

ASSESSING THE EFFECTIVE USE OF HOME
INHALED MEDICATIONS BASED ON PIFR

IMPLICATIONS FOR COPD MANAGEMENT
AND HOSPITAL READMISSIONS

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OBJECTIVES



Define and discuss COPD: social, economic, and individual hinderances



Describe PIFR and its importance



Discuss the research step by step



Evaluate the need for common PIFR measurements

Background: COPD, a progressive lung disease, often leads to hospital admissions due to exacerbation of the disease. Effective COPD management is crucial, and proper inhaler use is essential. Peak Inspiratory Flow Rate (PIFR) is a simple test that measures inhalation flow and might be a valuable tool for ensuring proper inhaler use. **Methods:** This pilot study investigated PIFR for hospitalized COPD patients. It was a prospective observational study with fifty participants at a single hospital. Researchers excluded nebulizer users and those without a COPD diagnosis. PIFR was measured at subjective baseline, and medical records were reviewed. Patients were followed for six months to track readmissions. **Results:** 74% of patients had PIFR below the optimal level for their inhalers. Medication changes based on PIFR were carried out for 20% of participants at the attending discretion. The study found a number of weak correlations. Additionally, Chi-squared, and Fisher Exact test resulted as inconclusive but may point towards PIFR-based medication changes. Further research is needed. **Conclusion:** This study offers inconclusive evidence concerning PIFR-guided therapy. Larger multi-center studies are needed to confirm these results and understand the long-term impact of PIFR on COPD treatment and hospital readmissions.

COPD

Characterized by “chronic respiratory symptoms (dyspnea, cough, sputum production, and/or exacerbations) due to abnormalities in the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that causes persistent, often progressive, airflow obstruction”.¹⁰

- Result of smoking tobacco abuse as well as exposure to occupational and environmental hazards such as biofuels and pollution.
- 15-17 million people in the US with COPD – most diagnosed in later stages - 392 million world-wide with an estimated 600 million by 2050.^{1,2,4,20}

- Sixth leading cause of death in the United States, third leading cause of death in the world, and third leading cause of readmissions in US.^{19,20}
- 923,000 ED visits and nearly 700,000 hospitalizations each year as a result.¹⁷
- Average 30-day readmission rate is 20% at an expense of 15-20k on generally occur during the first week of discharge.¹⁷
- Indirect (50) and direct costs (21) are nearly \$71 billion per year.² Direct costs for COPD between 2019 and 2038 are projected to total approximately 1 trillion US dollars.^{2,17}

