RECORDED HOME OXIMETRY PROGRAM Manual

Implementation Manual for the RHO Program- An Effective Home Oxygen Management Strategy

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UMass Memorial Children's Medical Center

University of Massachusetts Medical School

RHO Implementation Program Manual

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INTRODUCTION

Improvements in neonatal care have led to increased survival of premature infants, although many continue to have significant lung disease following discharge from the neonatal intensive care unit (NICU)[1]. Current estimates suggest a third of extremely preterm infants will require home oxygen therapy (HOT) after NICU discharge, including up to 60% of those born at gestational age of 23-24 weeks.[1-4] In infants requiring supplemental oxygen (O_2), HOT provides a means of facilitating NICU discharge, but its use is highly variable, [5, 6] ranging from 10% to 95% across the United States (U.S.). Studies suggest that NICUs with higher rates of HOT utilization have shorter lengths of stay (LOS), even adjusting for birth gestational age.[5, 7] To date, these have been observational studies without specific interventions for increasing HOT utilization.

Institutional variation in HOT appears to be related to provider preference, rather than patient severity of illness.[3, 5, 7] Longer NICU stays potentially put undue burden on families and contribute to increased parental stress, while impairing neurodevelopment and family bonding.[5, 8, 9] A critical obstacle to increased HOT utilization has been a lack of evidence-based consensus guidelines for its safe management.[6] There is little data to guide weaning, and little evidence regarding its safe discontinuation. A survey of pediatric pulmonologists found some recorded oximetry was frequently utilized prior to permanently discontinuing HOT.[10] More recently, NICU's in Australia have reported using recorded overnight oximetry to guide O_2 weaning in the inpatient and outpatient setting.[6] Although similar practices exist in the U.S., they are not implemented consistently. Inefficient oxygen management strategies may lead to an inappropriate prolongation of HOT, potentially risking O_2 toxicities.[11-13]

Although many families prefer their infants to be discharged on HOT as opposed to prolonged NICU hospitalization, prior research has also shown that HOT may increase family anxiety.[5, 9] Families also report that prolonged HOT can result in excessive parental stress and social isolation.[9, 14] Discussions with our parent advisory board (PAB) validates these reports that parental tension is increased not only with longer NICU LOS, but also with prolonged HOT duration. Decreasing HOT duration is therefore highly desirable but will require successful dissemination of an evidence-based weaning strategy.

Recorded home oximetry (RHO) provides objective data on oxygenation status but has only been utilized in research and standard clinical practice in limited settings.[15, 16] Increased availability of RHO could provide data to support O_2 weaning protocols, but efficacy and safety of HOT weaning strategies, with or without RHO, has not been previously reported. Recently, Rhein et al. completed a 4-year prospective multi-center randomized control trial (2014-2018, follow-up until 2019) in 9 academic centers, on the effect of RHO on duration of HOT, patient safety, and family experience as compared to routine monthly clinic-based HOT management.[17] The RHO trial was carried out in close collaboration with physicians and family members from across sites and focused on family engagement throughout the HOT management process. The intervention included transmission of RHO from parents to providers every 4-7 days and utilized a structured algorithm to determine whether to increase, decrease, or maintain O_2 flow rates (Appendix Table 1). The guidelines developed for the RHO trial were the first to set standard O_2 threshold targets for outpatient O_2 weaning in premature infants. Optimal targets remain controversial, but the protocol's consensus-based guidelines are consistent with all published statements and current national guidelines[15, 18-20].

Results of the RHO trial found time to discontinue HOT was 22% shorter in RHO infants (78.1 ± 6.4 days, retransformed mean ± standard error) versus the standard care group (100.1 ± 8.0 days, p=0.03) (**Table 1**).[17] Respective median times were 71 and 90 days. Oxygen duration was shorter for participants sending more frequent RHO data reports (10.3% shorter duration for each additional report provided per month, 95% CI -15.2 to -5.3%, p=0.0001). Despite its focus on a medically fragile cohort, there were relatively few adverse events (AEs) in the study, with fewer events in those randomized to RHO. Serious AEs occurred in 30 of 99 standard of care (30%) versus 19 of 97 RHO (20%) infants. Infants in both groups had less AEs compared to prior published cohorts, suggesting that the saturation thresholds utilized in the RHO trial were safe.[3, 21] Prior trials have demonstrated that higher O_2 target saturations, leading to prolonged O_2 use, may contribute to pulmonary toxicity.[11-13] This may explain the slightly higher AE rate in the standard care group. ***The RHO trial found that utilization of RHO is a safe and effective strategy for managing HOT in premature infants- shortening the duration of HOT, while increasing parent satisfaction and reducing adverse events***.

