is a difficulty with getting people on board with new policies, procedures, and interventions and that there is a perception that other departments resist change. Resistance to change occurs when those involved intentionally do not want to accept new changes and show this through their behavior, and written or vocal communication. This is different from the concept of backsliding where those involved initially accept the new changes, only to revert back to old practices.

All of the respondents felt that the proper policies and procedures were in place to help the IPC department reach its goals during the baseline interviews. However, there was a common theme of frustration due to the IPC department not having the authority to enforce their policies, procedures, and interventions to other departments. It was felt that this lowered the IPC department's credibility and allowed for other departments to brush them off or ignore their advice and directives entirely with the result being some goals not being reached. The issue that was identified here is that policies and procedures of the IPC department are being perceived as sufficient by its members, however the inability to enforce them is resulting in noncompliance to the quality improvement measures set forth within them.

Throughout the follow-up interviews, it appeared that the perception of the IPC department's policies and procedures had changed somewhat from the original baseline interviews. Only one respondent felt that the process for creating and updating policies was sufficient to help reach their goals, with one respondent disagreeing, and the other respondent undecided. It was discussed by two of the respondents that getting other departments on board

with the IPC department's policies, procedures, and interventions were one of their top three greatest challenges that they face in their current position.

All three respondents discussed financial implications to the IPC department as a result of the Hospital-Acquired Condition Reduction Program during the baseline interviews. All of them disagreed with CMS' current surveillance definitions for infections and felt that they do not take into consideration the cancer patient population and the complications they experience with having a compromised immune system, which makes them much more prone to infections then a patient without cancer. They feel that this will unfairly penalize cancer hospitals financially. One respondent pointed out that NYS is the only state that currently validates their infection data, which potentially allows RPCI to lose more money than other hospitals out of state since no one else is being checked for accuracy and being held accountable. The three respondents also shared the same idea that because CMS is looking into infections and affecting reimbursement, the IPC department has received more support and attention then what was previously given. Now that money is involved, the higher administration has more invested in the outcome.

The topic of financial implications was observed two times, which was 0.3% of all observations. Both of the observations referenced loss of reimbursement through the Hospital-Acquired Condition Reduction Program.

During the follow-up interviews, only one respondent discussed financial implications to the IPC department as a result of the Hospital-Acquired Condition Reduction Program. They explained that one of the areas they spend most of their time is answering questions, and felt that they receive more questions now that people see we will eventually be losing money. The respondent also expressed a little frustration with their perception of other departments having

the idea that the only reason the IPC department is in existence is to save the hospital money, and they forget the real reason the department exists is to help patients.

The three respondents defined the overall focus and goals of the IPC department during the baseline interviews. The consensus is that the main goal is overall patient safety through the monitoring and prevention of hospital acquired infections. This is done through the control of outbreak situations, putting in interventions and educating staff, surveillance of infections, staying current on literature, and implementing standard operating procedures and policies. The respondents also explained what they perceived to be the top three goals of the IPC department and included enforcing policies and procedures, educating other departments, conducting infection surveillance, and communicating with national organizations to stay current in the field as all top goals. All three respondents believed that the proper policies and procedures are in place to help reach these goals and that the Hospital-Acquired Condition Reduction Program will have an impact on the focus and goals of the IPC department. All respondents agreed that other departments at the RPCI are aware of the goals of the IPC department, and that they are dependent on these other departments to help reach these goals, therefore impacting their ability to reach these goals.

The overall focus and goals of the IPC department was observed 268 times, which was 45% of all observations. Fifty-five of these observations were relevant to the Hospital-Acquired Condition Reduction Program by involving the surveillance of, or initiatives to prevent Catheter Associated Urinary Tract Infections, Vascular Catheter-Associated Blood Stream Infections, and various Surgical Site Infections.

Throughout the follow-up interviews, only two out of the three respondents felt that the goals of the IPC department are being met and that the process for creating and updating policies

in the IPC department is sufficient to help reach these goals. All three respondents mentioned that there are projects they would like to work on in the IPC department, but do not have the time or resources to complete. The respondents explained that the projects they had in mind would involve programs that would target specific types of infections with the goal of lowering infection rates. One respondent had already begun work on a project to help lower surgical site infection rates for the Breast service, but explained that this project had to be put on hold due to time constraints from other work required of them. Only one respondent mentioned that they have adequate time and resources to complete all of the work required of them.

Throughout the baseline interviews, the interaction and communication with the IPC department and other departments at the RPCI was discussed frequently. All three respondents cited interaction and communication with other departments as one of the greatest challenges to the IPC department. This challenge included getting other departments to become compliant with the IPC department's policies and procedures, communication barriers with the other departments due to differing educational backgrounds and experience, and language barriers with vocabulary meaning different things to different departments. All three respondents also mentioned that they perceive the IPC department not getting taken seriously by other departments since they do not have an authoritative statement and cannot enforce their policies and procedures. Two of the three respondents mentioned that the relationships between the IPC department and other departments at the RPCI is positive for the most part, while the other respondent has the perception that other departments only view the IPC department as the enemy. All three respondents explained that the work they conduct has a strong dependence on other departments, which impacts the ability for the IPC department to reach its goals. There

was no consensus amongst the respondents on whether or not they felt the other departments are aware of the impact they have on the IPC department in reaching its goals.

Communication and interaction amongst the IPC department and other departments within the RPCI was observed 111 times and accounted for 18.6% of all observations. A total of six of these observations were relevant to the Hospital-Acquired Condition Reduction Program. Observations whose topic involved other departments at RPCI, but did not necessarily involved active communication between those departments and the IPC department was observed 288 times, accounting for 48.3% of all observations. Thirty-one of these observations were relevant to the Hospital-Acquired Condition Reduction Program, mostly relating to initiatives to prevent Catheter Associated Urinary Tract Infections, Vascular Catheter-Associated Blood Stream Infections, and various Surgical Site Infections.

