

Real talk: Rigorous evaluations of client side interventions are HARD.

Lessons-learned from WHO's youth-targeted ARMADILLO Study

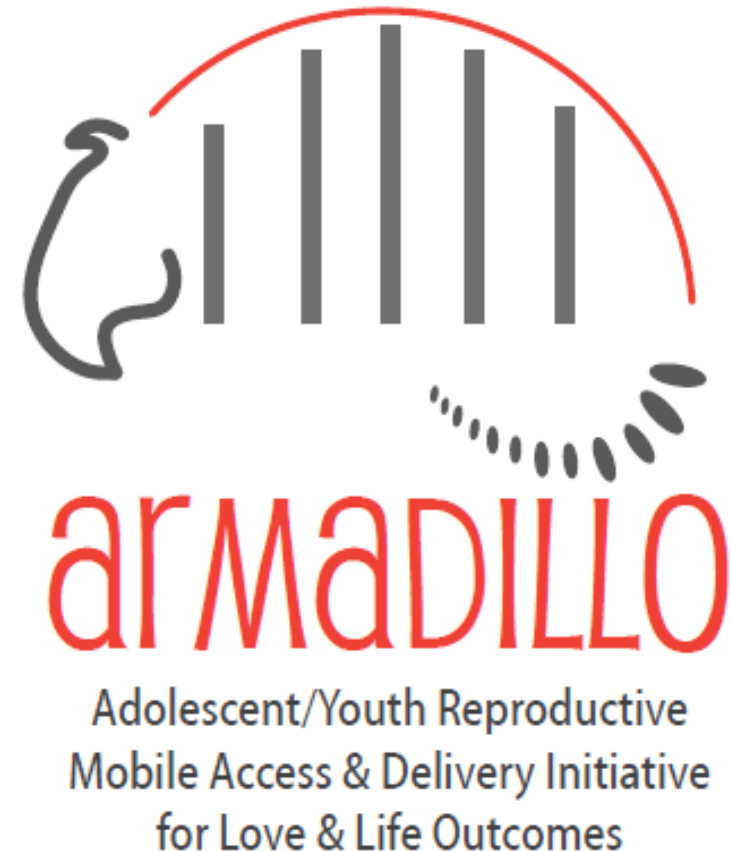
Lianne Gonsalves, Technical Officer  @liannegonsalves

Department of Reproductive Health and Research



Background: why ARMADILLO?

- ❑ There is a lack of rigorous evidence available for what works in digital for youth
 - ❑ This is especially evident in LMICs
- ❑ In response, WHO initiated the ARMADILLO Study



Background: ARMADILLO objectives

1. To develop an SMS intervention tailored for and vetted by youth (Stage I – formative phase)
 - On-demand, menu-driven, free
2. To evaluate the effect of this SMS-based intervention on SRH outcomes using a rigorous study design (Stage II – RCT)

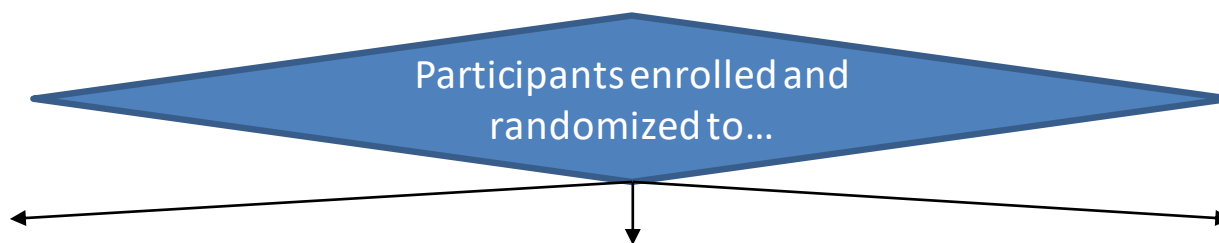
Conducted in two sites:

Lima, Peru (youth aged 13-17)

Kwale County, Kenya (youth aged 18-24)

KENYA SITE: STUDY OVERVIEW

Kenya study arms



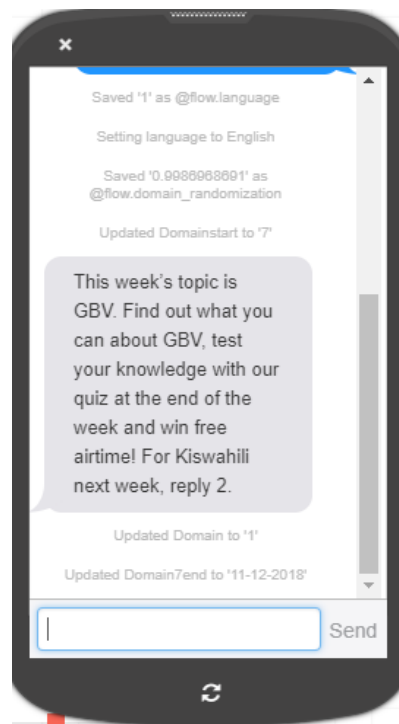
Arm 1: ARMADILLO intervention



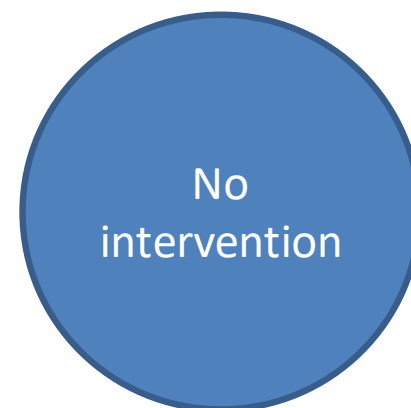
*New
SRH
topic
weekly*

*x7
weeks*

Arm 2: 'Contact'



Arm 3: Control



Two implementation decisions and their consequences

WHERE WE STARTED TO GO WRONG...

Decision 1: 'Hands-off' recruitment process

1. Confirm young person's identity
2. Determine eligibility to participate
 - Does youth own phone?
 - Ask to see phone
 - Enter phone number
3. Consent participant
 - Three arms described here
4. Complete baseline survey

Why? Familiar intervention format, didn't want to disappoint participants

ARMADILLO Study (Kenya)
Implementation and assessment of intervention
Consent Form 4: Youth Consent Form

[Informed Consent Form for study participants aged 18-24 Years]

Part I: Information Sheet

Introduction
Hello, my name is [enter name] and I work with the International Center for Reproductive Health- Kenya (ICRHK). In collaboration with the World Health Organization and Universidad Peruana Cayetano Heredia (UPCH) of Peru, we are making a program that will use text messages to allow young people in your area to access sexual and reproductive health information on their phones. We are conducting a study with the youth who can help us make the program relevant, understandable, and responsive to the needs of young people in your area. The informed consent form I am going to present to you has two parts, an information sheet, which will describe the study, and a certificate of consent for you to sign if you choose to participate. I will answer any questions you have about your participation and you will be given a copy of the full informed consent form.

Purpose of the Research
As you may know, it can sometimes be difficult for young people to feel comfortable asking questions about sexual and reproductive health issues, even when they have questions. Young people may feel embarrassed asking a health provider or going to a health clinic for information, even in areas where health services are 'youth friendly'. We want to understand the questions and knowledge about sexual and reproductive health including modern pregnancy prevention methods that young people in your community have. We also want to understand how we can best design a mobile phone program that will make sexual and reproductive health information accessible to young people in a way that makes them feel safe, comfortable and is respectful of their privacy.

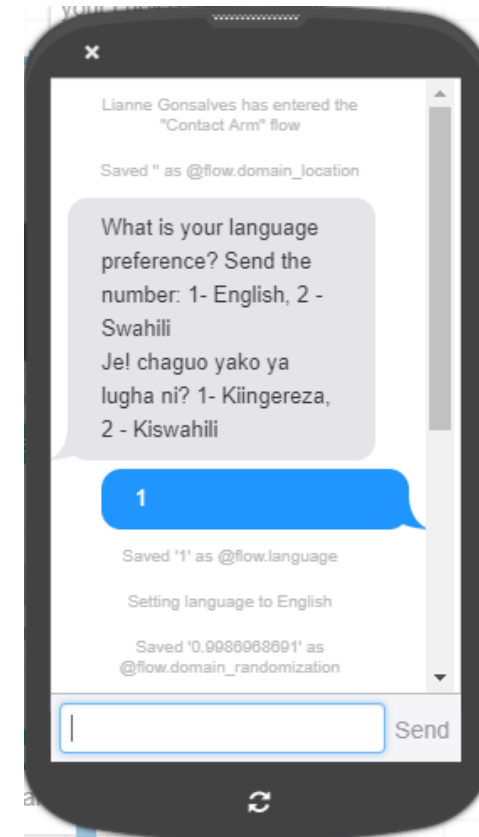
Research Procedure
You are being invited to take part in this research because we think your experience as a young member of this community can contribute much to our understanding of the sexual and reproductive health priorities of your peers. If you accept our invitation to participate, you will be asked to participate in a study where you will be expected to give answers to questions related to sexual and reproductive health in a survey. The survey will take no longer than 30 minutes. Then, you will be randomly selected to be in either an intervention group, contact or control group. Those in the intervention group will receive weekly messages relating to sexual and reproductive health and will use their phones to access these messages when they feel like. Those randomized to the contact group will be notified of a new topic like Pregnancy, Pregnancy prevention and STIs among others and they will be encouraged to learn about them on their own; those in the intervention and contact groups will receive weekly questions on what they have learnt and answers will be provided to all those who will respond. Those who will be in the control group will receive neither messages nor notifications but will be called upon at the end of the trial for an in-person assessment. Your participation in any of the 3 groups will not incur SMS charges. Those in the intervention and contact groups will also be given Ksh.50 as phone credit for responding to the study's questions delivered via SMS. The expected length of participation in the study is 7 weeks where you will be interacting with an SMS-based system that will be entirely free to use. Your participation is voluntary and you may refuse to participate in one or many components. At the end of the 7th week, you will be requested to participate in a second, in-person assessment. The survey will take no longer than 30 minutes. Finally, two months after the second in-person assessment, you will be requested to participate

