

Strategies for Supporting Adherence in REACH

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Reality Check

- Medication non-adherence is one of the greatest challenges in the medical field
- Adolescents are up to 4x less adherent than adult counterparts
 - Adolescent adherence tends to hover around 50% regardless of disease state
 - 48% asthma, 55% post-liver transplant, 60% psychotropic meds, 48% sickle cell, 62% HIV
- Non-adherence brings significant cost burden to healthcare systems

The Quest

- We are charged with “fixing” this great challenge of non-adherence
- Caveat: be brief, simple and scalable



3 Ps








Adolescent Prevention Adherence

- ATN 110/113
 - PrEP for YMSM ages 15-22 in US
- Plus Pills
 - PrEP for 15-19 yo males and females in Cape Town and Soweto
- HPTN 082
 - PrEP for AGYW 16-24 yo in Cape Town, Johannesburg & Harare
- HOPE
 - Dapivirine ring for women ages 18-45

- What are our expectations for adherence in REACH?

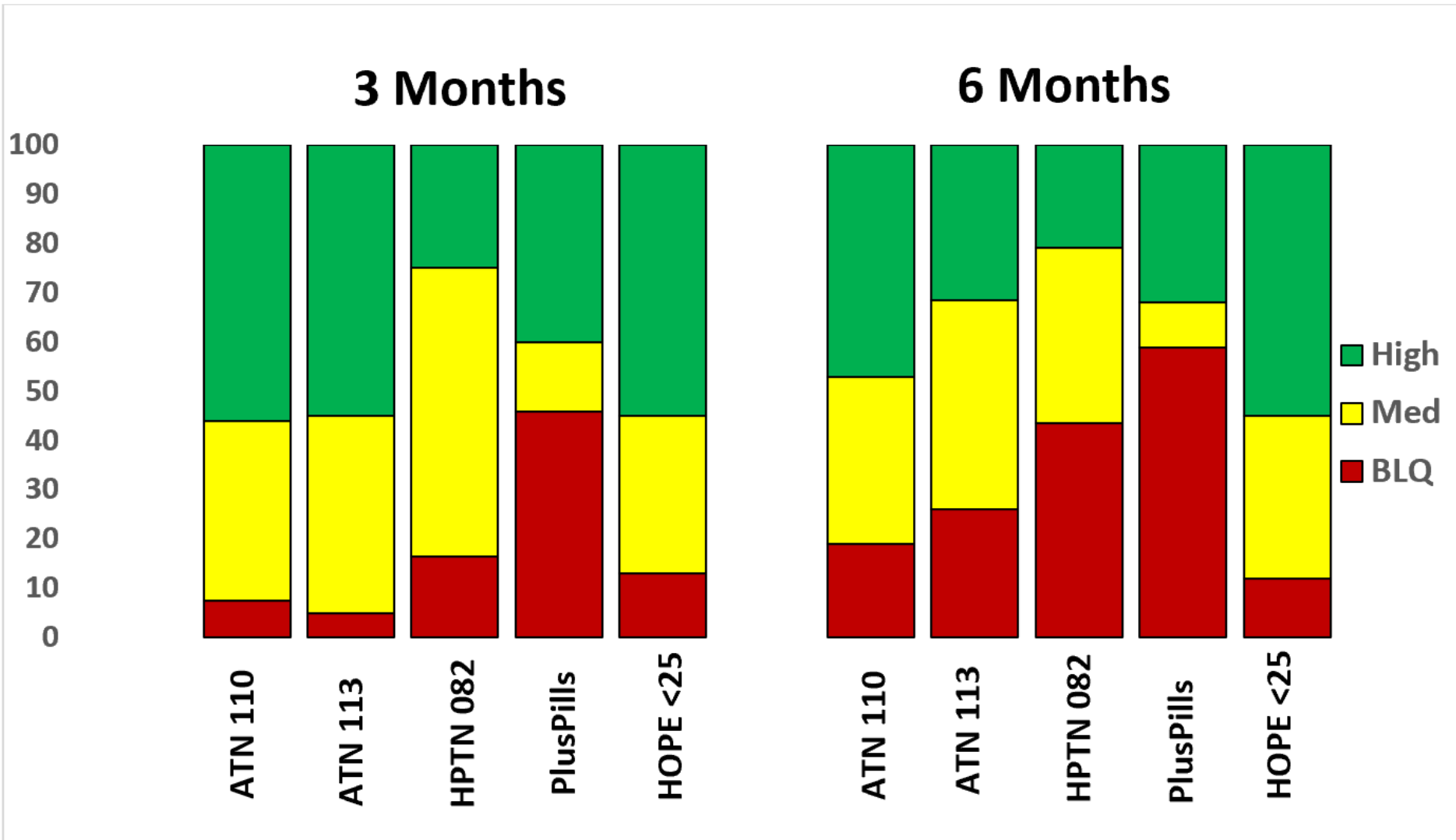
Adherence Measurement

| Sample Month | Results Month | Threshold | | Counseling Message |
|--------------|---------------|---------------------------|--|--|
