

# EPIC

Enhancing PrEP in Community

**Developing and implementing a mobile health (mHealth) adherence support system for HIV-uninfected men who have sex with men (MSM) taking pre-exposure prophylaxis (PrEP): the iText Study**

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*The views expressed herein do not necessarily reflect the official policies of the City and County of San Francisco; nor does mention of the San Francisco Department of Public Health imply its endorsement.*

# Adherence is the “Achilles’ heel” of PrEP

- **Adherence is critical for PrEP efficacy**

- In iPrEx, efficacy rose from overall 42% to an estimated >90% among those with detectable drug
- Lack of efficacy in FEM-PrEP and VOICE (low rates of drug detection)



- **Developing strategies to support PrEP adherence in real-world settings is critical to maximizing the public health impact of PrEP**

# Mobile phone strategies successful in supporting ART adherence: 2 RCTs in Kenya

THE LANCET

Articles

Volume 374 - Number 9724 - Pages 1-68 - July 3-9, 2010

www.thelancet.com

Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WeTel Kenya1): a randomised trial



Mobile phone technologies improve adherence to antiretroviral treatment in a resource-limited setting: a randomized controlled trial of text message reminders

**Potentially low cost, scalable adherence intervention**

**Almost all MSM in US own a cell phone (>90%), with few sharing phones, and infrequent service discontinuations in 2010 internet-based survey (N=1568)  
(Fuchs IAS Rome 2011)**

## iText study aims

- Develop an SMS-based support system (iText) to support PrEP adherence in HIV-negative individuals, based on the WelTel SMS model in HIV-positive pts
- Evaluate the feasibility, acceptability, and preliminary effectiveness of iText among MSM taking PrEP in iPrEx Open Label Extension (OLE)



# Methods: Formative work and pilot study

## Qualitative interviews

In-depth interviews (IDIs) with 59 iPrEx OLE pts in SF, Boston, Chicago to assess interest and recommendations for iText

## Develop platform

iText developed in iterative process with Capito Life Technologies

## 3-mo. iText pilot (iPrEx OLE)

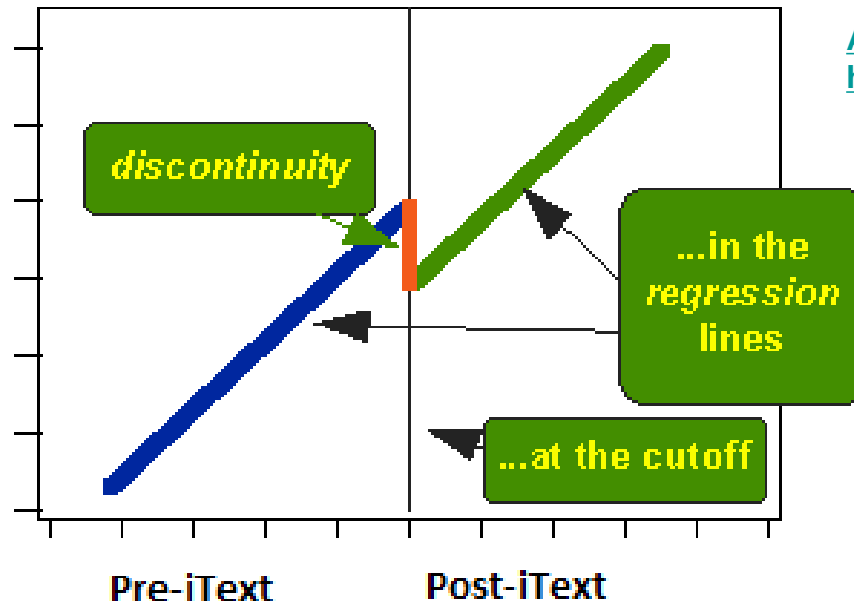
Weekly SMS check-in  
Phone support as needed  
Post-intervention survey, focus groups in subset

### iText Eligibility:

- Dispensed PrEP for at least 12 weeks, with a plan to continue for an additional 12 weeks
- Have an SMS-capable phone or active email account

# Evaluating impact on adherence: Regression discontinuity analysis

If there is a treatment effect, there will be a...



Adapted from  
<http://www.socialresearchmethods.net>

- Primary model included all pre- and post-observations, adjusting for age, race, site, start date, and duration in study

# Phase 1 Results: Formative work

- Substantial interest in SMS support, particularly among young MSM of color in Chicago; many in SF felt they had already established pill taking routines
- Some prefer other modes of communication (email, Facebook)
- Participants wanted some level of personalization (choose timing of messages, rotation of messages)
- Range of message preferences:
  - How are you?
  - Are you OK?
  - How is PrEP working for you?

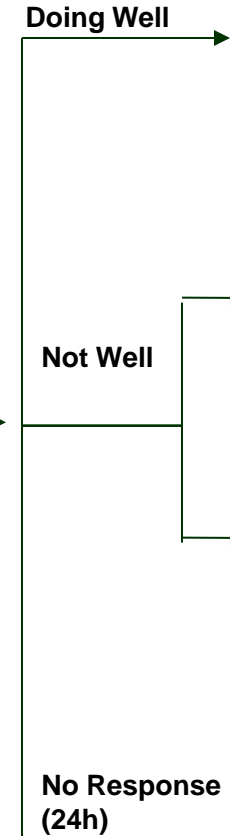
### Registration

Question	Responses
Hi, how are your doing?	Fine/Not Fine Well/Not Well Ok/Not Ok
Hi, are you ok?	Ok/Not Ok Yes/No
Hi, how is PrEP going?	Ok/Not Ok Fine/Not Fine Good/Not Good Good

### Semantics

Doing Well	Not Well
Fine	Not Fine
Well	Not Well
Good	Not Good
Ok	Not Ok
Okay	Not Okay
Y	N
Yes	No
Yah	Nay

### Response



### Follow-up

Thanks!

Mon 9 AM-Fri 12PM

Thanks for letting me know, I'll be calling you within 24 hours when I'm in my office

Fri 12:01 PM-Mon 8:59 AM

Thanks for letting me know. I'll call you on Monday when I'm in my office.

I didn't hear from you. How are you? I'll give you a call if I don't hear back in 24 hours.

**System programmed for SMS and email message delivery**





# All Participants Dashboard San Francisco

Welcome, AL.

