

*turning knowledge into practice*

# Palm Handhelds for Data Collection, Reporting, and Randomization

Stephen Litavec, Debra Fleischmann

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*RTI International is a trade name of Research Triangle Institute*

3040 Cornwallis Road  
Phone 919-485-2632

■ P.O. Box 12194

■ Research Triangle Park, North Carolina, USA 27709  
e-mail [slitavec@rti.org](mailto:slitavec@rti.org)

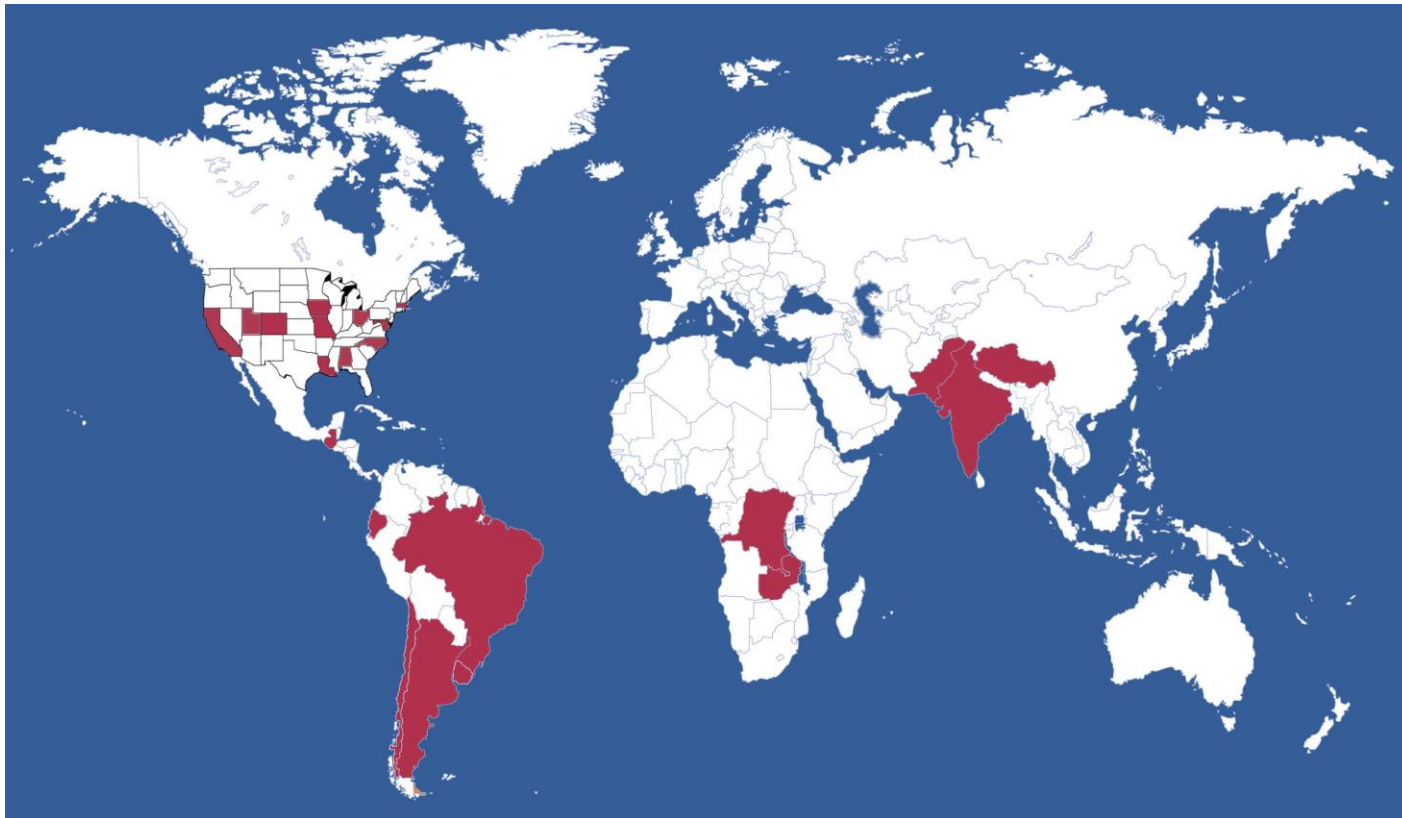
# Palm Handhelds for Data Collection, Reporting, and Randomization

