



Department of Health Administration/Executive

Master in Health Administration

Comparison Between Two Incident Report Systems
in A Tertiary Hospital: Pre-Post analysis

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DECLARATION

I certify that this Research Project I have presented for graduation in the Department of Health Administration, College of Business Administration, in King Saud University is solely my own work, except where I have clearly indicated that it is the work of others. To the best of my knowledge and belief, this research project contains no material previously published or written by another person, except where due reference is made. Quotation from this work is permitted, provided that full acknowledgement is made. This research project may not be reproduced without the prior, written consent of the author and the supervisor jointly, the data of this research is for study purposes only and it can't be shared due to restriction from SBAHC and it should be remain confidential.

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Date: 10/12/2021

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Abstract

Background: The patient safety is one of the major factors that the healthcare providers need to be maintained in right way. an incident report is an unusual event that happen in healthcare facility such as patient injury or inappropriate behaviour, it needs to be record by details in a form, so we can manage and avoid the risk in the future, using well design system for reporting the incident like Datix improve the workflow of reporting the incident.

Objective: The objective of this research is to evaluate improvement of using Datix as incident report at SBAHC.

Method: The research used Retrospective quantitative sample study from the incident report data, the secondary data were retrieved from Sultan Bin Abdulaziz Humanitarian City (SBAHC) with the IRB approval, the comparison is between the old IR system i-Help and Datix system, 6 Month period for each system, the sample that has been collected in total is $n=2169$ and then the data analysis by Excel.

Results: The lowest reported incident was 121 for i-Help in Jun 2018, and the highest reported incident was 252 for Datix in Jan 2021, the mean for i-Help 2018 is 145.33 and the mean for Datix is 216.17. with significant p-value ($p= 0.0053$)

Discussion: The operational enhancement of Datix system utilization has been evident through the literature review through the result of other hospitals which adopted the Datix system, Incident reports are used to enhance the performance of healthcare organizations in general. In that essence, SBAHC has implemented Datix system to replace the old system i-Help, the result of this study shows that there is a significant difference between the volume of registered incident reports after the implementation of Datix system.

Conclusions: Implementing of Datix system at SBAHC increase the number of incident report by almost 49% which indicate the well influence of using Datix as incident report system.

Keywords: Sultan Bin Abdulaziz Humanitarian City (SBAHC), Datix, Incident Report system (IR)

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1 Chapter One: Introduction

This chapter introduces the study and their purposes. The patient safety is one of the major factors that the healthcare providers need to be maintained in right way and not tolerate in this matter, an incident report is an event that happen in healthcare facility such as patient injury, workplace violence, behaviour. It needs to be record by details in a form, so we can manage, avoid, and decrease the risk from this event of happening again in the future which influence at the end in the patient safety and promoting the healthcare safety, using well design system for reporting the incident like Datix system which improve the workflow of reporting the incident.

1.1 Purpose of the Study

The purpose of this study is to evaluate incident reporting system at Sultan Bin Abdulaziz Humanitarian City (SBAHC) since they implement Datix software in 2019 for reporting the incident report (IR).

1.2 Study Questions

The major goal of this study is to evaluate the incident report systems The research questions that will be addressed are as follows: Is the implementation of Datix system has better influence on the reporting workflow of the incidents?

1.3 Significance of the Study

This study will form an academic basis for the review of the implementation of DATIX system and SBAHC and its actual added value to the important goals and indicators such as reporting workflow of reporting the incident, patient safety, patient satisfaction and intendent response compared to the old employed systems in SBAHC. The object of this research is to evaluate the difference between old incident reporting system i-Help and the new incident reporting system Datix at SBAHC.

1.4 The Problem

While the new IT systems are critical in change management and improvement of procedures and practices in healthcare systems. SBAHC has introduced DATIX system in 2019. There are few studies or review performed academically for the implementation of the Datix system and measuring the actual utilization and added value of the system on SBAHC environment.

1.5 Research Objectives

The objective of this research is based on assessment of the Datix system influence on the workflow of reporting the incident, compare the frequency of incident reporting between the old system i-Help and the new Datix system.