[Home](#)[Contact Us](#)[Log Out](#)

## Tasks

Participant Search  
 Participant Registration  
 All Participants Dashboard  
 My Participant Calls Needed  
 Calls Made  
 Study Metrics

## Reports

CaptioA Access DB

## All Participants Dashboard

 All
  Active
  Study Ended
  Withdrawn
  Test Patients


(Check as many as apply)

ID Number	Assigned Counselor	Activation Date	Week of Participation													
			1	2	3	4	5	6	7	8	9	10	11	12	13	
9470455	AD	11-07-2012	●	●	●	●	●	●	●	●	●	●	●	●	●	●
9470097	RG	11-09-2012	●		●	●	●	●	●	●	●	●	●	●	●	●
9470145	RG	03-01-2013	●	●	●	●	●	●	●	●	●	●				
9470636	AD	12-06-2012	●	●	●	●	●	●	●	●	●	●	●	●	●	●
FTEST002	Steve Corwin	05-09-2013		●	●											

● Doing Well   ● Not Doing Well   ● No Response   A=Call Attempted   C=Call Completed

## Phase 2 Results:

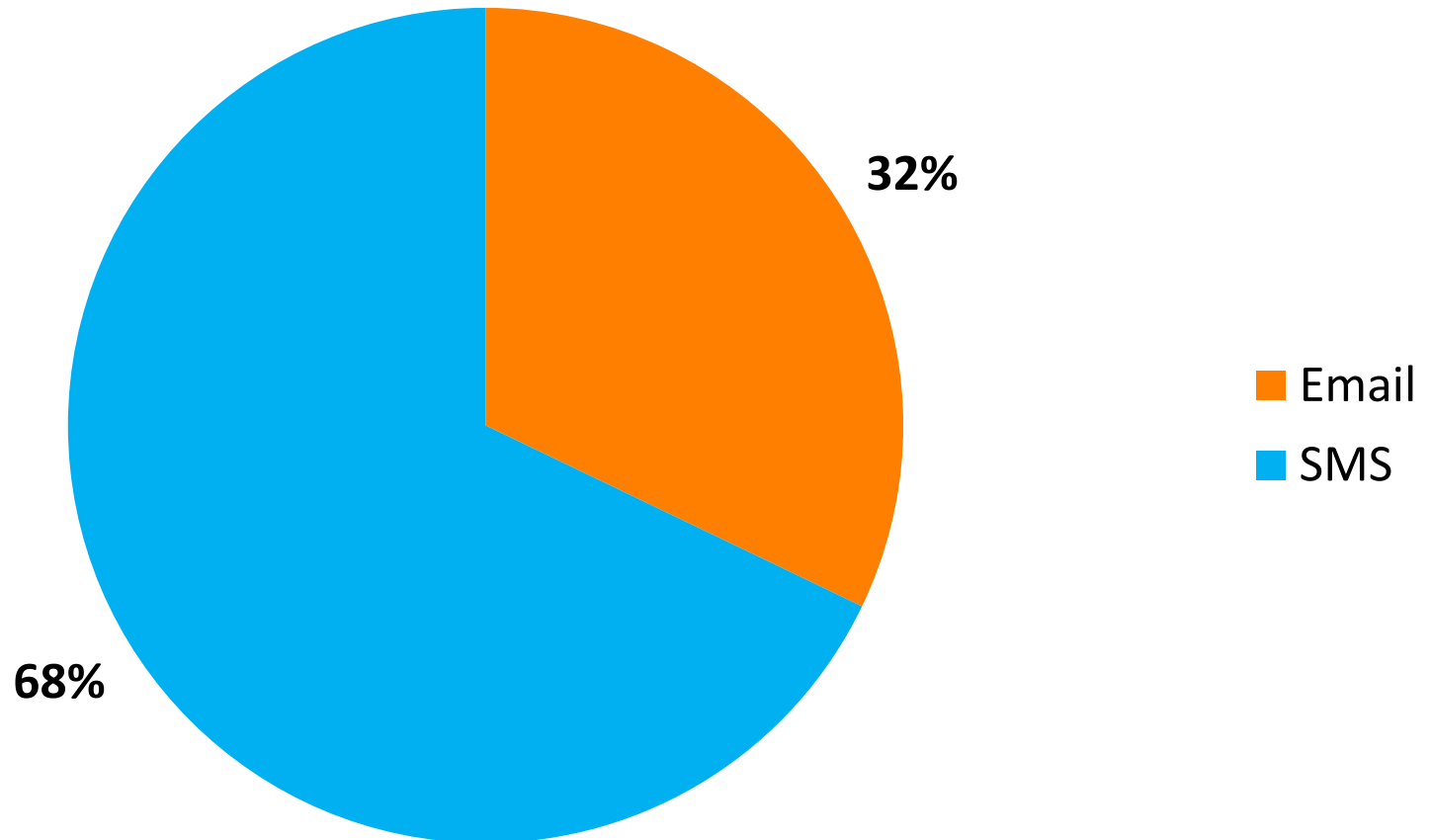
### High uptake among eligible participants

Recruitment stage	N (%)
Approached	68
Ineligible	6
Eligible (% approached)	62 (91%)
Refused	6
Enrolled (% eligible)	56 (90%)

## iText Pilot Study Participant Characteristics (N=56)

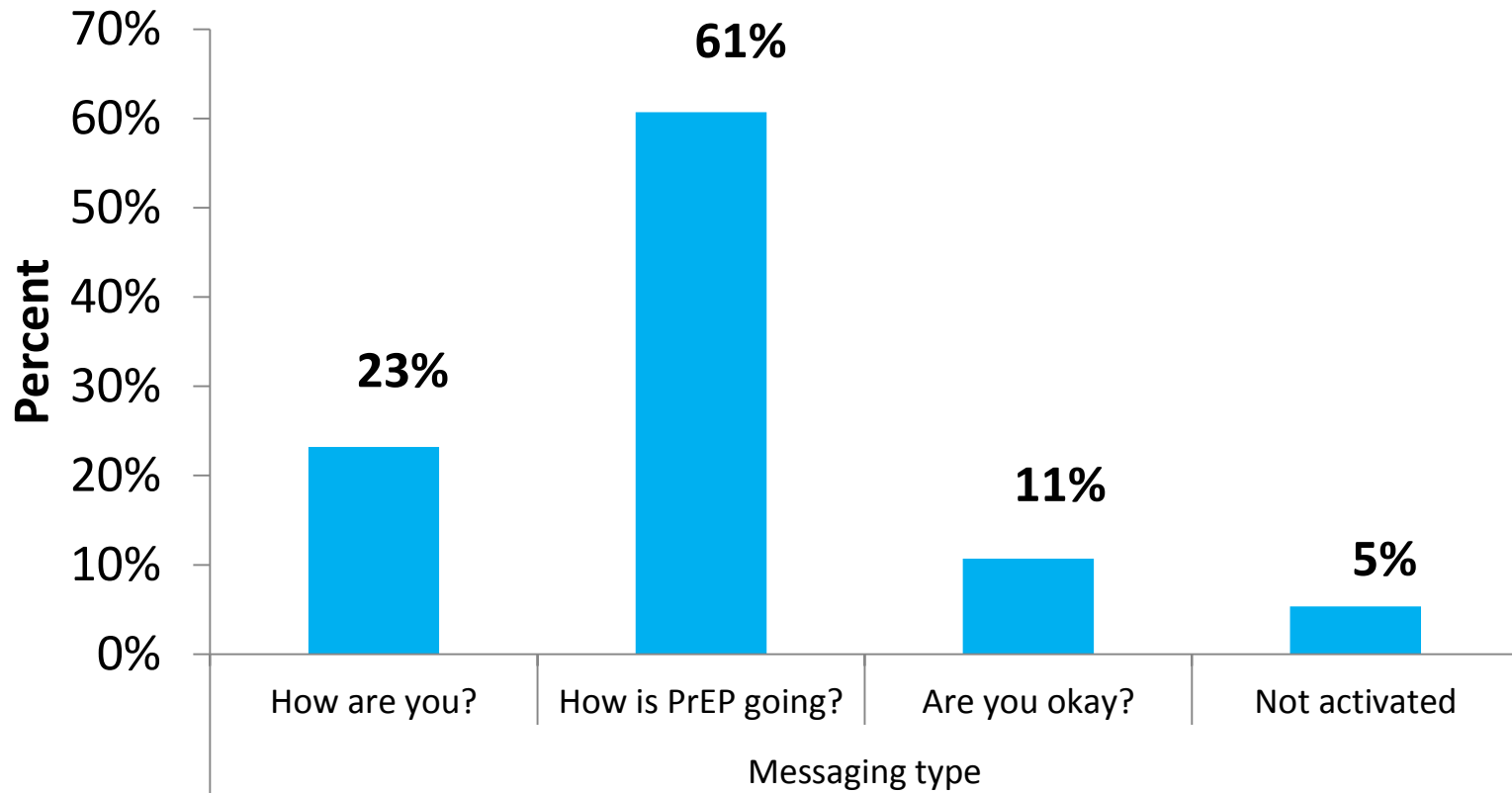
	San Francisco N=48	Chicago N=8
<b>Age</b>		
≤30 yrs	2%	100%
> 30 yrs	98%	0%
<b>Race/Ethnicity</b>		
White	79%	0%
Black	6%	50%
Hispanic	8%	25%
Other	6%	25%
<b>Education</b>		
Completed some college	94%	51%
<b>Living situation</b>		
Alone	27%	25%
w/male sexual partner	42%	13%
w/ family/friends	8%	63%
<b>Cell-phone plans</b>		
Have an unlimited SMS plan	78%	100%
Send/receive text messages daily	90%	86%

