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Summer Research Project Report
August 2, 2019

INTRODUCTION

I am an incoming medical student and part of the MD/PhD program at the University of Illinois at Chicago (UIC). I am interested in the social determinants of health and implementation science, and I have spent six weeks with the Population Health Sciences Program, led by Dr. Jerry Krishnan, as a pre-PhD rotation. This included spending one morning each week observing patient visits in the Asthma and COPD Transitional Care Clinic (A-TRACC), a new outpatient service for those recently admitted for lung disease exacerbations.

I conducted research on supplemental oxygen to assess the need for a structured approach to patient and provider education in the A-TRACC. More specifically, I focused on portable oxygen concentrators (POCs) for patients with Chronic Obstructive Pulmonary Disease (COPD); which models are most effective, how patients are matched with a particular unit, and patients' experience using them.

It became clear that only a specific subgroup of patients on supplemental oxygen are suitable for a POC, namely those who require less than 3 liters per minute (LPM) of oxygen. The A-TRACC and its patients would likely benefit from designating a specific individual - a "POC Point Person" - to oversee the POC matching process. This would help identify the most appropriate patients for POCs and ensure that they actually receive their units. Lastly, additional POC stakeholders should be consulted to create a coordinated effort to further streamline the POC matching process.

BACKGROUND

COPD is an inflammatory lung disease, most commonly caused by cigarette smoke (1). It is the fourth leading cause of death in the United States and affects an estimated 30 million Americans, as many as half of whom could be undiagnosed (2,3). While there is no cure for COPD, smoking cessation, medication, respiratory therapy, and surgical procedures can alleviate COPD symptoms and improve overall quality of life.

Supplemental oxygen is necessary for patients with COPD who cannot achieve sufficient oxygen saturation levels by breathing room air alone. Oxygen is prescribed for roughly 1.5 million Americans and is traditionally delivered through compressed oxygen tanks (4). Powered oxygen concentrators have emerged as an attractive complement - or even replacement - to compressed gas tanks, as concentrators do not need to be refilled and are available in rechargeable, portable models (4). However, both clinicians and patients may lack proper guidance on how to appropriately select, use, and maintain POCs (5, 6). Thus, my research explored the need to incorporate a structured approach for POC education in the A-TRACC.

The project can be divided into three phases - background research, device testing, and stakeholder engagement - and will be detailed below.

METHODOLOGY

Phase 1: Background Research

I began by surveying the scientific literature, using “portable oxygen concentrator” as a search term in the online PubMed database. I reviewed about a dozen articles that discussed the development, performance, and patient experience with POCs.

Next, I browsed the web to compare and contrast the leading POCs brands and modes. I conducted a Google search using “portable oxygen concentrators” as keywords and reviewed websites that collected and rated POCs. I then created an Excel spreadsheet (Supplemental Items) to collect and organize key device specifications.

Phase 2: Device Testing

Drive/DeVilbiss Healthcare generously lent us a POC to test within our laboratory. The iGo2 delivers oxygen in short boluses, known as “pulse flow,” at five different settings; higher settings deliver more oxygen per bolus. I tested the battery life at each of the five settings on three different occasions, for a total of fifteen trials.

Of note, while the nasal cannula was attached to the POC, the cannula itself was never worn. Normally, the iGo2 can sense an individual’s breath rate and thus deliver oxygen precisely when an inhalation commences. However, when no breathing is detected, the device defaults to an “AutoBreath” setting of 13 breaths per minute (BPM). All of the battery life tests were performed at this “AutoBreath” rate of 13 BPM. The time it took to fully recharge the battery was also measured over three trials.

Phase 3: Stakeholder Engagement

I was put in contact with a range of stakeholders to gain additional perspectives on POCs. I had phone conversations with Joe Lewarski, a respiratory therapist and executive of Drive/DeVilbiss Healthcare, Sam Giordano, also a respiratory therapist and former executive of the American Association for Respiratory Care (AARC), and Tim Murphy, a sales representative for Rotech Healthcare. At the UIC outpatient pulmonary clinic, I spoke with Maria Martinez (staff nurse), and I also interviewed a patient who uses a POC to manage his mild hypoxemia.

