Overview of Protocol Deviations: Summary and Trends to Date

MTN Annual Meeting
ASPIRE Protocol Team Meeting
February 10, 2013

Introduction

- Review of PD reporting process
- Summary of ASPIRE PDs to date
- Trends
- Questions

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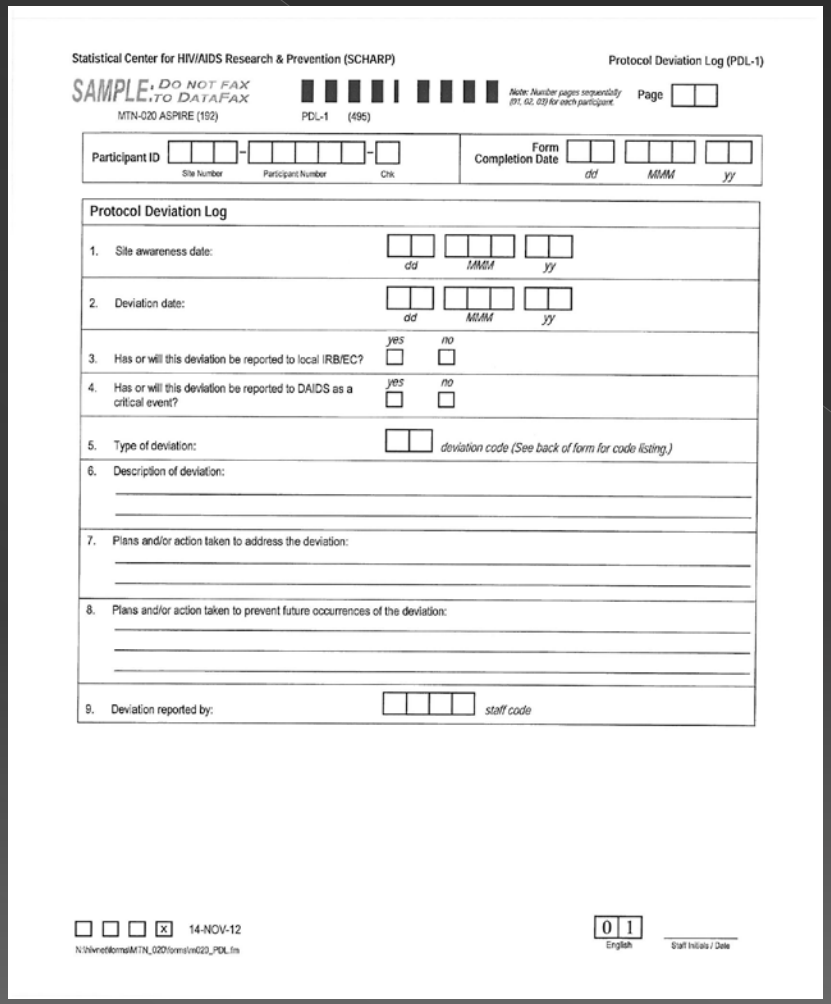
PD Reporting Process

- **Identify the PD**
  - Prospectively
  - Retrospectively
  - Prior to occurrence
- **Document the PD**
  - Site staff
    - No stipulation on who must document it, as long as it is recorded in the participant's study record
    - What works best at the site
- **Report the PD**
  - Complete PD CRF Log

Reporting



Statistical Center for HIV/AIDS Research & Prevention (SCHARP) — Protocol Deviation Log (PDL-1)

SAMPLE: DO NOT FAX TO DATAFAX

MTN-020 ASPIRE (192) PDL-1 (495)

Note: Number pages sequentially (01, 02, 03) for each participant. Page ☐☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number - Participant Number - Chk)

Form Completion Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy)

Protocol Deviation Log

1. Site awareness date: ☐☐ ☐☐☐ ☐☐ (dd MMM yy)
2. Deviation date: ☐☐ ☐☐☐ ☐☐ (dd MMM yy)
3. Has or will this deviation be reported to local IRB/EC? yes ☐ no ☐
4. Has or will this deviation be reported to DAIDS as a critical event? yes ☐ no ☐
5. Type of deviation: ☐☐ *deviation code (See back of form for code listing.)*
6. Description of deviation:
7. Plans and/or action taken to address the deviation:
8. Plans and/or action taken to prevent future occurrences of the deviation:
9. Deviation reported by: ☐☐☐ *staff code*