# About 2/3 of participants elected SMS, 1/3 email



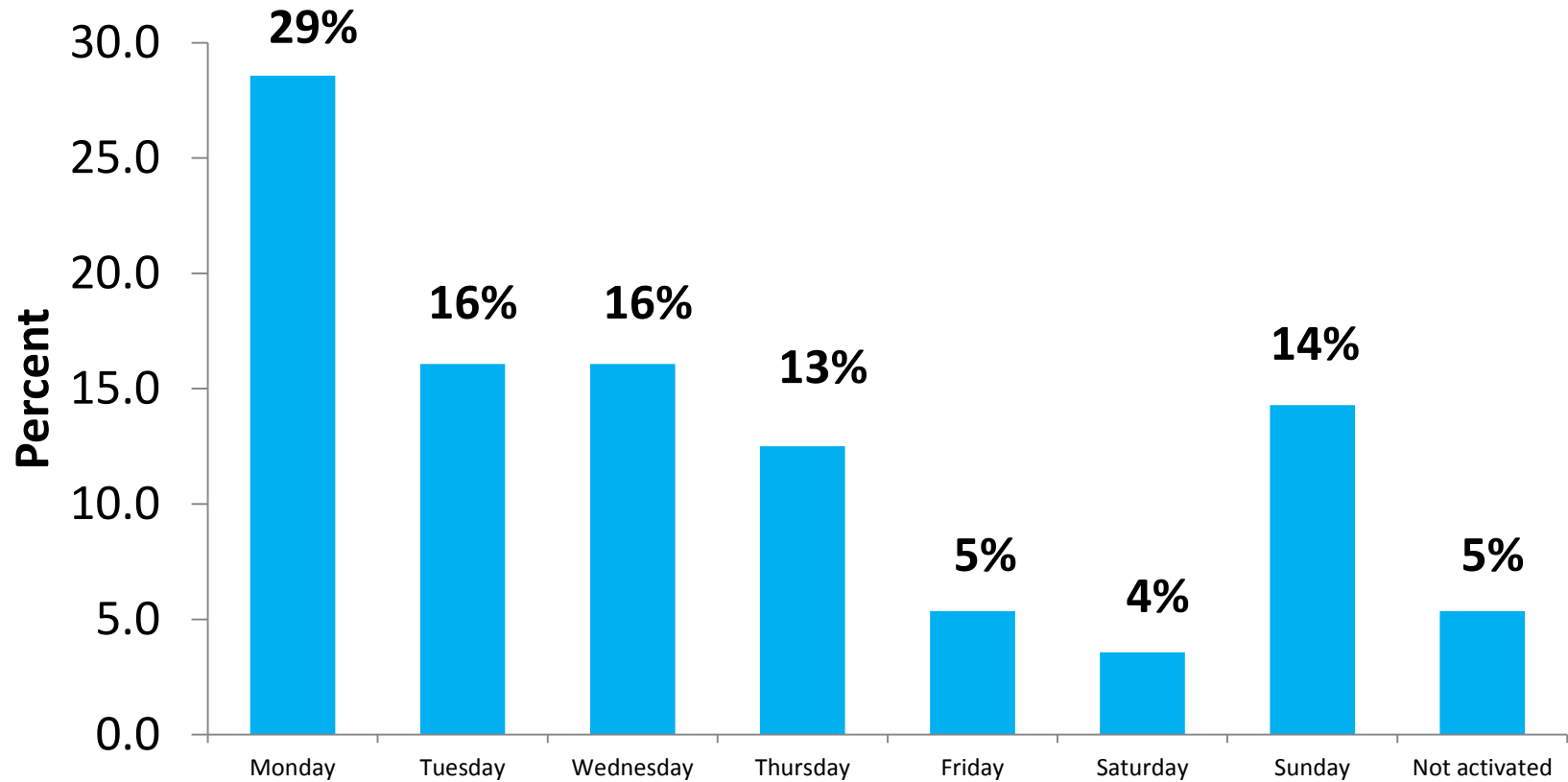
# Majority of participants wanted PrEP specific messaging