1.6 Limitations of the study

This study is limited to certain province, population, time, and specific health organizations. The limitations include the following: miss registered data from the old system i-Help, the study represent only one hospital.

1.7 The Research Inclusion

The research will cover SBAHC's organizational experience with implementing Datix IR system. Research is intended to cover Data collection and incident reports ID, the volume number of reports received and the date of the incident, and the various SBAHC programs incident reports for the Datix system versus the old incident report systems i-Help.

1.8 The Research Exclusion

The scope of the research does not include examining the nature of the incident and the actual details of the incident. Also, the action taken for the incident, the assigned integrator and the user who report the incident, the incident level of harm and the incident category.

1.9 Summary

The above chapter was addressing the purpose of the study and their Significance, also it mentions the objective of the research and their limitation, it mentioned the inclusion and exclusion criteria. The next chapter addresses the incident report, the human error and the Datix system with more details.

2 Chapter Two: Literature Review

This chapter explores incident report, human error in healthcare, Datix system for reporting the incident and their influence of using this system.

2.1 Incident Report (IR)

An incident-reporting system (IRS), such as Datix software, collects critical data on adverse events that can cause unwanted consequences, such as loss, trauma, or a near-miss to a patient (Mushcab et al., 2020). The Datix program was first created in 1986 by Brian Capstick to defend the National Health Service (NHS) facilities against patients' claims of medical errors. Datix would help providers in monitoring care quality, controlling health costs, minimizing brand damage, and complying with health safety regulations and policies. Datix had improved incident reporting by six percent between 2017 and 2018 in the John Hopkins Hospital even though about less than 40 percent of the employees understood how to implement the program (Mushcab et al., 2020). Nurse leaders and managers can use this evidence to create an action plan to train providers on the effective application of Datix.

Staff involvement in utilizing IRS to report incidents, locate and manage risks and inconsistencies can strengthen health systems and reduce harm to patients and hospital staff. Mushcab et al. (2020) indicate that nurses are ready to learn how to utilize Datix and motivate their colleagues to improve their attitudes and readiness to use Datix. In addition, while using Datix, nurses need to continue providing feedback about reports for further decision-making. Datix offers anonymity and confidentiality, and it is an effective IRS that could support nurses in their clinical work by giving them the freedom to identify and report what they feel Datix should have to continuously be better.

2.2. Human Error in Healthcare

Donaldson et al. (2021) define human errors as preventable actions that result in undesirable ramifications like medical incidents tied to discernible human factors (Higham

& Vincent, 2021). An error occurs if a person's action is against hospital protocols, overstretched a system, and is unintended by the individual (Saada et al., 2019). Moreover, the occurrence of most errors is inevitable in clinical practice because of other influential factors, such as the uncertainty in the medical field, difficult-to-identify issues, and people's behaviors that also push a provider to be predisposed to making medical errors. For instance, caregivers can develop stress and fatigue and increase their chances of making a mistake or slip (Robertson & Long, 2018; Smith et al., 2016). Moreover, human errors occur across the leadership organograms in different health organizations and present a critical problem that causes unintended severe injury to patients.

2.3 Incident Reporting, IRS and Cultural Change

Health care organizations utilize incident reporting (IR) to investigate severe incidents to learn about their causal relationship with patient injury (Al-Rayes et al., 2020). IR is linked to quality care and patient safety (Carlfjord et al., 2018; Mushcab et al., 2020). Data from the IR enables institutions' managers, leaders, and staff to convene and explore the information and decide on regularly improving care and strengthening health systems (Fukami et al., 2020). Managers can encourage their employees to utilize IRSs to ensure they understand and improve IR and its determinants (Al-Rayes et al., 2020). In their study, Ramírez et al. (2018) discovered that for effective IRSs, hospitals should utilize real-time assessment of declining incident rates and the method is shown to be an effective proxy for evaluating IRSs efficacy (Ramírez 2) et al., 2018). Consequently, since the introduction of the Datix system and automating IRS, a cultural transformation has occurred from blame, fear, and keeping silent among healthcare workers to increase safety, learning, and acting head-on to reduce incidents (Carlfjord et al., 2018; Flott et al., 2018)(Hazan, 2015). A systematic review by Lawati et al. (2018) recommends that assessing safety culture is the first phase to improving care and safety-associated views of caregivers(Lawati et al., 2018).