Table 1. Duration of home oxygen therapy, as influenced by study group and initial oxygen requirement

Influence		Duration, days*	p†
Study group:	Intervention	78.1 ± 6.4	0.03
	Standard care	100.1 ± 8.0	
Initial O_2:	≤125 cc/min	73 ± 5	<0.0001
	250 cc/min	98 ± 11	
	≥500 cc/min	149 ± 21	
	Nocturnal O_2 only	80 ± 46	

*Adjusted mean ± standard error, retransformed from log scale.
†Testing for equal means, or for zero rate of change.

Significance of the RHO Program

The RHO Program builds on our team's earlier studies involving oximetry acquisition and analysis, family-caregiver partnerships in HOT management, and preliminary research regarding family engagement in HOT management processes through data transmission. This will be the first large-scale implementation project of any home oxygen weaning strategy for preterm infants on HOT.

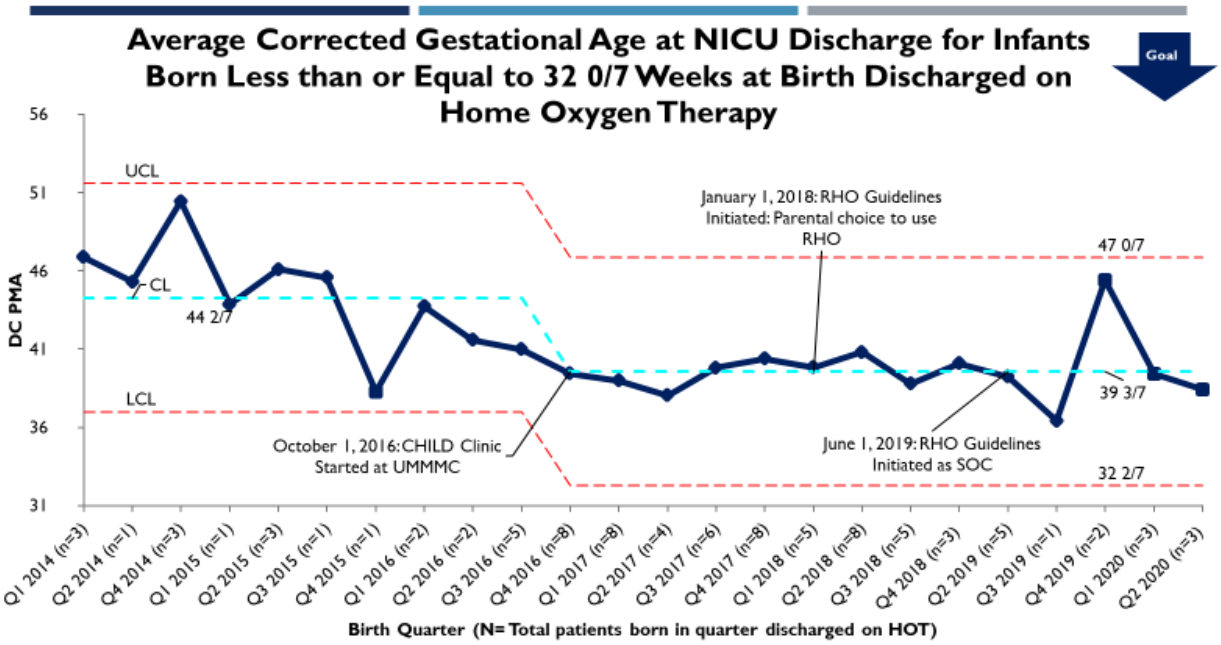
Preliminary Research

Prior to the RHO trial, our study team conducted the following series of studies: (1) a provider survey which determined that recorded oximetry is frequently utilized to discontinue HOT;[10] (2) several studies of recorded oximetry in infants, during which we acquired expertise in the acquisition and analysis of oximetry in this population;[15, 22] (3) a multicenter trial examining the impact of RHO on caffeine use and intermittent hypoxia.[16, 23] In addition, in 2013-2014, we conducted a pilot study at Boston Children's Hospital (BCH) to evaluate the feasibility of RHO as standard of care (SOC). In our pilot work, infants on HOT were randomized to SOC (monthly clinic visits) or to SOC plus RHO. The success of this pilot led to the PCORI-funded multicenter, randomized RHO trial.