Participant selected messaging question



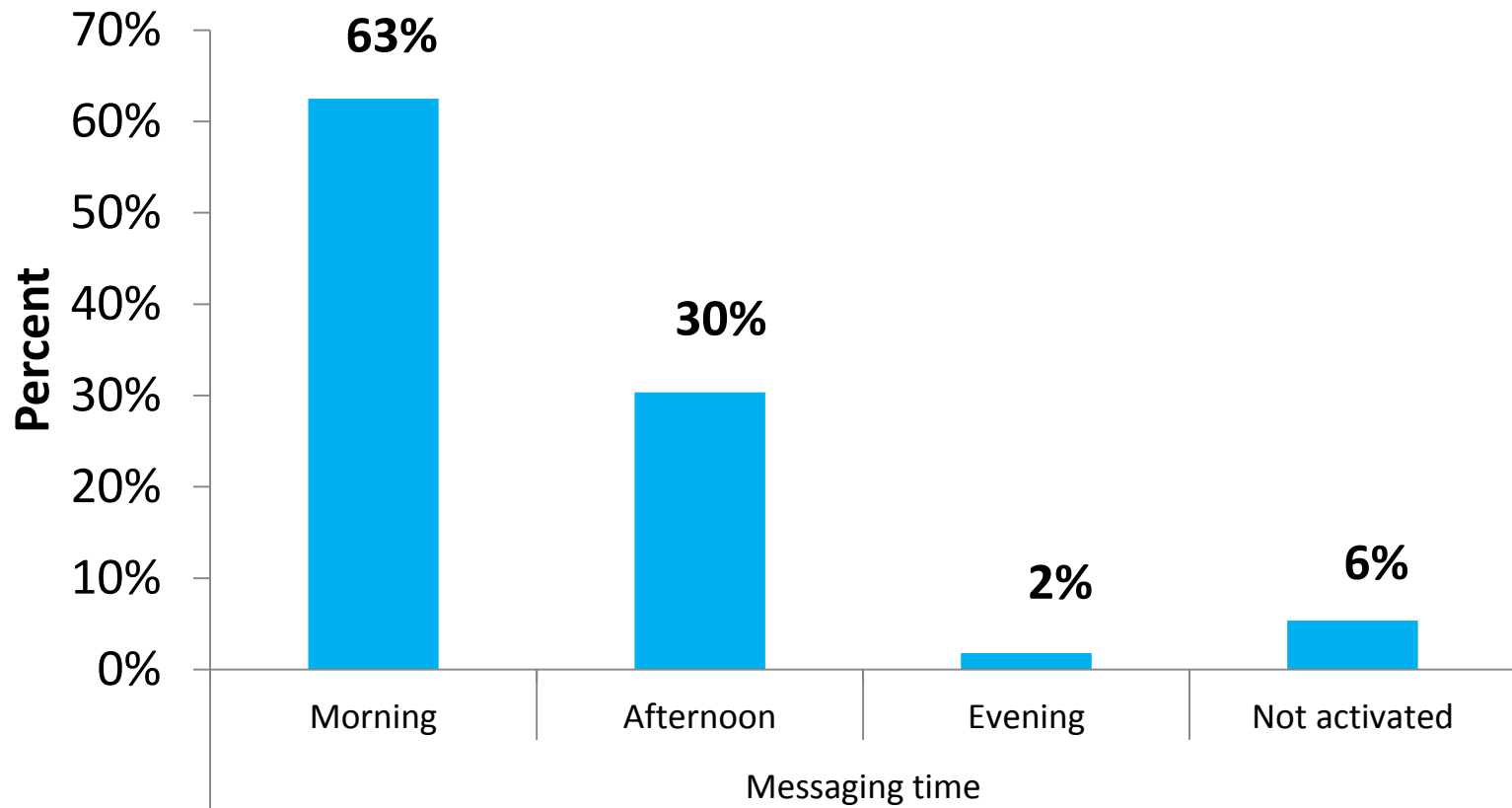
# Most preferred messages earlier in the week