During the follow-up interviews, all three respondents mentioned that responding to questions from other departments at the RPCI was one of the top three areas of work that they spend the most time on. They all explained that the potential for non-payment of services through the Hospital-Acquired Condition Reduction Program has had an impact on the questions they receive from other departments, and the education they provide to other departments. All three respondents mentioned that one of their top three greatest challenges that they face in their current position is getting other departments on board and updated with new projects and policies, and getting them to understand their importance. Again, all three respondents felt that the potential for non-payment of services through the Hospital-Acquired Condition Reduction Program has had an impact on this challenge of getting other departments on board. The three respondents all explained that they feel comfortable reaching out to other departments in the RPCI for help with meeting the goals of the IPC department, however two respondents

mentioned that there were some departments they were more comfortable communicating with than others.

The baseline interviews resulted in two of the three respondents mentioning communication with external entities as being part of their daily and monthly workload. This included interactions with government entities, professional groups related to infection prevention, and outside vendors who are selling infection prevention products. The same two respondents also mentioned working with external entities as being one of the top three goals of the IPC department. This was described by both respondents as collaborating with colleagues from around the country and world as a way to stay current with the literature and best practices and as a way to create a unified voice through the professional infection control organizations such as APIC and the Comprehensive Cancer Center Infection Control (C3IC) group.

Communication and interaction amongst the IPC department and external entities was observed 22 times and accounted for 3.7% of all observations. A total of eight of these observations were relevant to the Hospital-Acquired Condition Reduction Program. Observations whose topic involved external entities, but did not necessarily involved active communication with the IPC department was observed 96 times and accounted for 16.1% of all observations. Twenty-eight of these observations were relevant to the Hospital-Acquired Condition Reduction Program, mostly relating to interactions with the C3IC group and their initiatives to get surveillance definitions changed to be appropriate for cancer patient populations.

In the follow-up interviews, all three respondents mentioned that they felt comfortable with reaching out to entities outside of the RPCI for help with meeting the goals of the IPC department. Two respondents mentioned external entities as having a role in one of their greatest

accomplishments in their current position, with one being the collaboration with a vendor in bringing in a new hand hygiene monitoring system to the RPCI and the other with getting asked to present at a national conference to discuss a project that was implemented by the IPC department at the RPCI. One respondent did cite external forces as a reason for not having adequate time and resources to complete all of the work required of them with the amount of infection surveillance and reporting that is required through the CDC's National Health Safety Network.

The general interaction and communication amongst the IPC department staff was perceived as being generally good by all three respondents. It was explained that this is possible due to the small size of the department being only four members, and the comfort of each member being able to communicate with each other. One respondent did mention that there are some communication gaps when needing to cover for another individual, as they do not always have the background information on certain projects if they were not actively involved themselves. All respondents had the same general perception of how their work is dependent on other members of the IPC department. Each individual mentioned that much of their work can be done independently from each other, however all of the work is interwoven throughout the entire department. Each respondent mentioned that they feel they could step in and cover each other's work if they needed to.

Communication and interaction amongst the IPC department was observed 513 times and accounted for 86.1% of all observations. The large percentage of observations can be attributed to the design of the study focusing on observations confined to the physical location of the IPC department office. A total of 82 of these observations were relevant to the Hospital-Acquired Condition Reduction Program, including the surveillance of, and initiatives to prevent Catheter

Associated Urinary Tract Infections, Vascular Catheter-Associated Blood Stream Infections, and various Surgical Site Infections.

In the follow-up interviews all respondents mentioned that they felt comfortable reaching out to other members of the IPC department for help with meeting the goals of the department. One respondent did mention they sometimes need to get a push from management to get other IPC members to help them with meeting the goals of the department.

The baseline interviews resulted in two of the three respondents identifying infection surveillance as one of the top three goals of the IPC department. Infection surveillance was also identified by two of the three respondents as something that takes up a lot of time as part of their daily and monthly workload.

The topic of surveillance was observed 56 times, and accounted for 9.4% of all observations. A total of 30 of these observations were relevant to the Hospital-Acquired Condition Reduction Program which included the surveillance of Catheter Associated Urinary Tract Infections, Vascular Catheter-Associated Blood Stream Infections, and various Surgical Site Infections.

In the follow-up interviews, one respondent identified infection surveillance as being one of the top three areas of work that they spend the most time on. They also felt that the potential for non-payment of services by the Hospital Acquired Condition Reduction Program has had an impact on infection surveillance. They described the involvement of the members of the IPC department and the C3IC group on writing an opinion paper highlighting the ways they believe the current infection surveillance definitions provided by NHSN and used by CMS need to be changed to reflect best practice in the field, and to accommodate cancer patient populations as

especially having an impact. Two of the three respondents identified infection surveillance as one of the top three greatest challenges that they face in their current position. Both explained that getting the amount of infection surveillance that is required of them done in a timely manner is an issue and one respondent in particular mentioned that they feel the amount will get harder and more difficult in the future. Both respondents also felt that the potential for non-payment of services by the Hospital Acquired Condition Reduction Program has impacted the challenge of infection surveillance, with one respondent explaining they feel infection surveillance is becoming more and more time consuming as definitions and regulations change and more types of infections are becoming required to report. They feel that they are spending more time in the office working on infection surveillance when they should really be spending more time out on the floors and consulting in the inpatient and outpatient areas with the front line staff.

Based on the information that has been collected through the baseline interviews, observations, and follow-up interviews, it appears that at least two of the three IPC department members that were observed and interviewed by the researcher perceive an increase in the amount of infection surveillance they conduct based on the forthcoming Hospital-Acquired Condition Reduction Program. Therefore, the researcher finds support for the hypothesis that IPC department members perceive an increase in the amount of infection surveillance they conduct based on the forthcoming Hospital-Acquired Condition Reduction Program.