ARMADILLO Stage 2: Submitted 5 December 18

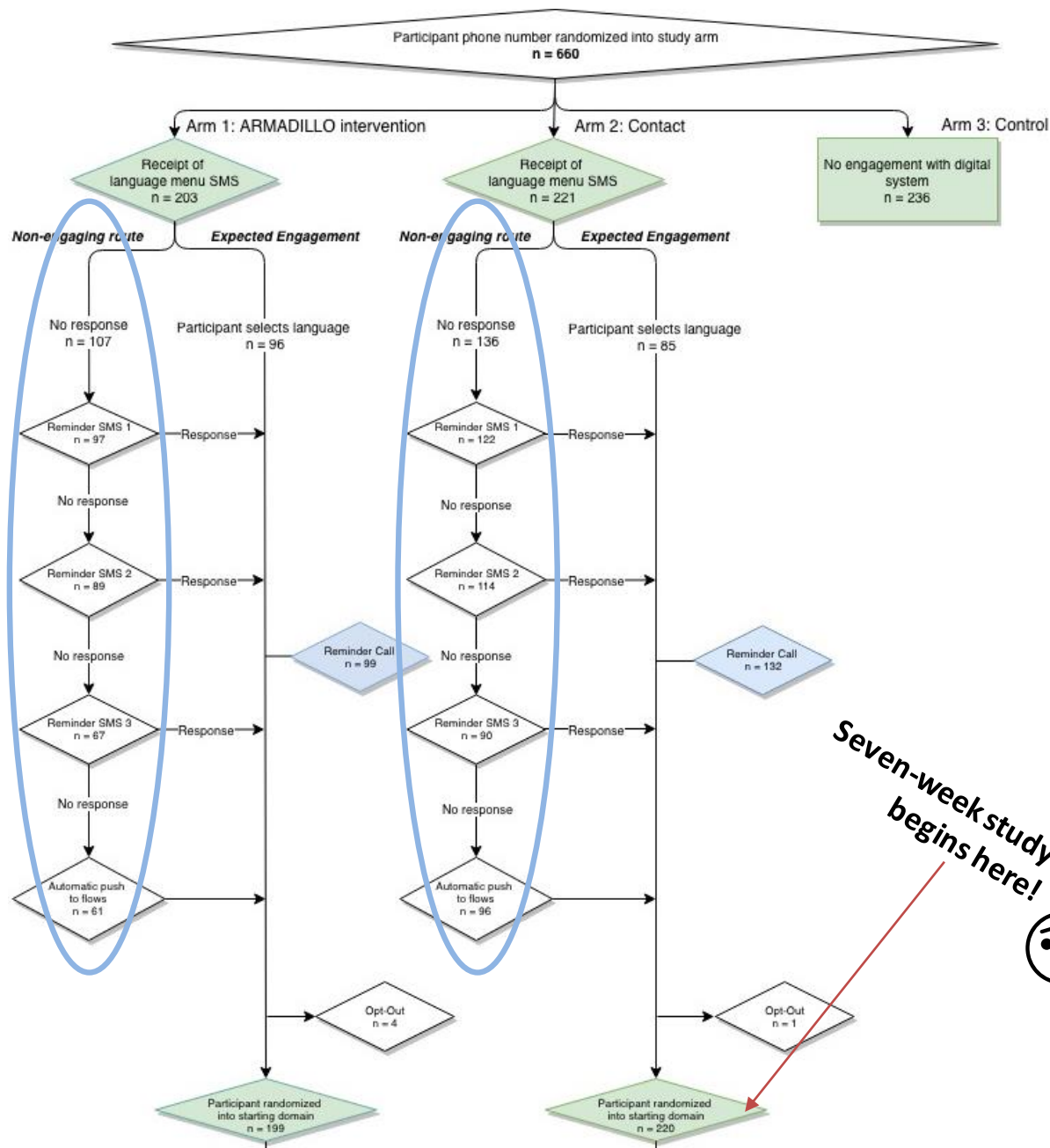
Decision 2: Language selection snafu

Issue: no clear preference for Swahili vs English in the study site. Therefore...

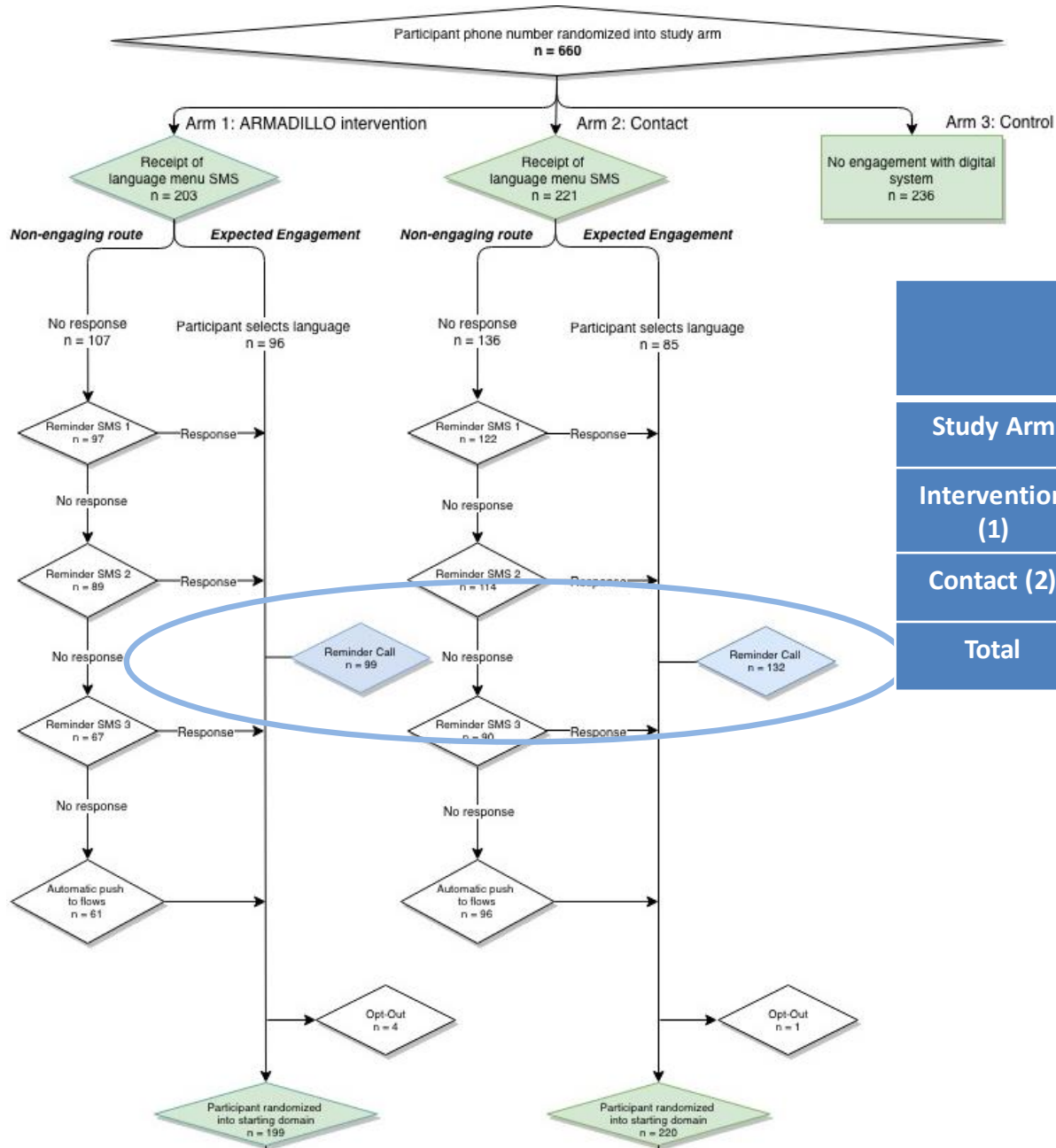
- ❑ After being randomized, and prior to receipt of first domain...
- ❑ ...Participants were sent an introductory language selection menu
- ❑ With their response, they received their first 'intervention' or 'contact' domain in their preferred language
- ❑ No response? *No study period start!*



The result. 'Stuck' participants



A chance to check in with participants



	Reached participant	Did not reach participant	Total non-engaging participants
Study Arm			
Intervention (1)	59	40	99
Contact (2)	77	55	132
Total	136(59%)	95	231

Reported for non-response to language menu

Reason for non-engagement	Intervention Arm (1) N=59 n(%)	Contact Arm (2) N=77 n(%)	Total N=136 n(%)
Eligibility-violation	15(25.4)	17(22.1)	32(23.5)
Assumed scam/spam	8(13.6)	22(28.6)	30(22.1)
Confusion	17(28.8)	10(13.0)	27(19.9)
Apathy	6(10.2)	5(6.5)	11(8.1)
Technical difficulties	9(15.3)	15(19.5)	24(17.6)
Other	4(6.7)	8(10.4)	13(9.5)

1. Have meticulous 'phone data collection' protocols
2. In efficacy assessments, train participants on the digital interventions
3. Client-side digital health interventions have analog discontinuation challenges

WHAT DOES THIS TEACH US?