2.4 Datix Software

Since its establishment in 1986 by Brian Capstick, Datix has evolved to become a worldwide pioneer and manufacturer of its software and the majority of modern health

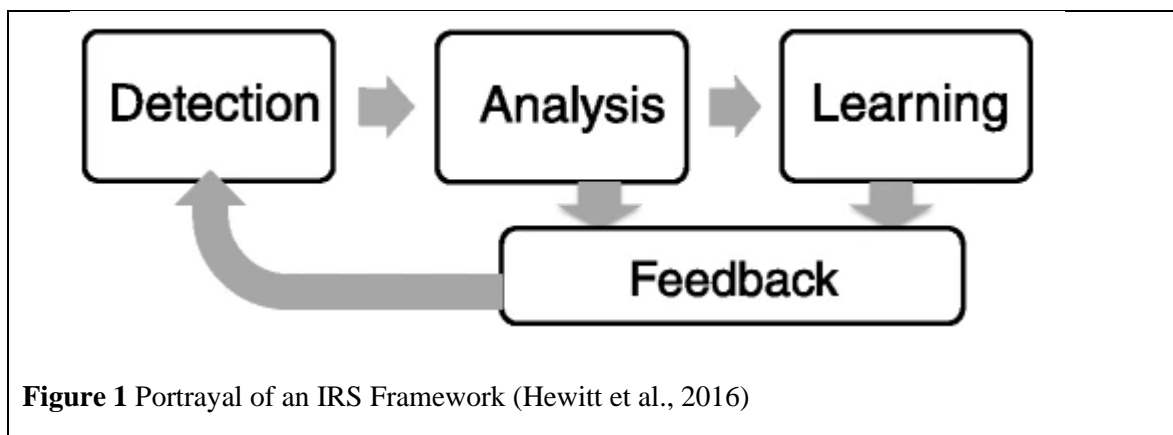
organizations are utilizing it to manage risks besides IR within the healthcare space (Datix, 2017). The software is essential for reversing patient harm and promoting safety, improving and initiating learning among providers, and creating a culture that promotes care safety (Mushcab et al., 2020). The Datix software system also provides detailed IR and safety solutions, giving a new perspective on data safety (Datix, 2017). The Datix program is readily available, easily usable, flexible, offers analytical features for comparing, contrasting, and prioritizing incidents, and is always evolving to reflect patient needs in the modern world (Datix, 2017).

2.5 Influence on Healthcare for Using Datix System

While there is little research on this topic, researchers have discovered that the implementation of the Datix system influences healthcare in both desirable and adverse ways. On the one hand, Mushcab et al. (2020) indicate that facilities utilizing Datix have over time improved IR and transformed the culture from partial to full reporting among their providers who have also developed positive attitudes towards the practice. The study also shows that providers experience challenges during the initial use of the program because it is complex and employees have inadequate skills, hence informing the need for training, which has improved reporting in hospitals (Mushcab et al., 2020). On the other hand, negative influence can also emerge from using the Datix program as there have been recent crucial cases of using Datix software for retribution among healthcare givers, a case dubbed as "datix-ing other people." Maxton et al. (2021) indicate that Datix gives nurses the freedom to do what they think is right, allowing them to use Datix as a venting vehicle to report people for trivial reasons. Moreover, the researchers found numerous Datix tweets portraying threats and abuse towards nurses (Maxton et al., 2021). These actions can make the Datix program a complaint drain causing fear among nurses. Sometimes nurse managers who do not appreciate learning and feedback can play foul by threatening, shaming, suspecting, or bullying their junior colleagues (Maxton et al., 2021).

2.6 Incident Reporting System Process Framework

In their study, Hewitt et al. (2016) developed a simplified IRS flow chart, as shown in figure 1 below that illustrates a "multi-stage process" involving four distinct stages namely, detection, analysis, learning, and feedback. Information about incidents is first entered during the detection phase, examined during the analysis phase, and then channeled to the learning phase where incident reporting influences a change in practice or knowledge increase. Feedback can be collected at the analysis and learning stages (Hewitt et al., 2016).



