Investigating Cervical Cancer Among Women Living with HIV

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Conflict Statement

I do not have any conflicts of interest to declare for this presentation.

Presentation Outline

- Background
- Purpose of the Study
- Study Design
- Preparation for the Study
- Plan Do Study Act (PDSA)
- Challenges to Implementation
- Review of Adopted Strategies
- Successes
- Recommendations
- Lessons Learned

Background

- In 2017, awarded a postdoc fellowship from the Global Health Equity Scholars program under the National Institutes of Health (NIH).
- Execute research within a low- or mid-income level country on issues that align with funding priorities at NIH.
- Eligibility criteria includes sponsorship by an in-country institution, commitment from mentors, 10-month research plan, and peer-reviewed selection.

Study setting - Clínica de Familia La Romana

- Primary care clinic
- Treatment and prevention of STIs
- 30,000 patients
- ≈2,000 living with HIV

Background - Problem

- Cervical cancer is an AIDS-defining condition in HIV-infected women. [1-4]
- Consistent Papanicolaou testing is effective for detection and treatment but used inconsistently in low- and middle-income settings.[5,6]
- National guidelines in the Dominican Republic recommended this exam annually for high-risk groups. [7]
- Prior research found that in Clínica de Familia La Romana (CFLR), ~half of women referred did not attend their referrals. [11]

Purpose of the Study

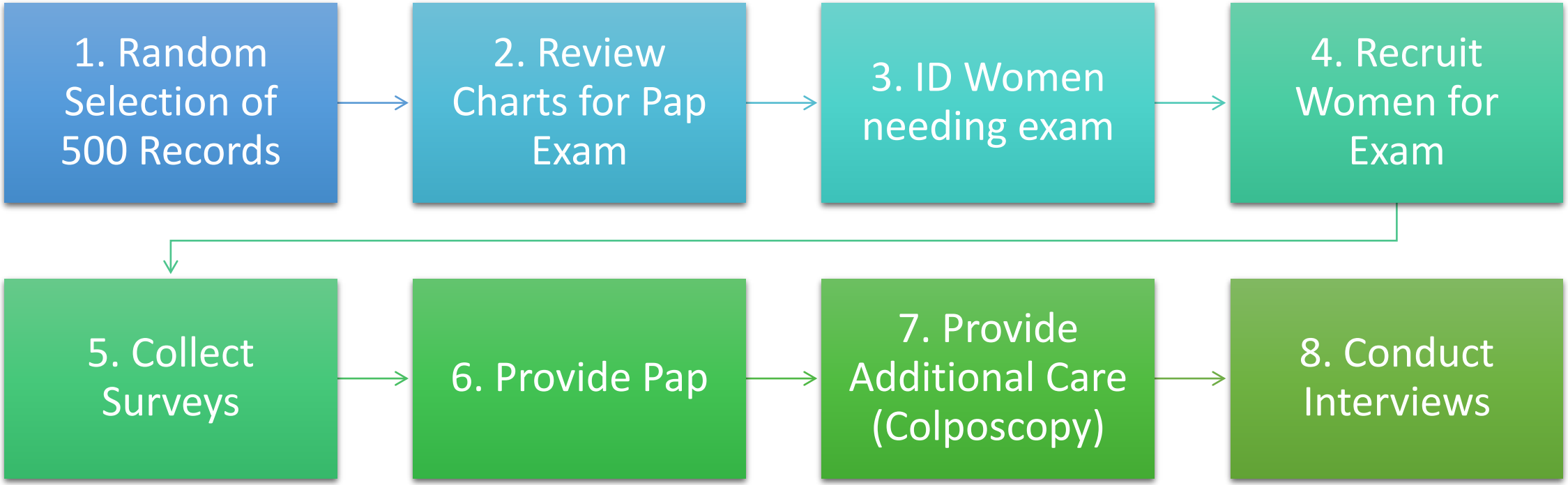
AIM 1	AIM 2	AIM 3
Estimate the proportion of HIV-infected women enrolled in the clinic aged >18 years who are due/overdue for cervical cancer screening.	Estimate proportion of HIV-infected women tested who had abnormal Thin Prep or HPV subtype testing and identify factors associated with these abnormalities.	Identify factors associated with non-attendance at specialized care.