RESULTS

Phase 1: Background Research

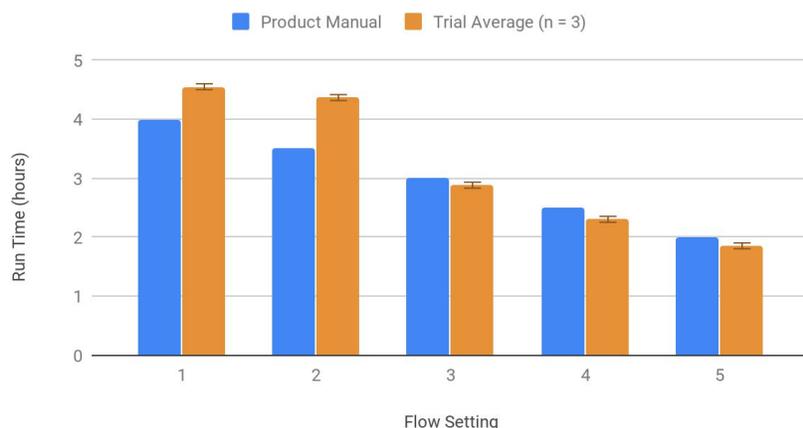
POCs have been on the market for a few decades and have undergone considerable technological improvements. Current models can adequately saturate many hypoxemic individuals at rest and during moderate activity (7). POCs do vary in specifications, however, including by size, weight, battery life, and most importantly, oxygen delivery. The maximum oxygen output ranges from 0.3 LPM to 1.2 LPM among leading devices (8). Furthermore, there are two types of oxygen delivery: 1) fixed minute volume, and 2) fixed pulse volume. Fixed minute volume devices deliver roughly the same amount of oxygen *per minute*, regardless of breath rate. Fixed pulse volume devices deliver roughly the same amount of oxygen *per bolus*; thus, as breath rate increases, so too does the overall amount of oxygen being delivered. As a design principle, fixed pulse volume devices are preferred as they offer a wider range of oxygen output. Ultimately, however, these differences in oxygen delivery may not be clinically relevant, so long as a particular POC can meet a patient's needs.

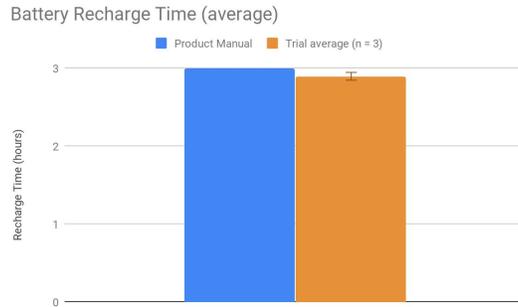
Lastly, I found a few web-based matching tools designed to help select an appropriate POC for patients (9, 10). Each tool has a series of questions about an individual's preferences and then recommends a device based on their responses. The most comprehensive matching tool is available through ConsumerAffairs, a web-based consumer news and resource platform. I went through the tool using one of Dr. Krishnan's long-time patients as a reference, selecting answers that seemed most appropriate for his circumstances. The results were sent to Pure Medical, an oxygen supply company, who recommend an Inogen POC (one of the leading brands). A list of the ConsumerAffairs matching tool questions can be found in the supplemental section.

Phase 2: Device Testing

The iGo2 tested was relatively new and performed well. Battery life outperformed the product manual estimates on settings 1 and 2 (lower oxygen output) and slightly underperformed on settings 3, 4, and 5. All trials were conducted at the unit's "AutoBreath" rate of 13 BPM. Recharge time outperformed the manual's estimate on all three trials. Overall, the iGo2 was easy to use and carry around. At higher settings, however, the unit gets warm to the touch.

Battery Performance (average)





Phase 3: Stakeholder Engagement - Industry Perspective

I spoke with Joe Lewarski (Drive DeVilbiss) and Sam Giordano (formerly of AARC) to elicit their perspective on the ConsumerAffairs matching tool. Mr. Lewarski felt that the tool was useful, but lacked more detailed questions regarding the user’s current oxygen usage and range of normal breath rate. He explained that an ideal POC candidate is one who requires less than 3 LPM of oxygen and whose breath does not exceed 25 BPM.

Regarding future POC development, especially as it concerns device connectivity to other monitoring devices (web, smartphones, etc.), Mr. Lewarski cautioned relying on technological improvements to drastically, or at least solely, improve clinical outcomes. During his roughly twenty years working with POCs, improvements both in device capability (oxygen purity, output, etc.) and user experience (weight, battery life, digital interface, etc.) have not significantly increased adherence to the device or improved clinical outcomes. Furthermore, additional features will make devices that cost typically cost around \$2,000 even more expensive.

Mr. Giordano also felt that the ConsumerAffairs matching tool did not adequately assess one’s oxygen requirements. The tool should first elicit a patient’s current oxygen prescription; anything greater than 3 LPM suggests that a POC would be unlikely to adequately saturate that individual. Mr. Giordano also emphasized that pulse oximetry should always be used when selecting any supplemental oxygen device. Thus, while a matching tool could be a useful first step in identifying a few POCs for a patient, the next step would be to “test drive” each unit with an oximeter and under the supervision of a trained professional, such as a respiratory therapist.