Detection Phase

At this stage, the health provider focuses on identifying the causal association between the incident and its determinants to inform prevention strategies. The provider also assesses the identified barriers, such as failure to report incompetence, fear of adverse consequences, blame culture, less time, lack of skills and knowledge, poor or no feedback, and ineffectiveness (Hamed & Konstantinidis, 2021; Rodziewicz et al., 2021). Moreover, providers need to enter more reports in the IRS and should be attentive to their larger institutional safety concerns while deciding to report.

Analysis Phase

Analysis of the data collected in the IRS requires stakeholder perspectives to avoid slowing down or failing at this stage. The IRS may collect overarching data and pose a barrier to proper analysis (Hewitt et al., 2016). Stakeholders in the disciplinary team can

convene to further investigate, discuss and solve the prevailing conflicts and issues, and share feedback to the reporters.

Learning Phase

Evidence explains that practices, such as quick judgment and victim-blaming, prevent learning among the investigators, management, and staff. On the other hand, learning can be achieved through employing the human factors approach and relaying feedback to the incident reporter (de Kam et al., 2020). The IRS must respond to the growing talents of caregivers to determine and learn from reports (de Kam et al., 2020). Carlfjord et al. (2018) reveal that IR outcomes are an excellent source for lessons and sharing with other locations.

Feedback Phase

The current Datix software incorporates the World Health Organization guidelines on ways IR can be established to consider feedback as an essential feature in the IRS (Hewitt et al., 2016). Having a system that recognizes hazards should be accompanied by adequate resources to conduct follow-up, generate feedback for the incident reporters, and investigate further based on the lessons identified.

3 Chapter Three: Method

3.1. Overview

This chapter describe the method use to study the research design, methods, data collection, sample size, the inclusion and exclusion criteria and ethical consideration.

3.2. Research Design

The research is retrospective study where data were retrieved from data from SBAHC as a secondary data, the comparison is between the old IR system i-Help and Datix system, 6 Month period for each system.

3.2.1. Dependent variable & independent variables

The study has dependent and it's the Incident report (IR) and for the independent variable the number of the IR that reported and response rate for incident.

3.3. Research Methods

This is a quantitative study using secondary data that use variables to evaluate the influence of implementing Datix system and the data was analyse by Microsoft Excel.

3.3.1. Data Collection

The data retrieved by the Quality Management Department at SBAHC, the following data is included in this study: incident reports ID, the volume number of reports received and the date of the incident, and the various SBAHC programs incident reports, whereas the following data is not included Nature of the incident and their description, the action taken for the incident and the investigators and the incident level of harm., and for the programs it was finalize into 3 steps:

Step 1: collecting the data by programs from Datix which include 18 different programs (Pediatric Specialty Program (PSP), Adult Neuro, Adult Non Rehab, Spinal Cord System of Care Specialty Program (SCSP), Wound Care, Stroke Specialty Program (SSP), Comprehensive Intensive and Integrated Rehabilitation Program (CIIRP), Brain Injury Specialty Program (BISP), Surgical Program - Non-Bariatric, Surgical Rehab, Child

Development Center (CDC), Out-Patient Medical Rehabilitation Program (OMRP - ADULT), Intensive Rehabilitation Program (IRP), Surgical Program - Bariatric, Lymphedema, Home Health Care (HHC), Amputee Specialty Program (ASP) and Prosthetics and Orthotics (P&O)).

Step 2: collecting the data program from i-Help which include 9 different programs (Pediatric Specialty Program (PSP), Adult Non Rehab, Spinal Cord System of Care Specialty Program (SCSP), Stroke Specialty Program (SSP), Comprehensive Intensive and Integrated Rehabilitation Program (CIIRP), Brain Injury Specialty Program (BISP), Out-Patient Medical Rehabilitation Program (OMRP) and Amputee Specialty Program (ASP)).