| Month 1 | Month 2 | ≥ 500 fmol/punch |  | <p><i>4 or more doses per week (>500 fmol/punch at wk 4 and >700 fmol/punch at wk 8)</i></p> <p><u>Key message:</u> You are doing great! Keep up the good work and remember that taking one PrEP pill every day is needed for strong protection against HIV.</p> |
| Month 2 | Month 3 | ≥ 700 fmol/punch | | |
| Month 1 | Month 2 | 16.6 – 499 fmol/punch |  | <p><i>~1-3 doses per week (between detectable – 499 fmol/punch at wk 4 and detectable to 699 fmol/punch at wk 8)</i></p> <p><u>Key message:</u> It looks like you are trying to take the PrEP medication, but are having some difficulties. Remember that taking one pill every day is needed for strong protection against HIV. How can we help you do even better?</p> |
| Month 2 | Month 3 | 16.6 – 699 fmol/punch | | |
| Month 1 | Month 2 | BLQ (<16.6 fmol/punch) |  | <p><i>No TFV-DP detected (below quantification of 16.6 fmol/punch)</i></p> <p><u>Key message:</u> It looks like you haven't been able to take the PrEP medication. Is PrEP something that you are still interested in? If yes, how can we help you?</p> |
| Month 2 | Month 3 | BLQ (<16.6 fmol/punch) | | |