Randomized, Multicenter RHO Trial. The RHO trial was a prospective, unmasked, multi-center randomized trial of premature infants from 9 NICUs enrolled after discharge on HOT, and attending their initial pulmonary visit (within 2 weeks of discharge). Infants were randomized to SOC (monthly clinic visits with in-clinic assessments and inpatient polysomnography [PSG] prior to discontinuing HOT) or the intervention group (SOC monthly visits plus RHO). Our primary outcome was mean time to discontinue HOT. HOT duration was significantly shorter for infants randomized to RHO. Parent-reported quality of

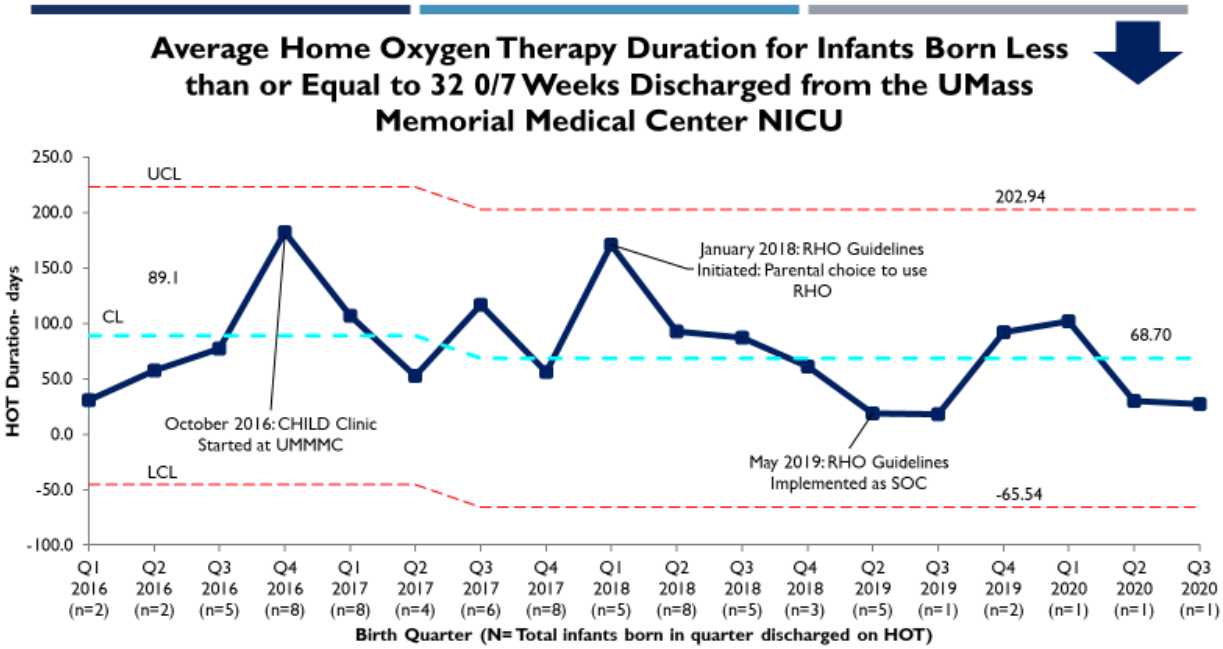
life improved after discontinuation of HOT for both groups, with no significant difference between groups, demonstrating that transmitting RHO data was not more stressful for families.