☐☐☐☒ 14-NOV-12

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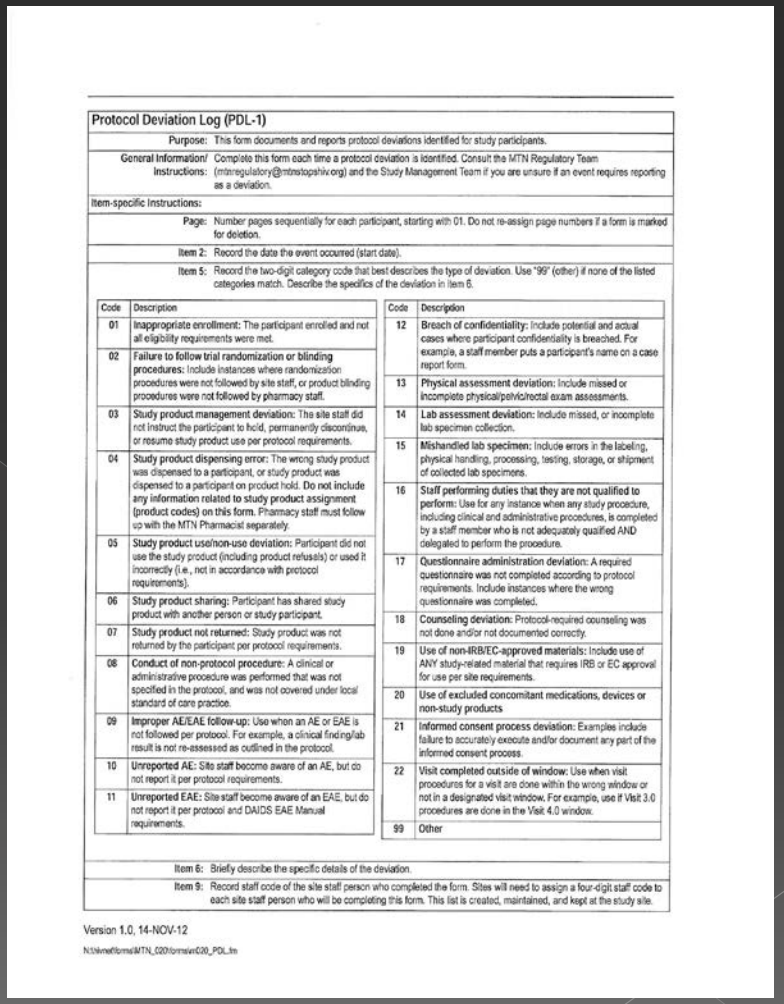
0 1 English Staff Initials / Date



Protocol Deviation Log (PDL-1)

Purpose: This form documents and reports protocol deviations identified for study participants.

General Information/ Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.

Item-specific Instructions:

Page: Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.

Item 2: Record the date the event occurred (start date).

Item 5: Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in Item 6.

Code	Description
01	**Inappropriate enrollment:** The participant enrolled and not all eligibility requirements were met.
02	**Failure to follow trial randomization or blinding procedures:** Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
03	**Study product management deviation:** The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	**Study product dispensing error:** The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff must follow up with the MTN Pharmacist separately.
05	**Study product use/non-use deviation:** Participant did not use the study product (including product refusals) or used it incorrectly (i.e., not in accordance with protocol requirements).
06	**Study product sharing:** Participant has shared study product with another person or study participant.
07	**Study product not returned:** Study product was not returned by the participant per protocol requirements.
08	**Conduct of non-protocol procedure:** A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
09	**Improper AE/EAE follow-up:** Use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.
10	**Unreported AE:** Site staff become aware of an AE, but do not report it per protocol requirements.
11	**Unreported EAE:** Site staff become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.
12	**Breach of confidentiality:** Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
13	**Physical assessment deviation:** Include missed or incomplete physical/pelvic/rectal exam assessments.
14	**Lab assessment deviation:** Include missed, or incomplete lab specimen collection.
15	**Mishandled lab specimen:** Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
16	**Staff performing duties that they are not qualified to perform:** Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
17	**Questionnaire administration deviation:** A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
18	**Counseling deviation:** Protocol-required counseling was not done and/or not documented correctly.
19	**Use of non-IRB/EC-approved materials:** Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
20	**Use of excluded concomitant medications, devices or non-study products**
21	**Informed consent process deviation:** Examples include failure to accurately execute and/or document any part of the informed consent process.
22	**Visit completed outside of window:** Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window.
99	Other

Item 6: Briefly describe the specific details of the deviation.