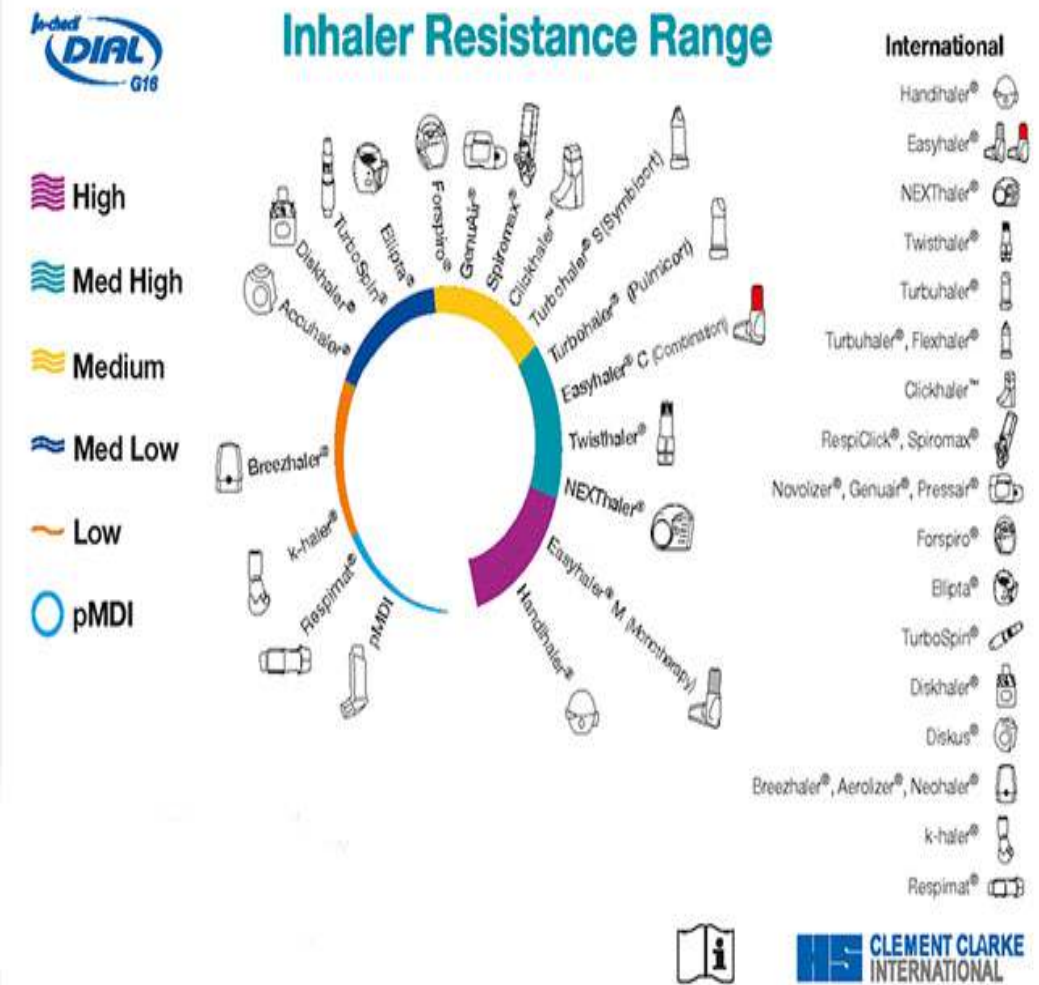
BRIEF ROL

- Researchers explained that among patients admitted to hospital for an exacerbation of COPD, “more than one-third did not receive recommended care, contributing to concerns that the high rates of readmission reflected poor care quality”.¹⁷
- The GOLD Strategy Report provides recommendations for the treatment of COPD including monitoring, non-pharmacological interventions, and the appropriate use of inhaled medications and their associated delivery devices.
- There is and has historically been a lack of guidance concerning prescribing inhaler devices, much of the selection being based on insurance coverage.¹⁰
- GOLD Strategy mentions determining the appropriate inhaler as important while retrogressively reporting that proper medication usage adherence is low for COPD patients.¹⁰
- A potentially valuable data point is the peak inspiratory flow rate measurement (PIFRm).
- Once the PIFRm is obtained, devices that patients can effectively use can then be easily selected and potentially prescribed.

PEAK INSPIRATORY FLOW RATE MEASUREMENT

- **What is it:** a very simple procedure that involves the patient inhaling through a device that can mimic the internal resistance of certain types of inhaler devices.
- **Why is it important:** The appropriate inhaled device with the most optimal use can be easily selected. Routinely evaluating the effective use of prescribed COPD management medications with PIFR_m as a biological marker is a fundamental step to optimizing patient care, decreasing admissions (and readmissions), and improving outcomes.

- What I used: G16 In-Check Dial PIFR device which provides a clinically effective *range*.



DESCRIPTION

- **Peak Inspiratory Flow Rate Assessment Details:** Device and Tech. Used: In-Check Dial G16 ATM. Instructed patient to take a deep breath and exhale fully before inhaling as forcefully as possible through the device.

Results	Peak Inspiratory Flow
Trial 1	*** L/min for pMDI/HFA
Trial 2	*** L/min for Low Resistance
Trial 3	*** L/min for Med-Low

- **Interpretation:** Effort: ***. Based on the PIFR values above, the patient's inspiratory flow rate is: Adequate/**NOT ADEQUATE***** and Does/**DOES NOT***** meet *optimal* flow for **current** inhaled medication therapy.