RESEARCH LESSONS LEARNED

1. Develop *phone data collection protocols*



Problem:

- ❑ We ended up with numbers that did not belong to our participants
- ❑ Reduces statistical power in analyses

Lesson:

Have data collector procedures to check and cross-check phone numbers and eligibility criteria

2. Train participants on the intervention

Problem:

- ❑ Participants were confused by ARMADILLO, *despite* its menu-based system being very close to MPESA

Lesson:

Efficacy (aka 'ideal-research-setting') evaluations should fully train participants on how to use the system

Save the 'usability' test for piloting and/or effectiveness studies

3. Factor phone-related discontinuation into sample size calculations

Problem:

- ❑ Participants' phones are helpful to track them down at endline – they are also a source of study discontinuation

Lesson:

Factor phone-related discontinuation challenges in calculating sample size

1. 'Phone ownership' is a fluid concept
2. Digital health campaigns should establish a credible presence
3. Interest in a service can be sporadic and/or fleeting

WHAT DOES THIS TEACH US?

SERVICE ROLLOUT LESSONS LEARNED

1. Phone ownership is a fluid concept

(And we desperately need better data as to what that means)

Lesson:

- ❑ Consider whether intervention requires phone *ownership* or phone *access* and
 - What those mean
 - Whether choosing one over the other makes engagement with users more effective, acceptable, equitable, and safe.

2. Digital health interventions should establish a credible presence

Lesson:

- ❑ Participants are overwhelmed with a variety of third-party messaging – of varying quality/credibility
 - And, in many settings: phone users have are wary of potential spam/scams
- ❑ Building a credible, visible presence is critical
 - Credibility should be among both intended users and the community at large

3. Interest in a digital health service can be sporadic and/or fleeting

Lesson:

- ❑ People are not waiting around by their phones for us to message them.
- ❑ User interest and bandwidth to engage will wax and wane over a campaign



Thank you!



The rest of the ARMADILLO Kenya team:

Jefferson Mwaisaka (ICRHK)

Winnie Wangari (ICRHK)

Prof. Peter Gichangi (ICRHK – PI)

Megan Schroeder (Ona)

Lale Say (WHO)

Role of personalized digital health intervention in improving routine immunization among Pakistani children - *Paigham e Sehat*

Principal Investigator:

Dr. Abdul Momin Kazi, MBBS, MPH

- Senior Instructor (Research), Department of Pediatrics & Child Health , The Aga Khan University, Karachi, Pakistan
- PhD (Candidate), Department of experimental medicine, University of British Columbia, Canada

Coinvestigators:

Dr. JP Collet , University of British Columbia

Dr. William McKelin, University of British Columbia

Dr. Asad Ali , The Aga Khan University



Routine Immunization

Routine immunization (RI) among children is one of the most successful and cost-effective public health intervention



- Globally

Estimated 1.5 million children still die due to vaccine preventable diseases each year

Measles outbreaks,
Polio epidemic and
High vaccination drop out



Shen AK, et al. Global Health: Science and Practice. 2014
Kazi et al AM. Bull World Health Organ. 2016

Pakistan ranks 4th in child mortality

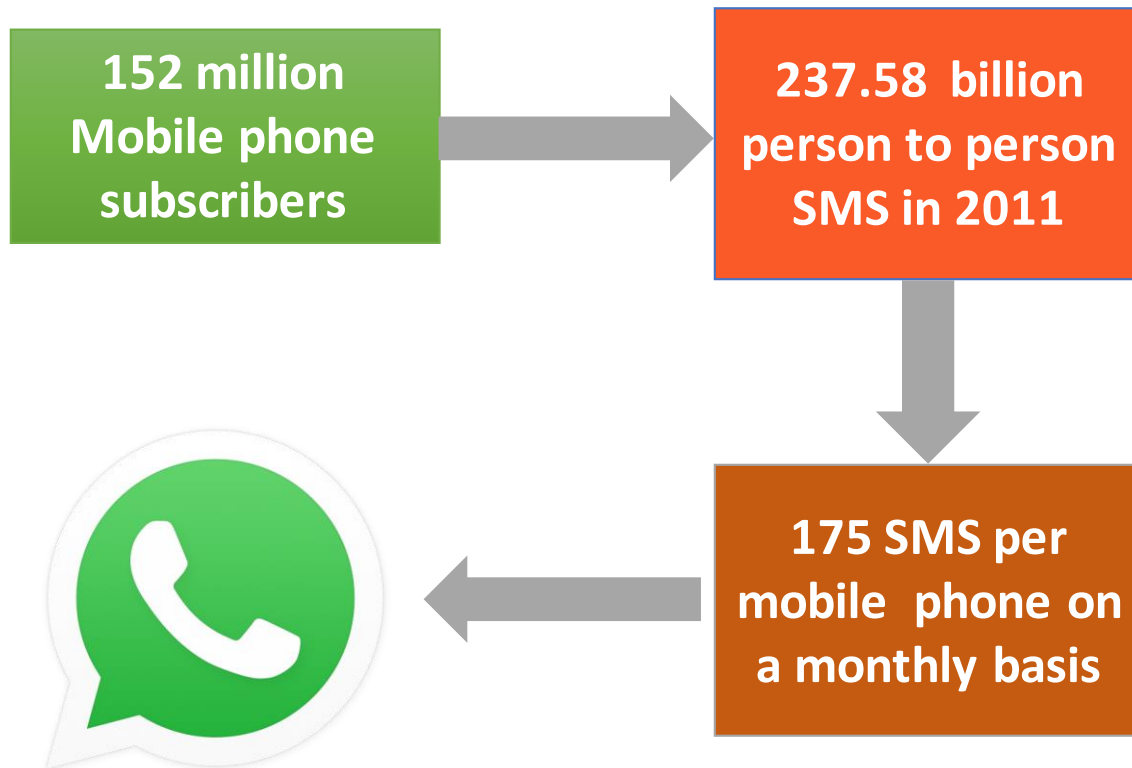
60% of all deaths are due to infectious diseases and many of them are vaccine preventable

Routine immunization coverage is estimated to be 59% at one year of age

Sindh and Baluchistan provinces being lowest with rates of 29% and 16% respectively

Mobile Phone and SMS Text

Similar to rest of the region Pakistan has also seen a global leap frog in Mobile phone usage



However less than 1/3 of the population use Smart phone and hence Interventions that can be used in simple function phone is recommended for generalizability

Study Objectives

Whether low cost, automated SMS messages and calls
Improve RI coverage in resource constrained settings
like Pakistan?

**Identify possible barriers
and factors related to
vaccine uptake and
adherence**

Compare the effectiveness of different types of
messages

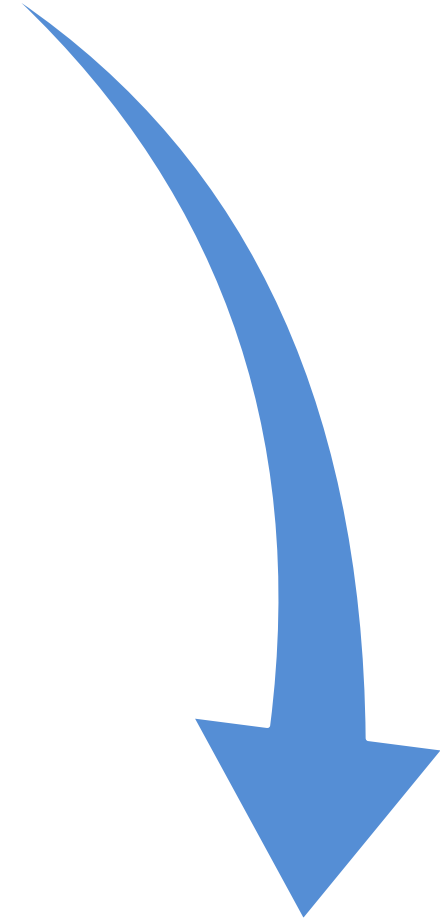
**Develop personalized
messages according to the
caregivers/family
preferences**