Phase 3: Stakeholder Engagement - Outpatient Clinic Perspective

I interviewed one patient with sickle cell disease after his A-TRACC appointment. A case report of the interview can be found in the supplemental section. The patient was in his mid-30s and experiences mild hypoxemia. He uses a POC roughly three times per week when he is away from home, and he reported being very satisfied with his device. It was particularly encouraging to hear how smoothly the process of getting his POC went.

Following his visit with a pulmonologist at Advocate South Suburban Hospital (Hazel Crest, IL), an interdisciplinary team of social workers and respiratory therapists from the hospital worked with a medical supply company to set him up with a POC. A representative from the

medical supply company brought the device to his home and used an oximeter to measure his oxygen saturation on the POC while at rest and with moderate activity. The unit has 5 settings; he was started on setting 2, although setting 4 was ultimately best for him. This interdisciplinary model is a great example to follow.

To understand if and how POCs are currently being distributed through the UI Health outpatient pulmonary clinic (where A-TRACC visits occur), I then had a conversation with Maria Martinez, one of the outpatient staff nurses. Once an order comes in from a physician for any supplemental oxygen device, Ms. Martinez (or one of the other nurses) submits the form to a medical supply company (form in Supplemental Items). The form does not include a section for POCs, however, and thus a special note has to be made on the document before submission. Similar to what Mr. Lewarski and Mr. Giodano expressed, Ms. Martinez also felt that suitable candidates for a POC had oxygen requirements of less than 3 LPM.

It can take up to two months for a UI Health patient to receive a POC once the order has been initiated. Demand for POCs has increased as manufacturers are allowed to advertise to the general public. However, this increased demand combined with cuts in Medicare reimbursements has strained medical device suppliers, resulting in lengthy wait times for patients. Ms. Martinez informs patients of this lengthy timeframe and instructs them to contact the UI Health clinic if they have not heard back from the supplier within one week of the initial order. However, during follow up visits many months later, it is not uncommon for patients to have still not received their POC. This presents an opportunity to improve the patient experience, namely by designating an individual within the UI Health system to monitor if patients are receiving their POCs.

Ms. Martinez put me in contact with a sales representative from Rotech Healthcare, Tim Murphy. Rotech is one of the medical supply companies where Ms. Martinez often sends supplemental oxygen orders. Mr. Murphy echoed Ms. Martinez' comment regarding rising POC demand and expressed concern for some patients whose expectations are set unreasonably high due to how POCs are marketed. While the devices can facilitate a more active lifestyle, both patients and providers are often unaware of the technical limitations of POCs; individuals who require substantial amounts of oxygen to remain adequately saturated (> 3 LPM) are often ill-suited for POCs. At least in Mr. Murphy's experience, he estimates that almost half of all patients who get POC orders are not reasonable candidates for the device. This highlights the need for more rigorous clinical assessments before recommending a POC for a patient.

Mr. Murphy also underscored how health insurance factors into their ability to distribute POCs to patients. The process requires substantial paperwork that must be completed to an insurance company's exact specifications. Any deviations, errors, or omissions can further complicate the process and delay getting a POC to a patient. Here too, clinics have an opportunity to expedite the process by ensuring that the required documents are correctly and completely filled out.

DISCUSSION

Maintaining mobility is essential for individuals dealing with chronic lung disease. Given the capabilities and ease-of-use of today's POCs, they should be made available for suitable patients to facilitate an active lifestyle. Based on my research, I recommended that the A-TRACC consider the following:

1. Routinely assess patients' suitability for a POC
2. Maintain up-to-date POC device information
3. Designate a UI Health team member to oversee the POC matching process
4. Consult additional POC stakeholders

1. Routinely assess patients' suitability for a POC

Ideal candidates for a POC are patients whose current oxygen requirement(s) is less than 3 LPM and whose breath rate does not exceed 25 BPM with moderate activity. Pulse oximetry should always be used to assess whether or not a particular POC is appropriate for a given individual. Furthermore, disease comorbidities, overall physical and mental status, insurance coverage, and patients' interest in the device should also be taken into consideration. For patients who are in stable condition, discuss POCs and how they may facilitate an active lifestyle.

2. Maintain up-to-date POC device information

Numerous resources exist to educate providers and patients on POCs. The Pulmonary Paper is a non-profit organization that publishes a POC guide each year (8). This is the most comprehensive POC resource I have come across, and I suggest that an up-to-date copy be always accessible for clinicians and patients in the A-TRACC. An overview poster of the POC guide has been created for reference in the A-TRACC office.

