Managing Research Compliance Utilizing an Electronic Compliance Database System

Michael K. Jensen, R.Ph., M.S.
Clinical Pharmacist
Corporate Compliance Manager – Pharmacy
Intermountain Healthcare
Salt Lake City, Utah

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Disclosure

- I have no financial relationships to disclose

- The electronic compliance manager tool I will be highlighting was developed by the Department of Pharmacy Services for Intermountain Healthcare, Inc., and is a copyright of Intermountain Healthcare, Inc.
  - Electronic database is currently active in use for pharmacy compliance
  - Conceptually applicable to the research setting... medication research in proposal
  - Presentation is to highlight conceptually how an electronic compliance manager can be used in a research compliance environment.

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Why is compliance so important to research?

- Protect and provide safety
  - Public / Patient Safety
  - Investigator Safety
    - Ex., drug study involving hazardous medication
    - Standing as a reputable investigator
  - Protect the data
    - Integrity of the study
    - Increases the impact of the research outcome
- Regulatory
  - Controlled substances
  - Government and regulatory oversight (FDA, JC, HHS, etc.)
- Cost control

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Common Reasons for Research Non-Compliance

- Pre-study Related
  - Failure to conduct complete literature research, prior literature reports
  - Failure to have a detailed, written and vetted protocol
    - sample size analysis
    - statistical assumptions to be made
    - identify limitations of measurement methods
    - identify adequate bias control measures
    - failure to determine and write a detailed time line
- IRB Approval
  - Adherence to responsibilities as clinical investigator
  - No approval obtained, lapse in IRB, no continuing review
- Study Related
  - Informed Consent (improper/outdated consent)
  - Protocol Deviations / Violations (changes made with no approval)
  - Drug and Device Accountability (record keeping inadequate)
  - Inadequate Medical Records (trial data not recorded (e.g., adverse events)

Portier W, Dunne C. Current challenges and opportunities in clinical research compliance. Ochsner J. 2006 Spring; 6(1):21-24
Clark GT, Mulligan R. Fifteen common mistakes encountered in clinical research. J Prosth Res 55 (2011) 1-6 .

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Compliance in Research: It's About Coordination

- Manual Oversight
  - Costly
  - Time consuming
  - Accuracy lower
    - data collection errors
    - competency of staff
    - study integrity harder to control
  - Bulky
    - paperwork and amount of filing
    - ability to retrieve more difficult

- Electronic Oversight
  - Less costly
  - Increased efficiency
    - Real time
  - Compliance assessment and controls improved

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RxCM: Electronic Compliance Manager

- Stores Documents associated with task completion and documents compliance.
  - Attachments can be added to each task for documentation, retrieval, verification
  - Demonstrate compliance with internal policies as well as State/Federal laws

- Dashboard function provides timeline alerts for task completion
  - Organizes workflow daily/weekly/monthly for staff

- Provides both corporate/local levels a method for managing compliance
  - Status assessment in real time
  - Ensures completion of required job functions for category compliance

- Provides validation tool for compliance audits/inspections.
  - Internal (Internal Process Control, Corporate Compliance, Internal Quality)
  - External (State DOPL, DEA, FDA, JC, etc.)

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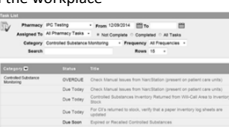## RxCM: Electronic Compliance Manager

- RxCM Functionality

Reports	• Standardized reports • Custom reports
Email	• Notification of upcoming tasks • Notification of tasks requiring follow-up

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RxCM: Electronic Compliance Manager

- Maintains Task Lists by category to complete/perform in compliance with the required category
  - Corporate Assigned Tasks
    - Controls/organizes compliance for categories of focus system wide
  - Local Pharmacy Assigned Tasks (created by the pharmacy)
    - Controls/organizes workflow for task completion by staff

- Organizes required categories of compliance in the workplace
  - Controlled Substances
  - Compounding USP 797/795
  - Pharmacy Licensing
  - 340B
  - Utah State DOPL Readiness
  - Medication Management (JC)
  - Medication Research ?
    - **In 2017, 640 medication research studies**

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Medication Research

- Next Steps for Pharmacy Compliance → Medication Research Compliance

- Food and Drug Administration Good Clinical Practice Guidelines state:
  - **4.6** Investigational Product(s)
  - **4.6.1** Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.
  - **4.6.2** Where allowed/required, the investigator/institution **may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist** or another appropriate individual who is under the supervision of the investigator/institution.