Participant selected messaging day



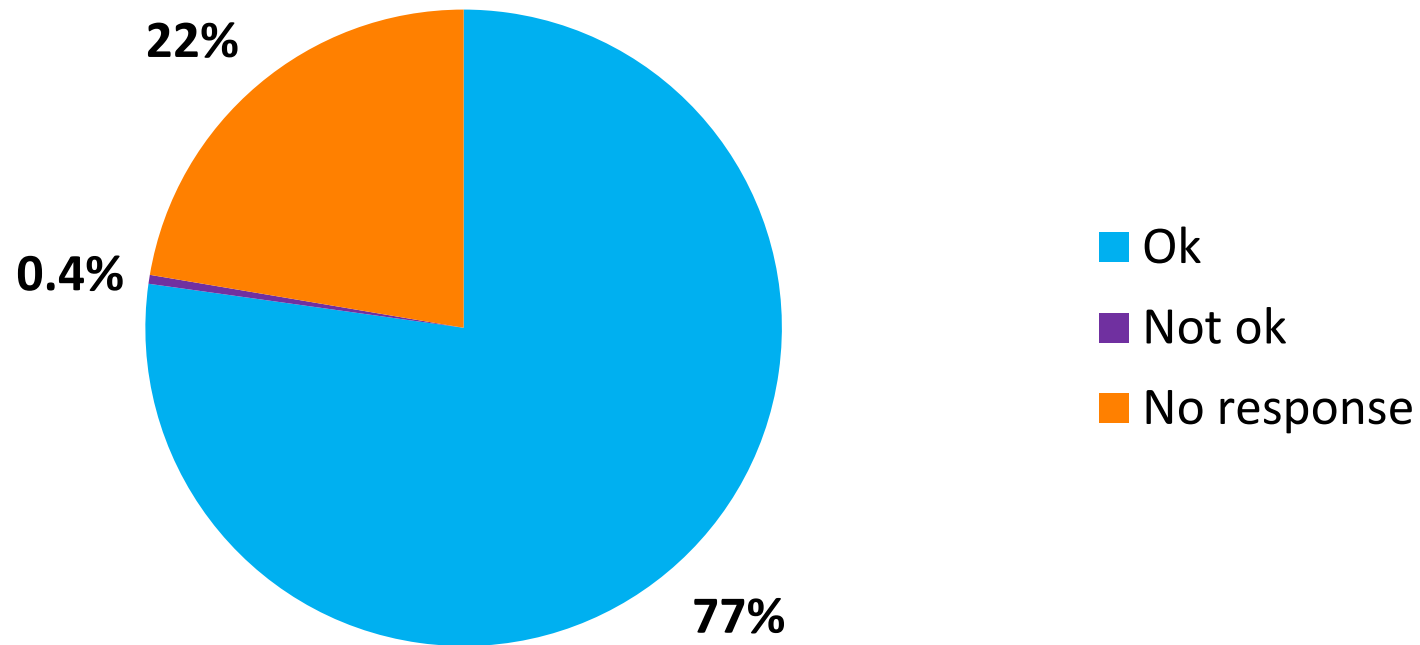
# Morning messages were most desired

Participant selected time of messaging



# Majority of responses were “ok” (N=667 messages)

## iText support strategy messaging responses

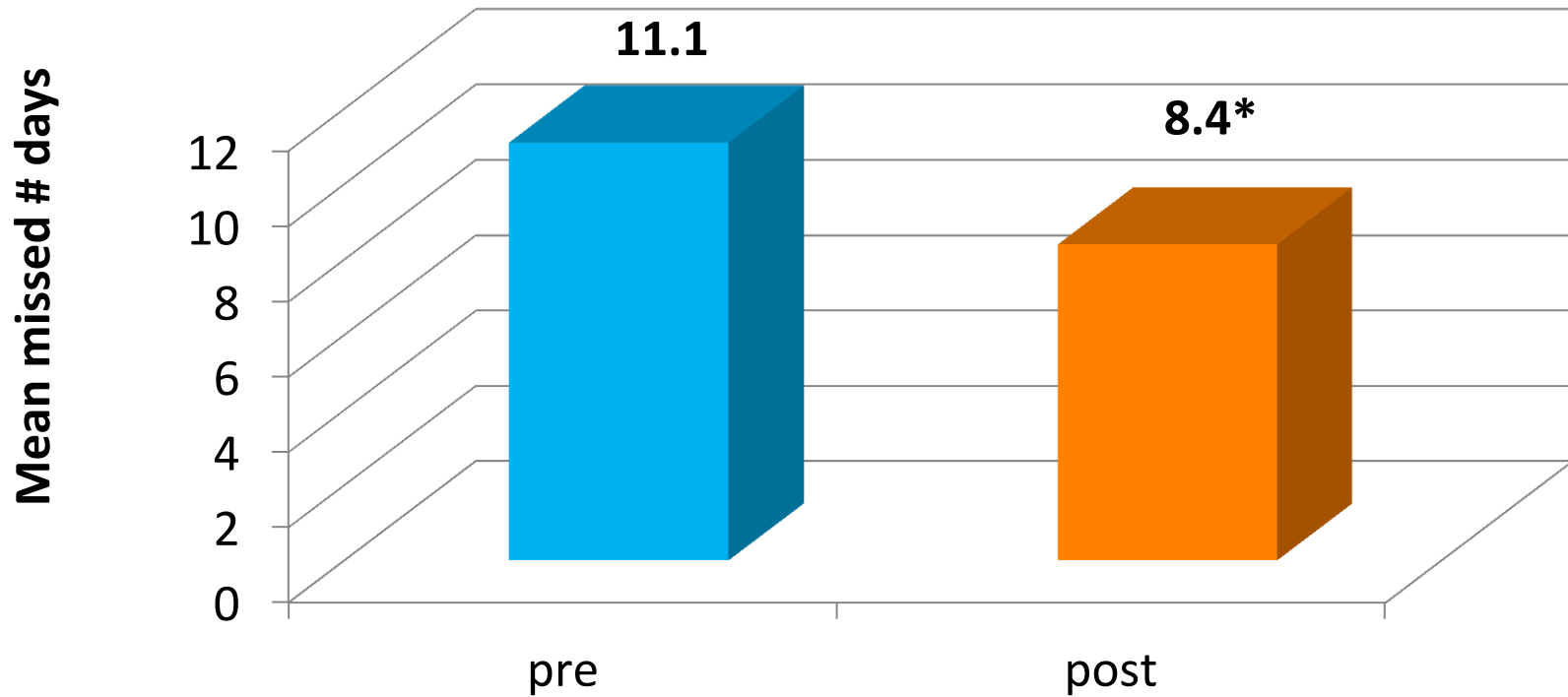


**Reasons for non-response: travel, phones were disconnected, no credit on phones, phone turned off, changing phones, just didn't feel like responding**



# Impacts on adherence: pill count

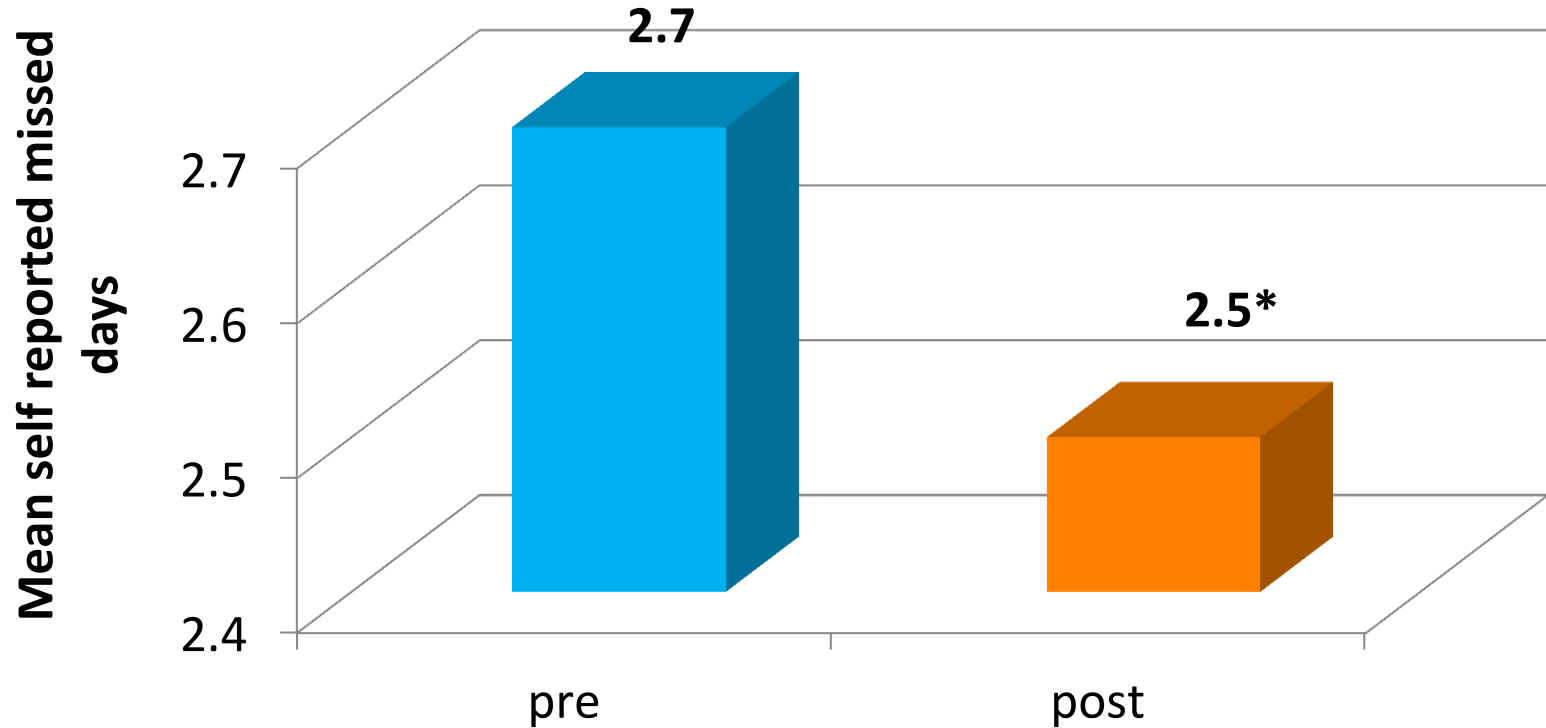
Mean missed # days pre and post iText, by pill count