Reminder

Educational and

**To improve vaccine
coverage and timelines**

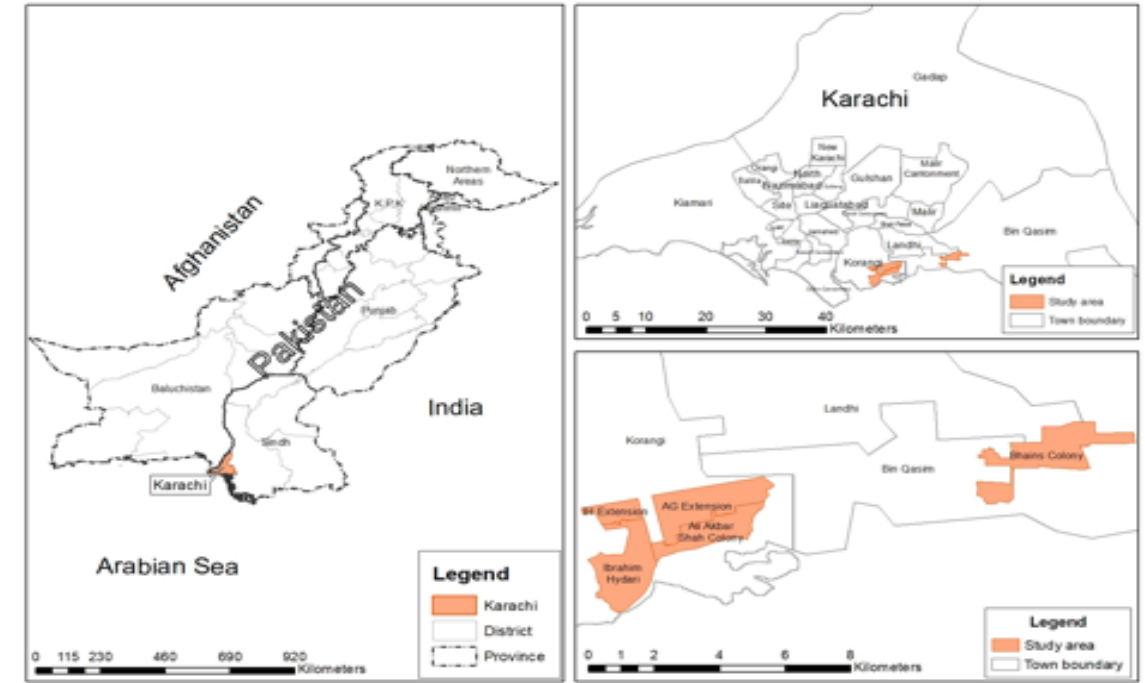
Interactive



Study Sites

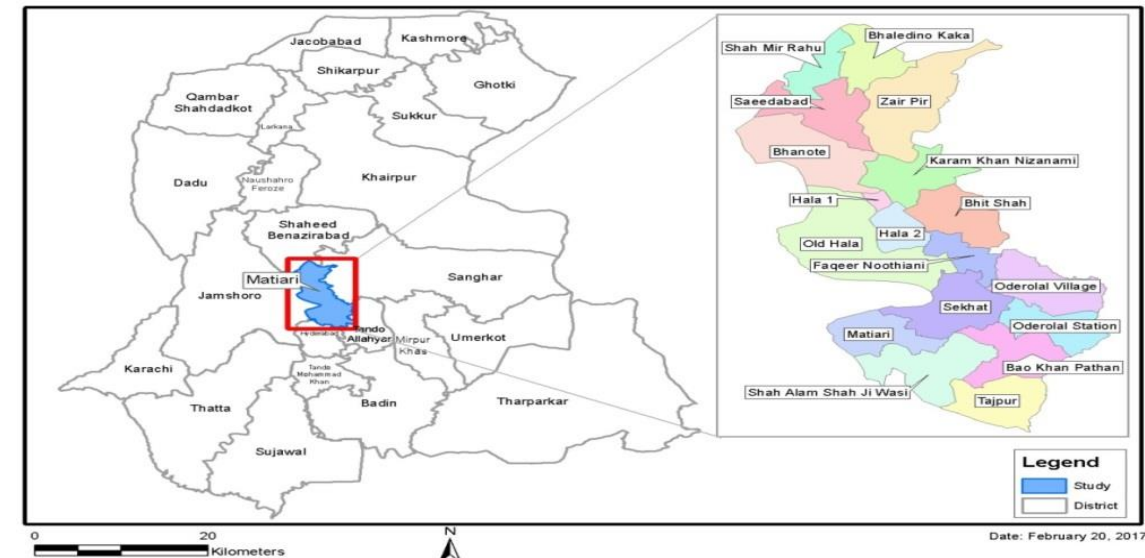
Urban Site

Health Demographic surveillance system (HDSS) at peri urban site in Karachi



Rural site

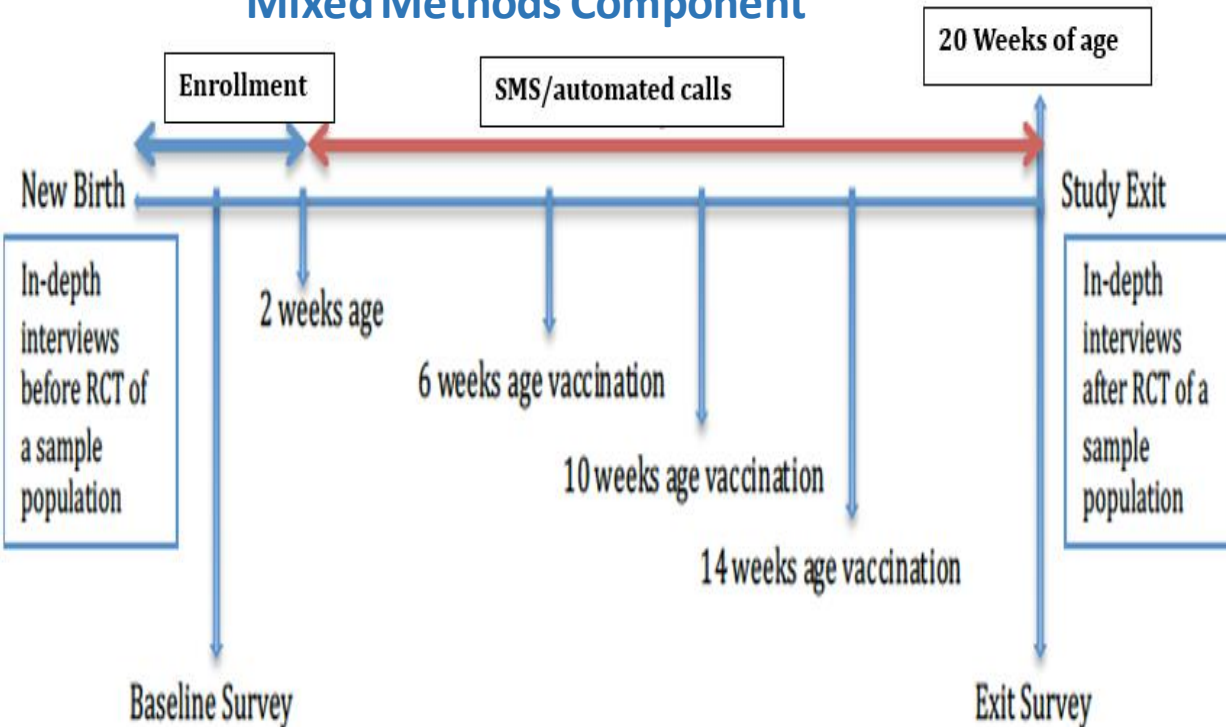
Matiari district of Sindh province located north of Karachi



Study Methodology



Mixed Methods Component



Qualitative component

• Before the trial

- I. Types of barriers perceived by caregivers,
- II. Designing the RCT and,
- III. Developing content for messages in several categories of barriers

Intervention

• After trial

- Explore factors associated with vaccine uptake
- According to study arm

Qualitative component

• The **baseline survey** a collect information on

- Basic demographics
- Mobile phone accessibility and usage, and
- Factors associated with mobile health messages

• A survey at the **end of the study** will be conducted to collect details

- Vaccine uptake and
- Timelines according to the schedule

Key In depth Interviews Findings

Barriers to RI Coverage

- Forget RI due date
- Lack of awareness for immunization
- Not permitted by family members
- Low level of trust for government EPI
- Religious beliefs
- Adverse effects

Messages

- Preferred language for SMS
 - Roman Urdu and plain Urdu for urban site
 - Sindhi written in Sindhi script for rural site
- Preferred language for automated calls
 - Urdu for urban site and
 - Sindhi for rural site

Development of Study Intervention

1. Literature search through Published Articles, Reports and Gray material for the creation and compilation of content according to categories



