Feasibility and Acceptability of Hair- and Dried Blood Spot-Derived ARV Biomarkers as Objective Measures of Treatment Adherence in South Africa

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INTRODUCTION

- ART adherence research and clinical care hampered by lack of objective measure of medication adherence
- Current strategies: unannounced pill counts, electronic monitoring devices, pharmacy records
  - **Do not** measure actual ingestion
- Newer strategies: drug levels in hair and blood
  - **Do** measure ingestion over the course of approx. several weeks

MONITORING ARVs IN BLOOD AND HAIR

- Two important aspects of objective measures of ART adherence should be that they
  - impose minimal burden on patients/research participants and on healthcare systems
  - be usable in a variety of settings (e.g., clinic, home)

- Dried blood spot (DBS) and hair samples are
  - Minimally invasive (DBS) or non-invasive (hair)
  - Usually considered minimal risk
  - Inexpensive to collect (i.e., materials and personnel)
  - Suitable for repeated sampling/ongoing monitoring

RESEARCH QUESTIONS

- How acceptable and feasible to patients are collecting hair and blood samples?
  - How burdensome/painful are giving regular samples?
  - Could collection occur at the clinic and at home?
  - Could patients collect DBS by themselves?
  - Are there concerns about the use of one's blood and hair samples?

SETTING

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PARENT STUDY

- Sub-sample of participants in the Masivukeni ART adherence RCT
  - NIMH-funded RCT of a laptop-based, multimedia and interactive ART adherence intervention
  - HIV+ adults initiating ART in Cape Town health clinics
  - Monitored via Wisepill

PILOT METHODS

- Eligibility
  - Enrolled in Masivukeni
  - On first line ART regimen (e.g., Atroiza or Odimune containing tenofovir) for 1-2 months
  - Attend 5 study visits, one month apart
  - Provide hair and blood samples at each visit