**RR=0.5 (95% CI 0.29-0.84, p=0.008) in model adjusted for age, race, site, duration in study, and start date**

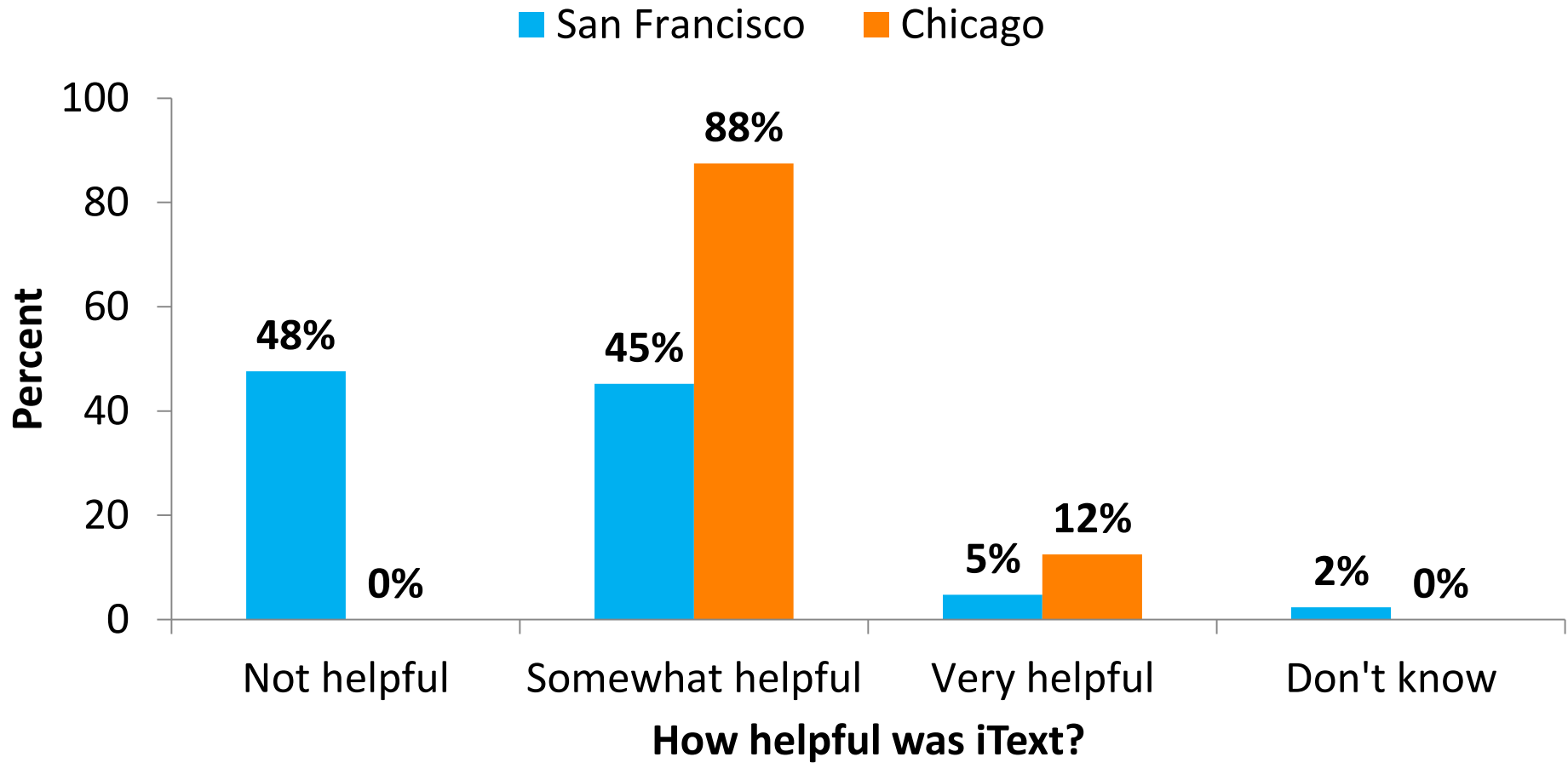
# Impacts on adherence: self-report

Self reported missed days pre and post iText

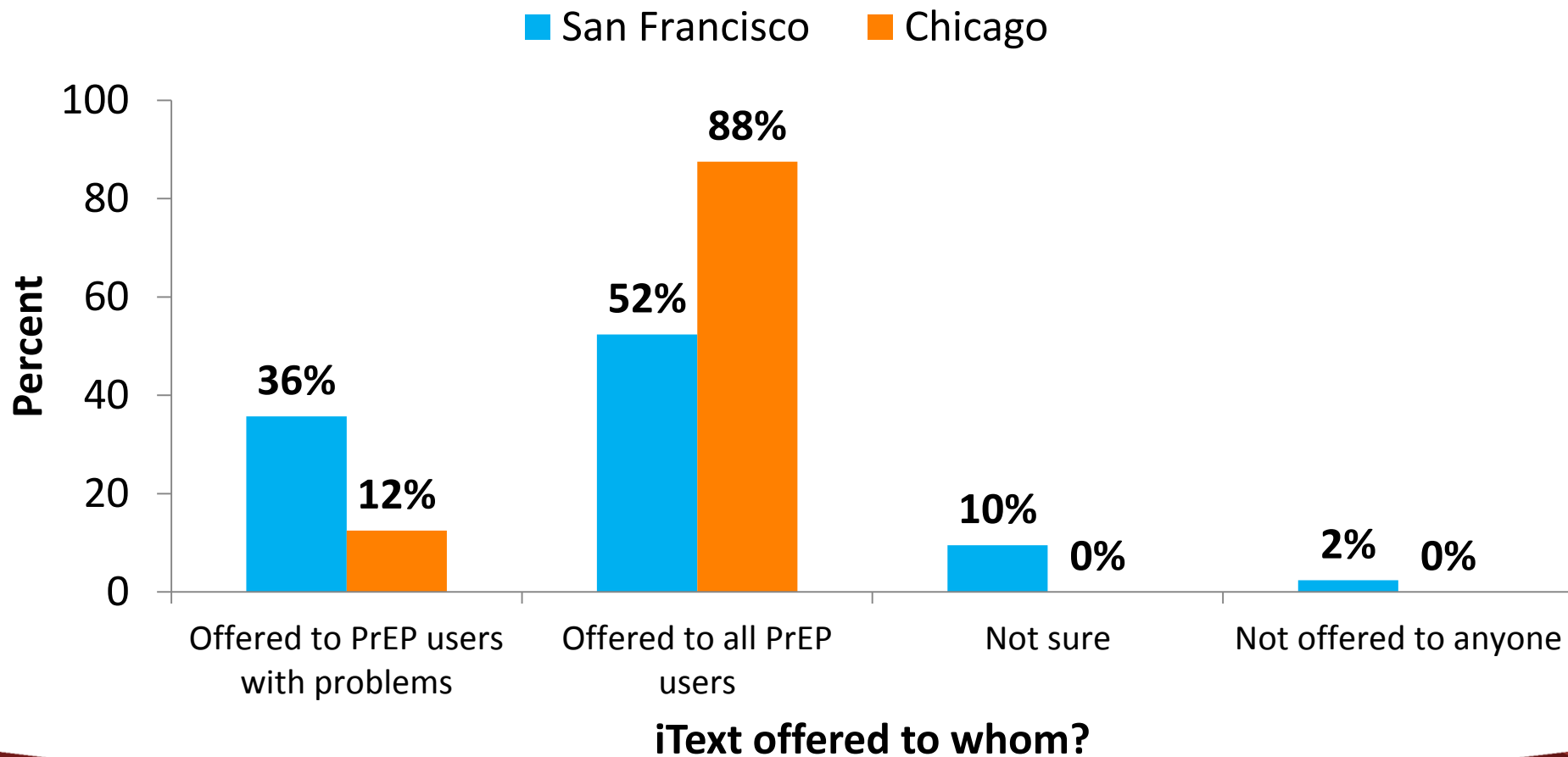


**RR=0.52 (95% CI 0.29-0.91, p=0.023) in model adjusted for age, race, study site, start date, and duration in study**

# How helpful, overall, would you rate the iText support strategy for you?



# To Whom should iText be offered?



# iText: post pilot focus groups

## PROVIDED ADDITIONAL SUPPORT AND SENSE OF SECURITY

...[You know when I wasn't on the I-Text study, I feel like I didn't really have a lot of support because I really didn't want to put too many people into my life, at that kind of level. So like **just getting those messages made me feel like there was always kind of somebody there** just in case something went wrong ... It's kind of like I was on my own before iText.”[C-FG]