2. In-depth Interviews (IDIs) for exploration and content validation



3. Content Development for automated SMS and Call in English and Local Languages and back translated



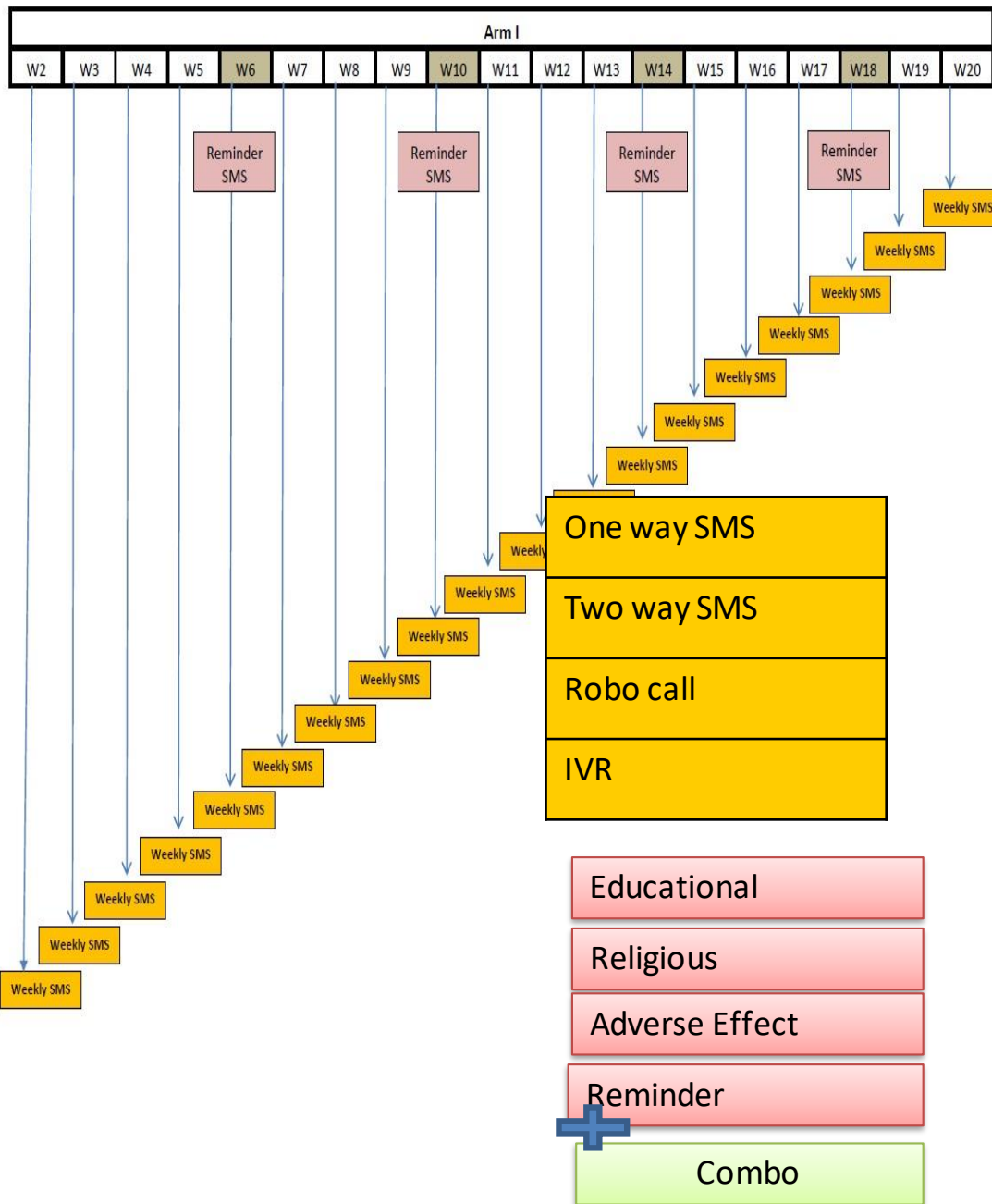
4. Stake holders meeting to finalize the content and include Health Experts, Research Experts and Technology Experts



5. Focused Group Discussion (FGD) on the final content with caregivers to explore their understand



Personalized content



English	Roman Urdu	Urdu	Roman Sindhi	Sindhi
AKU (Paigham e Sehat) Get your child vaccinated on time for 10 dangerous diseases like TB, Diphtheria, Ppertussis, Measles, pertussis, Measles, tetanus, hepatitis, meningitis, Pneumonia, diarrhea and polio.	AKU (Paigham e Sehat) Apne bacho ko 10 khatarnak beemariyo TB, Khanaq, kali khansi, khasra, tashanuj, yarqan, gurdun tor bukhar, pneumonia, dast or polio k hifazati teekay wakt per lagwae	اي.ڪي.يو (پيغام صحت) اپنے بچوں کو 10 خطرناک بیماریوں ، خناق، کالی TB کھانسی،خسرہ، تپشج، برقان، گردن تور بخار، نمونہ ، دست اور پولیو کے حفاظتی ٹیکے وقت پر لگوائیں	AKU (Pegham e sehat) Panhanje baran khay 10 khatarnak beemariyan T.B, khanaq, kari khangah, tashanuj, kari yarqan, gardan tor bukhar, pneumonia, dast ain polio ja hifazati teeka waqt tay lagayo	(پيغام صحت) يو. ڪي. اي. پنهنجي ٻار کي ٻي، خطرناڪ بيمارين تي 10 خناق، ڪاري کنگهه، جھٽڪا، سائي، گردن تور بخار، نمونيا، دست ۽ پوليو جا حفاظتي ٽڪا وقت تي لڳايو
AKU (Paigham e Sehat) Vaccines are available worldwide. Vaccination is mandatory for Hajj and Umrah pilgrims.	AKU (Paigham e Sehat) Dunya k tamam mulko mai hifazati teekay muhya hain Hajj or Umrah par jane wale afrad ko hifazati teekay lagwana lazim hai	پيغام صحت (AKU) دنيا کے تمام ملکوں میں حفاظتی ٹیکے مہیا ہیں حج اور عمرہ پر جانے افراد کو حفاظتی ٹیکے لگوانا لازمی ہے	AKU (Pegham e sehat). Dunya jay sabhni mulkan mai hifazati teeka mohya ahin, hajj ain umrah tay wiyan waran mahran khay hifazati teeka lagayan lazmi ahin	اي.ڪي.يو (پيغام صحت) دنيا جي تمام ملڪن ۾ حفاظتي ٽڪا مہيا آهن، حج ۽ عمرہ تي وڃڻ وارن ماڻھن کي حفاظتي ٽڪا لڳائڻ لازمي آهن
AKU (Paigham e Sehat) Its common to have pain and inflammation at the site of injection or to have fever or diarrhea. These are timely symptoms. For high fever and seizures please consult doctor	Teekay ki jaga per dard, sujan, bukhar, dast hona aam baat hai Yeh wakhti asraat hain is k elawa shaded bukhar ya jhatkay k lye doctor se ruju kren	پيغام صحت (AKU) ٹیکے کی جگہ پر درد، سوجن، بخار، دست ہونا عام بات ہے یہ وقتی اثرات ہیں اس کے علاوہ شدید بخار یا جھٹکے کے لیے ڈاکٹر سے رجوع کریں	AKU (Pegham e sehat). Teekay ji jay tay sur, sujhan, bukhar ain dast thian aam ghal ahay, ihi wakhti asraat ahin, in jay elawa shadeed bukhar ya jhatkan jay laye doctor san ruju kary	اي.ڪي.يو (پيغام صحت) ٽڪي جي جاء تي سور، سڃڻ، بخار، دست ٿيڻ عام ڳالهه آهي، اهي وقتي اثرات آهن، ان کان علاوه شديد بخار يا جھٽڪن جي لاءِ ڊاڪٽر سان رجوع ڪريو

AKU (Paigham e Sehat) Apne bacho ko 10
khatainak beemariyo TB, Khanaq, kali khansi,
khasra, tashanuj, yarqan, gurdun tor bukhari,
pneumonia, dast or polio k hifazati teekay
wakt per lagwae. Teko ki tadad ky ly 1 aur
teko ki ehmiyat ky ly 2 likh kr reply krein