- Overview
  - Projects using Palm systems
  - Data entry system and management
  - Screening
  - Randomization
  - Reporting
  - Issues
  - Results
  - Recommendations

# Global Network for Women's and Children's Health Research

- What is the Global Network?
  - Multi-site international research network
  - Addresses health needs of women and children
  - 10 Research Units
    - Asia
    - Africa
    - South America
  - 15 Individual protocols and 2 common protocols
  - Collaboration between U.S. based universities, research sites in a developing country, and RTI

# Global Network for Women's and Children's Health Research



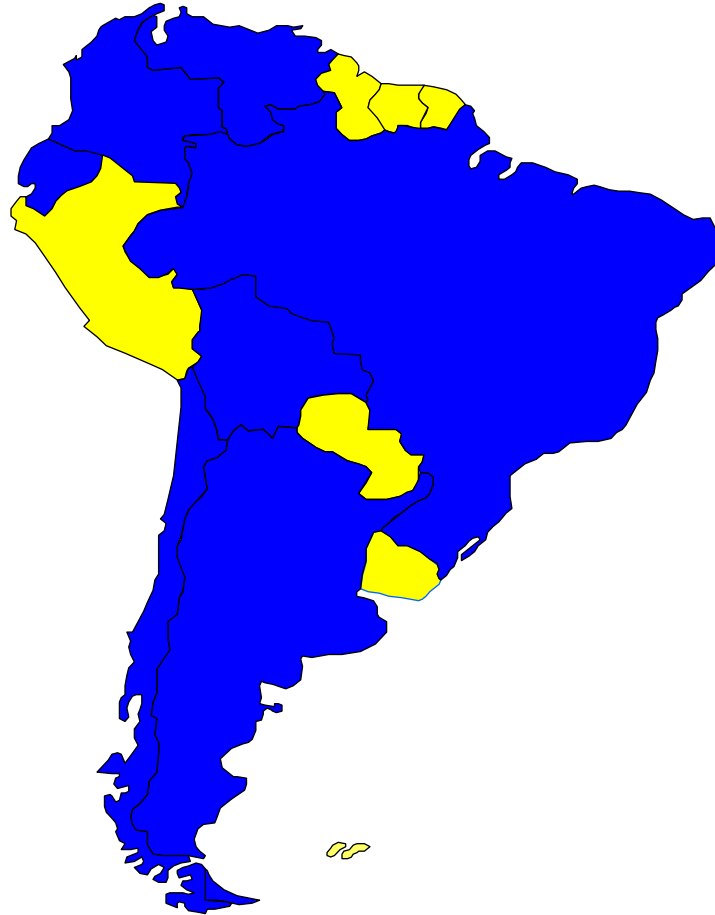
# Global Network for Women's and Children's Health Research

- Goals of the Global Network
  - Develop sustainable research infrastructures
  - Develop public health intervention capabilities
  - Strengthen international collaborative research

# Global Network for Women's and Children's Health Research

- Birth Defects Treatment and Prevention Program
  - Study of children born with cleft lip and/or cleft palate (CL/P)
  - 45 participating hospitals in 7 countries in South America
  - Palms used for data entry
- Bayley's Infant Neurodevelopmental Screener (BINS)
  - Tool used to measure infant development
  - Standardize its use in Spanish and Portuguese speaking countries
  - 50+ participating hospitals in 7 countries in South America
  - Palms used data entry, screening and randomly identifying subjects for follow up visits