Figure 1: Average CGA for Infants Born Less than or Equal to 32 0/7 Weeks Born at UMass at time of NICU Discharge



Successful Implementation of RHO at the UMass Center for Healthy Infant Lung Development (CHILD) Clinic. After completing the RHO trial, the program was implemented as standard protocol for managing and weaning HOT in premature infants in the CHILD Clinic at the University of Massachusetts Memorial Medical Center (UMMMC) (January 2018). Prior to implementation, the baseline average corrected gestational age (CGA) at NICU discharge was 44 2/7 weeks and mean duration of HOT was 143 days (4.8 months). In June 2019, the CHILD clinic acquired a data recording system that enabled wireless transmission of recorded oximetry from internet-enabled oximeters (Masimo RAD 97's home oximeters), provided by home care companies for clinical use. Starting in June 2019 all infants discharged from the UMMMC NICU received a WIFI enabled oximeter connected to the wireless system at UMMMC as standard of care from their home care company provider. The new oximeters eliminate the need for manual transmission of data. Since RHO implementation, infants at UMMMC requiring HOT are discharged at 39 3/7 weeks CGA, a five week decrease in average LOS (**Figure 1**). Average HOT duration also significantly decreased from 143 days to 68.7 days (**Figure 2**).

Figure 2: Average Home Oxygen Therapy Duration for Infants Born Less than or Equal to 32 0/7 Weeks Born at UMass



PRE-IMPLEMENTATION ACTIVITIES

BASELINE DATA COLLECTION

The RHO Implementation study is a quality improvement (QI) initiative at the site level, which means RHO will be implemented as the standard of care as there is literature supporting its utilization, effectiveness and safety for managing HOT in infants. *The UMass Medical School Institutional Review Board (IRB) has classified this study as non-human research at the site level and human research with a waiver of written informed consent for the overall implementation study*. Families who wish to not share even their deidentified infant's data as part of the implementation trial have the option to opt-out but will continue to be managed by the RHO program for their oxygen management.

VON Data Query

A majority of the baseline data will be queried from VON using Nightingale. This will require contacting the site's most frequently referring NICU(s) to identify their VON abstractor(s). They will be provided both a set of written instructions and walkthrough. Please refer to the *Baseline Data Collection Training Slides* and accompanying instruction sheet for full instructions).

The specific data to be obtained will be deidentified, aggregate data. Specifically, for each referring and site NICU, we will obtain: (a) the total monthly census of VLBW infants surviving to discharge, which we will call COHORT A, (b) the mean and median length of stay (LOS) for COHORT A (c) the monthly census of VLBW infants surviving to discharge who are discharged home on oxygen, which we will call COHORT

B (excluding those who did not survive to discharge), (d) the monthly census of VLBW infants who survive to discharge and are NOT discharged home on oxygen, which we call COHORT C, (e) the mean and median LOS for COHORT B, and finally, (f) the mean and median LOS for COHORT C.

Additional Baseline Variables

The study team at UMMS will provide the implementation site's pre-designated personnel with an Excel spreadsheet with all the variables to be collected as well as a list of operational definitions developed by the RHO study team. Please refer to the *Outpatient Data Operational Definitions* document and *Outpatient Data Collection Template* for additional details. Each site will be responsible for collecting these variables for all infants discharged on HOT over the last three years. In order to ensure accurate linking of the VON variables to the additional baseline variables, the infant's ID for the additional baseline variable collection will be their assigned VON ID.

NICU AND PULMONARY COLLABORATION

The RHO Program utilizes a multidisciplinary approach for home oxygen management and transition to home and the outpatient care setting. Effective communication between the NICU team and outpatient pediatric pulmonary team is essential to streamline home discharge and facilitate outpatient management of HOT.

Each participating center should identify a lead pediatric pulmonary team member and NICU team lead at each referring NICU. Examples of team leads include site principal investigators, attending physician, nurse practitioner, physician assistant, nurse or case manager.

UMass Tip: The case manager in the UMMMC NICU is the primary facilitator of home oxygen as they place the home care company orders and arrange insurance prior authorizations for home oxygen. Most importantly, their responsibility is to route the home oxygen order to the appropriate company who provides the WIFI enabled oximeters (Masimo RAD 97 oximeters) standardly to infants being discharged from the NICU. They are often the most informed of what insurance companies cover specific equipment or companies.

Additionally, the pediatric pulmonologists at UMass working in the BPD follow-up clinic have an active role in facilitating home oxygen discharge. They consult on referred patients approximately 2-weeks prior to anticipated discharge, help place appropriate orders, and conduct education and training with the family.