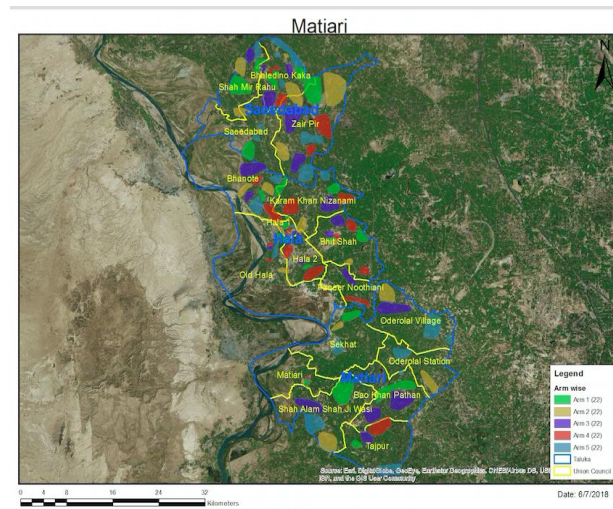
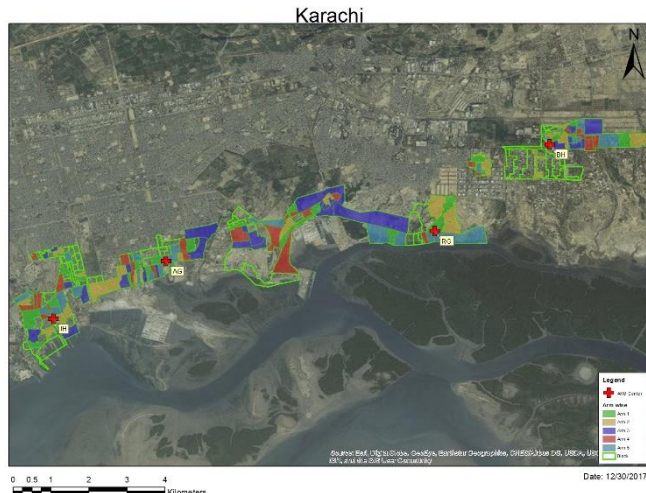
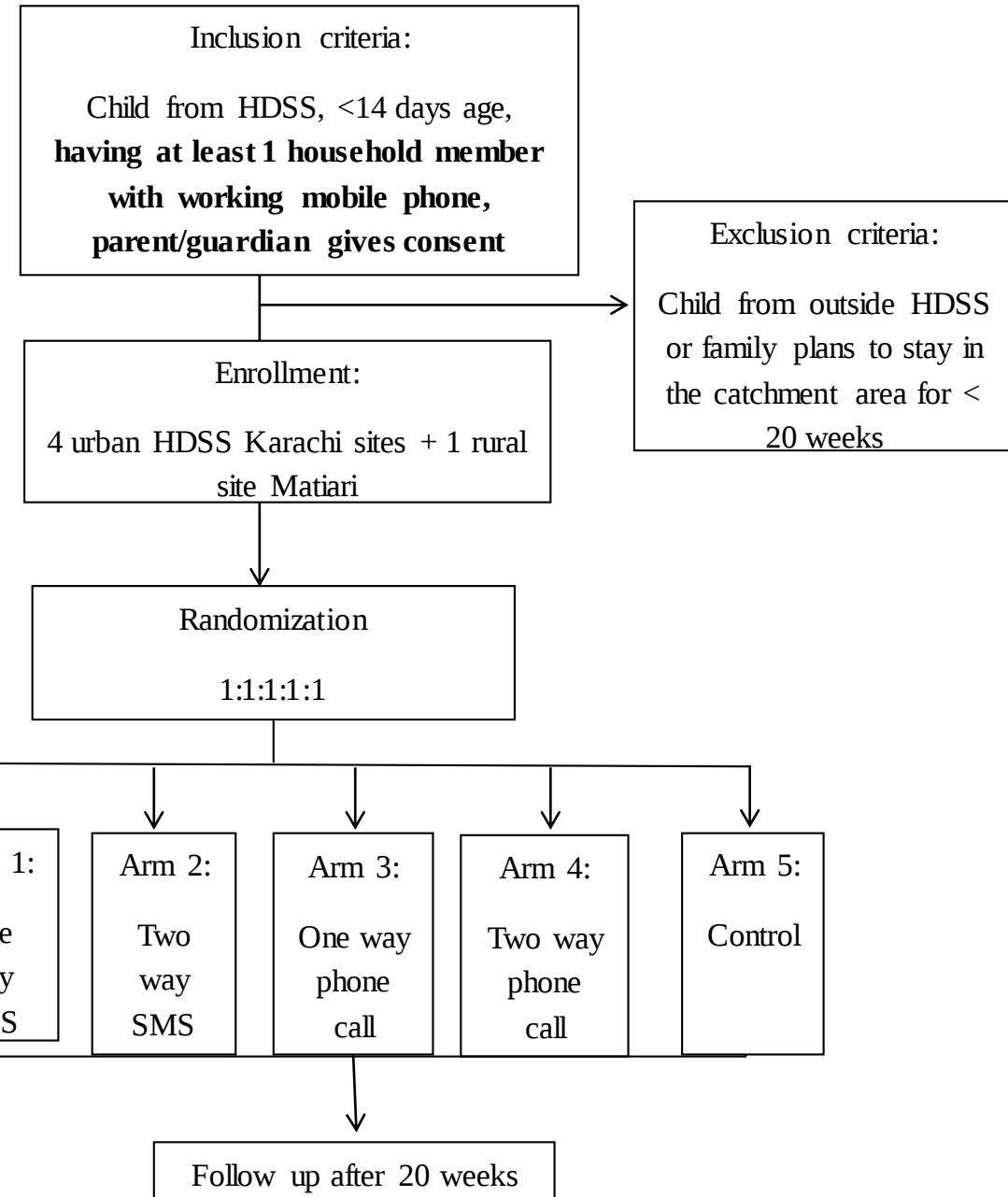
Two Way Audio

Ek saal ki umar se pehle bacho ko 10 tekey wakt per lagwain jis mai se ek padaish per lagta hai. Teko ki ehmiyat ky ly 2 likh kr reply krein

Hifazati teekay aap k bachay ki sehat k liy faidamand hain or khatarnak beemariyo se bachanay ka mehfooz tareeka hai. Teko ki tadad ky ly 2 likh kr reply krein

Cluster Randomized Control Trial n= 3383

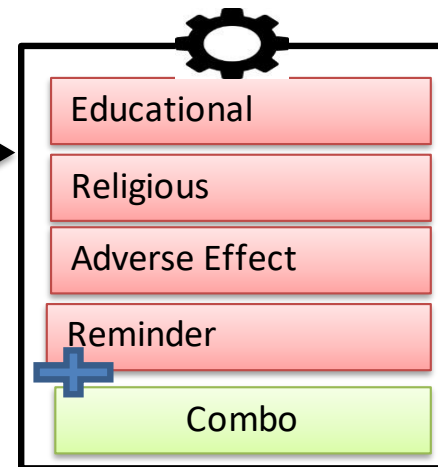
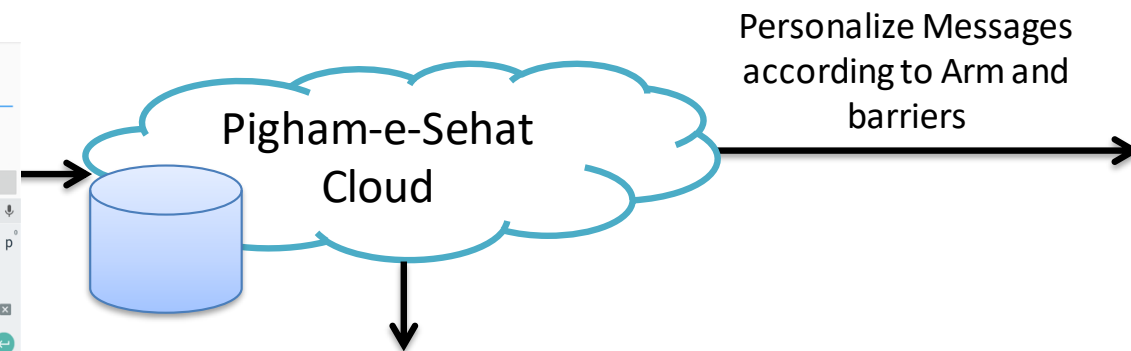
INTERVENTION ARM	WEEKLY AUTOMATED SMS TEXT AND AUTOMATED CALLS FROM ENROLMENT TILL 20 WEEKS OF LIFE
ARM 1 (INTERVENTION)	Parents/care giver will receive one way educational/reminder/proactive SMS messages related to routine immunization once a week till 20 weeks of age
ARM 2 (INTERVENTION)	Parents/care giver will receive two way (interactive) educational/reminder/proactive SMS messages related to routine immunization once a week till 20 weeks of age-parents will have the option to reply and receive more information related to immunization through text messages
ARM 3 (INTERVENTION)	Parents/care giver will receive one way educational/reminder/proactive automated phone call related to routine immunization once a week till 20 weeks of age
ARM 4 (INTERVENTION)	Parents/care giver will receive two way (interactive) educational/reminder/proactive automated phone call related to routine immunization once a week till 20 weeks of age-parents will have the option to reply and receive more information related to immunization through phone call
CONTROL GROUP	NO INTERVENTION
ARM 5 (CONTROL)	One time counselling at the baseline survey



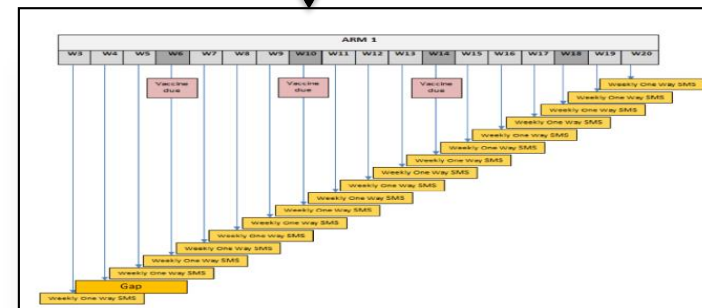
Baseline Data Collection



Community



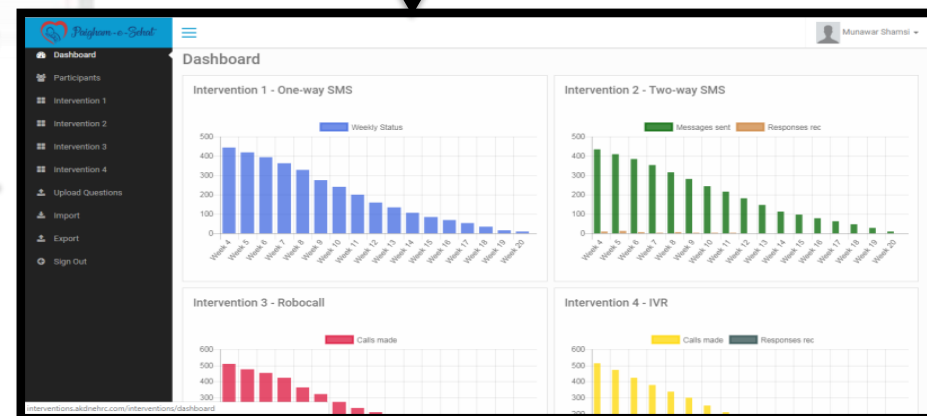
Baseline Monitoring Portal



Schedule Messages on weekly basis



Telecom network



Message Sending and Content Management Portal

Baseline data on Mobile phone		Urban Site			Rural Site		
Usage and Acceptability		Total N	Count	%	Total N	Count	%
Access to working phone		1436	1386	96.5%	1957	1940	99.1%
Provided mobile phone number		1386	1374	99.1%	1940	1924	99.2%
Type of mobile phone do you use?		1176			1728		
Simple function phone			860	73.1%		1428	82.6%
Smart phone (Android / IOS/Symbian)			298	25.3%		295	17.1%
Don't know			18	1.5%		5	.3%
Internet use on smart phone?		298	183	61.4%	295	261	88.5%
Prepaid connection		1176	1174	99.8%	1728	1718	99.4%
Receive SMS messages inquiring health?		1176	1105	94.0%	1728	1681	97.3%
Receive phone call inquiring health?		1176	1167	99.2%	1728	1722	99.7%
Mobile phone mode of communication preference ?							
Talking on mobile phone		1176	815	69.3%	1728	1196	69.2%
Both			350	29.8%		444	25.7%
Texting			11	0.9%		88	5.1%
Receive a weekly message related to RI		1176	801	68.1%	1728	880	1250.9%