# Participating Countries



# Getting Started

- Survey completed by each RRS (Responsible Reporting Specialist)
  - Configuration of the RRS's PC (Operating System)
  - Type and quality of Internet access
  - Technical experience of RRSs
- Project requirements
  - Multiple languages
  - Updates without interruption of data collection
  - Portable, accurate and easy to use in clinical setting
  - Sustainable



# Comparison of Personal Digital Assistants (PDAs)<sup>1</sup>

	<b>Palm</b>	<b>Pocket PC</b>
Cost	<b>X</b>	
Color Screen		<b>X</b>
Availability	<b>X</b>	
Speed		<b>X</b>
Screen Size		<b>X</b>
Memory		<b>X</b>
Development Tools	<b>X</b>	<b>X</b>
Experience	<b>X</b>	
Battery Life	<b>X</b>	
Market Share	<b>X</b>	

<sup>1</sup> Fall 2002

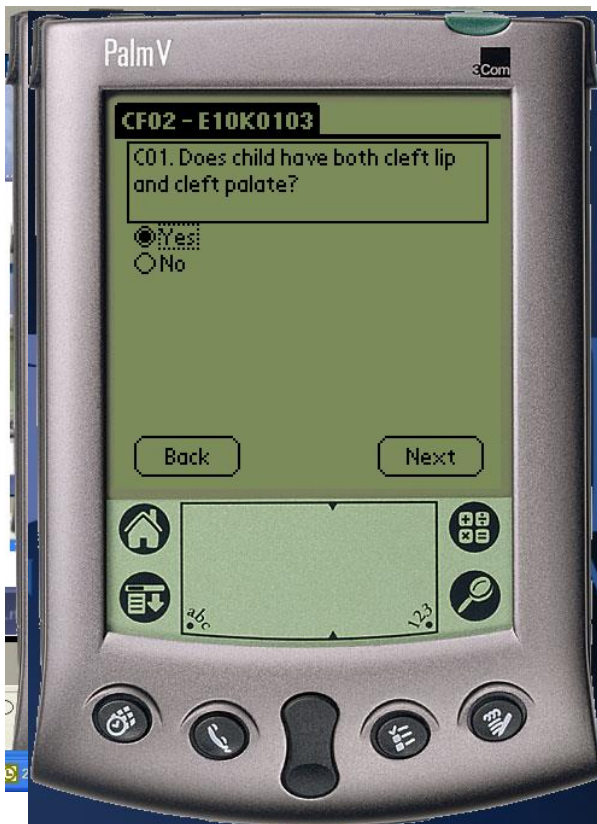
# Table Driven Design

- Database tables contain all question text, coded responses, and other screen text
- Flexible
  - Questions can be added, deleted, or updated by changing the table with a query or by replacing table
  - Allows changes to questionnaire without interruption to data collection