BPD Team Communication

As part of integrating the RHO program into your center's standard of care strategy for former preterm infants on home oxygen, it is vital to have strong collaboration and communication strategies implemented prior to going-live. Members of the team will include representatives from both the NICU and pediatric pulmonology teams.

- Communication around appropriate timing of NICU discharge for eligible infants early (about 2-weeks prior to anticipated discharge)

- Follow-up providers responsible for weaning oxygen outpatient should meet with the NICU care team and infant's family/caregiver leading up to discharge to secure and finalize discharge plans and provide education on equipment and home oxygen management plan (i.e., RHO Program)
- Ensure proper referral to home care company that provides RAD 97 oximeters licensed to the appropriate SafetyNET Remote Monitoring System
- Establish a workflow for communicating results of bi-weekly oximetry results after discharge with follow-up care team members

UNDERSTANDING THE HOME CARE COMPANIES INVOLVEMENT WITH IMPLEMENTATION

Local home care companies working with implementation sites will be integral stakeholders in the RHO program. The RHO leadership team and stakeholders will work with local implementation sites to establish working partnerships between centers and home care companies.

It is a goal of the RHO program that each center has two-to-three home care companies to refer patients to that provide the appropriate WIFI enabled oximeters as standard workflow to infants being discharged on supplemental oxygen.

Home care companies supplying the appropriate oximeters (RAD 97 Oximeters) will have to have the proper licenses to connect to the Patient SafetyNET (PSN) at UMMS or other assigned Data Coordinating Center (DCC). These licenses should be put in place prior to implementation and will be recycled from patient to patient. As an implementation center, you should understand the licensing process to help with any troubleshooting that may arise. For example, if an oximeter isn't loaded with the right license it will not connect to the PSN at your DCC. One way to tell is the WIFI symbol, when connected to WIFI, will be blue versus green. Your home care company representatives will know the appropriate members of the RHO team to contact and how to effectively solve this licensing connection issue.

Home care companies' workflow in obtaining referrals and providing home oxygen equipment will not change at participating centers. Referrals will be handled the same way and home care companies will complete education and training with the family prior to discharge from the NICU. Home care companies will need to provide a licensed oximeter (WIFI enabled-RAD 97) that communicates with your data coordinating centers PSN. Once the device is provided to the patient, they should notify the point person at that site to share the oximeters serial number. The serial number is required in order to properly admit the device into the PSN for remote monitoring. The point person at each site responsible for collecting the serial number and sharing with the DCC will then share the serial number through email prior to discharge. That way the oximeter can be admitted allowing remote continuous data capture of oximetry starting day of discharge.

As part of the regular home equipment teach, respiratory therapists will show families how to connect the oximeter to their home WIFI. Parent take-home instructions (Parent WIFI Connection Instructions) are available and site staff should follow-up with families and provide the printed instructions prior to discharge. Instructions should be shared with each home care company, participating site, and family discharged with a WIFI enabled oximeter. Instructions can be shared either in print or via-email at parent request.

IMPLEMENTATION OF EFFECTIVE COMMUNICATION AMONGST PARTICIPATING SITES AND RHO LEADERSHIP

MONTHLY SITE MEETINGS

Prior to implementation start the RHO leadership team will set up a standing monthly check-in call with each participating center. These check-ins are meant to help and support sites in identifying any barriers or facilitators to successful implementation. Sites will receive monthly reports of their site's quality improvement efforts and impacts of the program on their reported metrics; these reports will be reviewed during these monthly meetings to help guide any improvements that need to be addressed.

MONTHLY INVESTIGATOR MEETINGS

Monthly investigator meetings will be held prior to implementation and continue throughout the duration of the three-year project. These meetings will include agenda items related to implementation, identifying barriers and facilitators of implementation, and sharing progress of sites individual implementation of the RHO program.

