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# Implementation and evaluation of pulmonary arterial hypertension clinical program and pharmacist education at a health-system specialty pharmacy



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## Background

Pulmonary Arterial Hypertension (PAH) is a progressive, and debilitating disease, often resulting in poor prognosis when treatment is inadequate:

- ❖ 1 to 3 years mortality rates as high as 30%<sup>1,2,3</sup>
- ❖ Medical costs are approximately four times higher due to drug cost and extensive medical oversight.

Health system specialty pharmacies have evolved over the past decade to adapt to an exponential growth of high-cost specialty drugs being approved for complex disease state.

Clinical pharmacists in specialty pharmacies are well-equipped to provide meaningful interventions in collaboration with PAH clinicians to improve patient care outcomes and reduce overall healthcare cost:

- ❖ Individualized assessment of disease state.
- ❖ Medication reconciliation with drug interaction evaluation Assessment of monitoring parameters.
- ❖ Risk Evaluation & Mitigation Strategies (REMS) compliance.
- ❖ Evaluation of disease impact on patient quality of life.
- ❖ Side effect identification and management strategies.
- ❖ Safe and cost-effective medication fulfillment.

## Purpose

This study aims to develop and implement a PAH-specific clinical workflow, while providing enhanced pharmacist education, training & resources in a health-system specialty pharmacy setting.

## Methodology

This study is exempt by Institutional Review Board

### \* Study design

Single-centered, quasi-experimental implementation study with retrospective review from February 25th, 2020 to April 17th, 2020.

### \* Patient management program

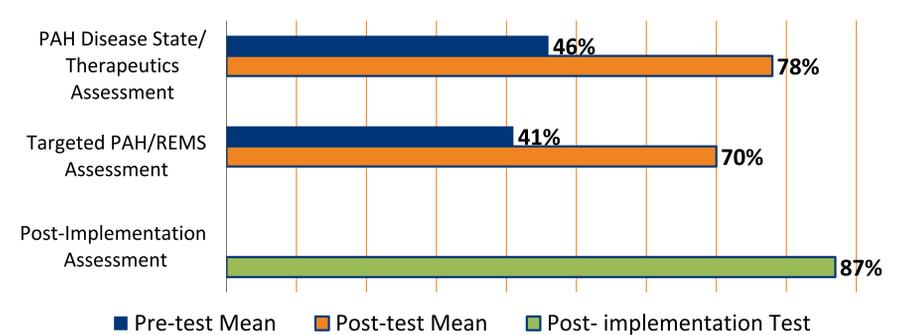
- **New patient assessment:**
  - Evaluate therapy appropriateness, monitoring parameters, patient history & baseline quality-of-life
  - Perform medication reconciliation and drug interaction evaluation
  - Manage REMS criteria and compliance
  - Provide medication and non-pharmacological education.
- **Patient follow-up assessment:**
  - Evaluate medication efficacy, safety profile, monitoring parameters, medication adherence & disease impact on quality-of-life
  - Perform medication reconciliation and drug interaction evaluation
  - Manage REMS criteria and compliance
  - Identify side effects and provide side effect management strategies, as appropriate.

### \* Study objectives and data analysis

- **Primary objectives**  
 Pharmacist competency and readiness based on targeted PAH/REMS education program and trainings.
  - Two on-site continuing education sessions
    - First session: PAH Disease State/Therapeutics
    - Second session: Targeted medication and REMS management
  - Two pre-and post clinical assessments before workflow launch.
  - Final clinical assessment one-month after workflow launch.
- **Secondary objectives**  
 Pharmacist clinical interventions and satisfaction with PAH/REMS-focused education and resources.
  - Post-implementation retrospective report based on specialty pharmacy electronic health record (EHR)
  - Post-implementation pharmacist satisfaction survey

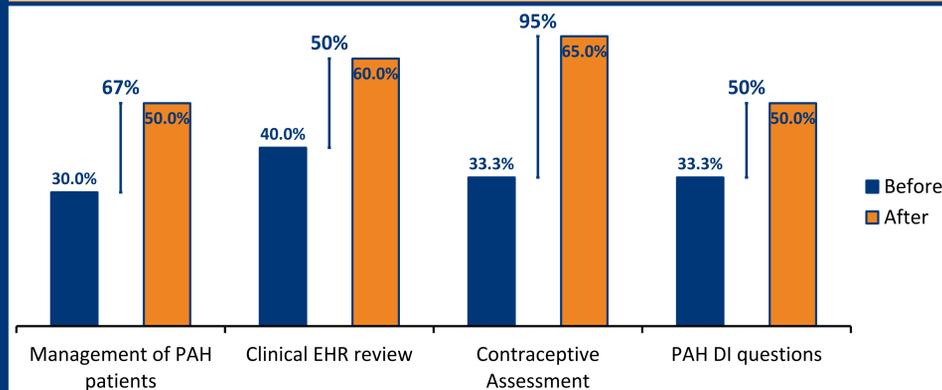
## Results

### Pharmacist competency before and after PAH/ REMS education program



- **PAH disease state and therapeutic assessment:** examine PAH competency on disease state, symptoms classification, first line therapy, drug interactions and lab parameters.
- **Targeted PAH/REMS assessment:** examine REMS compliance, drug interactions, non-pharmacological counseling points, common drug adverse effects, signs and symptoms of hepatotoxicity.
- **Post-implementation assessment:** Combination of general and targeted PAH competency.