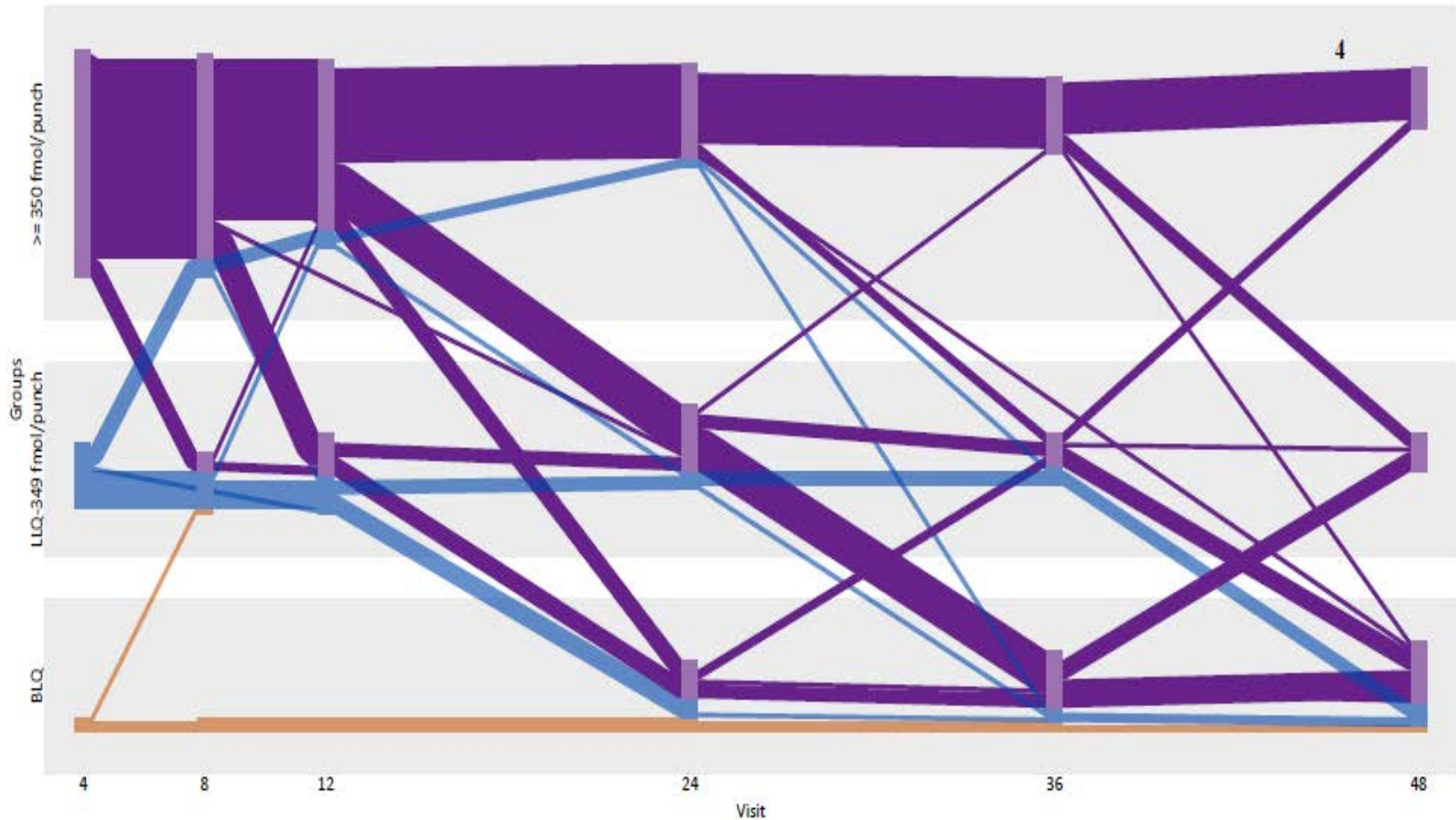
TFV-DP ≥ 700 fmol/punch was associated with 100% efficacy among MSM in the iPrEX OLE study & the 25th percentile of 4 doses/week on average (Grant Lancet HIV 2014)

** Plasma tenofovir >40 ng/ml associated with efficacy among women in Partners PrEP (Donnell JAIDS 2014)

Adolescent PrEP Trial Adherence



Adherence over time





We learn as we go

- Adolescent studies show that adherence declines over time; with less visits/contact
- HPTN 082
 - Standard adherence package – not all participants liked all components
 - Drug level feedback did not improve adherence over the standard package
- REACH incorporates frequent visits with adherence support choice
 - Pts decide what they need, how they want to receive it and with what frequency
 - DLFB spurs conversation about intervention needs

Adherence Support Menu

Adherence Support

Menu



☐ Daily Text Message

Once a day, we will send you an automated text message to help remind you to use your study product. You will choose from several message options.



☐ Weekly Check-In

☐ **Via Text Message** – once per week, you will receive an automated text message asking if you are OK. You will be expected to respond “OK” or “not OK”. If you don’t respond within 24 hours, a second message will be sent. If you respond “not OK”, a study team member will call you.

☐ **Via Phone Call** – once per week, you will receive a phone call from a study team member asking if you are OK. Based on your personal preference, they will leave a voice message or not.

☐ Peer Buddy

We will connect you with another participant who is also interested in having an adherence buddy. We will help you and your “buddy” develop a plan to support each other’s adherence.



Adherence Support

Menu



☐ Additional Counseling Visits

We will provide you with additional in-person counseling visits to discuss adherence in between regularly scheduled study visits.

☐ Adherence Support Groups

☐ **In-person groups** – we will arrange support groups for participants who would like to meet regularly to discuss the study, the pills or the ring, as well as other issues going on in their lives. A study team member will facilitate the group.

☐ **Online groups** – we will arrange secure, online support groups via apps, such as WhatsApp, on which participants can communicate with each other to discuss the study, the pills or the ring, as well as other issues going on in their lives. A study team member will facilitate the online group.

☐ Something Else

Can you think of another way that we can support you to use the study drugs as prescribed? Please let us know!