PILOT METHODS

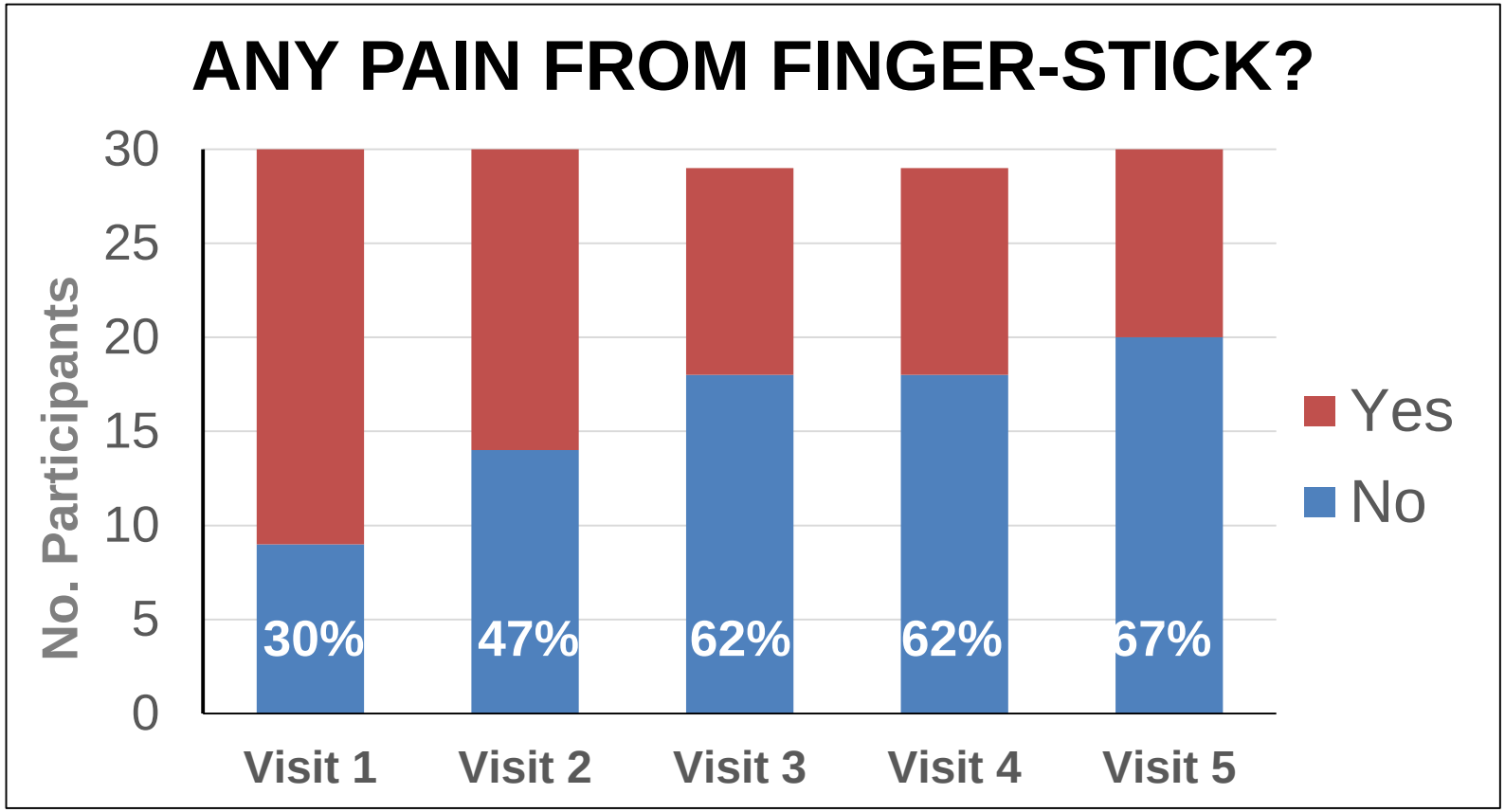
- At each monthly visit, nurse collected
  - Finger-stick for DBS sampling
  - Hair sample (approx. 100 strands)
  - Brief survey
- R300 (≈$30) incentive for each study visit

