

Feasibility, performance and acceptability of the Wisebag™: a Pilot Study

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The MTN Wisebag study: a pilot of VOICE (MTN-003-P01)

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- J. Piper (Medical officer)

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- G. Nair (Site investigator)
- D. Pillay
- A. Naidoo

□ **MTN Core**

- B. Galaska Burzuk

□ **FHI**

- K. Richards
- L. Levy

Background



Wisebag™ (Wisepill Technologies, SA)

- Innovative Events Monitoring Device (EMD) pill technology adapted for applicator retrieval monitoring
- Advantage:
 - Real time objective measure (opening events of a bag)
 - Provide information on pattern of use (date, time etc..)
 - Can include an adherence intervention (SMS reminders)
- Limitations:
 - Indirect measure (assess opening events)
 - Can underestimate (pocket doses) or overestimate use
 - Logistics of using/returning Wisebag to clinic
 - Cost

CAPRISA Wisebag study (N=10)

CAPRISA WISEBAG DISPENSER



PARTICIPANT CELLPHONE

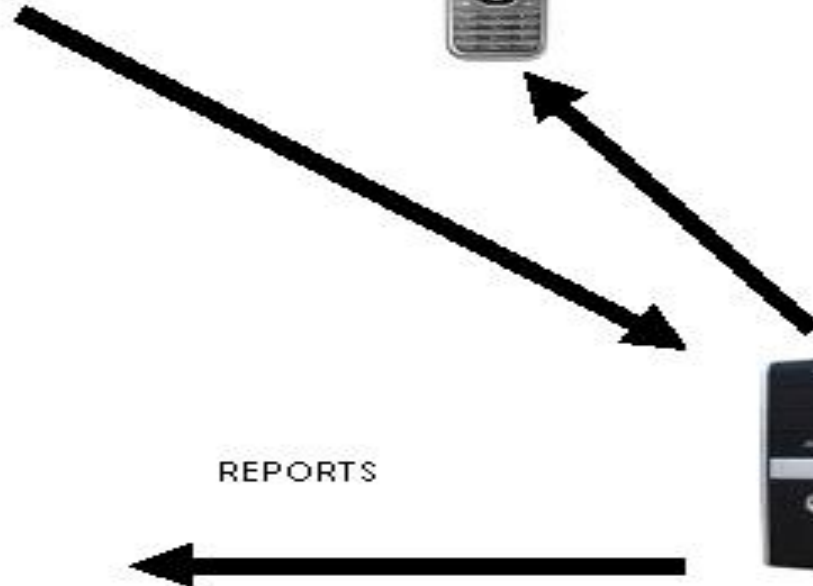


CAPRISA WISEBAG
DATABASE

REPORTS



WISEPILL WEB SERVER



Rationale

- Online Wisebag provides real-time data on opening events, but is expensive to roll out on a large scale
- Blinding of dummy vs active Wisebag
 - Receiving a Wisebag is “an intervention”, so can all ppt at a site receive a Wisebag (dummy or active) while keeping cost lower?
- Functional performance of offline vs. online device
 - Online feature only needed if you want real time data
 - Offline is lower cost, but at prototype stage
- Acceptability of daily Wisebag use

Study Objectives

- Blinding success of active vs. dummy Wisebag?
- Technical performance and user problems with Wisebag
- Participants' adherence to and acceptability of daily use



Active vs Dummy device BLINDED

Study Design

- HIV (-) VOICE screen-outs aged 19-42
- 50 ♀ blinded and randomized (2:2:1)
to 3 EMD types:
 - Online Wisebag (n=20); (\$200 per unit)
 - Offline Wisebag (n=20); (\$80 per unit)
 - Dummy Wisebag (n=10); (\$20 per unit)
- Regimen:
 - No study product
 - Open WB daily, peel off a sticker, place on diary card
- Duration: 14 days (day 1 @ clinic; 2-14 @ home)

Sample characteristics (N=50)

Characteristics	
Mean age	23.6
Has a primary partner	92%
Married	4%
≥ secondary education	80%
Earns an income	64%
Zulu ethnic group	86%
Has children	66%



Blinding, device performance & problems

Blinding (N=50)

Did not know or “guessed” which type of WB device they received 94%

Technical performance of “ active” devices: failure to record data

Online (N=20) 0%

Offline (N=20) 25%

Difficulty with the zipper (N=50)

For opening the Wisebag 18%

For closing the Wisebag 12%

Other user problems (N=50)