The theme of uncooperativeness from other departments working with the IPC department was found with all three respondents during the baseline interviews. All three respondents describe other departments being compliant with the IPC department policies and procedures as being one of the three greatest challenges of the IPC department. When asked to describe the general interaction and communication between the IPC department and other

departments at the RPCI, all three respondents described that with some departments there is a good working relationship, but with other departments there is an issue of them being uncooperative and not following the advice and recommendations from the IPC department. All respondents agreed this impacts the IPC department's ability to reach its goals. Two of the three respondents mentioned that they perceive other departments at RPCI recognizing the impact they have on the IPC department's ability to reach its goals, and described the potential of non-payment for services being a major reason for this.

Backsliding is a term that was first used by one of the respondents during the baseline interviews to describe a behavior, and for the purpose of this research it refers to instances where training and education were put in place, only to result in individuals reverting to old and out of compliant practices. The topic of backsliding was observed 21 times and accounted for 3.5% of all observations. A total of three of these observations were relevant to the Hospital-Acquired Condition Reduction Program. One of the observations had to do with improper documentation by physicians regarding signs and symptoms of infection, and two had to do with the improper management of foley catheters which is against IPC policies and procedures.

During the follow-up interviews, one respondent described getting other departments on board with IPC projects and understanding their importance was one of the top three challenges they face in their current position and that the potential for non-payment through the Hospital-Acquired Condition Reduction Program has had an impact on this. The researcher addressed the issue of backsliding directly in the follow-up interviews, as it was a topic that was brought up by all the respondents during the baseline interviews, and asked the respondents why they feel this was occurring. All three respondents identified a lack of strong leadership and accountability in other departments as a reason for why backsliding was occurring. Two of the three respondents

identified turnover of management positions in other departments as a factor for why information and accountability was not getting passed down to the frontline staff. One respondent explained that they perceived a culture throughout the hospital of a resistant to change, where the idea is that if something has always been done one way, then there should not be a need for change. This is an issue when the leadership does not accept the changes, and the attitudes begin to trickle down. The researcher asked the respondents if they felt that the problem of backsliding was originating from issues with conceptualization or model, implementation, or real world practice of the IPC policies and procedures, and projects. There was no consensus amongst the respondents as they all felt the issue of backsliding originated from different areas. All respondents had answered that they felt the IPC department does not have the resources to resolve the problem of backsliding on their own as they all felt that they are dependent on other departments in order to correct this issue.

Based on the information that has been collected through the baseline interviews, observations, and follow-up interviews, it appears that all three IPC department members that were observed and interviewed by the researcher perceive uncooperativeness from other departments in the RPCI with the implementation of new programs put in place to help lower infection rates based on the forthcoming Hospital-Acquired Condition Reduction Program. Therefore, the researcher finds support for the hypothesis that IPC department members perceive uncooperativeness from other departments in the RPCI with the implementation of new programs put in place to help lower infection rates based on the forthcoming Hospital-Acquired Condition Reduction Program.

Chapter V: Summary, Results, Implications

a. Implications of Possible Outcomes

The purpose of this participant observer case study was to explore the impact that the CMS' Hospital-Acquired Condition Reduction Program may have on the IPC department of the RPCI. This was done through focusing on the perceptions and perspectives of the individual IPC department members through the use of one-on-one interviews and direct observations conducted by the researcher. The researcher was able to gain more specific insight into how the Hospital-Acquired Condition Reduction Program has had a perceived impact on each of the IPC department members individually by focusing on the areas of administration practices, internal policy making, financial implications, overall focus and goals of the department, communication and interaction amongst other departments and external entities, and internal communication and interaction. This resulted in a large breadth of data that was collected which allowed the problem to be explicated into different areas of focus.

The data that was collected reflects that the individual IPC department members perceive the Hospital-Acquired Condition Reduction Program as having an impact on the IPC department. Through interviewing each individual IPC member separately, it was found that all three have their own perspective and perception of how the Hospital-Acquired Condition Reduction Program will have, or is already having, an impact on the work they do and on the IPC department as a whole.

The theme that arouse through each area that was focused on was the influence that other departments at the RPCI have on the ability of the IPC department to complete its work and reach its goals. This theme was brought up by each individual IPC department member

throughout the baseline and follow-up interviews that were conducted. This is also reflected in the fact that although only 18.6% of all observations that were collected involved the direct contact between the IPC department members and other departments at the RPCI, 48.3% of all observations involved other departments at the RPCI but did not require active communication between the IPC department and other departments at the RPCI. This shows that work conducted by the individual IPC department members involving other departments is more extensive than work that is directly involved with the other departments. Thus in order for the IPC department to ensure that the RPCI is in compliance with the regulations involved with the Hospital-Acquired Condition Reduction Program, there needs to be a good working relationship and cooperation from other departments at the RPCI. The support for the hypothesis that IPC department members perceive uncooperativeness from other departments in the RPCI with the implementation of new programs put in place to help lower infection rates based on the forthcoming Hospital-Acquired Condition Reduction Program indicates that there will be some perceived difficulties with getting the RPCI to be in compliance with the new regulations.

To summarize the overall findings in a more general sense, originally CMS had wanted to include the Prospective Payment System-Exempt Cancer Centers in the Hospital-Acquired Condition Reduction Program as a continuous quality improvement measure by motivating the cancer centers through the potential for loss of payment for what they deemed to be preventable hospital-acquired conditions. This new regulation has placed time constraints on the IPC department through the additional work created of answering questions by other departments regarding the new regulation, an increase in infection surveillance due to new reporting requirements, and a push to develop new policies, procedures, and programs with the goal of lowering infection rates of the hospital-acquired infections identified in the regulation. Due to

the future potential of financial penalties that have been identified by CMS, this has provided additional support from higher administration of the RPCI towards the IPC department in developing programs, policies, and procedures to target the identified infections, which has created additional work and time requirements for the IPC department. The members of the IPC department are feeling frustration due to the perceived backsliding by other departments of the programs, policies, and procedures that have been put in place to help lower infection rates targeted by the Hospital-Acquired Condition Reduction Program, which is leading to the goals of the IPC department not being able to be met. The frustration is intensified by the fact that the IPC department does not have authority over the other departments at the RPCI to enforce the policies, procedures, and programs designed to target the specified infections through the Hospital-Acquired Condition Reduction Program.