3. Designate a UI Health team member to oversee the POC matching process

The staff nurses at the outpatient pulmonary clinic are currently responsible for submitting supplemental oxygen orders to medical supply companies. They do not have the time, however, to follow up with patients and suppliers to ensure that ordered POCs are actually delivered. It would be advantageous to designate a UI Health team member - a "POC Point Person" - to ensure proper documentation and monitor POC deliveries. This could be a volunteer, student, medical assistant, social worker, or respiratory therapist.

4. Consult additional POC stakeholders

I gained invaluable insights by engaging with individuals who had different interests in POCs, including patients, clinicians, manufacturers, non-profit organizations, and medical device

suppliers. However, two major stakeholders missing from my research were health insurance companies and governmental agencies.

As payers of medical treatment and devices, it would be illuminating to elicit the perspective of health insurers with respect to POCs. Throughout my research, health insurers often attracted criticism for their strict guidelines that have to be followed to the letter in order for patients to obtain POCs. However, these companies have limited resources and it is reasonable that a legitimate need for an expensive device be clearly demonstrated. Multiple POC stakeholders discussed that a significant portion of patients obtain orders for devices that will not actually fulfill their oxygen requirements. I trust that health insurers would contribute valuable input that would further help streamline the POC process for everyone involved.

Secondly, as legislative bodies, governmental agencies set the rules of the game and have a tremendous opportunity to create a more equitable and sensible system. For example, Ms. Martnez noted that, per the Centers for Medicare & Medicaid Services (CMS), supplemental oxygen orders are only valid for 30 days (from the initial clinical testing date). Ms. Martnez noted that this timeframe is often too short for patients, necessitating repeat clinic visits and significantly delays the process; CMS could extend this timeframe. In another example, oxygen suppliers have indicated that cuts to their reimbursements have severely impacted their ability to run their business. Increasing their reimbursements could alleviate significant strain and allow suppliers to dedicate more personnel and resources to getting supplemental oxygen orders out faster. Thus, it is important to involve governmental agencies to ultimately craft new policies.

CONCLUSION

I had a productive six weeks learning about the various research projects and clinical activities of the Population Health Sciences Program. I investigated how POCs perform and how they might be made more easily available for suitable patients. Several resources were identified to evaluate leading POCs, and I recommend that the A-TRACC consider designating a specific UI Health team member to oversee the POC matching process for their patients. Engaging with additional POC stakeholders would yield greater insight into current barriers in delivery and hopefully illuminate collaborative solutions.

REFERENCES

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SUPPLEMENTAL ITEMS

Leading POCs: Specifications

Manufacturer	Model	Price	Weight with battery (pounds)	Continuous flow?	Continuous flow options (LPM)	Pulse flow options (ml / bolus, 20 bpm)	Max LPM @ 20 breaths/min	O2 purity (%)	Max battery life (hours)	Max battery life setting	Warranty (years)	Connectivity	Notes	Manual (Date)
Inogen	G5	\$2,400	5	-	-	1-6 (10-63 ml)	1.3	87-96	single battery: 4.5 double battery: 8	information not provided	concentrator: 3 accessories: 1	Bluetooth app	- App displays battery, flow setting, power, filter & canula life	2019
Philips	SimplyGo	\$2,500	10	yes	0.5, 1, 1.5, 2	1-6 (12-72 ml)	1.4	86-97	pulse flow: 3 continuous: 0.9	pulse flow: 2 continuous: 2 LPM	2-5	-	Unit on wheels	2013
Philips	SimplyGo Mini	\$2,100	5 (standard) 6 (extended)	-	-	1-5 (11-50 ml)	1.0	87-96	4.5 (standard) 9 (extended)	2	2-3	-	-	2016
O2 Concepts	Oxifreedom	\$2,500	6	-	-	1-5 (10-44 ml)	0.9	87-95	3.5	2	3	-	-	2018
ResMed	Mobi	\$2,300	5.5	-	-	1-4	-	87-96	internal: 6 external: 3	2	concentrator: 5 accessories: 1	-	-	2018
Caire	AirSep Focus	\$1,300	2.25	-	-	"pulse setting 2"	-	87-95	1.5	only one setting	3	-	-	2011
Invacare	Platinum	\$2,500	5	-	-	1-4 (11-44 ml)	0.9	87-96	3.5	2	3	-	-	2016
Caire	AirSep Freestyle 5	\$1,700	6.7	-	-	1-5	-	87-96	2.5	2	concentrator: 3 accessories: 1	-	-	2016
Precision Medical	EasyPulse POC3	\$1,700	5	-	-	1-3 (12-26 ml)	0.5	87-95	4	2	concentrator: 5 accessories: 1	-	-	2018
Precision Medical	EasyPulse POC5	\$1,700	6.6	-	-	1-5 (12-39 ml)	0.8	87-95	3	2	concentrator: 5 accessories: 1	-	-	2018
Drive DeVilbiss	iGo2	\$2,500	5	-	-	1-5 (13-50 ml)	1.0	87-94	3.5	2	machine: 5 compressor: 3 sieve beds, battery: 1	-	-	only paper version