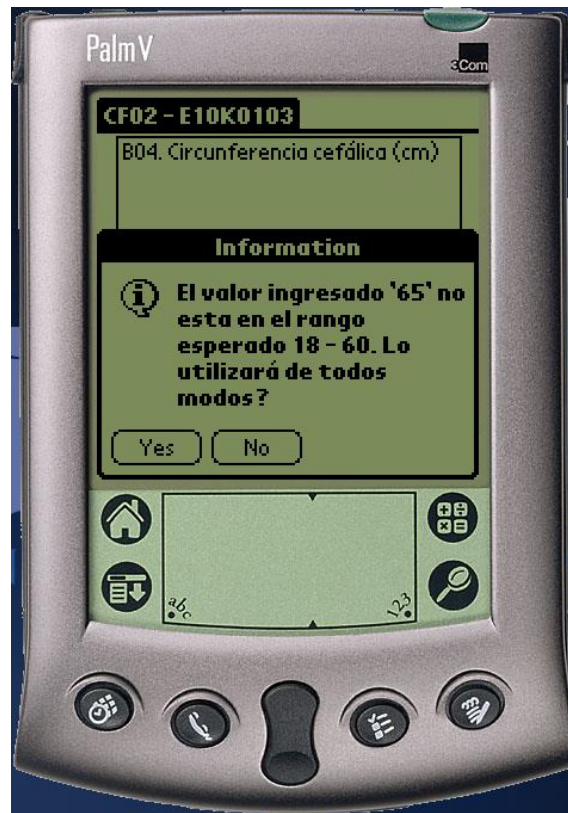
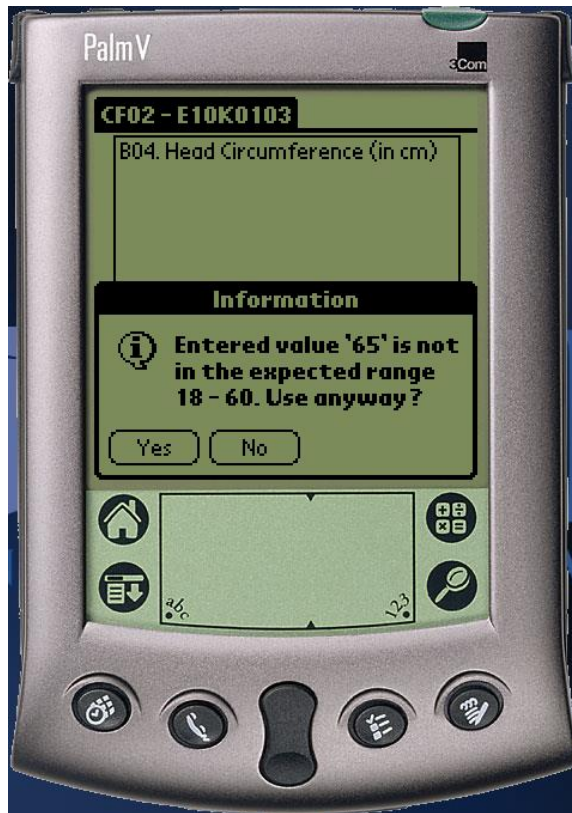
## Table Driven Design, *continued*

- Facilitates the inclusion of multiple languages
  - English, Spanish and Portuguese
- Produces high quality data
  - Gate questions/Skip logic
  - Range checks
  - Required fields

# Palm Entry Screens in 3 Languages



# DMS Error Messages in 3 Languages



# Palm Questionnaire Design

- Use gate questions to implement grids

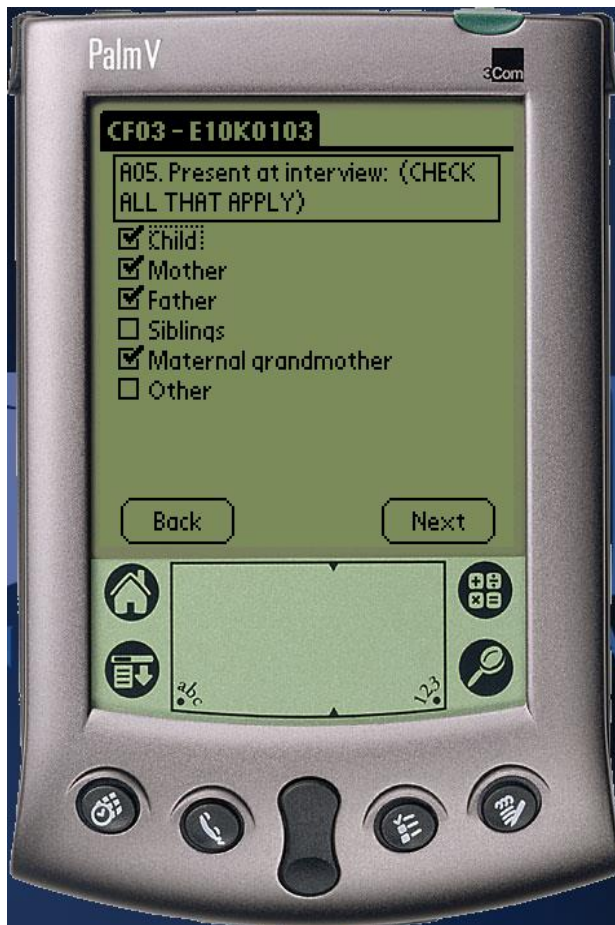
<b>SECTION B: HEALTH STATUS OF SIBLINGS</b>			
RECORD DATE OF BIRTH AND HEALTH STATUS OF EACH SIBLING. IF THERE ARE NO SIBLINGS, SKIP TO SECTION C TO COMPLETE THE FORM.			
#	a. DOB	b. Health Status	
		Does the child have a chronic health problem requiring medical treatment or hospitalization? If <b>Yes</b> , describe in the space provided (c.).	
1		1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No	c. _____ _____
2		1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No	c. _____ _____