The suggestion that the researcher will make is that in order for the issue of backsliding to be resolved, there needs to be an increase in communication of the importance of the IPC department's policies, procedures, and programs between the IPC department and the other departments involved. The IPC department should highlight the importance that the goals of the IPC department cannot be reached without the cooperation of the other departments at the RPCI, and if these goals cannot be reached, there will be potential for financial penalties against the RPCI. This would require follow up with the other departments after the policies, procedures, and programs to ensure compliance is being met, and to communicate any issues that may arise during the implementation process so that all parties may be involved and take ownership. In order to accomplish this due to current constraints of time and resources, it may be in the best interest for the IPC department to seek out additional resources, either through increasing the responsibilities of the current members of the IPC department, hiring of additional staff, or

having other departments take more responsibility in the development and implementation of the IPC department's policies, procedures, and programs.

b. Limitations of Study

There are certain limitations that are inherent to conducting a participant observer case study. The issue of bias arises since the researcher conducting the study on the IPC department is also an active member of the IPC department. The subject matter is one that the researcher has previous experience in through their employment which may have impacted their perspective on the topic. Unfortunately this was unavoidable based on the design on the study since it was a participant observer cases study.

The fact that the respondents and researcher have an active working relationship may have had an impact on the data that was collected. There is potential that the answers given by the respondents, and their behaviors while being observed, may have been skewed due to this relationship.

The sample size for the research conducted was small due to the fact that the IPC department of the RPCI consists of only four individuals, one of them being the researcher. This makes the conclusions and accepted hypotheses insignificant for use outside of the IPC department at the RPCI.

There were some limitations to the types of observations that were collected that may have an impact on the ability to accurately assess the day to day functions and activities of the IPC department. A significant amount of communication of each IPC member involves the use of computers and telephones. Since the researcher did not have access to each IPC members e-

mails or phone records, it is unclear what amount of work was involved in these areas, and how that could have potentially effected the observational data.

Some of each IPC department members work load consists of attending meetings outside of the IPC department office. Since nothing outside of the physical location of the IPC department was included in the observations, this information could not be included in the observational data.

c. Future Research

There are some suggested improvements that could be made to the design of this study for further research on the topic. There are benefits to conducting a similar study with a larger sample size. This would allow for a more diverse group to obtain data from. It would also be of help access to phone records and e-mails could be obtained to help strengthen the observational data. This would allow a more thorough understanding of the day to day work that is involved through each individual.

It would be of interest to explore the actual impact that the CMS's Hospital-Acquired Condition Reduction Program will have on the IPC department of the RPCI once the regulation has gone into effect. This could be done by conducting a follow-up participant observer case study using the same methodology at a time after the regulation has been in place, such as a year following, and then comparing the results from each study to see if the perceived impact had any resemblance to the actual impact.

A suggestion for future research would be to conduct similar studies amongst the other Prospective Payment System-Exempt Cancer Centers as a way to compare the results together to see what similarities or differences there may be. This can also be done by comparing a sample

of IPC departments of Prospective Payment System-Exempt Cancer Centers to a sample of non-Prospective Payment System-Exempt Cancer Centers.

This study has identified a need to gain the perspective from other departments besides IPC departments on the impact that the Hospital-Acquired Condition Reduction Program may have. This could include departments that work directly with IPC department, and the work they do that is under the purview of the IPC department policies and procedures. It would be important to explore identifying reasons for the perceived backsliding behavior that is occurring from these other departments, and try to find reasoning behind it. It would be important to find in future research if the problem of gaining cooperation from other departments to implement policies, procedures, and programs to help lower infections identified in the Hospital-Acquired Condition Reduction Program can be overcome, and if so, what steps were put in place to allow this to happen. It should also be explored if the potential for non-payment of services by CMS would be enough incentive to have higher administration step in and enforce the cooperation between the IPC department and other departments to ensure that compliance with the new regulation is being met.

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Appendices

Appendix A:

Site Agreement Form

Dear Infection Prevention and Control Administrator,

As a graduate student at Buffalo State College in the Public Administration program, I am conducting a research project to explore the effect that the Patient Protection and Affordable Care Act will have on the Infection Prevention and Control department of the Roswell Park Cancer Institute. I feel that observing the Infection Prevention and Control department, which you are the administrator of, would greatly benefit my study. I have discussed my research project with the Infection Control Coordinators in your department and they have agreed to participate. I hope you will agree to these terms, also.

I will be collecting data through participant observation of the site. I will be taking notes on the observations I make and they will be collected in a field journal. I will also conduct semi-structured open-ended interviews with the Infection Control Coordinators of the department. The time frame to collect data will be from June 2014 through September 2014.

Your department's participation will be helpful to my research project and is completely voluntary. There are minimal risks for you and your staff and all information will be confidential and used for research purposes only.

I would certainly appreciate your consideration of this request to further my graduate research at Buffalo State College for my own education and that of others on this subject matter in the discipline of Public Administration.

I look forward to hearing from you and setting up a time to further discuss my research project and fill out any necessary paperwork to begin my study. If there are any questions, please contact me at 716-903-8027 or e-mail at keppeldr01@mail.buffalostate.edu

Sincerely,

Daniel Keppel

- _____ **I approve the study** described above and will move forward on approving the researcher to conduct it within my department
- _____ **I do not approve the study** described above and will not move forward on approving the researcher to conduct it within my school

Administrator Name: _____ Facility Name: _____
(please print)

Administrator Signature:_____ Date:_____

**If you are unable to reach the researcher and have general questions or you have concerns or complaints about the research study, researcher, or questions about your rights as a research subject, please contact Gina Game, IRB Administrator, Sponsored Programs Office/SUNY Buffalo State at gameg@buffalostate.edu or (716) 878-6700.

