Management of Caloric-Specific Diets &/or Restrictions (CSDR) in Clinical Trials: A Learning Journey with PDCA Cycle

Singapore Healthcare Management 2017

SingHealth Investigational Medicine Unit (IMU)

Ramya MURUGAYEE d/o Ramalinggam
PEK Li Ping Shirley
Bianca Marie Lee MIRANDA
Alice CHAN Teck Meng

INTRODUCTION

- Food-Effect Bioavailability is important in clinical trials involving testing of new drugs. The purpose is to assess the **effects** of **food** on the rate and extent of absorption of a drug when a drug product is administered shortly after a diet (fed condition), as compared to administration under fasting condition.
- Hence, Diet requirements are specified in a Trial Protocol. The requirements must be planned, ordered & administered strictly according to the protocol. Any deviations will give rise to unreliable study data (e.g. blood test results, vital signs & electrocardiogram reports).
- Other requirements in the Trial Protocol include:
  - Photograph of Meal before & after consumption
  - Retain Diet Ticket (Meal ordered & administered)

AIM

- To ensure strict adherence to Trial Protocols with Caloric-Specific Diet Requirements &/or Restrictions (CSDR), Clinical Research Nurses (CRNs) need to be 100% accurate when serving Caloric-Specific Diets to Trial Subjects.
- To meet the 100% accuracy target, CRNs need to develop a process using the Plan-Do-Check-Act Cycle for quality improvement to ensure the Correct CSDR Diet is served to the Correct Trial Subject at the Correct Time.

METHODOLOGY

PLAN

- Formed eDiet Project Team & set objectives
- Utilised PLAN-DO-CHECK-ACT Cycle to improve processes
- Reviewed Incident Records of Trials with Diet-related Protocol Deviations to identify Issues & Root Causes
- Analysed data to develop Action Plan

ISSUES:

- Wrong Diet Administered to Wrong Subject
- Trial Booking Form did not state Specific Diet Requirements/Restrictions
- Diet Ticket was not retained as evidence that Diet was administered
- Photograph of Diet was not taken before &/or after Subject consumed Diet as evidence that Diet was administered
- No order of CSDR because No input in eDiet System
- Order for specific Diet was not communicated to F&B Staff: unable to reach F&B Staff via phone & CRN forgotten to send emails due to trial load

ROOT CAUSES:

- Inexperienced & new CRNs onboard
- Difficulty understanding the trial protocol
- Different wordings of written English in various Trial Protocols
- CRNs' emphasis were on PK sampling & not Diet, thus did not focus on Diet Requirements/Restrictions
- Electronic-Diet (eDiet) System required multiple steps
- eDiet system did not have fields to input CSDR requirements, had to make frequent phone calls & write emails to explain
- F&B Team restricted access to eDiet System, hence only limited number of users could use the eDiet System
- Frequent change of F&B staff created miscommunication

DO

- Developed improved work processes & documented in a Workflow Chart for standardisation & compliance
- Implemented a trial-run of the Workflow Chart
  - Conducted sessions on understanding the wordings pertaining to Diet in the protocol
  - Categorised specifics in CSDR such as Breakfast/Lunch/Dinner; High-Fat versus Low-Fat; Specific Micro-Nutrients and breakdowns: Proteins, Carbohydrates & Fats & percentages for Fat Calories; Restrictions such as no Herbs, Non-Caffeine etc
  - Amended Trial Booking Form to allow input for CSDR requirements
  - Created a Form for attaching Diet Ticket
  - Amended Timepoint Source Document to include actions to Take Photograph Before Eating/After Consumption, Send Photograph to Dietitian, Retain Diet Ticket
  - Provided all CRNs access to eDiet system & conducted refresher Training
  - Assigned CRN Special Diet Team with accountability for All Protocols with CSDR
  - Assigned CRN with responsibility for CSDR Diet daily
  - Entered Protocol & CSDR Requirements in eDiet System upon receipt of Trial Booking Form One Day Before Subject's Admission, another CRN will CHECK eDiet with Protocol before confirming eDiet Order
  - Verified Diet in Food Trolley with Diet Ticket, Administered Diet to Trial Subject & Documented in Timepoint Source Document (Initial & Date)
  - Liaised with Designated Research F&B Staffs on CSDR (F&B Dept designated two staff specially to liaise with SingHealth IMU for Research purposes)
  - Standardised text to input in Remark Box in eDiet System to communicate CSDR Requirements/Restrictions with F&B Team
  - Emailed CSDR Requirements/Restrictions that cannot be entered into eDiet System to Designated Research F&B Team

CHECK

- Evaluated the results of compliance to improved Workflow. All the CSDR Diets were Correctly ordered & administered to the Correct Subjects at the Correct Time as according to the Trial Protocols.

ACT

- Conducted training & Implemented the improved Workflow to all the CRNs and all were able to comply with the Workflow.

PDCA CYCLE is a repetitive 4-stage model for continual improvement of processes

RESULT

Full Compliance in following the steps of the improved Workflow.

ALL DIET with CSDR were served to Trial Subjects with ***ZERO percent (0%)*** deviation post-6 months following implementation of the improvements

CONCLUSION

- Utilisation of the PDCA cycle facilitated the CRN Team to systematically identify the issues, root causes, develop strategies to standardise the processes for ordering & administering CSDR requirements/restrictions.
- The Standardised Workflow facilitated the CRNs to be consistent in complying with the processes for ordering & administering Caloric-Specific Diet & Restrictions to Trial Subjects effectively and efficiently.
- The assignment of Designated CRNs & F&B Staff for CSDR greatly improved the communication between SingHealth IMU and F&B Team, hence enhancing the accuracy of CSDR Diet ordering & administering.

References: *Http://www.fda.gov/cder/guidance/index.htm U.S.Department of Health & Human Services, Food & Drug Administration, Center for Drug Evaluation Research (CDER) December 2002*
https://deming.org/management-system/pdsacycle PDCA Cycle by W Edwards Deming

Notes: CSDR: Caloric-Specific Diet &/or Restrictions
Food can change the Bioavailability (BA) of a drug and can influence the Bioequivalence (BE) between test and reference products. Food effects on BA can have clinically significant consequences esp greatest when the drug product is administered shortly after a meal is ingested. (*Http://www.fda.gov/cder/guidance/index.htm*)