<b>SECTION B: HEALTH STATUS OF SIBLINGS</b>	
RECORD DATE OF BIRTH AND HEALTH STATUS OF EACH SIBLING.	
1. Is there a sibling?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No    -> Skip to Section C
2. DOB of first sibling:	
3. Does the child have a chronic health problem requiring medical treatment or hospitalization?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No    -> Skip to B5
4. Describe chronic health problem requiring medical treatment or hospitalization.	
5. Is there a second sibling?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No    -> Skip to Section C
8. DOB of second sibling:	
9. Does the second sibling have a chronic health problem requiring medical treatment or hospitalization?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No -> Skip to Section C
10. Describe chronic health problem requiring medical treatment or hospitalization of second sibling.	

# Question Types

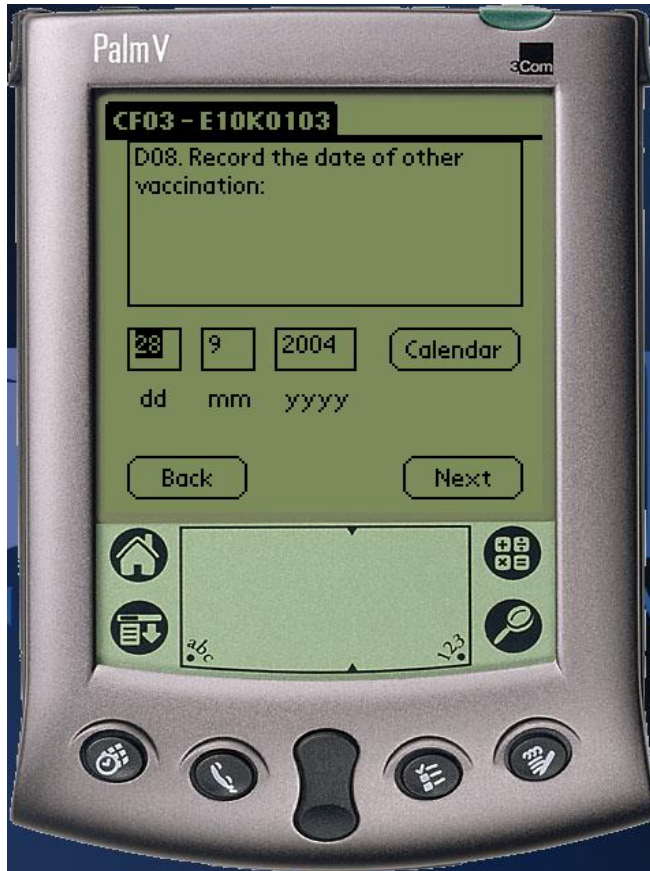
- Radio button (check only one)
- Checkbox (check all that apply)
- Date
- Calendar
- Numeric entry (with a range)
- Text entry
- Informational (no data entry, used to pass information or instructions to the user)