Appendix B:

INFORMED CONSENT

Patient Protection and Affordable Care Act and the Infection Prevention and Control Department of the Roswell Park Cancer Institute

NAME AND TITLE OF RESEARCHER: Daniel Keppel

Department/Room Number: N/A

Telephone Number: 716-903-8027

Email: keppeldr01@mail.buffalostate.edu

STUDY LOCATION(S):

Infection Prevention and Control department of the Roswell Park Cancer Institute office. Roswell Park Cancer Institute - Gratwick Basic Science Building Room 4919 – Elm & Carlton Streets, Buffalo, NY 14263

PURPOSE OF STUDY

Under the Patient Protection and Affordable Care Act, the Centers for Medicare & Medicaid Services will soon deny payments to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions. The purpose of this participant-observer case study is to explore the effects of the Centers for Medicare and Medicaid Services' Hospital Acquired Conditions Reduction Program on the Infection Prevention and Control department of the Roswell Park Cancer Institute.

SUBJECTS

Inclusion Requirements

You are eligible to participate in this study if you:

- Are 18 years of age or older
- Are a current staff member of the Infection Prevention and Control department of the Roswell Park Cancer Institute

PROCEDURES

The following procedures will occur:

Every participant will partake in an initial baseline one-on-one interview. The participant's daily interactions amongst the Infection Prevention and Control department of the Roswell Park

Cancer Institute will be observed. Then the participant will partake in a follow up one-on-one interview.

Participants will be asked to participate in the following activities:

- Baseline one-on-one interview (30-60 minutes)
- Follow-up one-on-one interview (30-60 minutes)

Timeframe:

- Baseline one-on-one interview to be administered over a one week period
- Observation of interactions amongst the Infection Prevention and Control department of the Roswell Park Cancer Institute will be observed over eight consecutive weeks
- Follow-up one-on-one interview to be administered over a one week period

Week 1	Baseline One-On-One Interview
Week 2	Observation
Week 3	Observation
Week 4	Observation
Week 5	Observation
Week 6	Observation
Week 7	Observation
Week 8	Observation
Week 9	Observation
Week 10	Follow-Up One-On-One Interview

RISK AND DISCOMFORTS

The possible risks and/or discomforts associated with the procedures described in this study are minimal and no greater than those encountered in everyday life. Minimal risk is expected for those participating in this study.

BENEFITS

The possible benefits you may experience from the procedures described in this study include access to a final report that will provide a set of recommendations that may be implemented in the Infection Prevention and Control department of the Roswell Park Cancer Institute.

CONFIDENTIALITY

Data Storage

The data collected in this study will remain confidential. The observational data and interviews will be stored in a locked filing cabinet that only the researcher will have a key for. Any data

that is stored electronically will be saved on the researcher's private computer which is protected by password and is only accessible to the researcher.

Each participant will be assigned a respondent number that is separate from the participant's name. All identifiable information about you will be removed, with only the respondent number to identify you. The respondent number that links your name to the data will be kept separate from the study data.

All data will be retained for at least three years in compliance with federal regulations.

IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the researcher at the top of this form.

If you are unable to contact the researcher and have general questions about your rights as a participant, please contact Gina Game, IRB Administrator, Sponsored Programs Office/SUNY Buffalo State at gameg@buffalostate.edu.

VOLUNTARY PARTICIPATION STATEMENT

Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Buffalo State. Your signature below indicates that you have read the information in this informed consent and have had a chance to ask any questions that you have about the study.

SIGNATURES

_____ _____

Participant's Signature ***Date***

_____ _____

Researcher's Signature ***Date***

Appendix C:
Name of Researcher: Daniel Keppel

Patient Protection and Affordable Care Act and the Infection Prevention and Control Department of the Roswell Park Cancer Institute

Over the next eight weeks I am going to be observing the Infection Prevention and Control department of the Roswell Park Cancer Institute. The purpose of this interview is to gain a better understanding of individual perspective pertaining to new regulation in the workplace.

Baseline Interview Questions

1. Can you describe the general focus and goals of the Infection Prevention and Control department of the Roswell Park Cancer Institute?

2. Do you feel that the proper policies and procedures are in place to help reach these goals?

3. Do you feel that the potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by the Centers for Medicare & Medicaid Services will impact the focus and goals of the Infection Prevention and Control department of the Roswell Park Cancer Institute?

4. *As of today*, what do you feel are the top three goals of the Infection Prevention and Control department of the Roswell Park Cancer Institute?

5. Do you believe these goals are known by other departments within the Roswell Park Cancer Institute?

6. *As of today*, what do you feel are the three greatest challenges of the Infection Prevention and Control department of the Roswell Park Cancer Institute?

7. Do you believe these challenges are recognized by other departments within the Roswell Park Cancer Institute?

8. What does your daily and monthly workload consist of?

9. Can you describe the general interaction and communication amongst the staff of the Infection Prevention and Control department of the Roswell Park Cancer Institute?

10. How much of your work is dependent on other staff members of the Infection Prevention and Control department of the Roswell Park Cancer Institute?

11. Can you describe the general interaction and communication between the Infection Prevention and Control department of the Roswell Park Cancer Institute and other departments within the Roswell Park Cancer Institute?

12. How much of your work is dependent on other departments within the Roswell Park Cancer Institute?

13. Does this dependence impact the ability of the Infection Prevention and Control department to reach its goals?

14. Do other departments recognize the impact they have on the ability of the Infection Prevention and Control department to reach its goals?

Appendix D:
Name of Researcher: Daniel Keppel

Patient Protection and Affordable Care Act and the Infection Prevention and Control Department of the Roswell Park Cancer Institute

Now that the eight weeks of observation of the Infection Prevention and Control department of the Roswell Park Cancer Institute has been completed, the purpose of this interview is to gain a better understanding of individual perspective pertaining to what was observed.