PROCEDURE

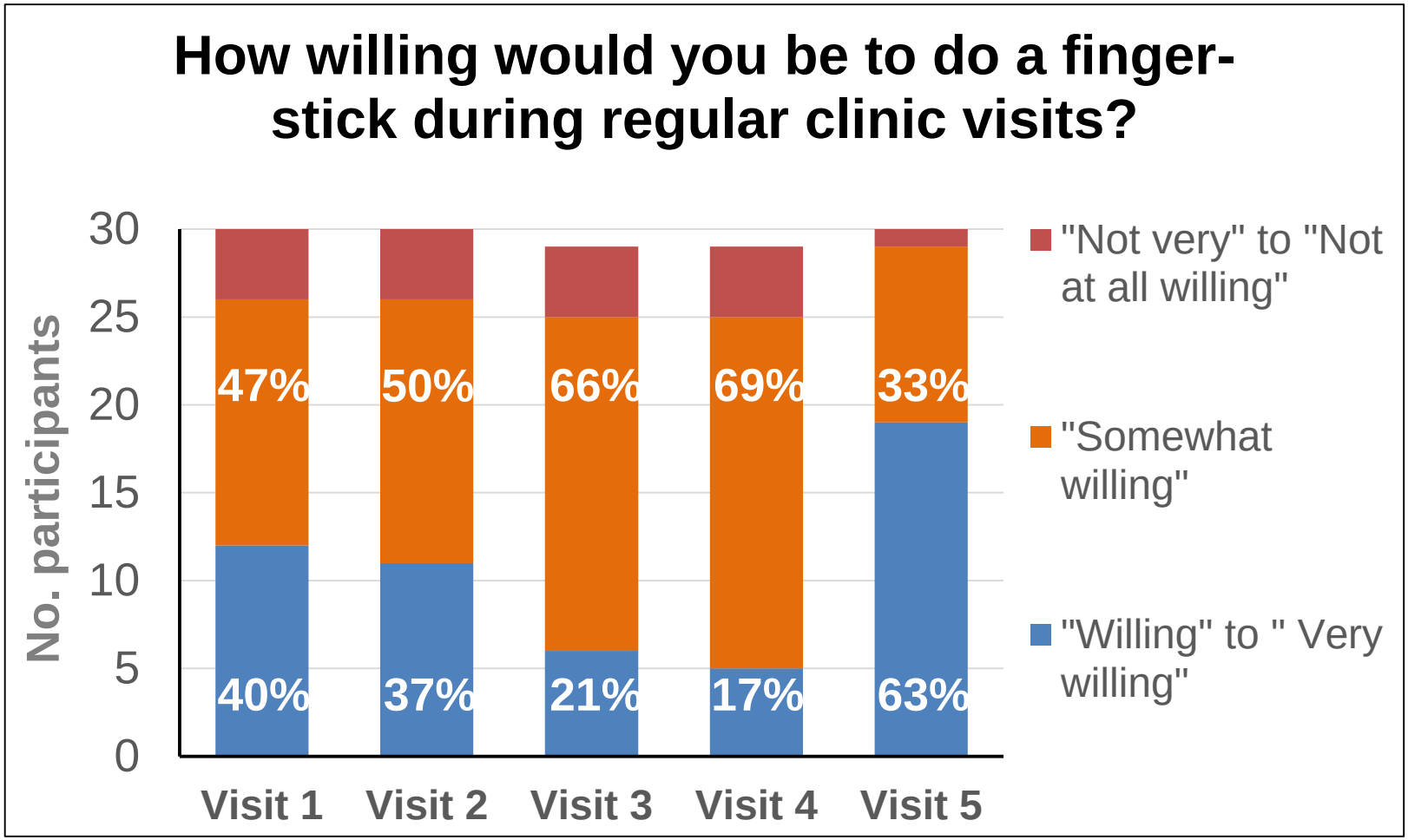
RESULTS: PARTICIPANT CHARACTERISTICS

- 30 participants enrolled
- Demographics
  - 90% women, 100% Black African
  - Mean age: 30 years (SD=5.25)
- 28 participants completed all 5 study visits; 2 completed 4 visits
- 148 total finger-stick and hair collection samples
- 148 completed surveys