# Check box - Radio button

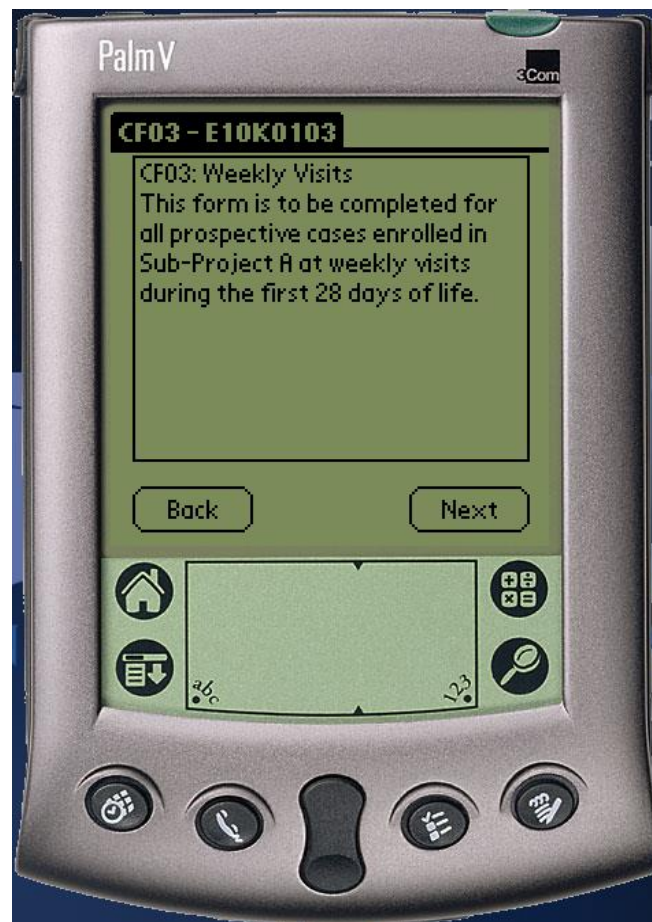
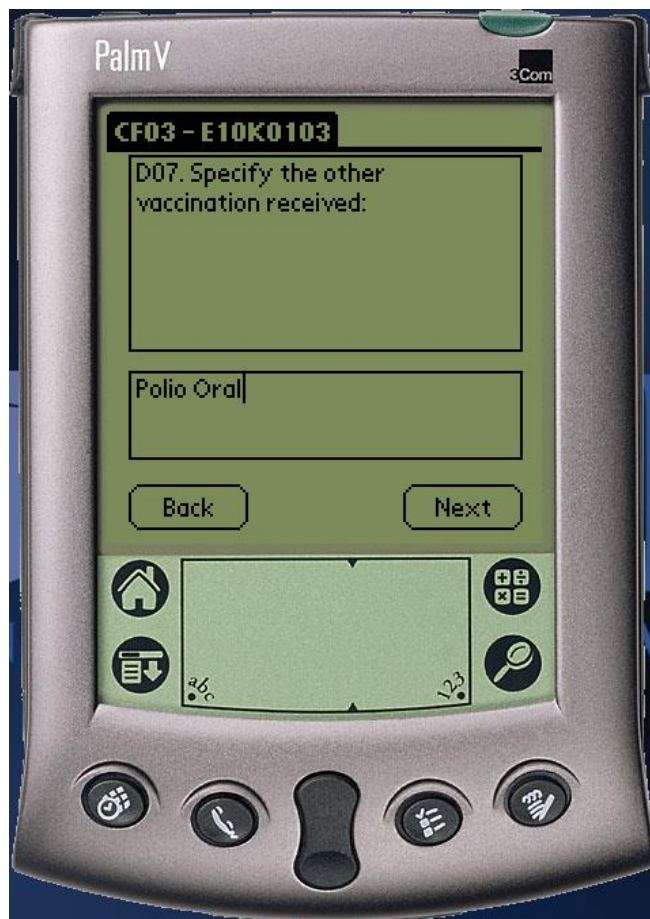