Item 9: Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

Version 1.0, 14-NOV-12

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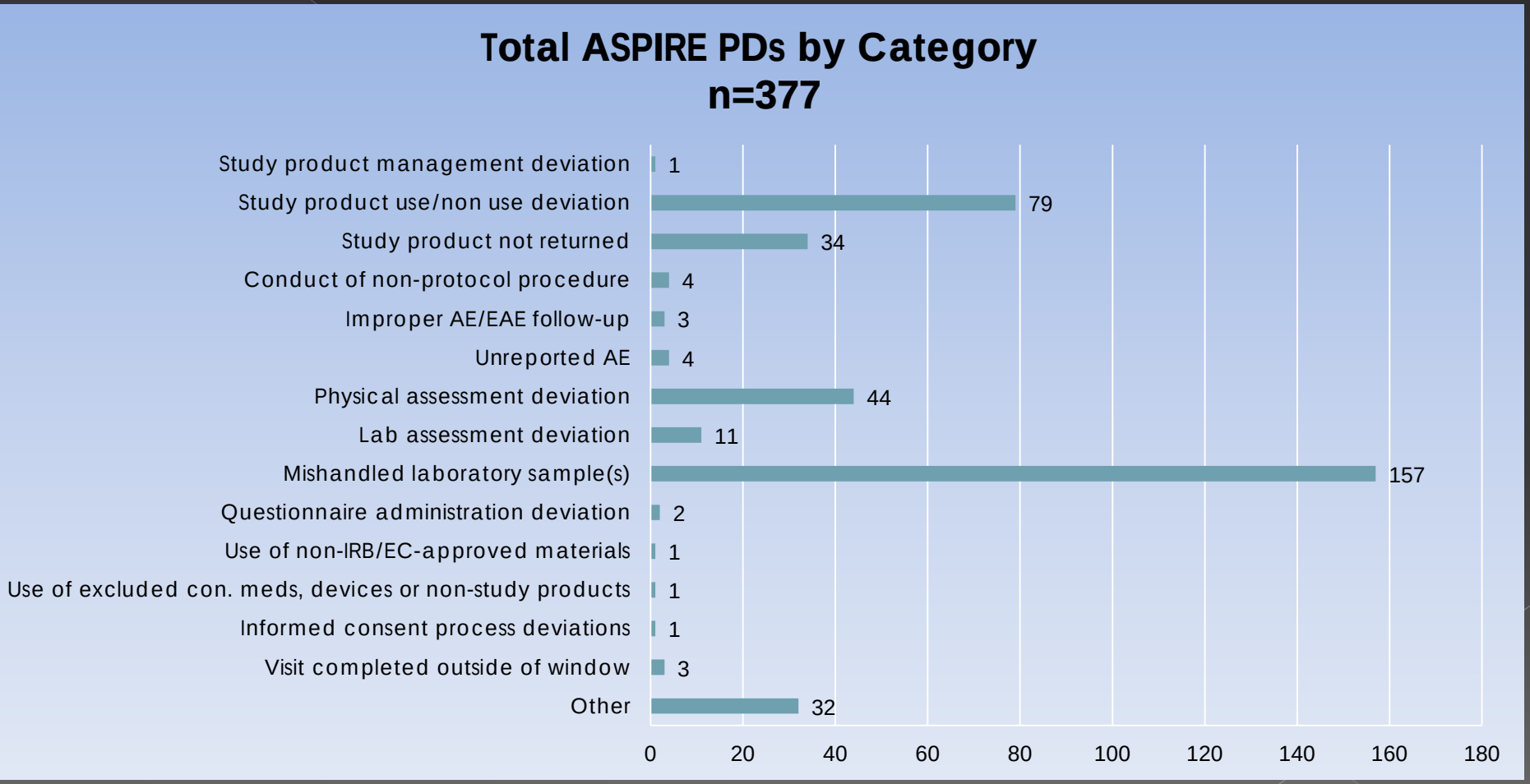
ASPIRE PD Summary and Trends



Summary and Trends

- 377 PDs reported thus far
- Three most commonly reported PDs
  1. Mishandled Laboratory Sample Deviation 42%
  2. Study Product Use/Non Use Deviation 21%
  3. Physical Assessment Deviation 11%
- Constitute 75% of all reported PDs in ASPIRE
- 2 PDs (~ .5%)have been reported to DAIDS as potential Critical Events thus far