Delivery System – Resistance	Inhalation Technique	Recommended IF range
pMDI, HFA, SMI – R0 – “None”	Slow and Steady	20-60L/min
DPI R1 – Low R2 – Medium Low R3 – Medium R4 – Medium High R5 – High	Hard and Fast	R1-R4 - $\geq 60\text{L/min}$ R5 $\geq 30\text{L/min}$
Nebulizer	Normal tidal breathing	20 – 40L/min unrestricted

CLARITY

- Minimal, or actuation flow, is the flow needed to overcome the internal resistance of the inhaler and receive *some* clinical effect.
- *Optimal* flow is achieved when the patient can overcome the inhaler's resistance and deliver the *highest* amount of medication to the peripheries of the lungs, yielding the highest intended effect.
- For instance, Mahler pointed out that dry powdered medication deposition can be as low as 15-40% depending on the inspiratory flow and effort.¹¹
- Once the PIFR_m is obtained, devices that patients can *effectively* use can then be easily selected and potentially prescribed.

NEBULOUS

- There is limited research concerning PIFR.
- 457/513 (89%) providers stated med selection is more important than delivery.¹¹
- Ohar et al.¹⁶ stated that PIFR and medication deposition depend on many factors intrinsic to the device, the patient, and the proper use.
- Other studies researching the same type of inhaler device suggested that PIFR is independent of deposition before or after coaching.³
- Of 303 patients, 20.1% were resulted as not having optimal PIFR and that this suboptimal finding was more prominent in females < 65in (27.4%).⁸
- Of 383 COPD patients there was a significant reduction of exacerbations in their PIFR-guided inhalation group vs conventional inhalation medication education group (control) of 11.9% vs 21.2%, $p = 0.019$.⁵
- Chen et al's. work suggested that improved device selection could reduce index admissions and therefore likely readmissions.^{5,6} These same researchers also found that 87-90% of pMDI and SMI inhalers were not being utilized effectively until PIFR-guided intervention and education.⁵

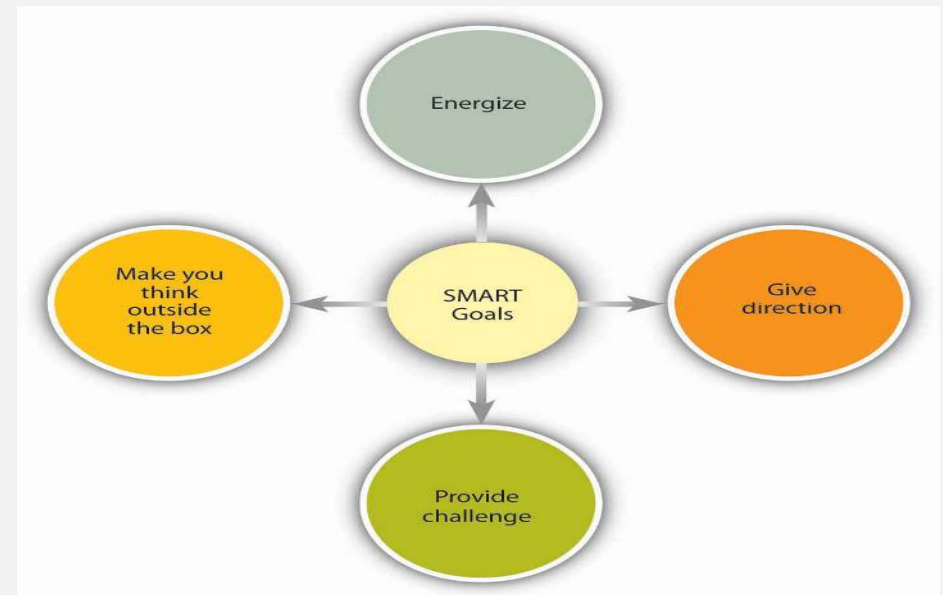
NEBULOUS

- Mahler¹⁵ pointed out two important studies: One states that there was a significant increase in 90-day readmission for patients with suboptimal PIFR and the other suggests there is little difference in those with PIFR-related therapy vs non-PIFR.
- Loh et al.¹³ found that, during an acute exacerbation of 123 COPD patients, 52% of patients did not meet the 60L/min flow rate at the unrestricted resistance level and that PIFR did not vary substantially during the acute exacerbation period, regardless of the day of evaluation.
- See what im sayin?