RESULTS: PAIN FROM DBS



RESULTS:
WILLINGNESS TO DO DBS REGULARLY



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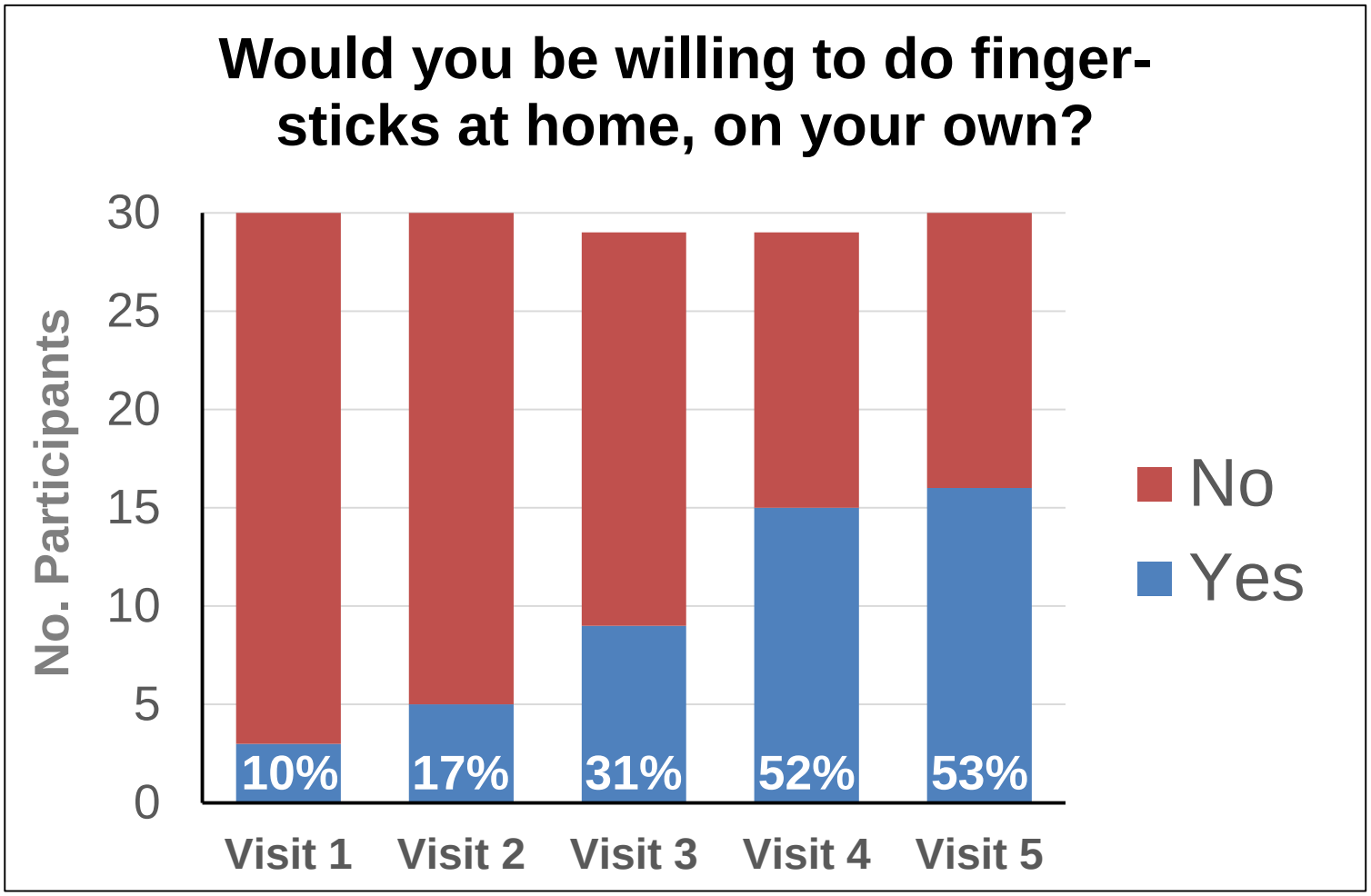
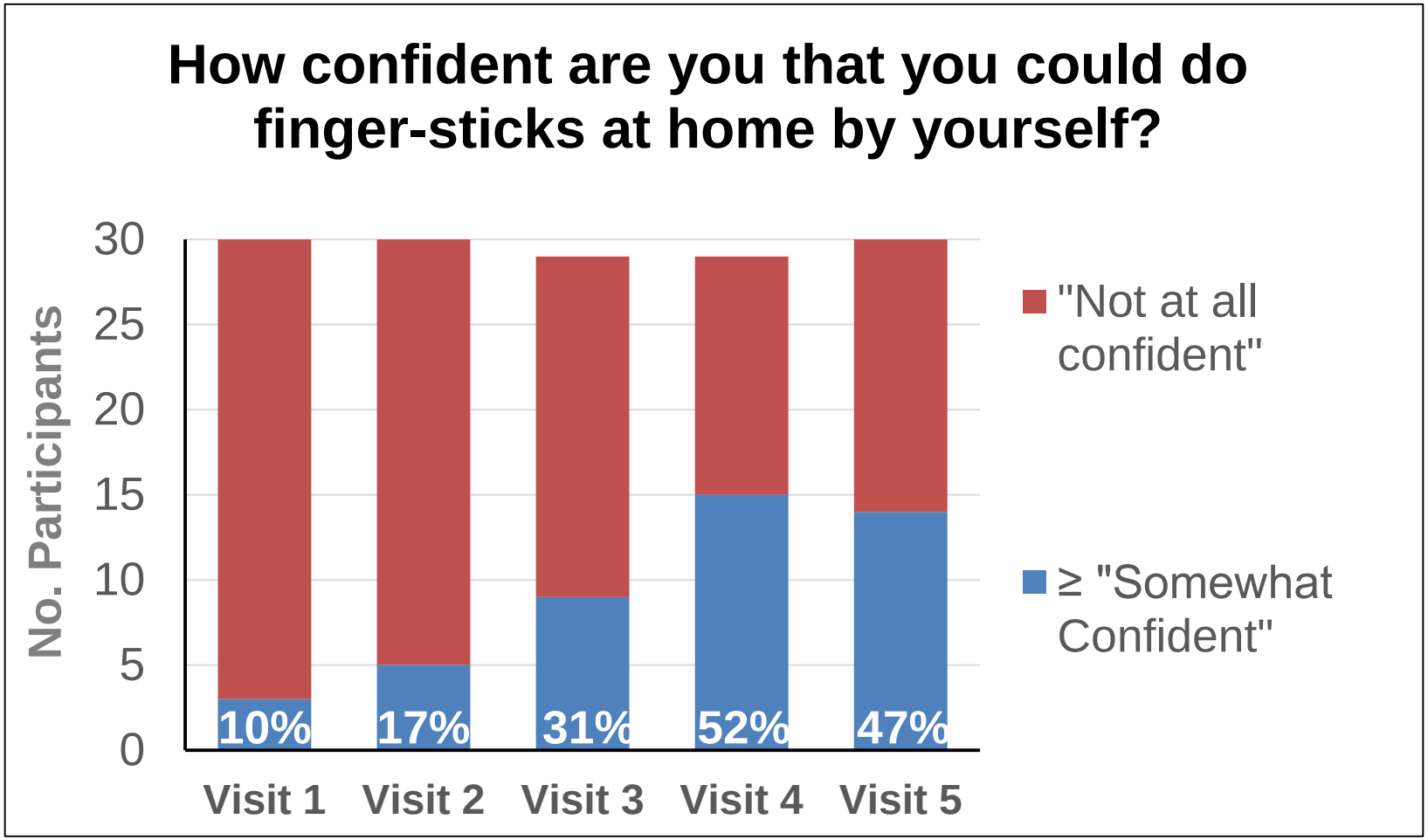
RESULTS:
WILLING TO TO DBS AT HOME



