



Roflumilast or Azithromycin to prevent COPD Exacerbations

QUARTERLY CLINICAL ROUNDTABLE SERIES

Session 3:

How to Be Successful Clinical Centers or Community Partners in RELIANCE

July 26, 2022, 12-1pm ET



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Henry Ford Clinical Center



Bushra Mina, MD
Lenox Hill Clinical Center



Community Partner
Randall Harris,
nominated by Umur
Hatipoglu at Cleveland
Clinic

*HEAR ABOUT REAL CHALLENGES
TO RECRUITING PARTICIPANTS,
WHAT'S BEEN WORKING, AND
HOW TO APPLY BEST PRACTICES*



This session is being recorded.

Please use the chat box to ask questions to be answered during the Q&A. Feel free to put your thoughts for this and future Roundtable events in the chat.

1. **Welcome / introductions** (Jerry Krishnan, 5 min)
2. **Henry Ford Clinical Center** (John Veljanovski, 10 min)
3. **Lenox Hill Clinical Center** (Bushra Mina, 10 min)
4. **Community Partner Pathway overview** (Jerry Krishnan, 5 min)
5. **Community Partner Randall Harris, nominated by Umur Hatipoglu at Cleveland Clinic** (10 min)
6. **Q&A** (Robert Wise, 20 min)

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Jerry Krishnan,
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Bushra Mina,
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John Veljanovski,
MD, MBA



Randall Harris,
MD



Robert Wise, MD



John Veljanovski, MD
Henry Ford Clinical Center Co-I



ABOUT

- a. Years in practice: 3 years, MD/ MBA
- b. Clinical focus: A mix of sleep medicine, NIPPV and multiple COPD studies
- c. Co-Director of Henry Ford COPD Research Initiatives

COPD PRACTICE

- a. Henry Ford is a large urban academic center in Detroit, MI and surrounded by several satellite campuses
 - i. Servicing both inpatient and outpatient
 - ii. Randomized both inpatient and outpatient RELIANCE patients. (Mainly outpatient)



WHY RELIANCE?

- a. Interested in the design of RELIANCE and comparative effectiveness research
- b. Dr. Ouellette was involved in selection process of which medications to study
- c. Evaluating if there's a difference between Azithromycin and Roflumilast in preventing exacerbations of COPD
- d. Benefitting our COPD patient population



WHAT IS WORKING?

- a. Research coordinators pre-screen upcoming patients to the clinic
- b. Meet weekly with me to review upcoming patients
- c. Clinicians identified as having a possible candidate receive an email at least 48 hours prior to their visit

RECOMMENDATIONS FOR OTHER SITES

- a. Pre-screen patients coming into clinic
- b. Have the consent on hand to provide to the patient
- c. Discuss study with pulmonary staff regularly at senior staff meetings to remind and update them on the progress of the study



CHALLENGES

- a. Introduction of RELIANCE - Introducing the study to patients and attempting to mimic real world process flows when first discussing RELIANCE as an appropriate treatment option
- b. Provider Time - Often posed with many questions about the study which impacts provider time and may be deterrent as it can often take 5 – 10 minutes of provider time
- c. Consenting Patient – After a patient has completed their visit and reviewing the consent process. It's often challenging to contact the patient and receive a signed consent from the patient requiring several phone calls/emails
- d. Insurance Coverage variation



Bushra Mina, MD
Lenox Hill Clinical Center PI



ABOUT

- a. 27 Years in practice in Manhattan, NY
- b. Transitioned from private to full time faculty practice in academic center
- c. Both inpatient (pulmonary critical care) and outpatient (pulmonary) practice

COPD PRACTICE

- a. Inpatient:
 - i. AECOPD
 - ii. Secondary diagnosis: Stable COPD
- b. Outpatient:
 - i. Routine follow-up visits
 - ii. Post-exacerbation/hospitalization
 - iii. Urgent visits



WHY RELIANCE?

- a. Clinical Academic Center
- b. Benefits to our COPD patients
- c. Real world PCORI study
- d. The objectives of the study
- e. Impact on future practice

WHAT IS WORKING?