SMART

- SMART objectives enhance goal-setting by ensuring clarity, measurability, achievability, relevance, and time-bound deadlines, optimizing effectiveness and success.
- Specific: To evaluate the objective effectiveness of currently prescribed COPD management medications based on PIFR measurements.
- Measurable: By measuring PIFR measurements vs the patients inhaled medication requirement.

- Achievable: By utilizing standardized procedures.
- Relevant: PIFR is an important indicator of airflow limitation and medication dispersal in COPD.
- Time-bound: PIFR measurements were obtained during the hospital stay for each participant.

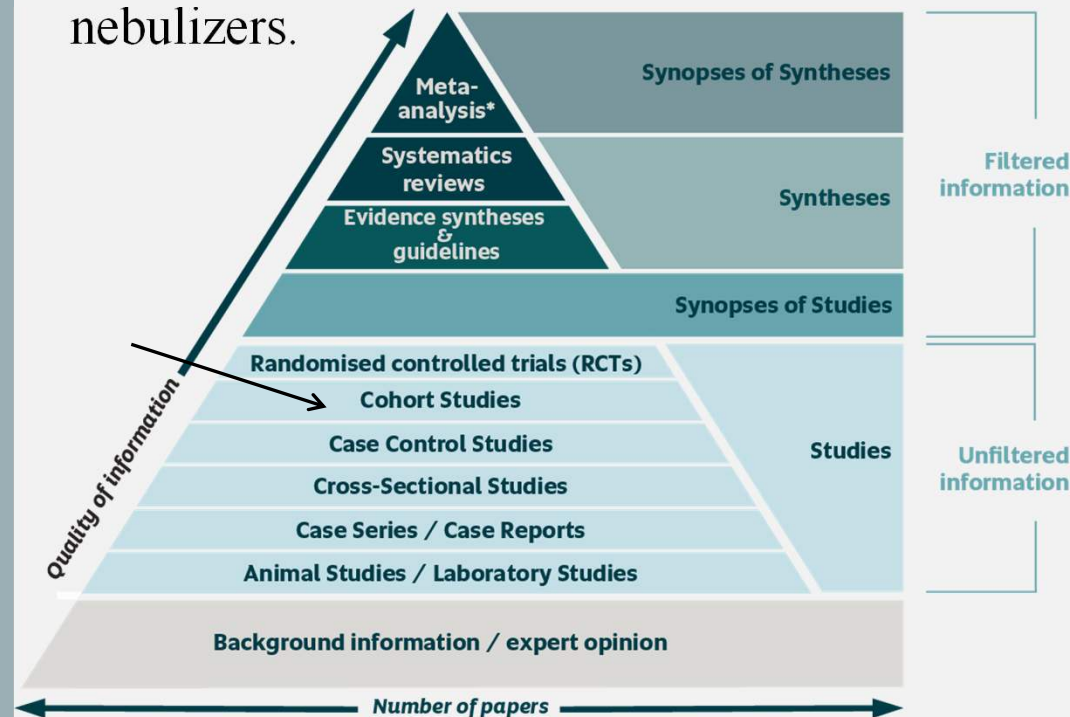


METHODS: STUDY DESIGN AND PARTICIPANTS

- Study Design: This research study utilized a prospective observational (cohort) design to measure peak inspiratory flow rates (PIFR) for hospitalized patients with chronic obstructive pulmonary disease (COPD).



- Participants: The study included hospitalized patients with a primary diagnosis of COPD who meet the inclusion criteria: (1) 18 years or older, (2) diagnosed with COPD, (3) are at expected baseline lung function or on day of discharge, and (4) are currently prescribed COPD maintenance medications other than nebulizers.



METHODS: DATA COLLECTION AND VARIABLES

- PIFR were measured at baseline lung function following standardized procedures recommended by Sanders¹⁸ and Ohar et al.¹⁶
- For validity of air flow limitation:
 - Loh et al.¹³ pointed out in their research that of 159 patients “inpatient spirometry had a sensitivity of 94%, specificity of 24%, positive predictive value of 83% and negative predictive value of 53% for predicting outpatient obstruction” (p.132).

