Clinic Flow Assessments:
Trends & suggestions to address them

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Thank you for hosting me

- To all the VOICE sites
- Visited all the CTU's
  - 12 of the 15 CRS's involved in VOICE over a 3 month period.
- Each CTU/CRS unique
- ***"No one size fit all"*** strategy to visit flow challenges

Reason for visit flow evaluation

- Reports of study visits taking between 3-9 hours
- Worry at the Network & CTU level
  - Study fatigue for participants & staff (retention)
  - Most sites at approx. 50% accrual then
  - Supply suffering from process (recruitment)
- Focus on improving efficiency across all VOICE sites was on waiting…
  - Never to rush procedures (Quality critical)
  - Rid visit flow system of any built-in redundancies

Overall impression of the sites

- Most with superb systems by most standards for maximizing efficiency;
  - Skill base (nurses/counselors)
  - Multi-trained (task-shifting easier)
  - Proven desire/commitment towards efficiency
- Only required a few tweaks, yet so critically important in maximizing overall visit efficiency
- So tended to work within the existent staffing levels
  - Encouraged manpower addition in minimal cases

Critical pathway to maximizing efficiency

- Often requires regular internal audit to determine what's working or not
  - Often non-complicated approaches
  - May at times require shadowing-in to assess functionality of systems
- Involves a candid review of site processes to determine BOTTLE NECKS in system
  - Recognition of problems requiring a fix is crucial, but can be hard esp. if problems or gains are less obvious
- Ways to deal with bottle necks
  - Cut time to make process more efficient without loosing quality
  - Task-shift to offload process
  - Add manpower

The hidden inefficiency secrets

(The Seven Deadly Wastes)

1. **Overproduction** is to produce sooner, faster or in greater quantities than the demand *(mostly in chart-noting)*
2. **Inventory** is raw material, work in progress or finished goods which is not having value added to it.
3. **Waiting** occurs when part of the work cycle is holding without added value *(so far the biggest culprit)*
4. **Motion** is the unnecessary movement of people, parts or machines within a process *(special phlebotomy room, nurses acting as runners)*
5. **Transportation** is the unnecessary baggage you pick up alongside movement of people or parts between processes *(inevitable consequence of motion)*
6. **Rework** is repetition of the work process to correct defects *(common with RRC, pre/post test, IC review & nurses re-writing Dr's. notes/findings)*
7. **Over processing** is the processing of material beyond the standard required with resultant trade-offs

Audit process

- Participant given leaflet highlighting all steps she had to go thru for the visit as per site's visit flow plan
- Clocking done as she entered room for procedures & upon completion of each step
- Time from completion of last procedures to initiation of next procedure **(wait time)** to determine rate limiting steps
- Also computed total wait time & total procedure time to give sites an idea of their levels of efficiency in visit flow process

Findings from quick internal audits

- 1st case:
  - Overall visit time for a semi-annual visit = 7hrs 38min
  - Total time spent on visit procedures = 2hr16min
  - Total time spent on WAITING = 5hr 22min
- 2nd case
  - Overall visit time for semi-annual visit = 6hrs (5hrs for a monthly)
  - Total time spent on visit procedures = 2hr 55 min
  - Total time spent on WAITING = 2hr 56 min
- 3rd case
  - Overall visit time for a month 4 visit = 7hrs 30min
  - Total time spent on visit procedures = 2hr 43min
  - Total time spent on WAITING = 4hr 47min

- Very limited adaptation of FHI template on order of procedures
  - Some with minimal or no changes at all
  - Adaptation to reflect visit flow that maximized efficiencies based on site’s skill base vital
- Recommendation
  - Alternative visit flow plans suggested
  - Sites have worked with FHI lead CRM’s to revise checklists

Key findings

- In a number of sites, time was also lost to inefficiencies in determining the following:
  - The critical window of opportunity for the QC1 process & where the focus ought to be
  - Differentiating between QC and data cleaning & when to prioritize what?
  - Extent of chart noting & in some cases what ought to be chart noted

Managing the QC process

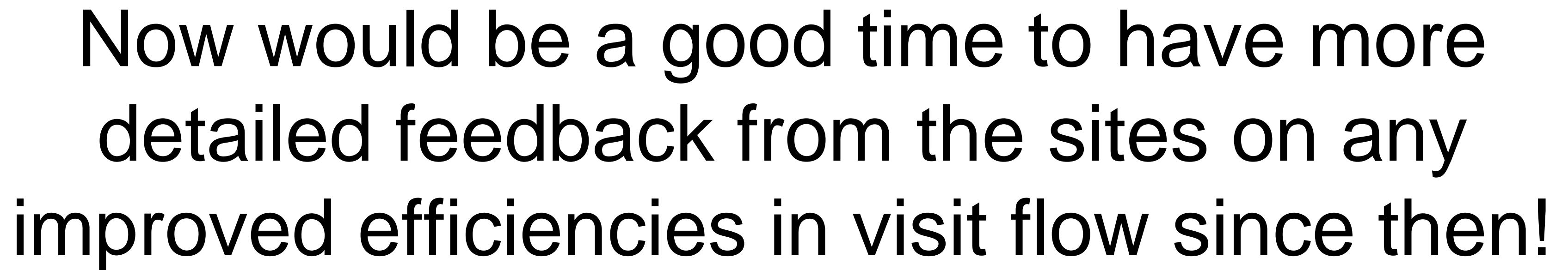
- QC is not synonymous with DATA CLEANING
  - Extent of chart notes directly impacts ability to identify potential QC's if critical review done concurrently
    - Significant time spent on chart note review as part of data cleaning
    - QC-1: Targeted towards procedure completion CRF's: (M&MH, AE & Sx logs, Con-meds, Interview administered forms)
- Primary QC (self-QC) best improved thru a targeted training approach
  - Most of us tend to make the same mistakes always
  - QC team needs to develop staff specific common errors
- Secondary QC (post-participant exit) is best addressed in following ways
  - Running an efficient clinic (allows time for staff to attend to QC's
  - Proactive process to ensure all staff complete their QC's
    - Develop visual stimulus to each staff's QC's (individualized shelving)
    - Track time binders await QC resolution (impacts mean days to faxing)

Chart noting

- Key is to chart the interaction with your participant or findings from your interaction as you implement study procedures
  - Almost always based protocol, SOP's, your checklists etc.
- Shouldn't really be a re-documentation of your checklist or SOP
  - Don't tell what you did (as in SOP or checklist)
- Tell what transpired when you did what you're supposed to do
- Examples:
  - Risk Assessment done. Rather highlight the risk profile you found when you did the assessment
  - Elements of IC review per participants needs. Rather tell what was reviewed specifically for this participant & source of confusion
  - IC comprehension assessed & issues requiring clarification reviewed. Rather tell which aspects you reviewed & outcome of your review
  - IC documentation which re-writes the IC SOP missing all the juicy questions asked by participant & how you addressed these

Feedback at last VOICE protocol team call (Feb 15th, 2011)

- **WHI:** Had reduced screening visits to 3-4 hours vs. 6-7 hours previously
- **PHRU:** Revamping approach to implementation with training & move towards task-shifting
- **MRC:** Implemented changes which had reduced visit length by at least 1-1.5 hours
- **eThekwini:** implemented a # of changes & was in process of revision of visit checklist
- **Zim CTU:** Had just started implementation of various suggestions (monitoring hadn't started)
- **Kampala** had been visited that week & **Aurum** was yet to be visited



Unless…..