Inpatient

- Confirm eligibility
- Make follow-up visit

Prior-Authorization

- Enter Rx via Vivo Pharmacy and put on hold until further notice
- Before dispensing, confirm coverage and copay with pharmacy

Outpatient

- Patient arrives at appointment made during inpatient visit
- Consent and randomize

Prescription

- Order prescription and send to patient's pharmacy of choice



RECOMMENDATIONS FOR OTHER SITES

- a. Collaborate with local IT to generate query list
- b. Spread the word through support groups
- c. Participation of pharmacists for drug prior authorization or appeal



CHALLENGES

- a. Spanish-speaking patients without Spanish-translated ICF
- b. Roflumilast authorization and expensive copay
- c. Patients are taking >30 consecutive days of azithromycin or roflumilast
- d. Community partners for Northwell require CITI training

CHANGES WE'VE MADE

- a. Collaborate with ambulatory faculty pharmacist to ensure pre-authorization is approved or submit an appeal if needed before randomization
- b. To ensure consistent follow-up, consent obtained in outpatient setting
- c. Generate a query list with IT team to guarantee all patients are screened
- d. Patient is referred and screened by coordinator using mutual EMR and patient is e-consented



3 steps for clinicians to refer their patients to RELIANCE:

STEP 1

Identify potentially eligible patients during routine care (in-person or telehealth).

- ✓ Hospitalized for COPD exacerbation or respiratory complications of COVID-19 in the last 12 months;
- ✓ Have severe COPD with associated chronic bronchitis;
- ✓ Currently take a LAMA, ICS/LABA, or LAMA/LABA;
- ✓ May need treatment escalation with either roflumilast or azithromycin (and you have no preference).

STEP 2

Introduce the RELIANCE study

RELIANCE provides materials to help introduce the study.

If patient expresses interest, confirm eligibility and hand them an envelope of RELIANCE materials to support enrollment by the RELIANCE call center.

STEP 3

Submit 23-minute online referral form. RELIANCE takes it from there!

The RELIANCE call center confirms interest and eligibility.

A central study MD writes the first Rx and sends to your patient's pharmacy.



Randall Harris, MD

Community Partner

Nominated by Umur Hatipoglu at
Cleveland Clinic



Randall Harris, MD | Community Partner | Cleveland Clinic
Akron General

ABOUT

27 years clinical Pulmonary Medicine, post fellowship

COPD PRACTICE

- a. Inpatients with COPD on the pulmonary floor service and the MICU
- b. Outpatient practice is general pulmonology (COPD is a bit more of a minor component)



Randall Harris, MD | Community Partner | Cleveland Clinic
Akron General

WHY RELIANCE?

- a. Co-Director of a COPD readmissions project since 2019
- b. Attend COPD intrahospital meetings, on COPD readmissions committee at the regional hospital



WHAT IS WORKING?

- a. It's relatively easy to enroll, once you find the appropriate patient population
- b. The kits that were provided are simple and user friendly, and can easily be handed off to the patients
- c. Flexible definition of severe COPD is helpful—recent PFT not mandatory

RECOMMENDATIONS FOR OTHER SITES

- a. Keep the RELIANCE signage in my outpatient office to remind myself about the study
- b. Since the eligibility criteria is severe COPD and recently hospitalized, recommend engaging hospitalists and others involved in hospital discharge



CHALLENGES

- a. Hospitalization within 1 year criteria eliminates a lot of potential candidates
- b. Struggle sometimes with telling patients that one is FDA-approved for this purpose and the other is an off-label indication
- c. Expense of roflumilast in combination with GI upset and not knowing if it is better than azithromycin can cause hesitation in patients, we need to stay impartial/ equipoise
- d. I'm not in office every week, and I don't have a specific COPD clinic since I'm a general pulmonologist

CHANGES WE'VE MADE

- a. Including intradepartmental colleague's patients
- b. Asked the nurse practitioners to keep us notified about eligible patients



Q&A



Robert Wise, MD

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Become a Community Partner: Complete this brief form <https://www.redcap.ihrp.uic.edu/surveys/?s=KLDND4KT8N> to nominate yourself or a colleague to learn more, or point your phone camera at the QR code below.