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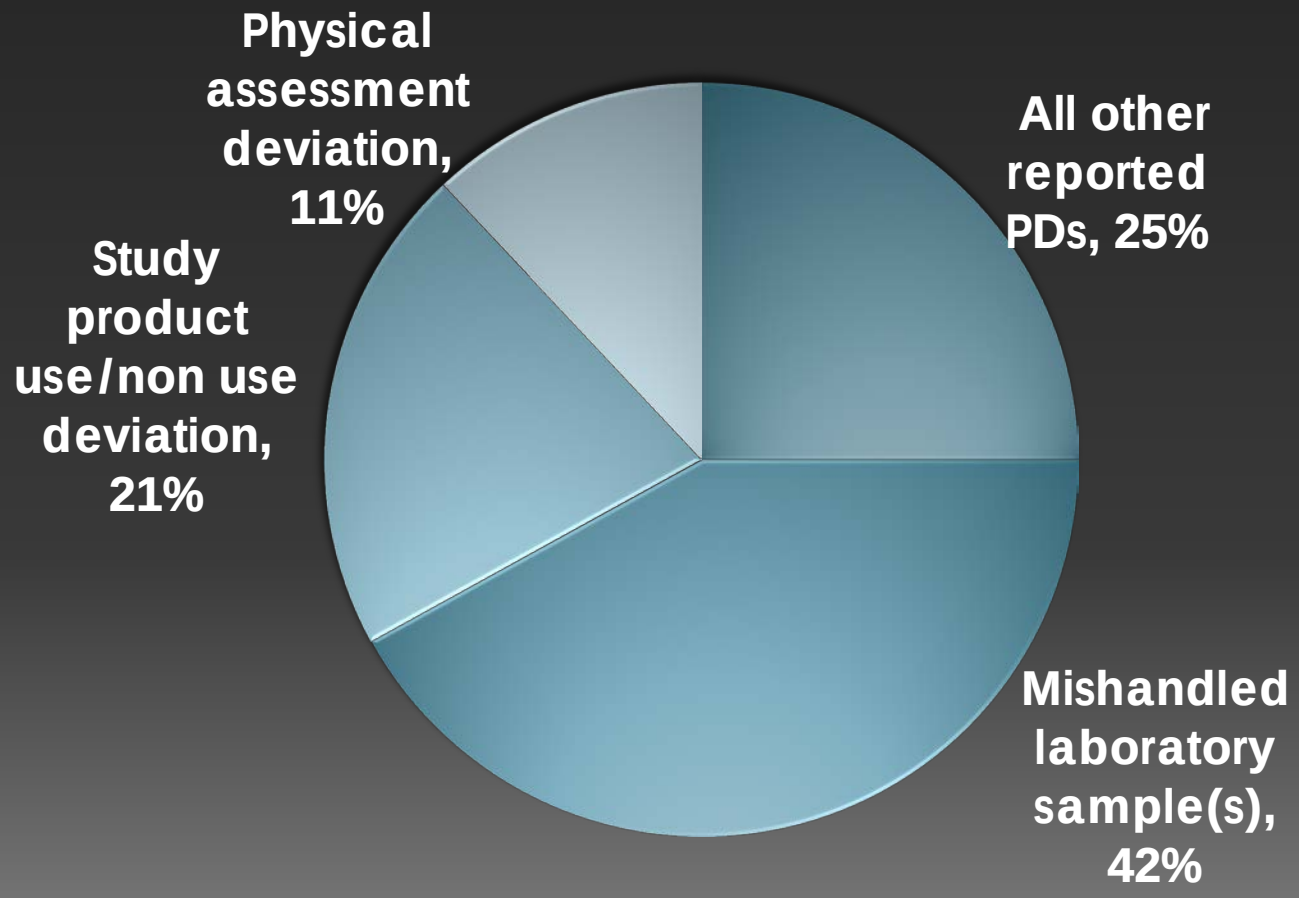
Summary and Trends



Summary and Trends

- **FDA's "Most Commonly Cited PD's*" are:**
  - **Inappropriate enrollment (participant failed to meet eligibility criteria)**
  - **Physical assessment deviation (incomplete, incorrect, and/or missed assessment)**
  - **Laboratory evaluation deviation (incomplete, incorrect, missed evaluation and/or review of laboratory results/reports)**
  - **Study product non-adherence**