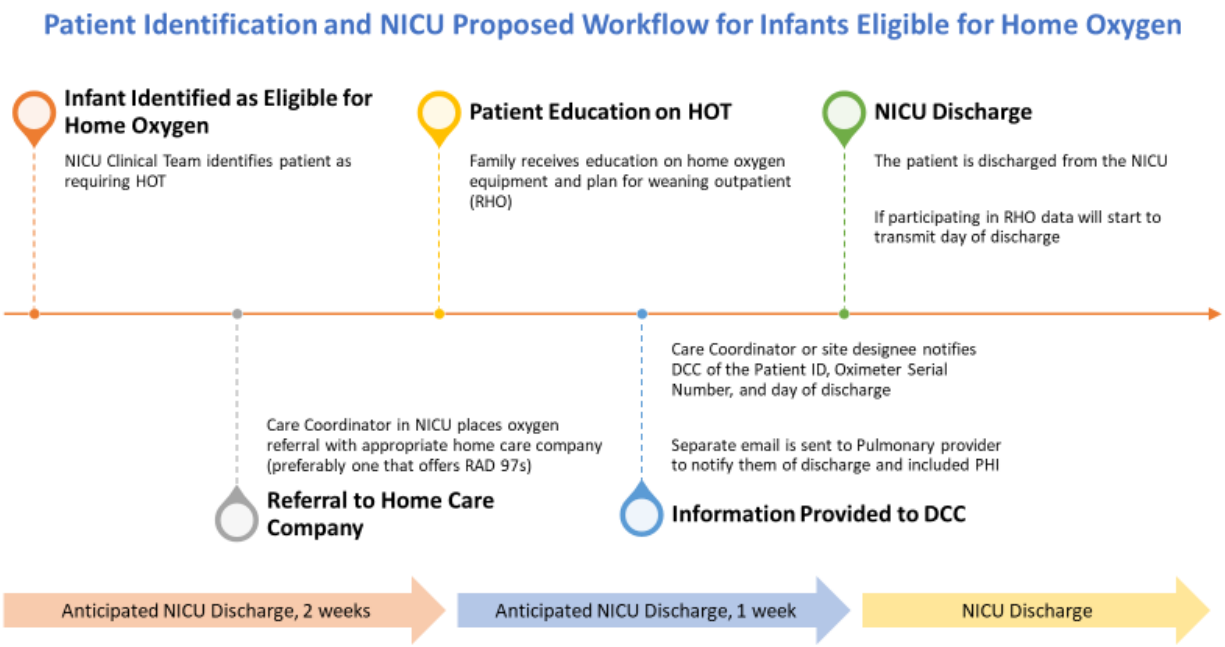
ON-SITE TRAININGS

The RHO Leadership team will conduct on-site trainings with each implementation site prior to going-live. Training materials will be reviewed and shared with sites. Any site-specific modifications to the program will be identified at these trainings and the RHO leadership team (Rhein and White) will help guide these modifications by sharing their own experiences with real-world implementation.

Home Care Company Site Trainings

The RHO Leadership team alongside Masimo Corporation will conduct site trainings with each implementation centers identified home care companies. These trainings will be focused on training respiratory therapists and staff on the proper equipment and how to troubleshoot any problems with equipment. Any Implementation Center staff member that will be speaking with families to relay RHO results should also participate in this training as it will be helpful to understand the newly available oximeter and its functions.

NICU AND PRE-DISCHARGE ACTIVITIES



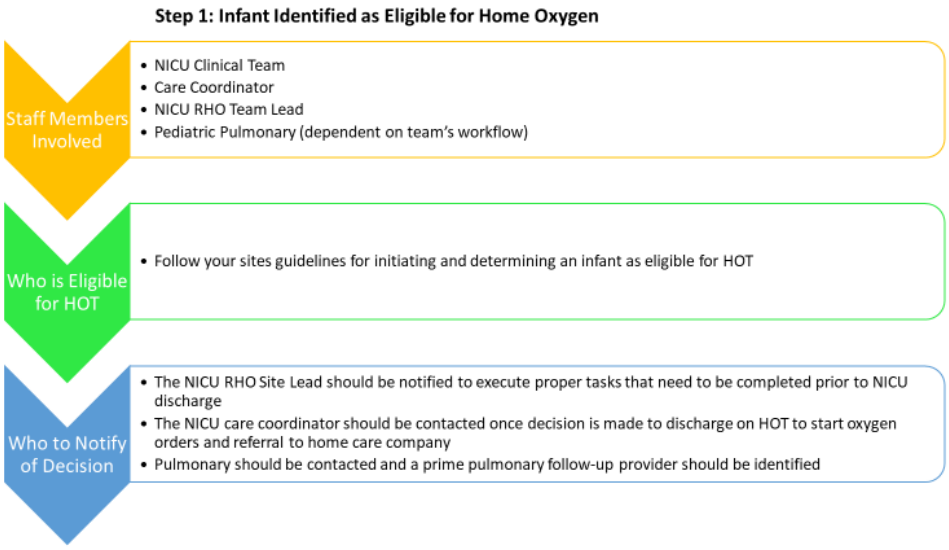
Identifying Infants as Eligible for Home Oxygen Therapy