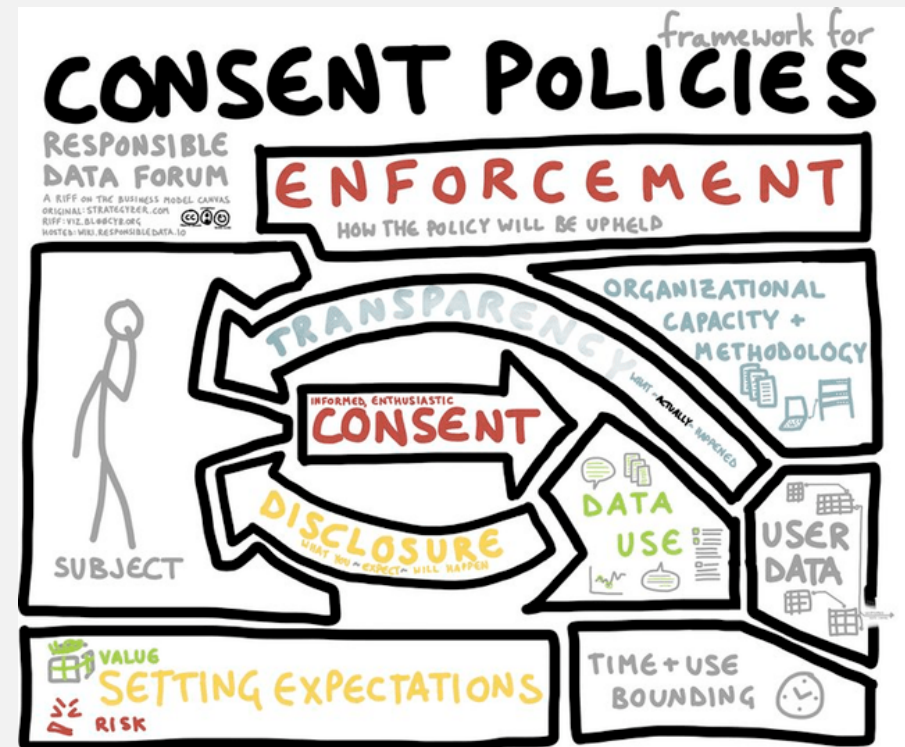
- Data on patient demographics (age, gender), social determinants of health (SDOH), COPD severity, length of hospital stay (LOS), discharge medications, readmissions, and smoking history were collected through review of electronic medical records.

Grade	LOS	Age	PIFR	SDOH	Sex M	Sex F	PackYrs
0	8.38	65	47	2	3	10	45.36
1	8	76	37	1.3	1	2	26.6
2	8.81	65	45	1.45	7	4	54.63
3	7.88	70	42	1.23	7	10	59.5
4	6.5	62	33	2	3	3	29
Tot. Avg.	8.06	67	43	1.6	21	29	49.13

METHODS: PROCEDURE

- Identification and Enrollment: Potential participants were identified through medical record review by the pulmonary disease navigator, who approached eligible patients for enrollment in the study. An interview was conducted with patient in which other clinical data was obtained, including PIFRm.
- EMR documentation of PIFRm and enrollment was then carried out. All patients opted for EMR documentation, and as such, all consent forms were scanned into the platform for the subjects viewing.

- Informed consent and the HIPPA forms were explained in detail to the patient and time was allotted for any review.
- Consent was then obtained from each participant or their authorized representative.



BACKGROUND

- Medication Management: The pulmonary disease navigator collaborated with the healthcare team to ensure that patients medication recommendations echo the appropriate COPD management medications based on the 2024 GOLD Guideline criteria.
- However, this was a clinical duty instead of a research outcome for this pilot and recommendations were carried out at the attending physician's discretion.

- Follow-up Assessments: Set patient specific alerts and review electronic medical records for 30-day all-cause hospital readmissions for COPD patients.