# Date - Calendar



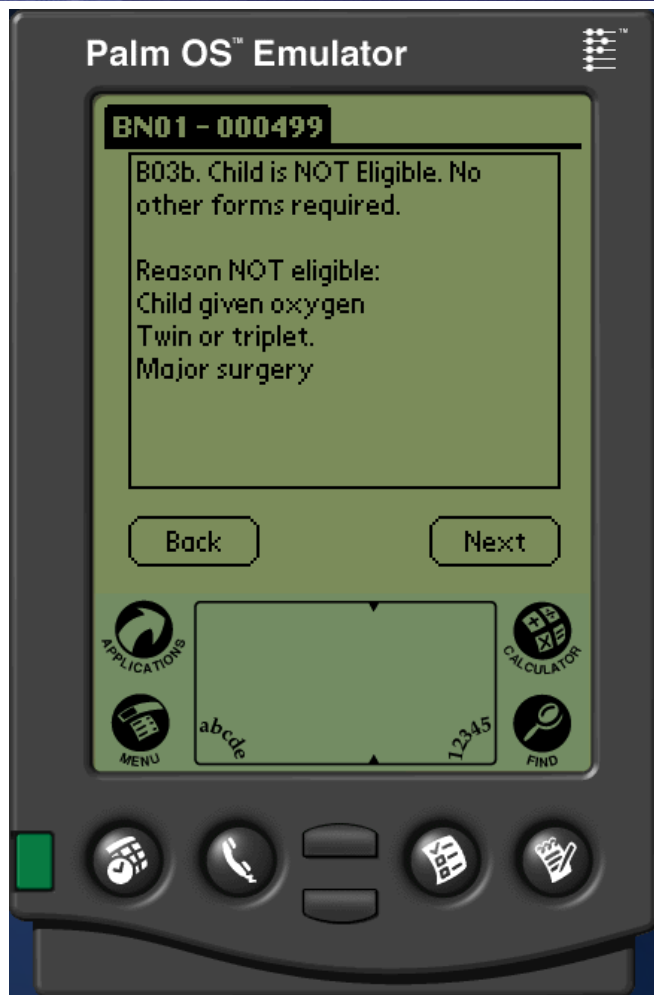
# Text entry - Informational



# Screening (BINS)

- Children in 6 age groups are screened into the study
  - 13 screening criteria including:
    - Birth weight
    - Apgar score
    - Complications
    - Multiple births
    - Consent
    - Gestational age

# Screening Forms



# Randomization (BINS)

- ~10 Participants enrolled per age group
  - 1 Selected for follow up visit
  - 1 Selected as a replacement if 1<sup>st</sup> follow up visit is not completed
- Mass distribution to unknown number of users
  - Unique seed required for each user

# Randomization for Follow Up



# Enrollment Report

Palm OS™ Emulator

**Enrollment Report**

Age	Se	Ex	En	Ne	Se	Ex	En	Ne
03-04	M	5	1	4	F	5	1	4
05-06	M	5	0	5	F	5	0	5
07-10	M	5	0	5	F	5	0	5
11-15	M	5	0	5	F	5	0	5
16-20	M	5	0	5	F	5	0	5
21-24	M	5	0	5	F	5	0	5