Step 3: We took the most and common program between the two systems i-Help and Datix which include 7 different programs (Pediatric Specialty Program (PSP), Adult Non Rehab, Spinal Cord System of Care Specialty Program (SCSP), Stroke Specialty Program (SSP), Comprehensive Intensive and Integrated Rehabilitation Program (CIIRP), Brain Injury Specialty Program (BISP) and others.)

3.3.2. The Sample Study

The study collects secondary data sample, the IR sample that has been collected in total is n=2169, the incident report that has been collected from i-Help system n= 872 and from Datix system n= 1297.

3.3.3. Participants

The sample for this study was drawn from the quality management department, the following data is included in this study: incident reports ID, the volume number of reports received and the date of the incident, and the various SBAHC programs incident reports, whereas the following data is not included Nature of the incident and their description, the action taken for the incident and the investigators and the incident level of harm and the incident report category.

3.4. Methods of Sampling

The method of selecting the sample was non-Probability sampling convenience sample the data that was collected from SBAHC was from 2016 until 2021, the selected data in this research for Datix system the first six months in 2021 and it was selected because we want to use recently data, and we select the first six months for i-Help system to compare it with the same period of time with Datix system but in a different year, also the year 2018 was selected to assume that the staff have more awareness toward reporting the incident and have more experience of using i-Help system.

3.5. Ethical Consideration

The research was approved by the Institution Review Board (IRB) in SBAHC on 7 November 2021 (IRB No: 58-2021-IRB), with the condition of not releasing the data for other than research purposes.

3.6. Statistical Methods

T-test was performed to explore the significant differences between two means of data from JAN to JUN in 2018 for i-Help incident report system, and 2021 for Datix incident report system.

3.6.1. Missing Data

Due to heavy restrictions and miss registration of data, the response rate and duration of the incident and the incident report utilization by the users for the i-Help system are missing which may support the study.

4. Chapter Four: Results

4.1. The current study

The No. of incident per month are shown in the table below:

Table 1 below illustrates the different between i-Help in 2018 and Datix 2021 in reporting the IRs per month with total incident reported (n=2169), the lowest reported incident was 121 for i-Help in Jun 2018, and the highest reported incident was 252 for Datix in Jan 2021, the mean for i-Help 2018 is 145.33 and the mean for Datix is 216.17. with significant p-value (p= 0.0053).

Table 1 No. of incident per month for i-Help and Datix

<i>Month</i>	<i>i-Help 2018 n(%)</i>	<i>Datix 2021 n(%)</i>
<i>Jan</i>	141 (16.2)	252 (19.4)
<i>Feb</i>	138 (15.8)	251 (19.4)
<i>Mar</i>	168 (19.3)	222 (17.1)
<i>Apr</i>	158 (18.1)	211 (16.3)
<i>May</i>	146 (16.7)	146 (11.3)
<i>Jun</i>	121 (13.9)	215 (16.5)
<i>Total</i>	872 (100)	1297 (100)

Table 2 t-Test of no. incident for i-Help and Datix

<i>t-Test</i>	<i>i-Help 2018(old)</i>	<i>Datix 2021(new)</i>
Mean	145.33	216.17
Variance	267.86	1496.56
Observations	6	6
<i>P</i> -value	0.0053	