An illustration representing data analysis. It features a central magnifying glass over a pie chart. Below the pie chart is a bar chart with four bars of varying heights, each with a dark green base and a light green top. To the right of the bar chart is a line graph with five data points connected by a blue line. In the background, there are various data visualization elements: a blue document icon with lines, a green speech bubble, a blue browser window with a pie chart, and a blue grid. A dark grey rectangular box with a white border is overlaid on the center, containing the text 'DATA ANALYSIS' in white, uppercase letters.

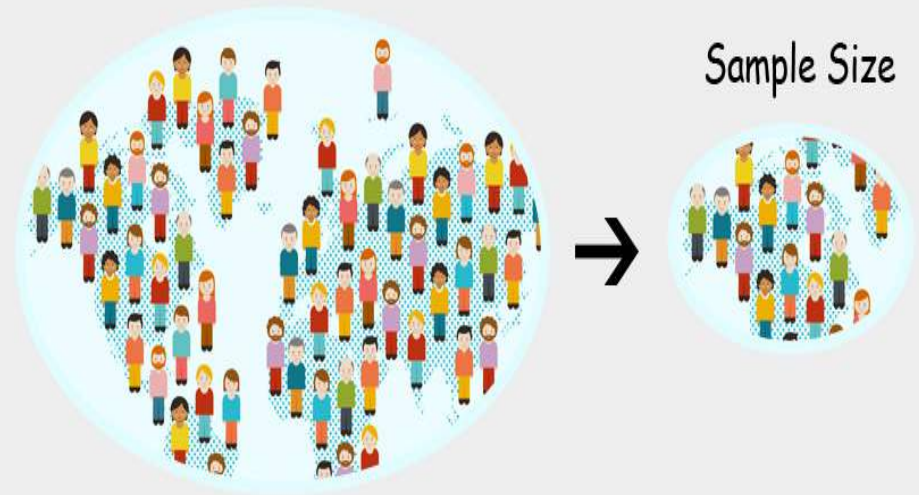
DATA ANALYSIS

- Descriptive and basic statistics were used to summarize the demographic characteristics, baseline PIFR, and medication regimens.
- Simple statistical analysis was used to quantify what percentage of patients were not currently prescribed appropriate medication.
- Basic correlative statistics were also utilized to draw any further conclusions.

LIMITATIONS

- The study is limited to a single county medical center, which may limit the generalizability of the findings. The study's duration and sample size ($n = <100$) may also impact the statistical and correlative power, and generalizability of the results. Technician error as well as patient effort may also be a limitation.

- Other variables not considered in this study could influence outcomes. For example, comorbidities, socioeconomic status, or access to healthcare.



RESULTS

- 50 hospitalized patients with COPD were included in the analysis.
- 78% of participants were Caucasian, 18% were Black, and 4% were other.
- The mean age of the participants was 66.92 years (SD = 9.43)
- Average smoking history of 1.25 pack per day (SD = 0.58) at 49.13 years (SD = 28.34)
- 42% being male and 58% being female.
- Average length of hospital stay was 8.06 days (SD = 5.45).

26% of patients were grade 0, 6% were grade 1, 22% were grade 2, and 34% were grade 3, and 12% were grade 4. 56% had moderate to severe COPD based on GOLD criteria

A total of 73.68% (n=37) were found to fall below optimal flow regarding their current inhaled medication therapy. 26.32% were on appropriate inhaled medical therapy.

20% (10) patients medication was changed to reflect optimal use. Only three readmitted in 6 months, and only one of them being a high utilizer.

RESULTS

- Though correlatively weak, yet in line with other literature, average PIFR for ages 64 and under was 45.27L/min for Med-low resistance and 40.93L/min for 65y and older with R2 of 0.027 when using the entire data set.
- An average PIFR of less than 50L/min for Med-low was found in all grade groups.

46% were high utilizers and nearly half of them (47.8%, or 11) readmitted in 6 months

a TOTAL of 38% (19) readmitted in 6 months

Grade 3 patients represented the highest LOS at a total of 134 hospital days.

403 hospital days were recorded for all 50 participants.