Early REACH Lessons

- What options are chosen?
- Frequent contact
- Establishment of trust takes time – and team will be tested
- Participants learn from their peers
- Adherence can be improved, but it takes
A LOT OF WORK



Case Examples – Uganda

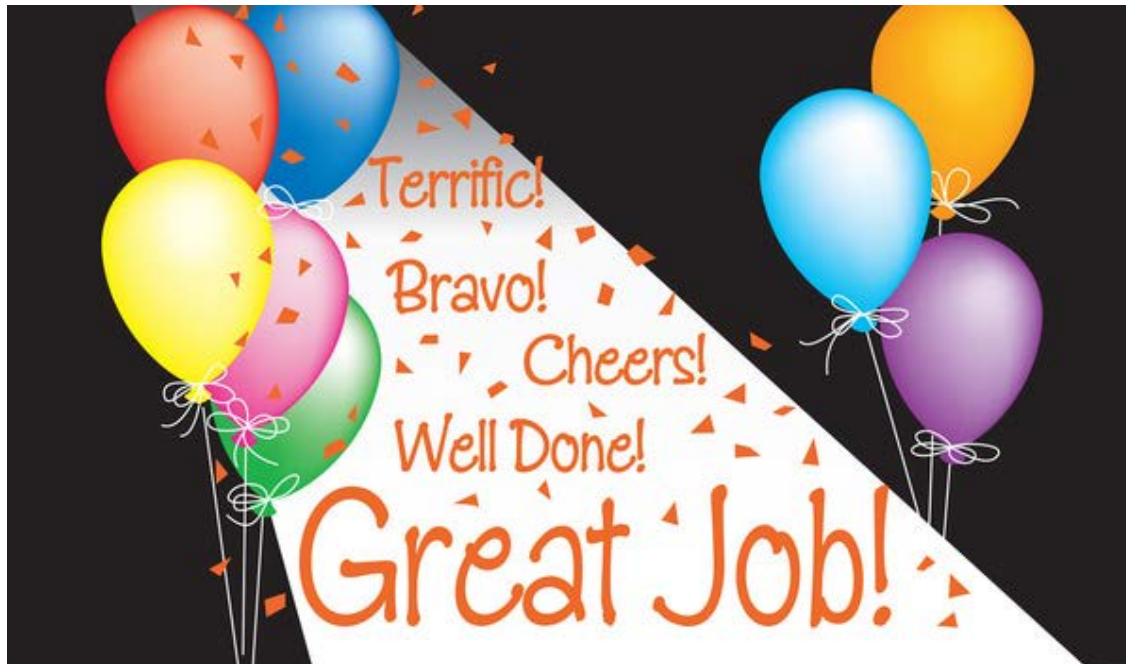
- Early drug level results showed some adherence challenges, particularly for the PrEP arm
- Participants were not always comfortable acknowledging non-adherence – some refused to accept “red” results
- In initial adherence groups, participants weren’t forthcoming with adherence challenges
- What did the team do?

Support, Support, Support!

- Multiple innovations
 - Invited HIV+ youth to come to the groups and share strategies for medication adherence
 - Separate groups for PrEP vs. Ring users – bi-weekly for PrEP, monthly for ring
 - Participants began requesting additional individual sessions (almost weekly) – and opened up about barriers
 - Celebration held for 1st cross-over participant; and birthday party for all
 - Used community meetings for HOPE and DREAM results to dispel myths

What happened?

- The “reds” have moved to “yellow”
- Several “yellows” have moved to “green”



Drug Level Wireless Signal Guide



HIGH LEVELS



MEDIUM LEVELS



LOW LEVELS



Case Examples - Zimbabwe

- A couple of early participants started off in the yellow category
- There was some delay in site receipt of drug levels, so two consecutive months of yellow were discovered
- Team was very concerned about seroconversion due to sex work
- What did the team do?

Support, support, support!

- Encourage multiple options on the adherence menu
 - Daily texts, weekly check-ins and WhatsApp groups
 - Focused counseling sessions on social support, disclosure and empowerment
 - Adherence groups became very popular
 - “PrEP Champions” from HPTN 082
 - Integrated adherence and risk reduction counseling
 - Pts had awareness of high risk in sex work

What happened?

- Participants moved from yellow to green!



The Counselors...



- Are amazing!