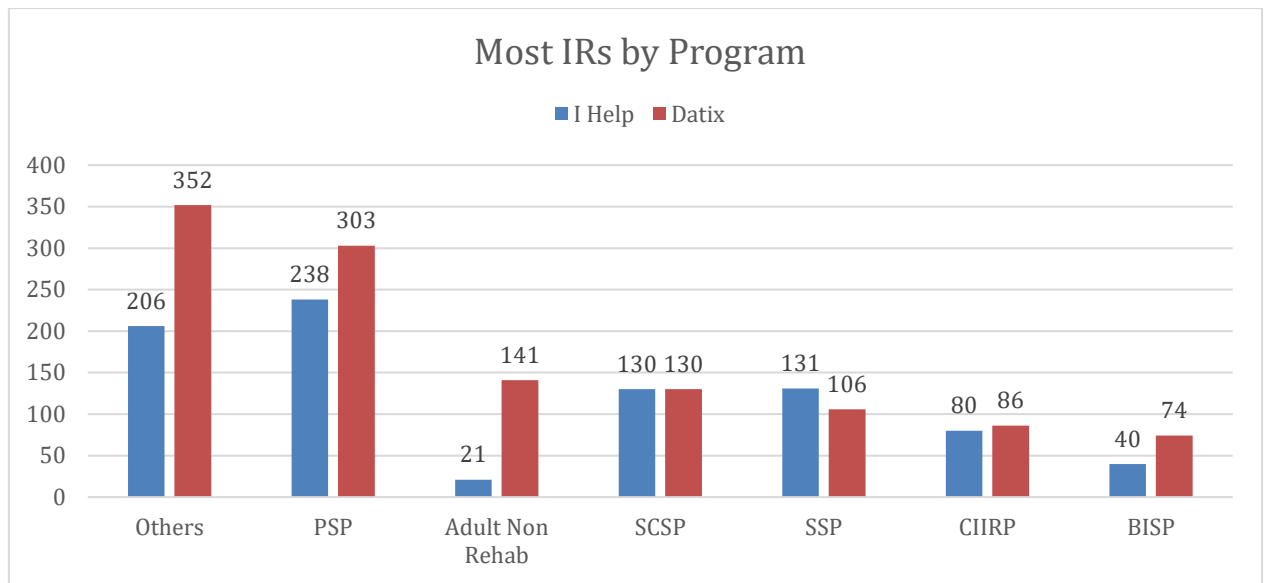


Figure 2 Most IRs by program

In figure 2 it shows the most IRs by program, to check the influence of using Datix upon programs, there are 846 IRs from i-Help had been analysed also, 1192 IRs from Datix with total incident reported (n= 2038), PSP represent Pediatric Specialty Program, SCSP represent Spinal Cord System of Care Specialty Program, SSP represent Stroke Specialty Program, CIIRP represent Comprehensive Intensive and Integrated Rehabilitation Program, BISP Brain Injury Specialty Program.

Table 3 t-Test Most IRs by program

<i>t-Test</i>	Others	PSP	Adult Non- Rehab	SCSP	SSP	CIIRP	BISP
<i>P-value</i>	0.056	0.013	0.0007	0.5	0.099	0.35	0.024

5. Chapter Five: Discussion

5.1. Major results

In healthcare organizations, having a robust incident reporting system that can aid in identifying risks to prevent patients from being harmed, and used as a learning tool for healthcare organizations is considered essential in order to maintain not only patient safety but also quality measures.

Incident reports are used to enhance the performance of healthcare organizations in general. In that essence, SBAHC has implemented new system Datix to replace the old one, and the result of this study shows that there is a significant difference between the volume of registered incident reports after the implementation of Datix system, the study shows the programs that was affected by Datix system, out of the 7 programs that mention in the result 5 of them Datix have more incident reported than i-Help in general and 3 out of the 5 is significant (with $p\text{-value} < 0.05$), which supports the findings of the research titled “Electronic adverse incident reporting in hospitals”(Walsh et al., 2010).

While in 2018 there were prominent barriers to support and encourage incident reporting processes including but not limited to: time constraints and lack of Ease accessibility by users(Evans et al., 2006; Kingston et al., 2004; Lawton and Parker, 2002; Schectman and Plews-Ogan, 2006; Taylor et al., 2004; Waring, 2005), implementing Datix system has dramatically assisted in changing the organizational culture by considerably tackling the conventional barriers and activating more incident reports to the point where the number of registered IRs had increased almost by 49% in the first year of implementation. One of the major factors that contributed to the increase of IRs in 2021 was the positive attitude and perceptions of healthcare workers in SBAHC on incident reporting after the implantation of Datix system due to the anonymity feature.

5.2. Trends

Datix systems has become the modern trend in incident reporting systems. The Datix system has many advantages and more friendly interfaces providing optimized user experience and better data management/recording. The operational enhancement of Datix

system utilization has been evident through the literature review through the result of other hospitals which adopted the Datix system (Mushcab et al., 2020). In the study the introducing the Datix system has increased the number of incidents by almost 49%. The implementation of Datix system has incentivized incident capturing and made incident reporting more accessible to the hospital staff under study which is reflected through the increase in number of incident reporting.