- The Joint Commission Medication Management Standard : MM.06.01.05

  Rationale: The hospital safely manages investigational medications

  A 1. The hospital has a written process addressing the use of investigational medications that **includes review, approval, supervision, and monitoring**.
  A 2. The hospital's written process for the use of investigational medications specifies that the **pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications**.

  Good Clinical Practice: Consolidated Guideline. Federal Register, 1997, Vol. 62, No. 90.

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RxCM: Electronic Compliance Manager

• © 2017 Intermountain Healthcare, All rights reserved A Central APEX Application, version: 1.92

Login

Main Screen

Task List Function

Task List Function

Main Screen

Main Screen

Manage Tasks Function

Manage Tasks Function

- Create Task

Maintenance Function

Maintenance Function

- Add New
- Edit

Dashboard Function

- Dashboard

Reports Function

Reports Function

Reports Function

- Raw Data Spreadsheet Sample

Title	Status	Frequency	Category	Due	Completed	Month	Site Category	Year
PM #1 Laminar Airflow Workbench (LAFW)	Completed On-Time	Daily	Sterile Compounding	3/14/2017	3/14/2017	March	Hospital	2017
Sterile inner gloves	Completed On-Time	Daily	Sterile Compounding	3/14/2017	3/14/2017	March	Hospital	2017
Perform Split Billing Automatic and Manual Accumulation Accuracy.	Completed On-Time	Monthly	340B	3/10/2017	3/9/2017	March	Hospital	2017
Perform Split Billing Automatic and Manual Accumulation Accuracy	Completed On-Time	Monthly	340B	3/10/2017	3/10/2017	March	Hospital	2017
Verify all 340B Audit Reports (Appendix 2-4) for previous month have been confirmed and sub	Completed On-Time	Monthly	340B	3/10/2017	3/1/2017	March	Hospital	2017
All counters, pass-through windows, work surfaces, sink areas are disinfected daily	Completed Late/Incomplete	Weekdays	Sterile Compounding	3/1/2017	3/2/2017	March	Medical Group	2017
Pressure controls are recorded	Completed Late/Incomplete	Weekdays	Sterile Compounding	3/1/2017	3/2/2017	March	Medical Group	2017
Compounding Aseptic Isolator (CAI)	Completed On-Time	Daily	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
Chemo Floor mopping performed from cleanest room (buffer) to less clean area (anteroom)	Completed On-Time	Weekdays	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
Chemo Pressure gauge or velocity meter	Completed On-Time	Weekdays	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
PM Laminar Airflow Workbench (LAFW)	Completed On-Time	Daily	Sterile Compounding	3/1/2017	3/1/2017	March	Hospital	2017
Reconciling Controlled Substance Waste Discrepancies in AcuDose-Rx	Completed On-Time	Weekdays	Controlled Substance Monitoring	3/1/2017	3/1/2017	March	Hospital	2017
Reconciling Manual Admits to the ADT	Completed On-Time	Weekdays	Controlled Substance Monitoring	3/1/2017	3/1/2017	March	Hospital	2017

Reports Function

- Individual Study Reports

Reports Function

- Overall Compliance Report by Study

Conclusion

- The use of an electronic compliance database manager provides an efficient method for coordinating, managing, and documenting aspects of compliance for related activities in the health-care setting.

- An electronic compliance database manager provides a tool to organize activities of compliance, tailored to the demands required based on the setting or project being conducted.

- The use of an electronic compliance database manager provides the compliance specialist the ability to organize, validate, audit, report, trend, and assess all research compliance requirements in a healthcare setting.

Questions ?

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