- Are learning from each other and from the REACH participants
- Need support from the site teams
- Are excited about the peer review process

Peer Review

REACH (MTN 034) – Adherence Support Counseling Feedback Form: Enrollment Visit

| | | |
|---|-----------------------------|-------------|
| Counselor: | PTID: | Site: |
| Date of Session: | Session Duration (minutes): | Visit Code: |
| Product initiating: <input type="checkbox"/> Ring <input type="checkbox"/> oral PrEP | Date of Review: | Reviewer: |

Please make a note if a session task was covered out of order, at a different point in the session.

| |
|--|
| <p>1. Introduction, welcome, affirm attendance</p> <ul style="list-style-type: none"> <input type="checkbox"/> Counselor welcomes or greets participant OR mentions that the visit will now shift to the counseling portion of the visit. <input type="checkbox"/> Thanks participant for coming <input type="checkbox"/> Affirms participant's attendance (i.e., commitment to study, commitment to fighting HIV, effort to get to appointment, etc) <input type="checkbox"/> Introduces that sessions are recorded and reason why <p><u>Notes:</u></p> |
| <p>2. Provide overview of counseling session</p> <ul style="list-style-type: none"> <input type="checkbox"/> Describes expected length of session <input type="checkbox"/> Emphasizes importance of open communication (i.e., sharing positive AND negative experiences with using the Ring or oral PrEP) <input type="checkbox"/> Reviews expectations for both counselor and participant <p><u>Notes:</u></p> |
| <p>3. Reviews information about Ring or PrEP per the REACH adherence counseling manual (depending on random assignment)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Asks participant what they have heard about product <input type="checkbox"/> Affirms correct information offered by participant <input type="checkbox"/> Shares information clearly <input type="checkbox"/> Responds to participants questions and concerns <p><u>Notes:</u></p> |
| <p>4. Explore upcoming Ring or PrEP use adherence</p> <ul style="list-style-type: none"> <input type="checkbox"/> Explores potential barriers and facilitators to adherence <input type="checkbox"/> Helps participant consider common barriers <input type="checkbox"/> Works on daily plan with participant using calendar activity <input type="checkbox"/> For PrEP: Assists participant to identify ideal time of day for taking tablet <p><u>Notes:</u></p> |

REACH (MTN 034) – Adherence Support Counseling Feedback Form: Enrollment Visit

| |
|--|
| <p>5. Assess confidence and goals regarding adherence to study product</p> <ul style="list-style-type: none"> <input type="checkbox"/> Uses confidence ruler <input type="checkbox"/> Evokes reason why she is confident <input type="checkbox"/> Encourages participant to identify more than one reason why she feels confident <input type="checkbox"/> Asks about goals for adherence until the next study visit <input type="checkbox"/> Helps participant identify issues that may interfere with goals <p><u>Notes:</u></p> |
| <p>6. Assist with adherence support options</p> <ul style="list-style-type: none"> <input type="checkbox"/> Introduces the adherence support menu and describes all of the options listed <input type="checkbox"/> Asks participant if there are other options she'd like to include <input type="checkbox"/> Encourages participant to pick items she thinks may work best for her <p><u>Notes:</u></p> |
| <p>7. What else? Wrap-up</p> <ul style="list-style-type: none"> <input type="checkbox"/> Invites discussion of additional questions and concerns <input type="checkbox"/> Asks again what questions remain, and thoroughly discusses until none remain (if necessary) <input type="checkbox"/> Acknowledges and appreciates the participant for coming to the appointment <input type="checkbox"/> Discusses plans for next session <input type="checkbox"/> Reminds participant to contact the clinic if she needs to talk or has questions <p><u>Notes:</u></p> |

Overall Feedback

a) What did the counselor do well in this session?

b) What could the counselor improve on from this session?

c) Other general feedback for the counselor?



Summary

- ❑ Adherence challenges are very common for adolescents
- ❑ REACH offers a multitude of intervention options with choice
- ❑ Improvement can be seen among those with early struggles, but it takes a LOT of work
- ❑ Requires Persistence, Positive attitude & Patience - - and a whole lot of teamwork!

Acknowledgements

- The REACH Counselors for all that they do
- Elizabeth Brown for assistance with HOPE data
- FHI: Lisa, Morgan, Tara, Sherri for being the “team”
- The Microbicide Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health



THANK YOU!
