

The Art of Communicating with Nursing Staff

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Overview

- Relevance
 - Deviations from standard practice
 - SBAR
 - In-servicing
 - Misc
 - Patient identification
 - Investigational Drug Service
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Definitions

□ Art

- A superior skill that you can learn by study & practice and observation
- Skill in conducting any human activity
- A system of principles & methods employed in the performance of a set of activities

□ Communication

- Something imparted, interchanged, or transmitted
- The exchange of thoughts, messages, or information, as by speech, signals, writing, or behavior





Relation to RESEARCH

- **There are several factors that have the potential to increase the likelihood of errors**
 - Deviations from standard practice
 - No standardized method for developing procedures for research-related procedures in hospital setting
 - Apprehension from clinicians caring for research subjects
 - Misconceptions
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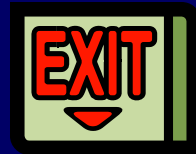
Decreasing Risks

- **Education = Increasing awareness**
 - Knowledge is Power
 - Extends beyond SIVs
 - Begins with YOU
 - In-servicing
 - Utilize Study Sponsors
 - Study team
 - Passive Education
 - Unit-specific newsletters
 - Flyers
 - Research Binders/folders in patient care areas
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Decreasing Risks

□ Presence


- Get to know the nurses
- Be available during blood draws or study drug administration
- Provide approved sponsored educational in-services related to your research
- Round with your “team”





Decreasing Risks

- **Knowing when** your study procedures deviate from routine practices
 - Dosage forms
 - Storage locations
 - Dispensing
 - Infusions
 - Blood draws
 - Assessments



**Choose the
right level
of care**



Decreasing Risks

- **Clearly written orders**
 - Refer to dispensing SOP
 - Must include basic information
 - Study name
 - Exactly what needs to occur
 - If a medication,
 - Drug name/Diluent
 - Dose/Strength, if not blinded
 - Route
 - Frequency & Rate of infusion, if applicable
 - Pertinent study information
 - **Limit** the use of **abbreviations**
 - Use **common terms**
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What's Already in Place

- Multi-disciplinary feasibility review
 - Green sticker
 - Study Data Sheets
 - Copy of consent on Chart
 - In-servicing (as recommended during feasibility review)
 - Pre-printed –study specific ordersets
 - OCR/CORE staff
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S.B.A.R.

□ Situation

- What is happening at the present time?

□ Baseline/Background

- What are the circumstances leading up to this situation?

□ Assessment

- What do I think the problem is?

□ Recommendation/Resolution

- What should we do to correct the problem?
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In-servicing

- Be creative!
 - Involve Nurse educators & clinicians
 - Utilize available resources
 - Use both passive & active techniques
 - Involve other disciplines
 - Medical residents
 - Pharmacists
 - R-E-P-E-A-T!
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Patient Identification

□ Reporting

■ Pharmacy Systems

- Helps identify patients based on medications prescribed

■ Laboratory Data

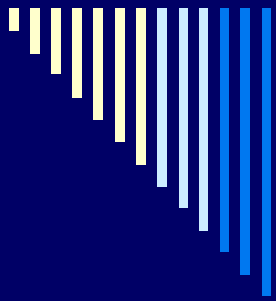
- Helps identify based on laboratory values

■ Non-affiliated healthcare providers

- Enlist the help of:
 - Specific Services
 - Residnets
 - Pharmacists
 - Nurse Educators/Clinicians - Clinical ladder programs

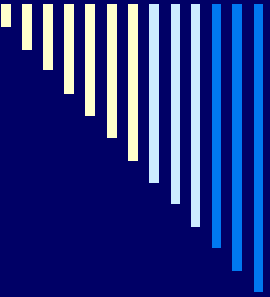


The Investigational Drug Service



The I.D.S.

- Managed by Department of Pharmacy with oversight from the Office of Clinical Research
- Primary responsibility of:
 - Shacreyett Burton, PharmD -
 - Kristyl Bishop, CPhT
- Located in the main pharmacy, East Pavillion 2nd Floor
- Office hours: 8am – 4pm Monday-Friday
 - No coverage for weekends, holidays, or vacations



Standard Operating Procedures

Defined by the International Conference on Harmonisation (ICH):
"detailed, written instructions to achieve uniformity of the performance of a specific function" ...necessary for a clinical research organization...to **achieve maximum safety and efficiency** of the performed clinical research operations.

