DFcollect in Action

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September 27, 2018
Background

- International Clinical Research Center (ICRC), U of Washington Department of Global Health
  - Majority of ICRC’s work is conducting longitudinal clinical research studies and implementation projects related to HIV prevention
  - Most of ICRC’s studies are conducted in sub-Saharan Africa
- A current ICRC study is using an initial, custom version of DFcollect (version 1.0), the new tablet app from DF/Net
Objective

Share our experience using DFcollect for clinical data collection:

- Describe the size and scope of the study
- Why we selected electronic data collection over paper CRFs
- Why we chose DFcollect
- How our sites are using DFcollect
POWER Cohort Study

- For people at high risk of HIV, PrEP (Pre-Exposure Prophylaxis) is a daily pill that reduces their risk of acquiring HIV.

- POWER is an open label PrEP implementation project testing different PrEP delivery models to determine cost-effectiveness and scalability:
  - Up to 3000 adolescent girls and young women at high risk for HIV are offered PrEP in “real world” (vs. research) clinics
  - Participants are seen ~quarterly; POWER data are collected for up to 3 years
  - Began in June 2017; currently have 1120 participants
POWER sites

Three sites, each overseeing 1—3 public and private locations that provide family planning and reproductive health services.
Cape Town – mobile delivery

Desmond Tutu HIV Foundation
Tutu Teen Truck

- Provides free healthcare to young people ages 12-24
- Drives to resource-limited communities (e.g., townships) and other places where young people gather (e.g., near schools, shopping centers, sports fields)
- Announces locations 4 weeks in advance and via social media and messaging (e.g., Whatsapp)
Johannesburg – youth-friendly clinic

University of Witswatersrand
Reproductive Health and HIV Institute

- Primary health care clinic, offers family planning
- Located in a densely populated residential area close to the urban center

Photo by ICRC staff
Kisumu – family planning clinics

Kenya Medical Research Institute

- JOOTRH – large public teaching hospital
- KMET – private reproductive health facility

Photos from JOOTRH Facebook page and ICRC staff

#DFUG2018
Why EDC?

The “real-world” assortment of sites/locations means there are differences in:

- Physical space available (e.g., for storage of paper records)
- Communications/connectivity (e.g., landline for fax machine; cell service; Wi-Fi)
- Clinic structure/flow (e.g., which procedures are conducted by clinic staff vs. POWER research staff)
Why EDC?

- UW requirement that paper research records must be kept for 30 years
- General desire among ICRC investigators to move towards electronic data collection (EDC)

Photo of data room in a (non-POWER) clinic in Kenya, by Jennifer Morton
Why DFcollect?

Data collection wish list:

- At the sites:
  - EDC
  - Mobile
  - Minimal physical space requirements
  - Multiple simultaneous users
  - Enter data while offline
  - See previously completed CRFs

- For the study/central data manager:
  - See CRF data as individual forms
  - Change data in the central database (e.g., make QC corrections)
  - Customizable user permissions
  - Customizable visit map
Why DFcollect?

Data collection with DFcollect:

- **At the sites:**
  - EDC
  - Mobile
  - Minimal physical space requirements
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- **For the study/central data manager:**
  - See CRF data as individual forms
  - Change data in the central database (e.g., make QC corrections)
  - Customizable user permissions
  - Customizable visit map
  - 10+ year history of outstanding customer support from DF/Net
Using DFcollect – which device?

- **Technical considerations**
  - Android running 5.0 Lollipop or later
  - Wi-Fi connectivity
  - If cell-capable, unlocked or compatible with service in Kenya & South Africa

- **Other practical considerations**
  - Availability
  - Budget
  - Theft appeal
  - Site preferences
Using DFcollect – which device?

- Selection process (Summer/Fall 2016)
  - Initially chose Nexus 9”, but it was subsequently discontinued
  - The sites were divided on the preferred size: very small (7”) vs. very large (11-12”)

- Ended up with the 8” Samsung Galaxy Tab A
  - ~$200 (Fall 2016)
  - 16 GB internal, 1.5 GB RAM
  - 11 hour battery life
  - Wi-Fi only

- Set up
  - Added a PIN prior to sending into the field
  - Requested that the sites install and manage app-blockers
# Using DFcollect – data entry

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<th></th>
<th>Cape Town</th>
<th>Johannesburg</th>
<th>Kisumu</th>
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</thead>
<tbody>
<tr>
<td><strong>Existing clinic data system</strong></td>
<td>Direct-entry into custom EDC system using tablets</td>
<td>Paper files</td>
<td>Paper files</td>
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<tr>
<td><strong>How data get into DFcollect</strong></td>
<td>• POWER-specific questions were programmed into their existing EDC forms</td>
<td>• Use paper ‘worksheet’ versions of POWER CRFs</td>
<td>• Data are direct-entered into DFcollect</td>
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<td></td>
<td>• POWER staff go to central office to abstract from their own electronic database into DFcollect</td>
<td>• POWER staff later abstract data from paper records into DFcollect</td>
<td>• Paper ‘worksheet’ versions of POWER CRFs are available as a back-up; if used, POWER staff would later abstract from those into DFcollect</td>
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Successes with DFcollect

- Technical:
  - It works! To date, >16000 CRFs from 1120 participants.
  - Generally intuitive/user-friendly for data entry on the tablets
  - Have successfully made a number of changes since activation:
    - Amended the visit map
    - Amended CRFs
    - Added site-specific CRFs
Successes with DFcollect

- Operational:
  - Acceptable to site users with varying degrees of experience using tablets
  - Tablet theft/loss has not been a problem (1 theft)
  - Tablet storage space has been adequate
# Challenges with DFcollect

## Challenges with DFcollect version 1.0

<table>
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<tr>
<th>Challenge in DFcollect version 1.0</th>
<th>Workaround/Solution</th>
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</table>
| Cannot change previously synced data via DFcollect*                                              | 1. Now: site emails QC corrections to me, I make change in central database via iDataFax  
2. Soon: enabled in version 2.0                                                                  |
| Changes made in central database (via iDataFax) or study setup are not reflected in DFcollect    | Work with sites to refresh DFcollect monthly                                                                                                         |
| until the database stored on each tablet is refreshed                                            |                                                                                                                                                      |
| Syncing delays attributed to: 1. Wi-Fi disruptions  
2. Auto-logout after 5 minutes of inactivity*                                                      | 1. Provide sites with Mi-Fi hotspots  
2. Soon: time to auto-logout can be managed centrally in version 2.0                                                                            |
| DFcollect is ‘hardwired’ to the real POWER study, so cannot test changes using development study | 1. Now: test as much as possible in iDataFax  
2. Soon: enabled in version 2.0                                                                     |

*In version 1.0, these features were by design per ICRC request*
Summary

Very satisfied with DFcollect and support from DF/Net!

- Thank you to the DFcollect development team at DF/Net
- Extra special thanks to Laura Joldersma!
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