# iText: post pilot focus groups

## *Perceived Efficacy on PrEP Adherence Varied*

### HELPFUL

It's just **my whole attitude was just so much better** and I just felt like I was so -- I was like really **in control** when I started getting the text messages. [C-FG]

### NOT/LESS HELPFUL...

And I mean I take the pill every morning religiously. It doesn't... it didn't help me. I mean it just didn't help me. [SF-FG]

### BUT WOULD BE FOR THOSE JUST STARTING PrEP...

So if **you're starting out** and maybe you would have some symptoms or something you wanted talk to somebody about it, maybe that makes sense. [SF-FG]

# iText: post pilot focus groups

## *Other recommendations – greater personalization and interactivity:*

- Allow additional tailoring of frequency and timing of text
- Addition of online social network strategies (Black Gay Chat, Jack'd, Facebook) to add human element
- Open-ended “text discussion” vs. phone call

## *Operational guidance:*

- Fix glitches!
- Emphasize purpose of texts more clearly and offer reminder texts as an add in feature

# Limitations

- 1) Pre and post study design has limitations for determining the effects of the iText intervention.
- 2) Adherence outcomes are currently only available from self-report and pill count data -> will analyze drug level data
- 3) Late implementation within OLE, with participants having been on PrEP for several years (including randomized phase)



## Conclusions and next steps

- **iText PrEP support found to be feasible and acceptable in iPrEx OLE –**
  - Young MSM of color in Chicago >> older, more PrEP-experienced MSM in SF
  - May be most helpful when starting PrEP
- **Formative work and pilot testing critical**
- **Next steps will be to refine intervention and evaluate the efficacy of iText in an RCT in a real-world setting (PrEP demonstration project)**

# Acknowledgements

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- Jonathan Katz

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- Vanessa McMahan
- Pedro Goicochea
- Lorena Vargas
- Kenneth Mayer
- Sybil Hosek
- Jennifer Brothers
- Robert Grant

## Our study participants!



National Institute  
of Allergy and  
Infectious Diseases





## 3 participants responding not okay

### 1) San Francisco

- Participant had 1 week of sore throat, cough, body aches, feeling feverish -> decided to stop study drug
- Spoke with clinician – low suspicion for ARS
- Participant instructed to come in for rapid HIV test prior to restarting study drug.

### 2) Chicago

- Unable to contact ppt by phone, but reached through Grindr (IRB-approved outreach strategy)

### 3) San Francisco

- Responded not okay to test the system
- Participant contacted the same day and appreciated quick follow-up.

# Higher acceptability of iText as a support strategy in younger MSM of color, bivariate analyses

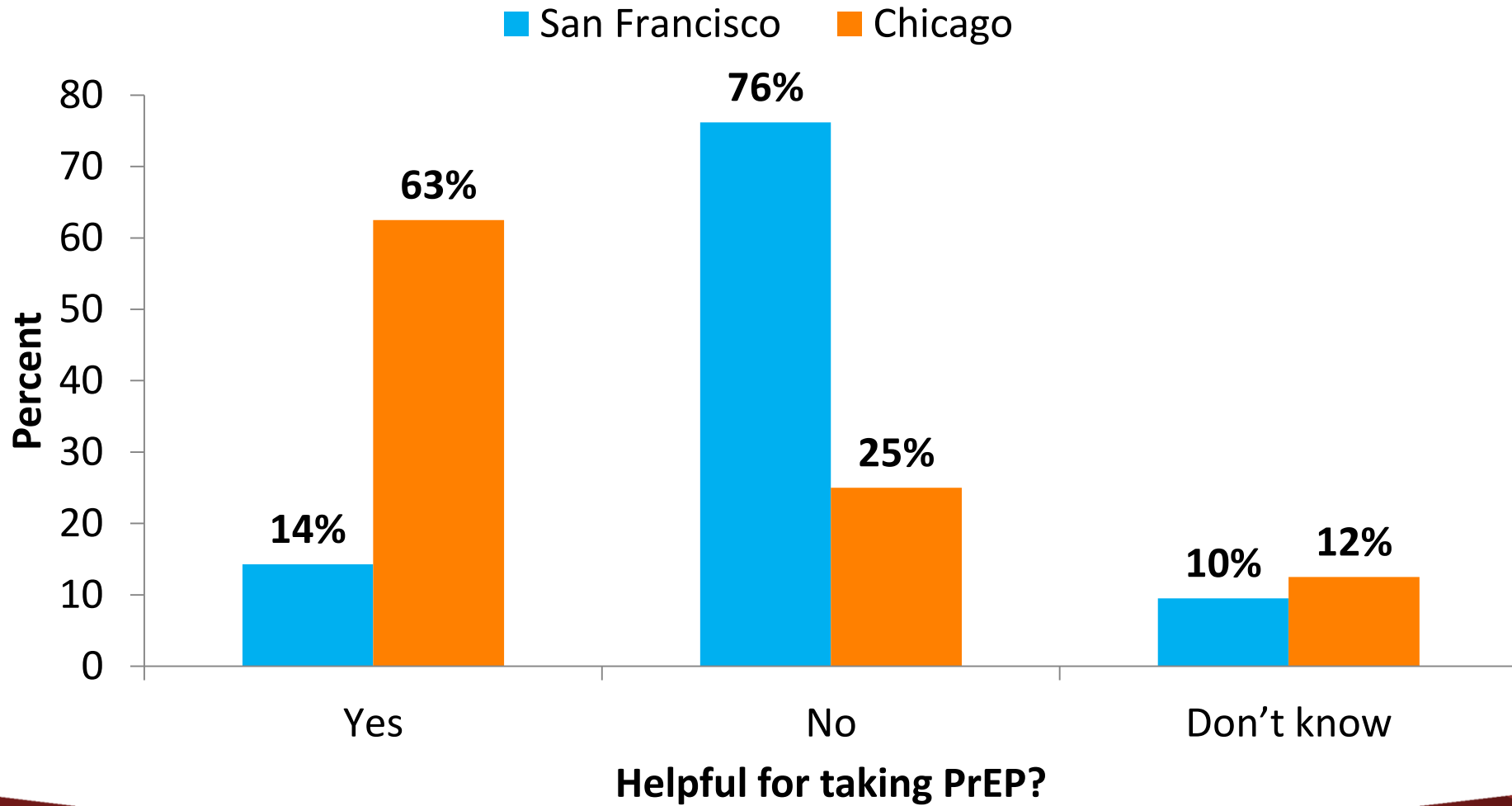
Domain	Comparison	Odds ratio
<b>Helpful for them</b>	Non white vs white*	7.3
	< 30 years vs > 30 years**	7.3
	Chicago vs . SF **	10
<b>Future use</b>	Non-white vs white*	4.7
	< 30 years vs > 30 years*	12.5