Storage problem of Wisebag at home 10%

Problems with others using the Wisebag 10%

Problems with others gossiping about Wisebag (n=1) 2%

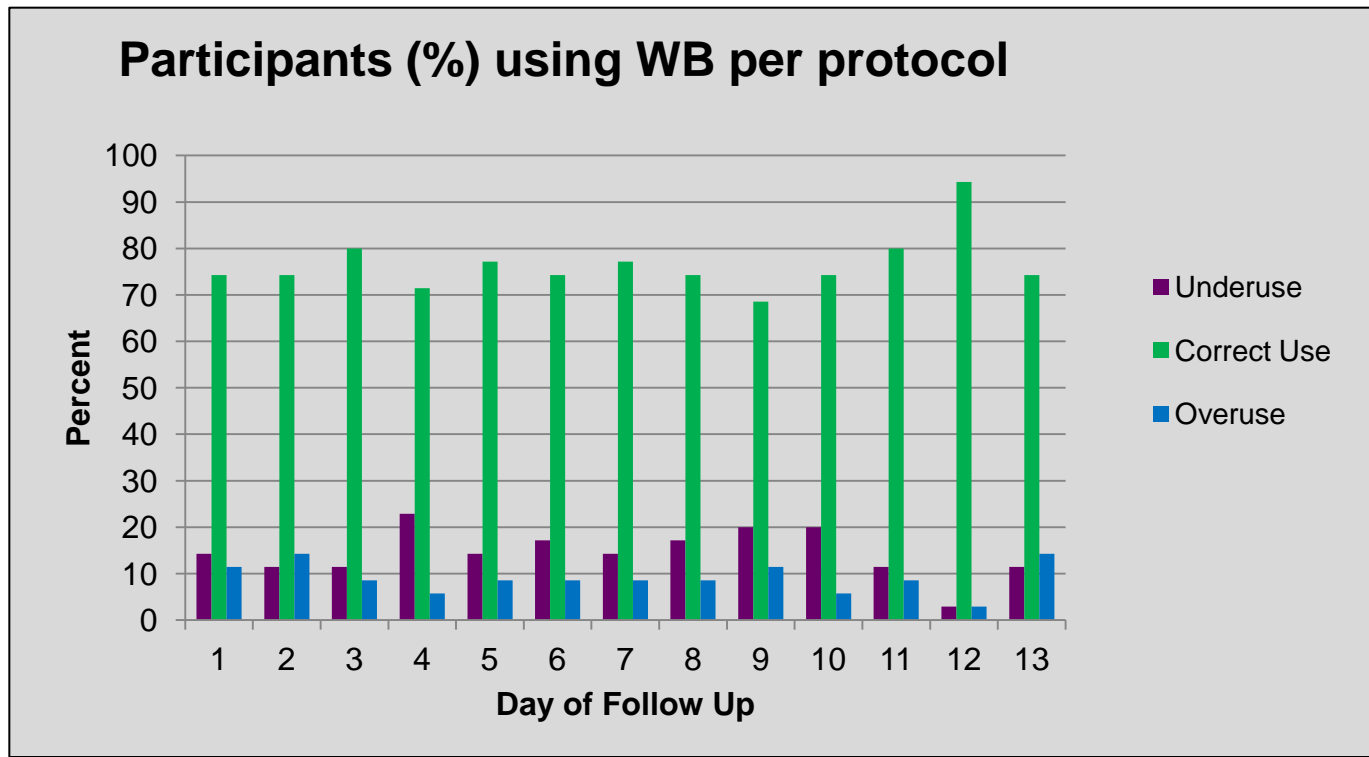
Adherence to daily opening

Main reasons for non-use

■ Travelling	32%
■ Forgot	32%
■ Sickness	4%
■ Stolen	2%

Main reasons for over-use

Wanted to show WB	16%
Curiosity	4%
Verify if sticker inside	2%
Show to a security guard	2%



Adherence correlation across measures

	FTF interview (N=50)	diary card (N=48)	WB events (N=35)
100% adherence	48%	46%	26%
Correlation			
diary card	0.96 p<.0001 (n=48)		
WB events	0.54 p<.0008 (n=35)	0.56 p<.0007 (n=33)	



Acceptability (n = 50)

- 94% liked using Wisebag
- 98% felt very comfortable or comfortable being seen carrying it
- 100% were very comfortable or comfortable with the notion of using Wisebag to carry gel applicators in a future study



Next steps

- Pretest new version of offline device
- Validation study: WB opening events compared to applicator tests (DSA and UV light) for daily HEC gel use with microlax applicators (in collaboration with Population Council and AECOM)



Conclusion

- ❑ Blinding was successful and can be rolled out in clinical trial settings
- ❑ New version of offline EMD must be tested
- ❑ Adherence low, and opening events showed much lower adherence than self-report, even over short duration and with no product
- ❑ Main reason for non use = forgetting. Online functionality with reminder SMS may be most useful in future trials

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