**** FDA site inspections occurring during 2008 and early 2009***

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Summary and Trends

Laboratory evaluation deviation	• Mishandled Laboratory Sample Deviation (42%)
Study product non-adherence	• Study Product Use/Non Use Deviation (21%)
Physical assessment deviation	• Physical Assessment Deviation (11%)

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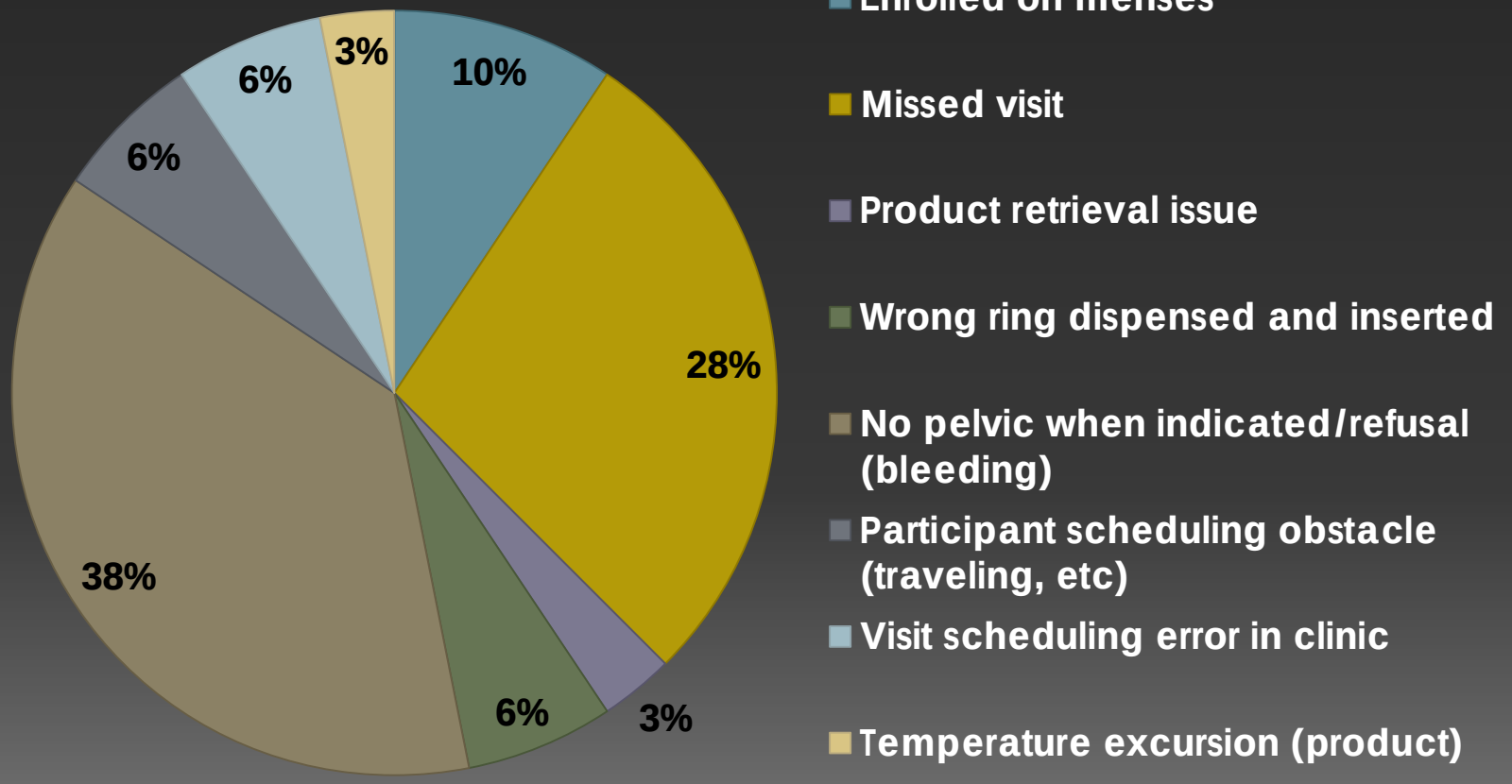
Breakdown of "Other" PDs

n=32



Questions & Discussion

Thank you!