It is therefore a must that all people and sites involved in clinical studies (both at the sponsor and at the investigative sites) have appropriate SOPs in place in order to conduct clinical research and to ensure compliance with the current regulations.



SOP: Charging

To assure that pharmacy services in support of investigational drug studies conducted in the Hospital are appropriately allocated & reimbursed

- The IDS prepares pharmacy budgets for all studies, regardless of funding source.
 - IDS fees are evaluated annually by the Office of Clinical Research and the Department of Pharmacy
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SOP: Receipt, Storage, & Monitoring

- All inpatient studies are required by Hospital policy to use the Investigational Drug Service for storage, control, and dispensing of investigational study
 - This procedure does not cover outpatient studies. Exceptions may be granted, on a case-by-case basis, for studies requiring both inpatient and outpatient dispensing of study drug.
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SOP: Receipt, Storage, & Monitoring

- Correct Address
 - ATTN: Investigational Drug Service
Department of Pharmacy Services, G-203
Tampa General Hospital
2 Columbia Drive, Tampa, FL 33606
 - If urgent shipment is required and requested by the investigator, it is the responsibility of the Principal Investigator/Designee to notify the IDS
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SOP: Receipt, Storage, & Monitoring

- ❑ Stored separately from pharmacy stock
 - ❑ Controlled substances may not be stored outside of TGH Department of Pharmacy.
 - ❑ May be required to provide equipment for storage if requirements cannot be meet by IDS routine storage
 - ❑ Investigational Drug Service Quality Audit Form
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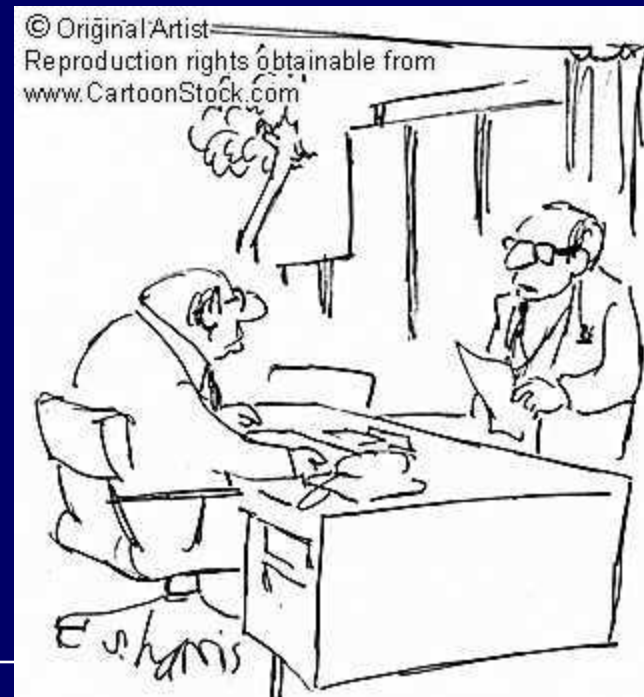


SOP: Dispensing

- Pharmacy Procedural Drug Data Sheet or “Short Sheet”
 - A protocol specific document prepared by the IDS staff that outlines the process dispensing, preparation (including randomization, if any), delivery, and documentation requirements. This document also contains basic study information and contact information for principal investigator, study coordinator, and sponsor

SOP: Dispensing

- It is the responsibility of the PI to ensure that the IDS has received all protocol amendments
- Scheduled visits
- NO drafting
- NO snooping



"It was more of a 'triple-blind' test. The patients didn't know which ones were getting the real drug, the doctors didn't know, and, I'm afraid nobody knew."



When IDS staff are unavailable

- Integrated into usual medication ordering system
 - Write orders
 - Ensure that a copy of consent is received in pharmacy
 - Speak with the Charge Pharmacist
 - Unit based pharmacist
 - See phone extension list
 - Ask the nursing staff for that area
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Q & A Session

