

Utilising HFACS and HFIX Framework to Improve Communication for Research Subject Safety

AIM

To Improve the Process of Team Communication and Coordination

INTRODUCTION

In a clinical research setting, clear communication is vital in ensuring the accuracy of procedures and subject safety

- The Human Factor Analysis and Classification System (HFACS) identified factors contributing to prevalent issues.
- The Human Factors Intervention Matrix (HFIX) was utilised to resolve the communication issues within the Clinical Research Nurse (CRN) team.

FINDINGS



1. Dosing times of Investigational Drug were affected due to 7 out of 750 meals (**0.93%**) being served at incorrect timings
2. 4 out of 250 Full Blood Count (FBC) tests (**1.6%**), with platelet count drops of $\geq 50,000/\text{mm}^3$, over a 24-hour period were not monitored every 12-hour henceforth

Note: Low platelet levels increase risk of bleeding

METHODOLOGY

This was used to solve the 2 issues at hand

HFACS AND HFIX FRAMEWORK

Human Factor Analysis and Classification System (HFACS)	Human Factors Intervention Matrix (HFIX)				
	Organisational	Human / Staff	Technology	Task	Operational / Physical Environment
Lack of Teamwork (poor communication and coordination)		Hire Locum Staff	Audio-tape Handover	Specific Staff Assignment	
Attention and Memory Failures			Clear Procedures in Timepoint Sheet		Display Bed Label for Subject with Fasting Time
Task and Procedure Design	Revision of SOP *		Specific Procedures in Timepoint Sheet	Nursing Task List	
Stress and Mental Fatigue		Flexible Shift in Schedule			

Note: SOP* – Standard Operating Procedures

iM>SPC-107(PO)
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 Fasting Starts : 1130 hrs Ends: 1530 hrs
 Other Instructions:
 Low Residue and Low Fat Diet
 Intake 3 Litres of water daily. On Fluid Balance Charting
 Non-dairy Products
 Specific Instructions: Take 12-hour FBC if Platelets Counts drop of $\geq 50,000/\text{mm}^3$ over 24-hour period
 Observe for Bleeding. At Fall Risk.

RESULTS

1. Full compliance to Dosing Time of Investigational Drug was achieved. All meals were served at specified FASTING time with **ZERO (0%)** deviation post-10 months HFIX implementation.
2. All platelets counts with drop of $\geq 50,000/\text{mm}^3$ were monitored every 12-hour till platelets trends reverse, with **ZERO (0%)** deviation post-10 months intervention.

IMPACT

- ☆ Full compliance with trial protocol
- ☆ Subject safety assured
- ☆ Human errors reduced
- ☆ Effective communication enhanced team unity
- ☆ Reputable site for early phase clinical trial

CONCLUSION

1. Equipped with tools and techniques to communicate within the team effectively
2. Compliance with Standard Operating Procedures (SOP) and trial protocols were developed and maintained
3. Enhanced Subject Safety and Staff Satisfaction

References:

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