\*p<0.05, p <0.01

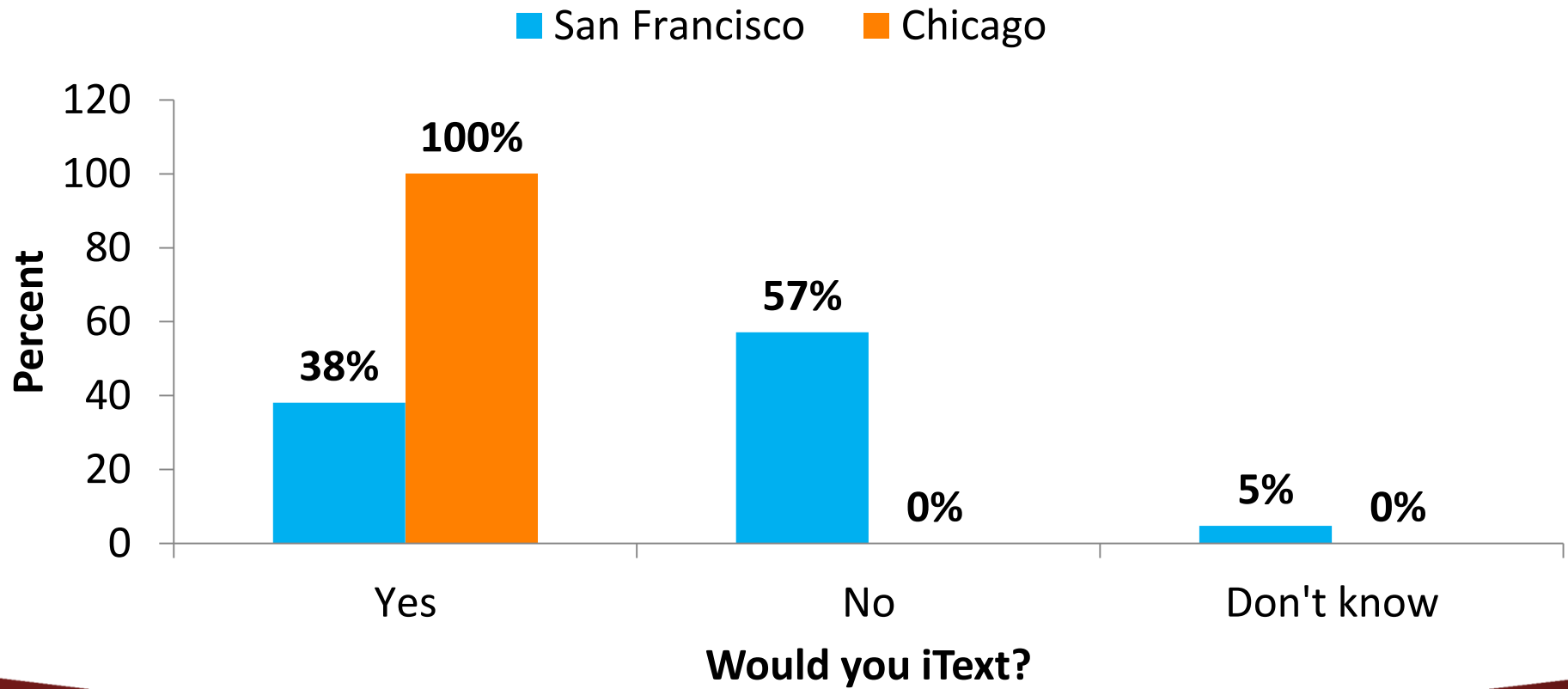
## Faster response time to SMS (text) messages

Response time					
Variable	N	Mean	Std Dev	Range	P-value
SMS (in hours)	370	4.4	8.6	(0.001, 46.7)	0.03
Email (in hours)	139	6.1	9.4	(0.02, 43.8)	

# Did getting these messages help you take PrEP?



# If you were to continue taking PrEP, either in the study or elsewhere, and iText was available to you, would you use it?





# iText: post pilot focus groups

*Some confusion over purpose of iText*

## REMINDER

That was my impression that **it was supposed to be a reminder** ... to take the pill. [SF-FG]

## CHECK-IN

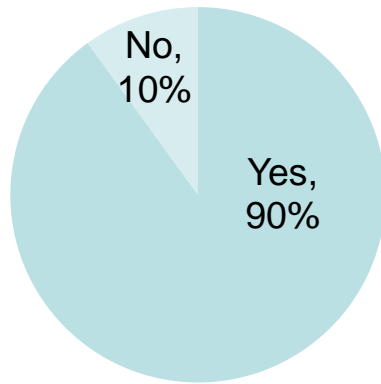
...[it was to] provide some form of communication, consistent communication with the participants that would allow them to seek -- **to get help...outside the [days between visits]** [C-FG]

# Almost all MSM in US own a cell phone

Internet-based survey among 1568 HIV-uninfected MSM (2010)

**Own a Cell Phone**

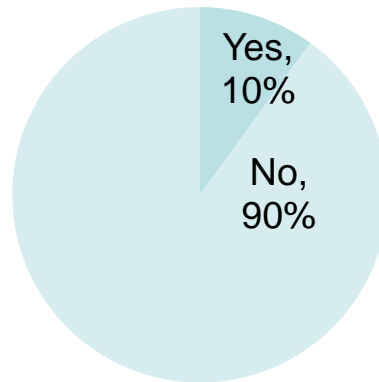
(Base: total MSM Sample)



n=1568

**Share Cell Phone**

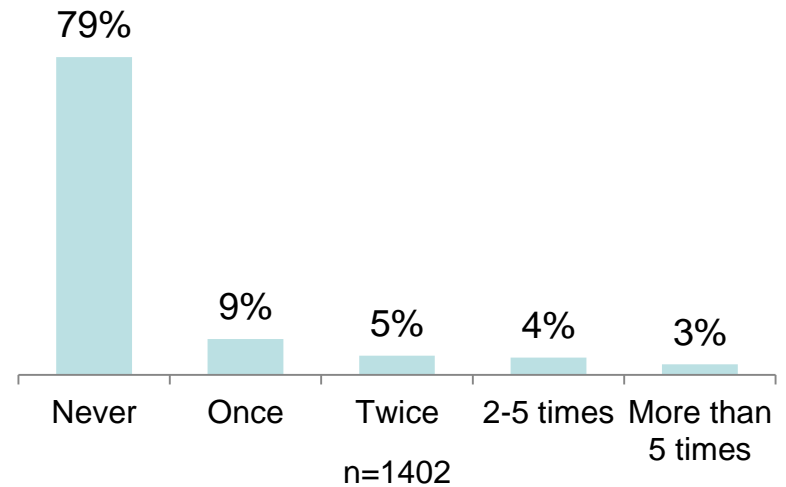
(Base: have cell phone)



n=1374

**Times Service Disconnected in Past Year**

(Base: have cell phone)



Fuchs IAS Rome 2011