Conclusion I

- Information regarding families' perceptions of vaccination and the daily life challenges were used to develop personalized mobile phone messages
- The results of this study will be useful to understand the respective effects of SMS text messages vs automated phone based communication to improve RI coverage and timelines
- This information will be further used to developing more complex interventions including personalized app and ML and AI models





Thanks

Study Funded through Rising Star Grand Challenges
Canada

Acknowledgement

Dept. Pediatrics and Child Health

University of British Columbia

AKDN eHRC

Ministry of Health

Study team



Disease	Causative agent	Vaccine	Doses	Age of administration
Childhood TB	Bacteria	BCG	1	Soon after birth
Poliomyelitis	Virus	OPV	4	OPV0: soon after birth OPV1: 6 weeks OPV2: 10 weeks OPV3: 14 weeks
		IPV	1	IPV-I: 14 weeks
Diphtheria	Bacteria	Pentavalent vaccine (DTP+Hep B + Hib)	3	Penta1: 6 weeks Penta2: 10 weeks Penta3: 14 weeks
Tetanus	Bacteria			
Pertussis	Bacteria			
Hepatitis B	Virus			
Hib pneumonia and meningitis	Bacteria			
Measles	Virus	Measles	2	Measles1: 9 months Measles2: 15months
Diarrhoea due to rotavirus	Virus	*Rotavirus	2	Rota 1: 6 weeks Rota 2: 10 weeks



PROMOTING ANTENATAL CARE ATTENDANCE THROUGH A TEXT- MESSAGE INTERVENTION IN SAMOA

.....

Jessica Watterson, PhD, MPH
*University of California, Berkeley & **IDEO***

OUTLINE

- Background
- Study design & methods
- Results
- Discussion

BACKGROUND: MATERNAL HEALTH IN SAMOA



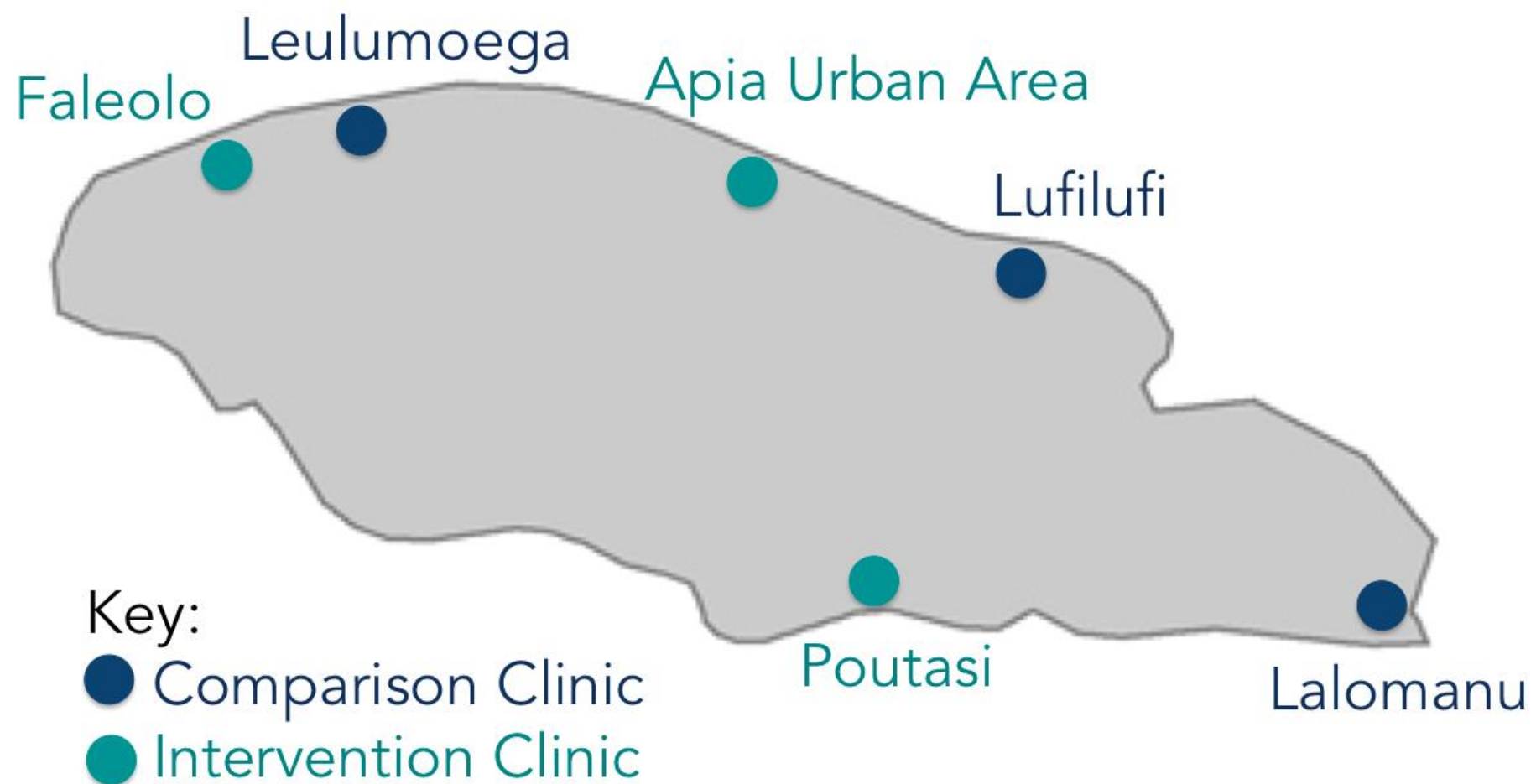
- Samoa, an independent nation in the South Pacific
 - 90% mobile phone ownership ¹
 - 99% literate ²
- Maternal health indicators:
 - Free antenatal care (ANC)
 - 82% facility delivery ³
 - Only 73% of pregnant women receive 4+ ANC visits ³
 - Only 12% register in first trimester ³
 - 23% of mothers feel they don't need ANC because their baby is in good health ⁴

BACKGROUND: TEXT MESSAGES FOR MATERNAL HEALTH

- Many text messaging programs for maternal health exist but few have evaluated behavior change or health outcomes
- Studies in Zanzibar, Malawi, and India have found:
 - Increased ANC attendance ^{5, 6}
 - Increased knowledge, preparedness and satisfaction with care ^{7, 8}

STUDY DESIGN

- Upolu, Samoa, March - September 2014
- 6 National Health Service (NHS) clinics



INTERVENTION



- 2-3 messages per week, based on gestation
- Education and reminder messages
- Adapted and translated from MAMA library



DATA COLLECTION

Chart and logbook review (quantitative)

- **Outcome:** Number of antenatal visits attended
- **Control variables:** age, parity, partnership status, employment, distance from village to clinic, gestation at registration