RESULTS:
CONFIDENCE DOING DBS BY SELF

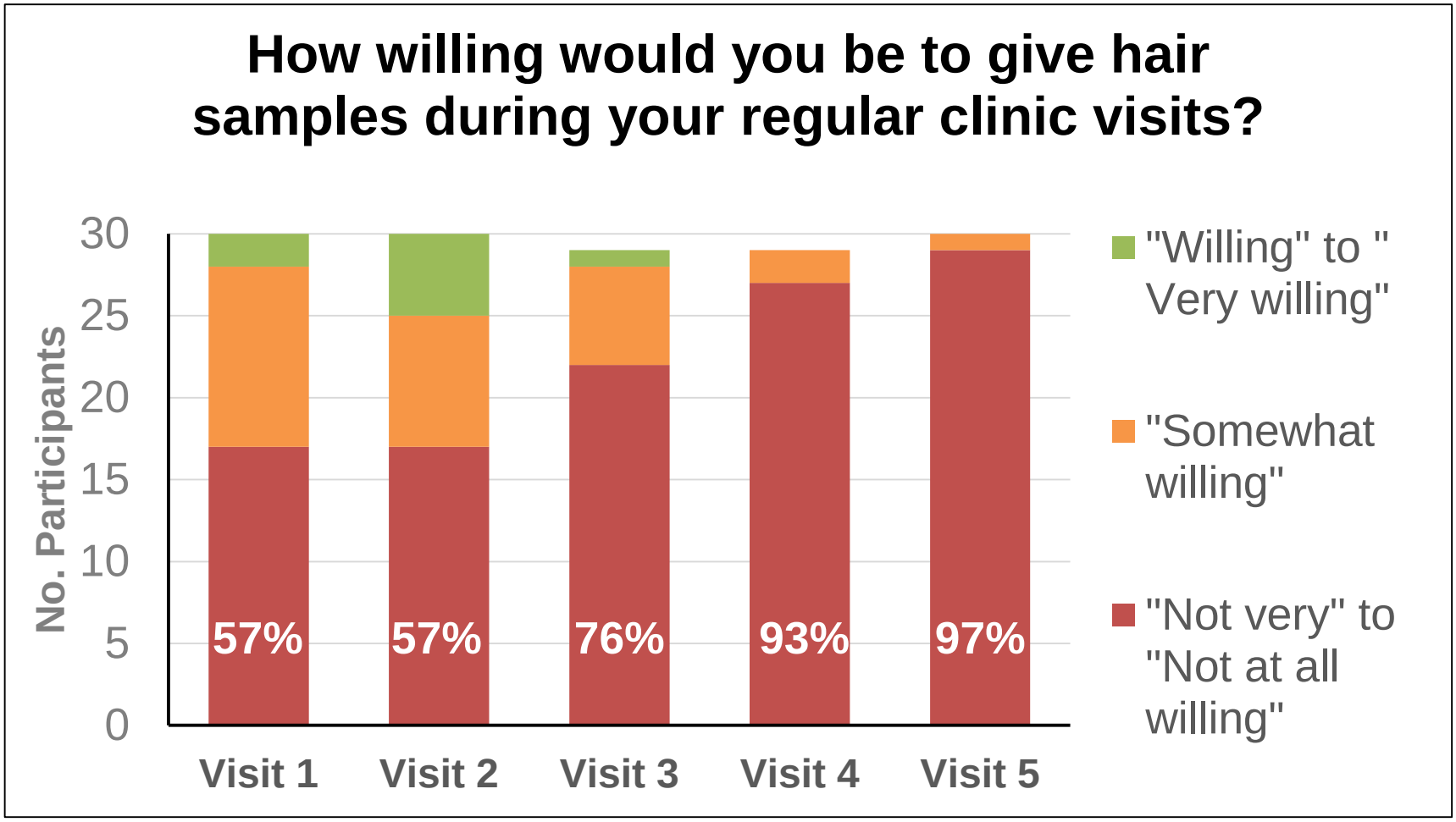


RESULTS:
DBS ACCEPTABILITY AND FEASIBILITY

- What was it like for you to have your finger pricked and give blood samples today?
  - Most responses: “a little painful”, “slightly sore”, “wasn’t too bad”, “wasn’t painful”

- Throughout all visits, ≥ 90% of participants reported willingness to have a health worker come to their home to do finger-stick.

RESULTS:
WILLINGNESS TO GIVE HAIR REGULARLY



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RESULTS:
HAIR ACCEPTABILITY AND FEASIBILITY

- No one at any point reported experiencing any pain from the hair collection procedure
- What was it like for you to give a hair sample today?
  - Most responses: “fine,” and “okay”. One participant responded “a bit stressful,” another, “I’m just worried my hair isn’t growing quickly enough.”

RESULTS:
CONCERNS ABOUT USE OF BIO-SAMPLES

- No participant at any visit reported concerns about long-term storage and future use of their hair or blood samples

CONCLUSIONS

- Finger-stick for DBS was acceptable to most patients and may be feasible in resource-limited settings
- Hair samples were less acceptable than DBS, especially for regular and repeated collections
- Repeated exposure to procedures appeared to increase willingness and confidence for DBS sample collection by the patient her/himself at home
- Further studies might examine the setting of sampling, and potential barriers to more widespread use in clinical practice
- Research is needed to evaluate the ability of tenofovir DBS to measure ARV adherence

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