Follow-Up Interview Questions

1. Do you currently feel that the goals of the Infection Prevention and Control department are being met?

2. Do you feel that the process for creating and updating policies in the Infection Prevention and Control department is sufficient to help reach these goals?

3. As of today, what do you feel are the top three areas of work that you spend the most time on?

4. Do you feel that the potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by the Centers for Medicare & Medicaid Services has had an impact on the three areas of work that you spend the most time on?

5. As of today, what do you feel are the top three greatest challenges you face in your position?

6. Do you feel that the potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by the Centers for Medicare & Medicaid Services has had an impact on the three greatest challenges you face in your position?

7. As of today, what do you feel are the top three greatest accomplishments you have had in your current position?

8. Do you feel that the potential for non-payment of services to Prospective Payment System-Exempt Cancer Centers for certain Hospital Acquired Conditions by the Centers for Medicare & Medicaid Services has had an impact on the three greatest accomplishments you have had in your current position?

9. Do you feel that you have adequate time and resources to complete all of the work required of you?
10. Are there any projects you would like to work on but don't have the time or resources to complete?

11. Do you feel comfortable reaching out to other members of the Infection Prevention and Control department for help with meeting the goals of the department?

12. Do you feel comfortable reaching out to other departments in the Roswell Park Cancer Institute for help with meeting the goals of the Infection Prevention and Control department?

13. Do you feel comfortable reaching out to entities outside of the Roswell Park Cancer Institute for help with meeting the goals of the Infection Prevention and Control department?

14. A common theme was identified regarding certain goals becoming unattainable due to the communication breakdowns between the Infection Prevention and Control department and other departments at the Roswell Park Cancer Institute. More specifically it was identified that a lack of follow through from the other departments had resulted in "backsliding" in the implementation of certain interventions, policies, and education. Why do you feel this is occurring?

15. Where do you feel the problem of "backsliding" is originating from? Do you feel it stems from an issue with the conceptualization or model, issues with implementation, or issues with the real world practice?

16. Do you feel that the Infection Prevention and Control department has the resources to resolve the problem of "backsliding" on their own?

Appendix E:

Qualitative codebook

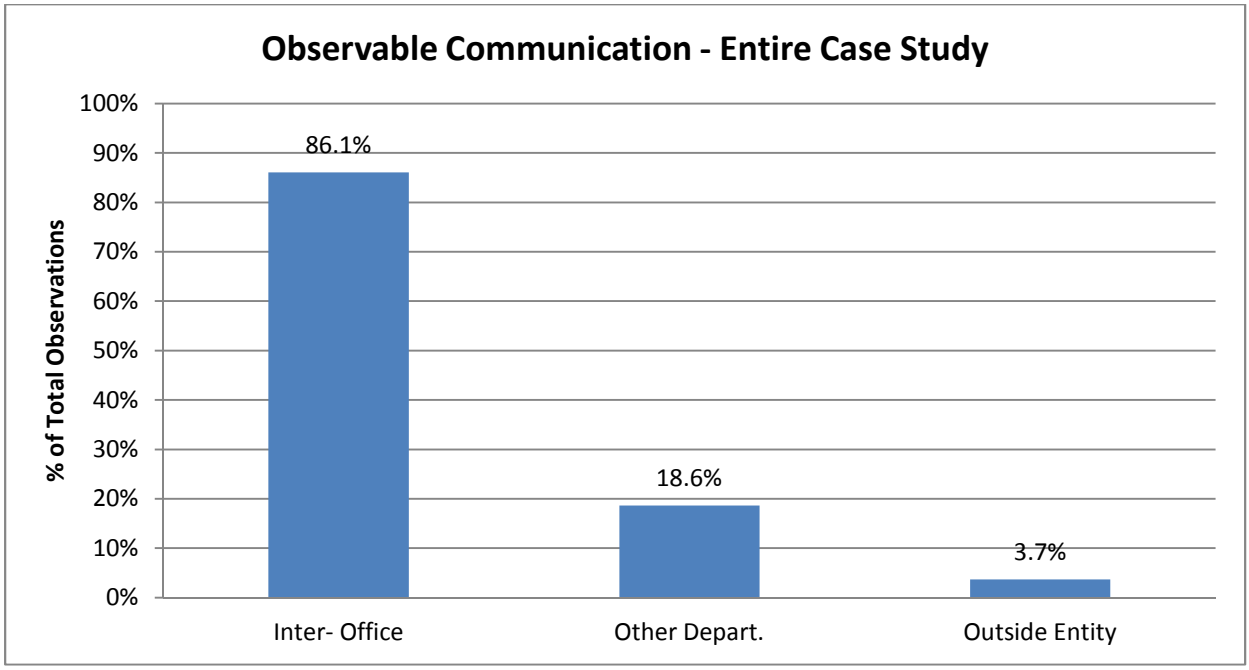
Codes	Code Label	Definition	When to use
IPC respondent 1	1	IPC respondent 1	When an observation actively involves IPC respondent 1.
IPC respondent 2	2	IPC respondent 2	When an observation actively involves IPC respondent 2.
IPC respondent 3	3	IPC respondent 3	When an observation actively involves IPC respondent 3.
Researcher	Me	The researcher	When an observation actively involves the researcher.
Inter-office communication	Inter-Office	The observable communication amongst the IPC department.	When an observation actively involves communication between any combinations of IPC respondent 1, IPC respondent 2, IPC respondent 3, the researcher.
Other departmental communication	Other Depart.	The observable communication amongst the IPC department and other departments within the RPCI.	When an observation actively involves communication between any IPC respondent or the researcher, and any department at the RPCI outside of the IPC department.
Outside entity communication	Outside Entity	The observable communication amongst the IPC department and entities outside of the RPCI. This may include but is not limited to government, professional organizations, and vendors.	When an observation actively involves communication between any IPC respondent or the researcher, and any entity outside of the RPCI.
Administrative practices	Admin Pract.	An observation in which the context involves the enforcement, approval/disapproval, and/or interpretation of standard operating procedures and policies. IPC departmental decision making as a whole. Priority setting of the work the IPC department does. Dealing with employee performance issues.	When an observation involves content pertaining to administrative practices as defined.