RESULTS

- A two-tailed t-test analysis comparing the mean grade of COPD vs the mean PIFR resulted in a **statistically significant** outcome ($t = 12.628$, $p = .00023$ at $p < 0.05$). This suggests a strong correlation ($R = 0.6311$) between these variables.
- This correlation supports the expected trend and suggests that COPD grade is a reasonable indicator of inspiratory flow, though not the only factor.
- This explains a moderate portion (around 40%) of the variation. The remaining variation(s) could be due to factors not considered or a non-linear relationship.

Pearson correlation coefficients were calculated for various factors:

Grade vs LOS: -0.05

Age vs LOS: -0.08

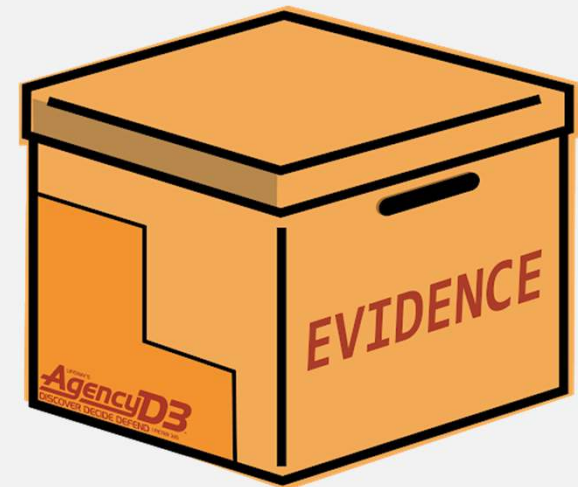
SDOH vs Age: -0.3

SDOH vs Grade: -0.17

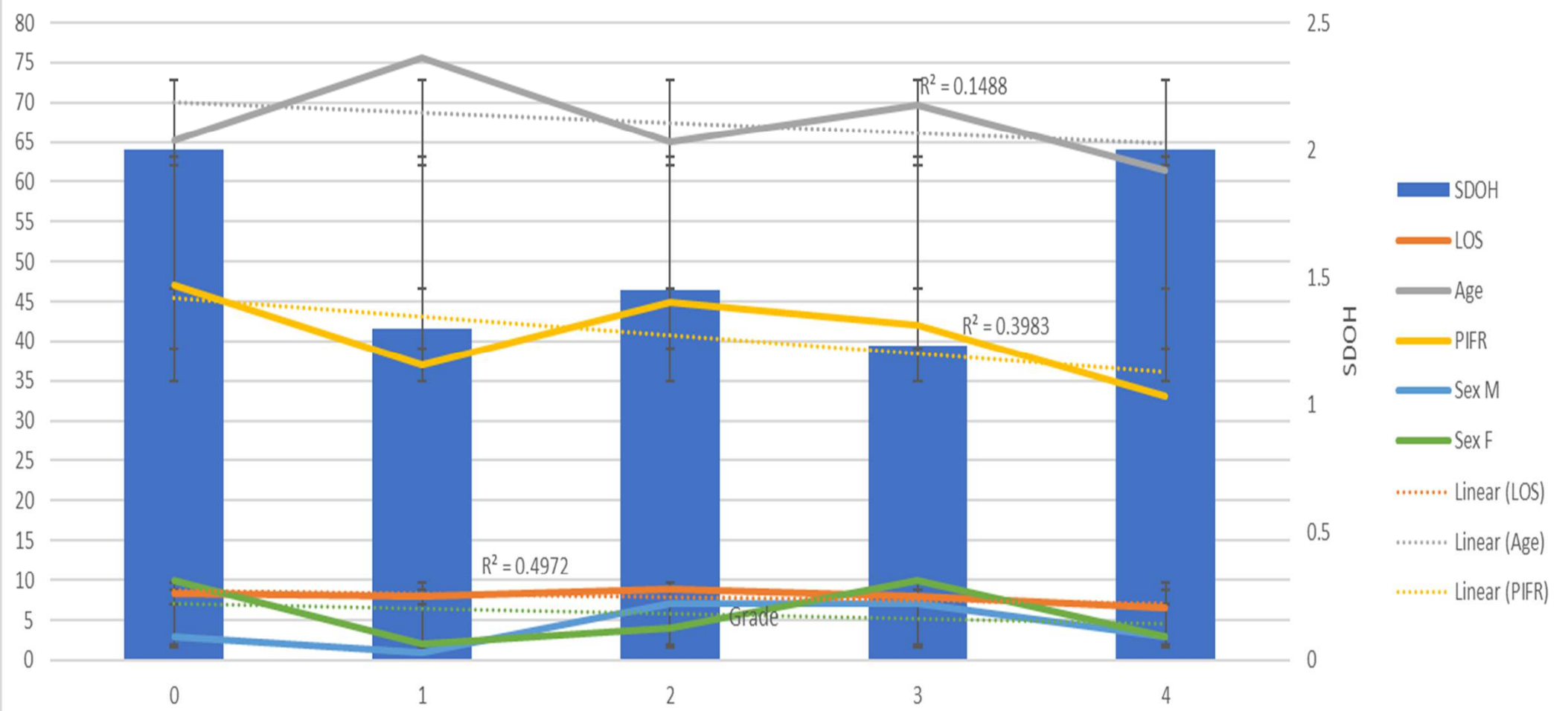
RESULTS

- When comparing medication changes and readmissions:
 - *Chi-Squared* = 3.9339 with $p = .047321$ at $p = <.05$ which is significant
- For validity, and due to the small sample size:
 - *Fisher Exact Test* resulted as $p = .0709$ when p is set to $< .05$ which is not significant.
- These results are inconclusive

- The resulting p-value was 0.0709. With the conventional significance level set at 0.05, the observed association does not reach statistical significance. However, it's worth noting that the p-value is marginally above this threshold, suggesting a trend towards significance.



Multiple values by 'Grade'



Grade	LOS	Age	PIFR	SDOH	Sex M	Sex F	PackYrs
0	8.38	65	47	2	3	10	45.36
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DISCUSSION

- COPD is a pandemic that does not seem to gather much attention in relation to other top diseases such as heart disease and cancer.
 - A de-sensitization of the people grants that veil.
- With the advent of vaping, new designer drugs, and ever-growing pollution, this problem is sure to evolve and push the boundaries further. Furthermore, observing the monumental economic impact of COPD is alarming beyond that of immediate intervention.
- PIFR-guided inhalation therapy is individualized care.