### Pharmacist readiness before and after PAH/ REMS education programs



Level of readiness is ranked based on a scale of 0 to 3:  
 0 = Not at all comfortable; 1 = Slightly comfortable; 2 = Very comfortable; 3 = Extremely comfortable

Table 1: Patient Demographic

Demographic	Mean values (range or no. %)
Age, year, mean	44 (4 – 66)
Sex, female, No. (%)	5 (42.8)
Reproductive potential	2 (28.5)
New start	1 (14.2)
Continuation of therapy	8 (85.7)
<b>PAH Medications Prescribed (n = 9)<sup>a</sup></b>	
Bosentan (Tracleer)	4 (44.4)
Ambrisentan (Letairis)	5 (55.6)
Tadalafil (Adcirca)	4 (44.4)
Sildenafil (Revatio)	3 (33.3)
<b>Patient Assessment</b>	
New patient assessments	9
Patient follow-up assessments	4
Assessment time	15 minutes (7-25 minutes)
Prescription Turn-Around Time	3.5 days (0 – 9 days)*

\* 0 = same day delivery  
<sup>a</sup> some patients prescribed combination therapy

Table 2: Pharmacist Interventions

Pharmacist Interventions	Number of Encounters
Verified provider is REMS certified	9
Patient REMS validations	13
Drug utilization review	13
Drug interaction review	13
Lab parameters assessed	8
Lab request sent to MD	2
Required labs discussed with patient	12
Pregnancy risk discussed with patients	5
Hepatotoxicity risk discussed with patients	8
Medication/Non-pharmacological education provided	9
Drug interactions identified	1
Side effect Management	1
Therapy discontinuation due to adverse effects	0
Quality of life assessed	5

## Results (cont.)

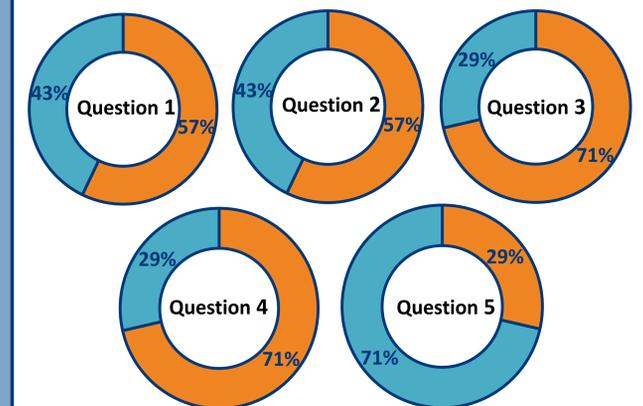
### Pharmacist Satisfaction

#### PAH/REMS Education and Workflow Implementation

1. The PAH education and training sessions met my expectations and was relevant to my clinical practice.
2. The PAH/REMS education and training sessions provided me with the resources I need to effectively assess patients and identify interventions that are safe and evidence-based.
3. After targeted REMS training, I feel more equipped to assess patient for REMS criteria prior to dispensing high risk PAH medications.
4. The new PAH-specific “new patient” and “patient follow-up” assessments provide appropriate platforms for my patient education and assessment needs.
5. The implementation phase of the PAH workflow allows for accurate and safe process to dispense PAH orders.

#### Rating Systems

Strongly agree Agree Disagree Strongly disagree



## Discussion and Conclusions

Primary and secondary results show upward trend in pharmacist competency and readiness following a series of targeted PAH/REMS education sessions and training.

- Both pre/post assessments demonstrated a 70% increase in pharmacist competency.
- High level of proficiency was sustained one month after the rollout of the new workflow with mean competency remaining at 85% or above.
- The 67% increase in overall pharmacist readiness further demonstrated pharmacist competency in PAH management.

A retrospective EHR review from February 25th, 2020 to April 17th, 2020 demonstrated that clinical pharmacists are equipped to provide thorough patient education, disease assessment, medication management, REMS compliance, and pharmacist interventions in collaboration with PAH clinicians.

- Drug utilization and interaction review were assessed for all patients enrolled in new PAH clinical programs.
- High cost, complex medication regimens were dispensed and delivered to patients safely within an average of 3.5 days to ensure patient continuation of therapy.
- All medications dispensed to patients met REMS criteria to ensure the benefits of the medication outweigh its risks
- The majority of pharmacists reported high satisfaction with the PAH/REMS education, clinical resources and workflow implementation.

## References

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3. McGoon, Miller. REVEAL: a contemporary US pulmonary arterial hypertension registry. Eur Respir Rev. 2019; 21: 123; 8-18.