Se = Sex      En = Enrolled  
Ex = Expected      Ne = Needed

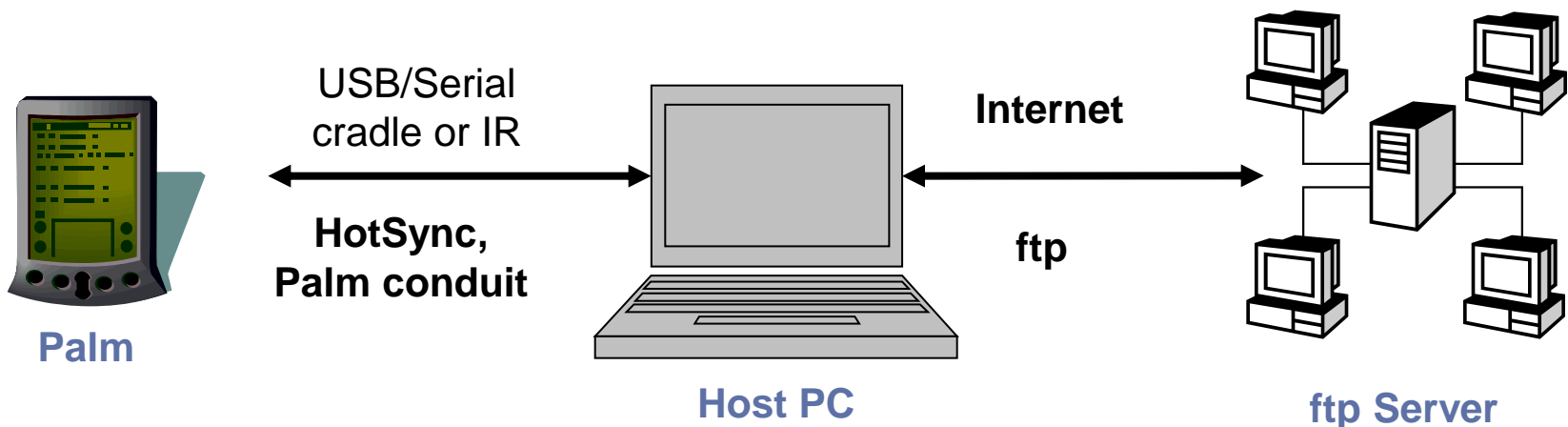
Back

APPLICATIONS      CALCULATOR  
MENU      FIND

abcde      12345

# Data Flow

- Data transmitted to RTI
- Software updates transmitted to users





# Training

- Extensive training on:
  - Palm use
  - GN Software
  - Review of data forms
  - Study procedures
  - Research ethics
  - Reporting of protocol violations and adverse events

# User Survey

<b>Table 3: Results of user survey</b>	<b>Percent</b>
Problems with using the Palm system	60
Have doubts regarding the use of the Palm devices	17
Have doubts regarding the use of the Global DMS program	23
Experienced difficulty transferring data to the FTP site	40
Recommend the use of the Palm system to other colleagues	93

RRS Survey of PDA Use, November 2003; number participating in survey=30

# Problems and Solutions

Issue	Solution
Difficulty installing the system	Contacted each user to work through problems and get them running
Hardware problems with the Palm	Purchased any required hardware and contacted user to complete installation
Lost battery power/systems	Reinforced the idea of keeping Palm charged, methods to reinstall files
Problems transmitting data to the FTP site	Worked with each user to find problem, suggested updates to internet software and provider
Varying Palm models	Purchased each type of Palm and tested
Communication	Be patient, work to be understood

# User Survey Responses

- How has the system assisted you in your work?
  - “It has helped me. I have data readily available in a user friendly system.”
  - “It helps me to fully complete records.”
  - “It has helped me a lot; however I still complete the paper forms.”
  - “Once you have it in your hand, it is very agile and easy to use. However, I prefer to use paper forms in front of the mother since using the Palm during an appointment for me is very cold, distant and impersonal.”

RRS Survey of PDA Use, November 2003; n=30

# Results to Date

- Birth Defects Treatment and Prevention Program (January 2003 Start)
  - Goal is 1800 Participants
    - 1050+ Enrolled
    - 3000+ Forms Completed
- BINS Study (January 2005 Start)
  - Goal is 3000 Participants
    - 35 Enrolled
    - 85 Forms Completed

# Recommendations

- Start on a small scale to find errors and problems early.
- Use in studies with frequent data collection
- Plan comprehensive training, with frequent follow-ups
- Aggressively monitor data to identify problems and provide timely solutions.
- Standardize equipment to save time on testing, deployment, and problem solving.

# Q & A