 - The procedure is non-invasive and easy to perform. It is dual functional in that PIFRm tell the clinician what the patient can do and aids in teaching the patient how to best do it.
- However, PIFRm along with much of the inhaled medication realm, is misunderstood, or rather, underutilized. Inhalers are not a one size fits all.
- PIFR limitations seems to be most prevalent in individuals over 60 years old, females <65in tall, and those with grade 3 or 4 COPD.
- The limitations that are nonexhaustive in this research impact one of the direct causes of symptoms in the COPD population – airway diameter. Proper and effective inhaler use is paramount in the treatment of COPD.

CONCLUSION

- This research brings much discussion and literature concerning PIFRm.
 - As is some of the current research on PIFR-guided therapy - this pilot study provides inconclusive evidence concerning the potential benefits of PIFR-guided inhaler therapy in COPD management and further research is needed.
- Moving forward, future studies should aim to address the limitations of this pilot study:
 - Incorporating a larger sample size, multi-center collaboration, more correlative variables, and standardized protocols for PIFR assessment and documentation.
 - Additionally, longitudinal studies are warranted to evaluate the long-term impact of PIFR-guided inhaler therapy on clinical outcomes such as exacerbation rates, quality of life, and healthcare utilization, including readmissions.

DISCUSSION ON SOLUTIONS

- Implement PIFRm and recording IP and OP
- Develop a readmissions team for COPD
 - To meet quarterly?
 - Set a standard as a team for readmissions
 - < 20%, <15%, <10%
- Coding – use proper verbiage and remove dx where diagnostics are not available – BIG ONE – smart phrase to address this?
- Inhaler financial assistance programs (now possibly \$35).

Can PIFR be integrated easily and what are the costs/training expenses?

Is there an agreed upon threshold for medication changes (other than listed in the study)

Weak neg correlation for SDOH vs age/grade suggests further exploration as exacerbating/readmission factors.

Larger samples to define a link – would be easy

PIFR in Order set/Eval