6. Recommendations

The recommendation for the future study is to measure the satisfaction of using Datix as incident reporting system by the users, measure the response rate and the duration to check efficiency of the two incident report systems i-Help and Datix, explore the effect of the “just culture” in reporting the incident, include more than one hospital in the future study to generalize the data and evaluate the cost effectiveness of the incident reporting systems.

7. Conclusion

Implementing of Datix system in SBAHC increase the number of incident report has increased by almost 49% comparing to the old system i-Help, which indicate the good influence of using Datix as incident report system, it enhances and improve the workflow of reporting the incident which become more efficient to use it rather than the old system i-Help. Also, the Datix system have more option and feature for the staff to report the incident. Receive more report for incident give the advantage for the SBAHC to analyse the incident data to build and develop risk-reduction strategy based on data trends to prevent and minimize errors and learn from the incidents, which Datix has proved during this study that it's more efficient to use Datix as an incident report system rather than i-Help.

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9. Appendices



مدينة سلطان بن عبد العزيز للخدمات الإنسانية
SULTAN BIN ABDULAZIZ HUMANITARIAN CITY



Date: 07/11/2021
IRB No.: 58-2021-IRB

To: Engr. Abdullah Mohammed Al Zahrani
PI: "Influence of implementation of Datix system on incident reporting at SBAHC"
MSc, King Saud University
Sultan Bin Abdulaziz Humanitarian City
E-mail: amalzahrani@sbahc.org.sa

Subject: Approval for Research No. 54/SBAHC/MSc/2021
Study Title: Influence of implementation of Datix system on incident reporting at SBAHC
Study Code: 54/SBAHC/MSc/2021
Date of Approval: 04/11/2021
Date of Expiry: 03/04/2022
Board approval: All members except absentee

Dear Engr. Abdullah Mohammed Al Zahrani,

Your Project has been approved and you have the permission to conduct this study following your submitted documents as follow:

1. Curriculum Vitae for the PI researcher
2. Letter from the researcher requesting SBAHC participation in the clinical study
3. Research proposal according to SBAHC IRB Guidelines
4. Research Obligatory Agreement. Available upon the completion of the other requirements

You are required to obey by the rules and regulations of the Government of Saudi Arabia, the SBAHC IRB Policies and procedures and the ICH-GCP guidelines. You have to note that this approval mandate responding to IRB's periodic request and surveillance result. Drawing your attention to the following:

- Amendment of the project with the required modification to providing Periodical report for this project specially when study extension is required or expiry before study completion
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the IRB as soon as possible

- Personal identifying data should only be collected when necessary for research.
- Secondary disclosure of personal identifiable data is not allowed.
- Monitoring: projects may be subject to an audit by the IRB at any time.
- The PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years.
- Data should be stored securely so that a few authorized users are permitted access to the database.

The IRB registered with the IRB KACST Registration No. H-01-R-090. It is authorized to conduct the ethical review of clinic studies and operates in accordance with ICH-GCP Guidelines and all applicable national/local and institutional regulations and guidelines which govern Good Clinical Practices.

For Future Correspondence, please quote the project number and project title above and you are requested to keep IRB informed about your study progress and submit project progress report every six (6) months. A final report should be provided upon completion of the study.

Wish you a success in your research project.

Yours sincerely,



Prof. Khalid Al-Rubeaan
Chairman-IRB
Sultan Bin Abdulaziz Humanitarian City





NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Abdullah Alzahrani

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:

Introduction
Institutional Review Boards
Informed Consent
Confidentiality & Privacy
Participant Safety & Adverse Events
Quality Assurance
The Research Protocol
Documentation & Record-Keeping
Research Misconduct
Roles & Responsibilities
Recruitment & Retention
Investigational New Drugs

STATUS:

N/A
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed

Course Completion Date: 28 September 2021

CTN Expiration Date: 28 September 2024

Tracee Williams, Training Coordinator
NIDA Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.