ConsumerAffairs POC Matcher (sample patient response in green)

1. Do you currently have a prescription for oxygen from a doctor?
 - a. Yes
 - b. No
 - c. I'm not sure

2. How often does your breathing interrupt your normal physical or social activities?
 - a. Never
 - b. Sometimes
 - c. Usually
 - d. Always

3. On average, how often do you travel on an airplane?
 - a. Weekly
 - b. Monthly
 - c. A few times a year
 - d. Less than a few times a year

4. Which of the following features are important to you? (Select all that apply)
 - a. Long battery life
 - b. Quiet machine
 - c. Lightweight
 - d. LCD Screen
 - e. I'm not sure

5. Do you need a continuous flow or pulse dose oxygen therapy?
 - a. Continuous
 - b. Pulse dose
 - c. I'm not sure

6. Are you interested in a specific brand of portable oxygen concentrator?
 - a. Inogen Philips Respironics
 - b. OxyLife
 - c. OxyGo
 - d. I'm not sure

7. How soon do you need a portable oxygen concentrator?
 - a. 1-to-2 weeks
 - b. 3-to-4 weeks
 - c. 2-to-3 months
 - d. I'm not sure

8. Will you need financing to purchase a portable oxygen concentrator?

- a. Yes
- b. No
- c. I'm not sure

9. What is your budget for a portable oxygen concentrator?

- a. Less than \$2,000
- b. \$2,000 - 3,000
- c. \$3,000 - 4,000
- d. \$4,000+

10. What is your ZIP code?

60612 (UIC Hospital)

Patient Interview Case Report (interviewed on 7/29/19; answers highlighted in green)

1. Since when have you been on oxygen? ~ 1 year

a. Oxygen prescription: 4L

2. Do you have a pulse oximeter? If so, how do you use it? (What values do you look for?)

~ 2x per day, morning and night

3. When did you get a portable unit? Why did you get one?

Recommended by previous pulmonologist for better portability

a. Model: Precision Medical EasyPulse, PM4150

4. How did you select your particular portable unit? (Doctor? Patient? Online?)

Unit brought to his home by South Suburban, unclear if options were given.

5. How did you learn to use your portable unit?

Representative from South Suburban brought the POC to his home and started him on setting 2. Oximetry testing at rest and while walking; setting 2 was insufficient, setting 4 worked

6. When do you use your portable unit? Do you adjust the flow settings?

~ 3x per week, as needed

7. What do you like about your portable unit? Which features are most important?

Satisfied overall with the unit

8. Is there anything you do not like about your portable unit? What would you change?

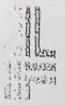
First unit malfunctioned and was replaced by supplier. No major complaints otherwise.

9. Did your health insurance cover all or some of the cost of the unit? Roughly how much was the unit?

Unit was fully covered by insurance



UIC Outpatient Pulmonary Clinic Supplementary Oxygen Order Form



UNIVERSITY OF ILLINOIS
Hospital & Health Sciences System

1801 W. Taylor
Chicago, IL 60612
Phone: (312) 996-3300
Fax: (312) 996-3896

Patient: _____

DOB: _____

DME _____

Fax # _____

PULMONARY CLINIC DURABLE MEDICAL EQUIPMENT ORDER FORM
New order Adjustments Discontinuation

Diagnosis: _____

ICD 10 code/s: _____

Length of need: _____

OXYGEN ORDERS

Date of test: _____

SaO₂ on RA: _____%

Qualifying SaO₂ level: _____%

Liter flow at rest: _____

Liter flow with exercise: _____ (SaO₂ _____%)

____ Evaluate for Oxygen Conserving Device and provide if patient qualifies (keep SaO₂ ≥90%)

____ Nocturnal Oximetry Study

on room air

w/ oxygen

NEBULIZER ORDERS

Nebulizer: _____

Medication: _____

Supplies only: _____

Sig: _____

OTHER MEDICAL EQUIPMENT

____ Hospital bed

____ Wheelchair

____ Bath aid

____ Scooter

____ Other

Physician Name: _____

Physician Signature: _____

NPI: _____

Date: _____