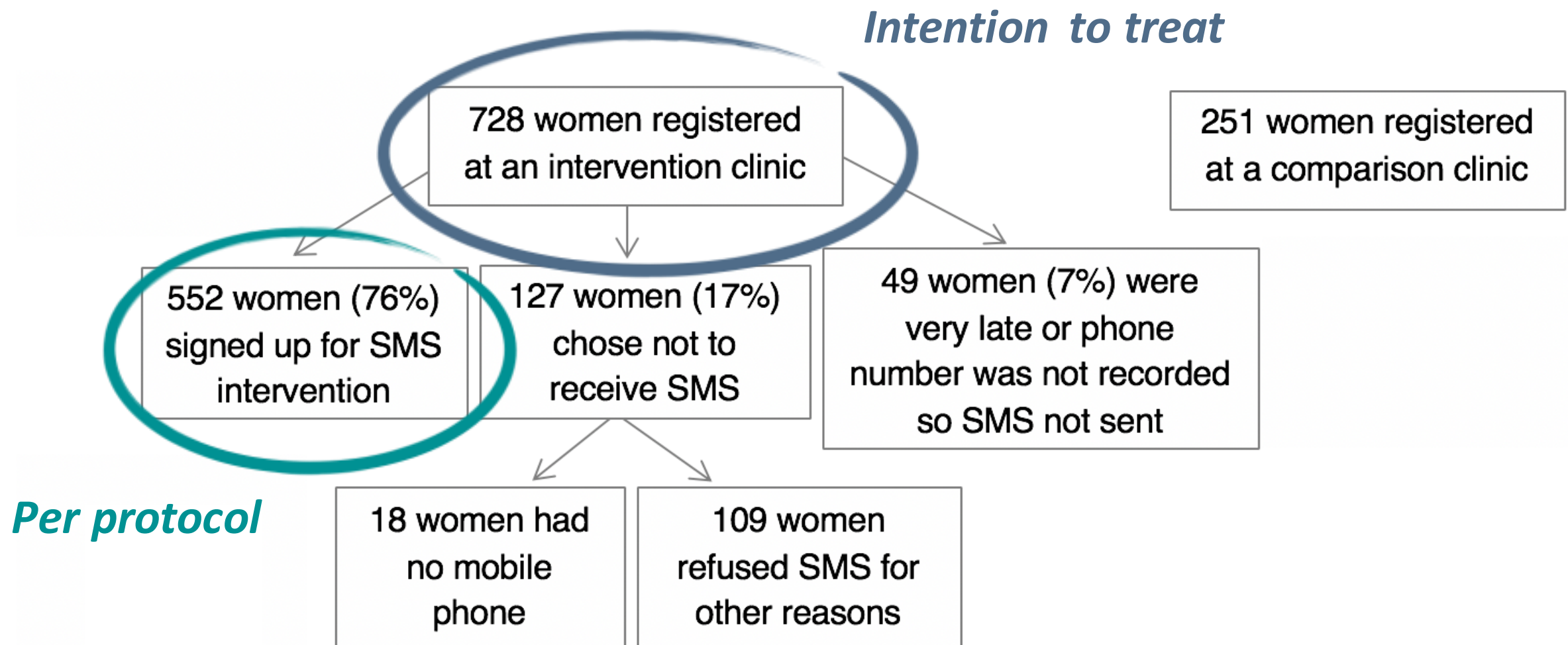
Survey of implementing midwives (mixed-methods)

Implementation notes (qualitative)

DATA ANALYSIS

- Descriptive statistics
- Multivariate regression, controlling for individual characteristics and accounting for clustering in clinics
- Qualitative data was systematically reviewed for common themes

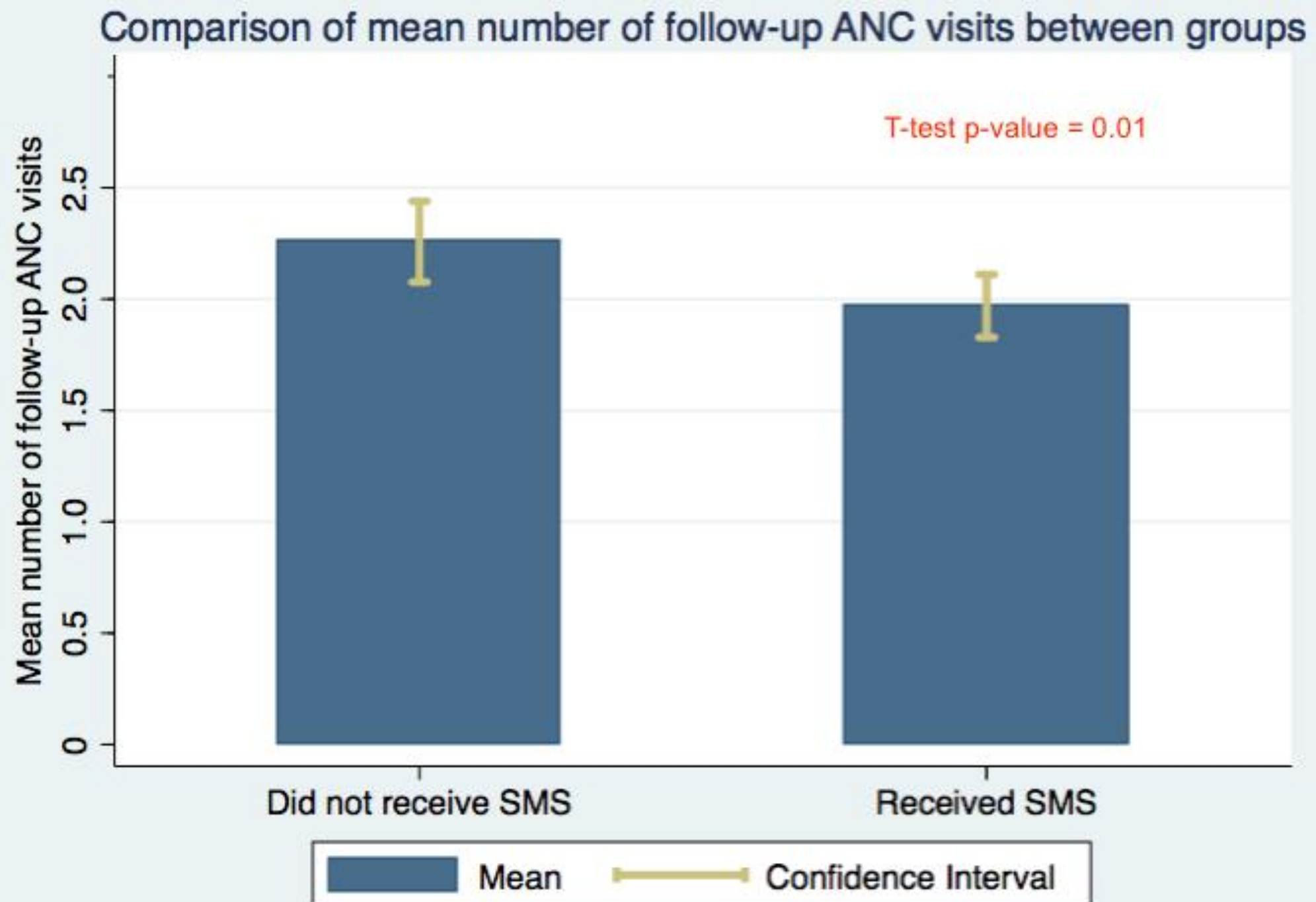
REGISTRATION RESULTS



BASELINE CHARACTERISTICS

	Intention-to-Treat			Per-Protocol		
Variable	Intervention (n=577)	Comparison (n=188)	p	Intervention (n=446)	Comparison (n=319)	p
Continuous variables: Mean (SD)						
Age	26.7 (6.4)	27.1 (6.5)	0.53	26.6 (6.3)	27.2 (6.5)	0.18
Parity (including current pregnancy)	3.2 (2.0)	3.3 (2.0)	0.62	3.1 (1.9)	3.3 (2.1)	0.25
Distance from home village to registration clinic (km)	11.9 (13.1)	6.6 (7.2)	<0.00	12.3 (13.9)	8.3 (8.6)	<0.00
Gestation at registration (weeks)	27.2 (6.7)	26.5 (6.0)	0.13	27.4 (6.5)	26.6 (6.6)	0.10
Number of follow-up antenatal visits attended	2.2 (1.9)	2.6 (1.7)	0.01	2.1 (1.7)	2.5 (1.9)	<0.00
Categorical variables: n (%), excluding missing						
Married/in partnership	519 (89.9%)	171 (91.0%)	0.69	401 (89.9%)	289 (90.6%)	0.75
Employed and/or partner employed	405 (70.2%)	89 (47.1%)	<0.00	327 (73.3%)	167 (51.9%)	<0.00

COMPARISON OF ANC ATTENDANCE BETWEEN GROUPS



COMPARISON OF ANC ATTENDANCE BETWEEN GROUPS

	Intention-to-Treat			Per-Protocol		
Variable	Estimate	SE	p	Estimate	SE	p
Intervention Group	-0.32	0.19	0.15	-0.37	0.15	0.05
Age at Registration	0.01	0.02	0.56	0.01	0.02	0.59
Married/in partnership	-0.12	0.27	0.68	-0.12	0.29	0.70
Parity	-0.04	0.05	0.45	-0.04	0.05	0.44
Employed and/or partner employed	-0.22	0.15	0.21	-0.19	0.18	0.33
Distance from home village to registration clinic (km)	0.00	0.00	0.39	-0.00	0.00	0.34
Gestation at registration (weeks)	-0.02	0.01	0.01	-0.02	0.01	0.03
Constant	3.17	0.45	<0.00	3.14	0.41	<0.00

IMPLEMENTATION RESULTS

Barriers

- Inconsistent registration for messages
- Sharing of mobile phones
- Late ANC registration

Facilitator

- In-person registration

Suggestions

- Incorporating more traditional local practices into messages, such as avoiding abdominal massage
- Include husbands or partners

DISCUSSION

Limitations

- No randomization at individual level
- No data on pregnancy complications
- One intervention site was larger than all others
- Missing records/data

DISCUSSION

Potential explanations for these results:

- Some evidence that bidirectional or more interactive programs might be more effective ^{6,9,10}
- Women might substitute information for more time and resource intensive ANC

Evaluation and human-centered design is essential

Further study of the effectiveness of specific features and in specific contexts is needed

THANK YOU

- Participating midwives and women
- Caricia Catalani, DrPH, MPH
- Diego Castaneda, DrPH, MPH



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