Study Design

Data collected in three (3) phases

- ***Phase 1 Chart Reviews***
  - ID patients needing Papanicolaou (Pap)
- ***Phase 2 Patient Surveys***
  - Provide Pap to patients
  - ID patients needing additional services
- ***Phase 3 Patient Interviews***
  - Patients needing colposcopies, etc.

Study Implementation Steps



Preparation to Engage with the Clinic

Enrolled in Spanish-language classes in the US while preparing IRB application.

Enrolled in Spanish-language classes in the Dominican Republic during the delay in IRB approval from US and the DR.

Spent six months immersed in another clinic engaging with the providers and patients, trained staff on research methods, and directed a clinic-led service investigation.

Plan Do Study Act (PDSA) – Onsite Prep

Introduced the study to the entire clinic.

Performed community visits with the CHWs/Navigators

Completed a process flow assessment of patients in clinic.

Observations

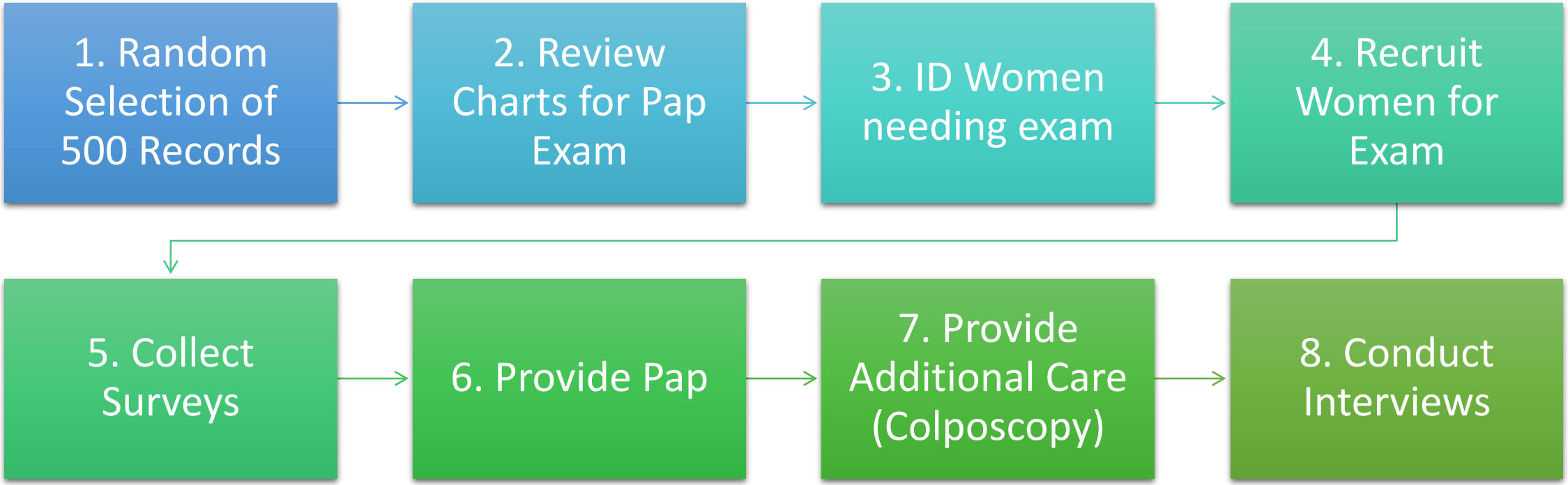
Interviews with key staff

Interviews with mentor and clinic administrators

Established work area within the common area dedicated for visiting researchers.

Assigned dedicated space for Phases 2 and 3 (*surveys* and *interviews*).