Policy making	Policy Making	An observation in which the context involves the creation, amendment, or updating of an IPC department policy or an RPCI policy.	When an observation involves content pertaining to policy making as defined.
Financial implications	Financial Imp.	An observation in which the context involves finances regarding the ACA or the CMS's Hospital-Acquired Condition Reduction Program.	When an observation involves content pertaining to financial implications as defined.
Involving other departments	Inv. Other Dept.	An observation in which the context involves a department at the RPCI outside of the IPC department.	When an observation involves content pertaining to a department at the RPCI outside of the IPC department. This does not require active communication between the IPC department and another department at the RPCI.
Involving outside entities	Inv. Outside Enti.	An observation in which the context involves an entity outside of the RPCI. This may include but is not limited to government, professional organizations, and vendors.	When an observation involves content pertaining to an entity outside of the RPCI. This does not require active communication between the IPC department and an entity outside of the RPCI.
Goals of the IPC department	Goals of Dept.	Per Respondents 1, 2, and 3's definitions of the IPC department's goals. The main goal is patient safety through the monitoring and prevention of hospital acquired infections. This is done through control of outbreak situations, putting in interventions and educating staff, surveillance of infections, staying current on literature, and implementing standard operating procedures and policies.	When an observation involves content pertaining to the goals of the IPC department as defined.
ACA/CMS specific	ACA/CMS Specific	An observation in which the context involves the ACA or the CMS' Hospital-Acquired Condition Reduction Program.	When an observation involves content pertaining to the ACA or the CMS' Hospital-Acquired Condition Reduction Program.

Infection Surveillance	Surveillance	Per the CDC, "Surveillance is the ongoing systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event." For the purpose of this research "health-related event" refers to infections.	When an observation involves content pertaining to surveillance as defined.
Backsliding	Backsliding	As defined by Merriam-Webster, "to revert to a worse condition". For the purpose of this research it refers to instances where training and education was put in place, only to result in individuals reverting to old and out of compliant practices.	When an observation involves content pertaining to backsliding as defined.
Other	Other	Any other work related activity that has not already been previously mentioned and defined.	When an observation involves content other than what has already been previously mentioned and defined.

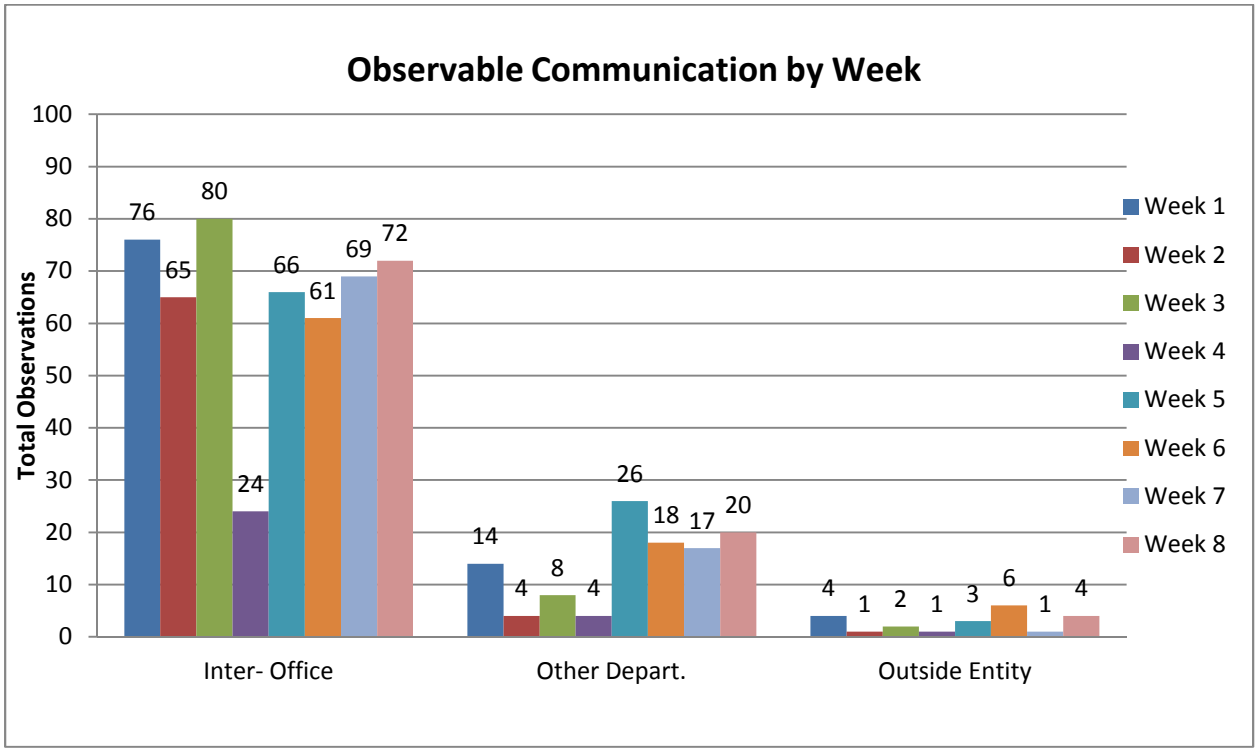
Tables

Table 1:



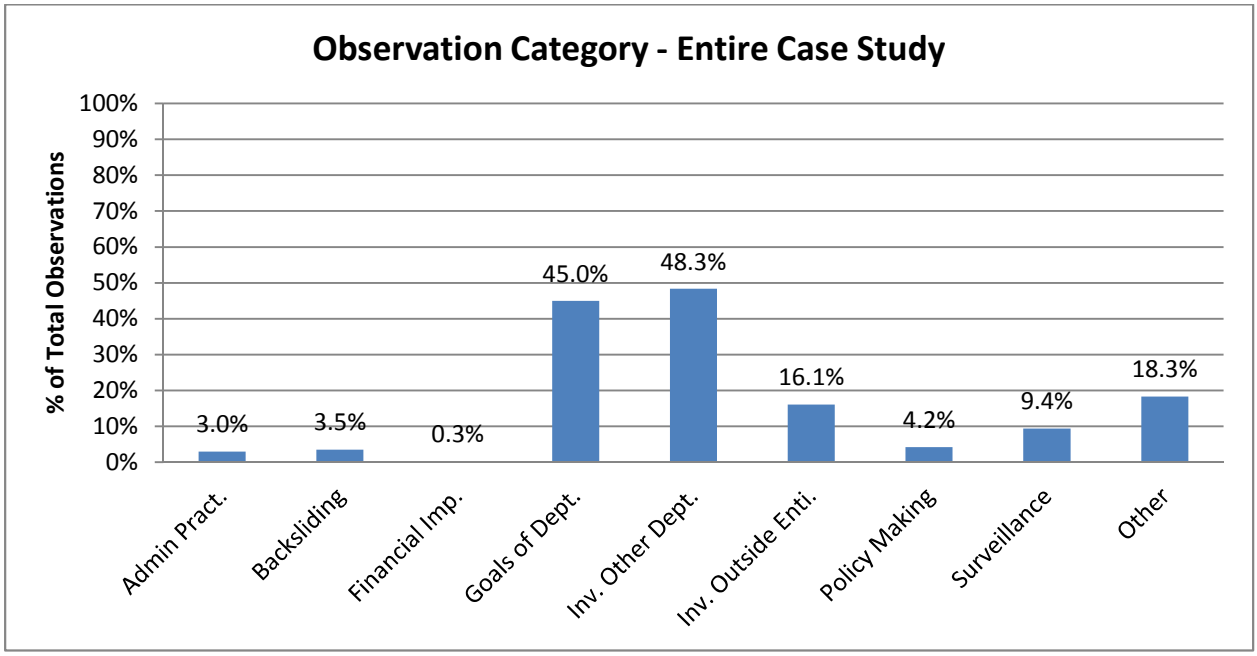
Please see Appendix E – Qualitative Codebook for definitions of categories.

Table 2:



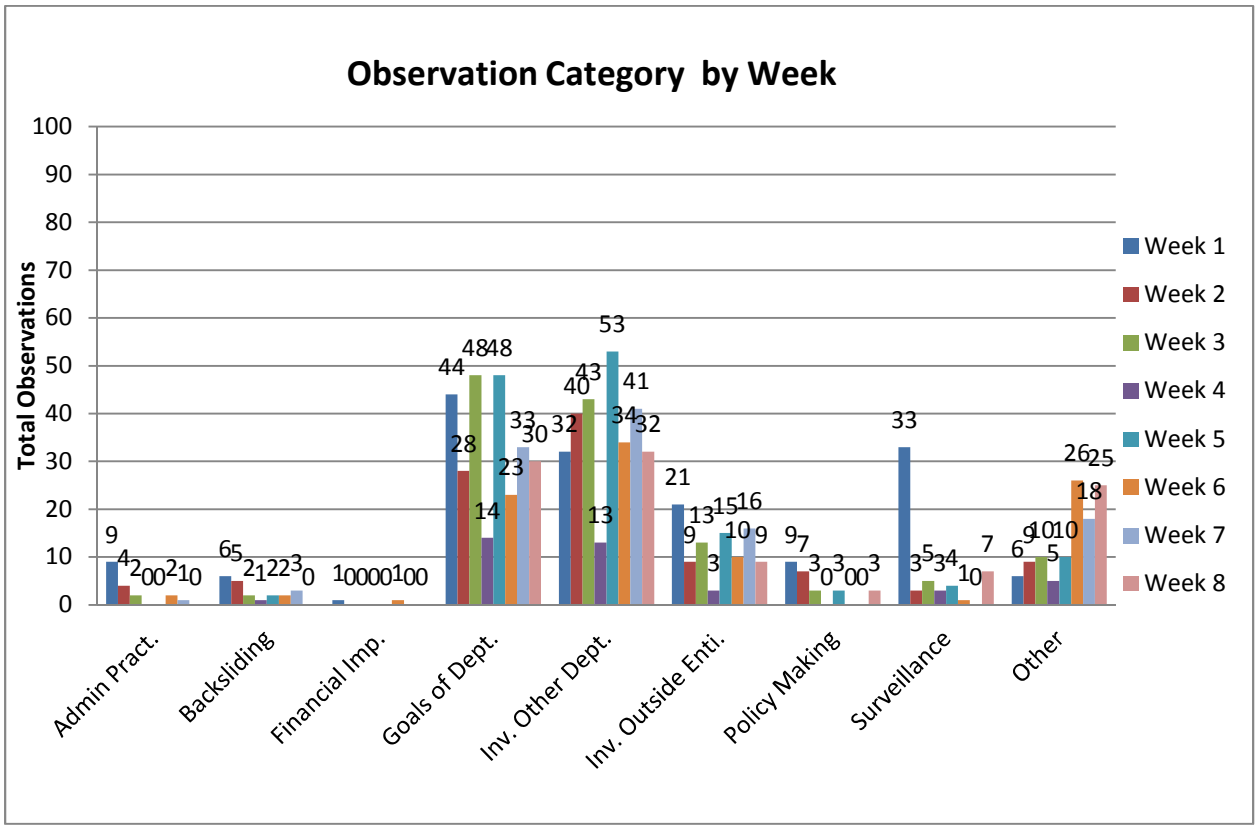
Please see Appendix E – Qualitative Codebook for definitions of categories.

Table 3:



Please see Appendix E – Qualitative Codebook for definitions of categories.

Table 4:



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