Study Implementation Steps



PDSA – Implementation

- **Challenge obtaining the randomly selected records for Phase 1**
  - Construct a master list of all record numbers for women 18+ diagnosed with HIV
  - Finding the randomly selected records from the list
    - ✓ Working with paper files (just beginning EMR)

- **Recruitment process not aligned with operations**
  - **Timing** - not sure when to approach patients
  - Making **appointments did not work**
  - **Incomplete contact information** for patients was common (only captured once by the National office)
    - ✓ May contribute to a greater issue of loss-to-follow up

PDSA – Implementation

- **Encountered process and structural complications**
  - Unclear process in place to monitor samples sent to the centralized lab
  - Pilot testing a new laboratory for the clinic
  - Inconsistent and incomplete annotation in patient records (testing, procedures)
  - Errors in patient contact information

PDSA – Assessment

- **Initial plan did not fit the operation of the clinic.**
- **I needed help and was not the best person to collect the data.**
- **Completion of this study depended on me first addressing issues of process and structure.**
  - ✓When to approach a patient in the clinic?
  - ✓How to contact patients for Phases 2 and 3 of the study?
  - ✓How to get samples collected and returned to the clinic?
- **I needed better buy-in and marketing.**

Strategies that Changed the Tide (Acts)

- ✓**Hired a research assistant.**
- ✓**Used Neon Pink Paper in patient records.**
- ✓**Worked on the clinic floor with the line staff and gate keepers.**
  - ➢(nurses, patient navigators, and medical records dept.)
- ✓**Enlisted an onsite advocate.**

Strategies that Changed the Tide (Acts)

- ✓**Worked with the Medical Director to formalize a process for collecting lab samples internally.**
- ✓**Established a delivery process and schedule for lab samples.**
  - ✓Dedicated delivery person and obtained his cell phone number
- ✓**Explained to key gatekeepers that the project paid for colposcopies.**
- ✓**Increased my visibility.**

Successes - Enrollment from Medical Records (Phase 1)

1,038 women received treatment for HIV

537 records randomly selected for this study

372 records contained sufficient data for inclusion in Phase 1

327 women were eligible for a Papanicolaou examination

95 of the eligible women received the Papanicolaou examination

Successes

We successfully identified women who needed this exam.

Diagnosed cervical cancer in one patient.

- *-- possibly saved her life*

Lessons Learned - Benefits

Review	Connect	Market	Village
Performing the chart review was a needed exercise for the clinic.	Communication creates buy-in.	Sharing and linking are opportunities to market the project.	Research that has tangible direct benefits can create support.

Lessons Learned – Solutions

Explore

Established buy-in with vendors and all stakeholders.

- **Verbal MOU**

Collaborate

Linked to existing projects within the clinic.

Expand

Recognized and involved front-line staff as an integral part of the project.

- **Often overlooked**

Recommendations – For Study

Explore	Plan
Link enrollment and outreach to other projects at the clinic.	**Consider alternative scenarios and have intermediate checks about the implementation.**

Recommendations – For Clinic

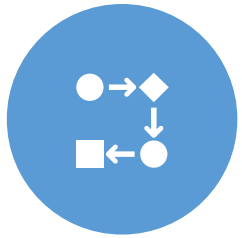
Develop	Revise	Explore
Audit and consistently update patient records. • **May address the continued issue of loss-to-follow up**	**Revise current record keeping for screening exams.**	**Explore dialog with National office on how information is documented at intake.**

Recommendations – Future Studies

WORK WITH LOCAL PARTNER TO ENSURE STUDY DESIGN WORKS WITHIN THEIR CLINICAL PROCESS

CONSTANTLY MONITOR INITIAL DATA COLLECTION TO ENSURE DATA IS BEING COLLECTED APPROPRIATELY

FIND A LOCAL CHAMPION WHO SPEAKS THE LANGUAGE AND CAN HELP YOU NAVIGATE AROUND OBSTACLES



DEDICATE TIME TO UNDERSTAND THE CLINIC'S FLOW, PROCESS, AND CULTURE

FLEXIBILITY RATHER THAT RIGIDITY

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Any questions?