The utilization of HOT varies between institutions and neonatal providers. The American Thoracic Society (ATS) strongly recommends the use of HOT in patients with BPD who are chronically hypoxic.[18] Infants whose last discharge delaying factor should be considered eligible for HOT and a decision should be made between the NICU and pulmonary teams if HOT is safe and appropriate for that particular infant and their family.

Parent preference of home oxygen is important to consider in the decision of discharge on HOT. Parents benefit from being apart of the conversation around HOT and the decision for discharge on HOT vs. staying in the NICU. A recent survey of parents whose children were potentially eligible for HOT found that while in the NICU 50% of families would prefer earlier discharge on oxygen vs. longer stay and when asked at 3 months post-NICU discharge a total of 80% of parents would prefer home oxygen (97% who initially preferred HOT and 60% who initially preferred staying in the NICU).[5] There were no demographic or illness severity characteristics that impacted parental choice regarding discharge on HOT. Parents should be informed of the benefits RHO provides with shorter durations of HOT, increased physician-family communication, decreased risk of readmission, and improved growth and developmental outcomes.

Many insurance prior authorizations can take upwards of 2-weeks for approval. The delays in insurance authorization for HOT can further extend NICU LOS and increase health care utilization costs for the family. If the decision is made early these delays can be avoided. Work with your local home care companies to establish a workflow on when an appropriate time would be to identify a patient as being eligible for HOT and completing the oxygen prescription orders and referrals would be at your center to prevent an extended NICU stay.

UMass Tip: Clinical practice guidelines (CPGs) at UMass identify criteria for potentially deeming an infant and family as eligible for HOT. For example, an infant who has failed two room air challenges should be considered as eligible for HOT. Every 2-weeks the CHILD Clinic (Pediatric Pulmonary) pulmonologists conduct BPD rounds in the UMMMC NICU. At this time, the NICU census is reviewed and children adjusted post 34-weeks CGAs respiratory status and feeding plan are reviewed. For infants whose last discharge delaying factor is an oxygen requirement the referral and home prescription oxygen orders are placed approximately 2-weeks before the anticipated discharge date. This allows the case manager in the NICU and home care companies time to sort out insurance authorizations, home delivery, and equipment education to avoid potential delays in NICU discharge. It should be specified at the time of oxygen referral to the home care company if the infant qualifies for an internet enabled oximeter (RAD 97).



Please refer below to RHO Program eligibility criteria.

Workflow Suggestion

- NICU clinical team identifies patient as requiring home oxygen therapy using their center's guidelines for discharging on HOT
    - Contact NICU RHO Site Lead
    - Contact NICU Care Coordinator to initiate referral to home care company. If available, the patient should be referred to a home care company that supplies RAD 97s
    - Contact pediatric pulmonary lead to arrange consult and identify follow-up provider
    - Inform NICU site lead or identified personnel responsible for communicating with DCC that the infants discharge is anticipated and share relevant and requested information with the site

RHO Program Eligibility and Exclusion Criteria

Infants eligible to be followed by the RHO Program will be identified prior to NICU discharge by both the NICU and pulmonary teams. The RHO Program is being implemented as the standard management guideline to wean home oxygen in the outpatient setting, this is NOT research. Meaning any infant who is identified as needing HOT and meet eligibility criteria at your center will have their oximetry data transmitted to the DCC to receive bi-weekly downloads. The below inclusion/exclusion criteria apply to those infants whose data will be collected as part of the RHO Implementation Trial. Families who opt-out to having their child's follow-up data be included as part of the trial will continue to receive standard RHO utilization including bi-weekly oximetry reports and monitoring.

RHO Implementation Trial Inclusion Criteria:

(1) An infant with a birth gestational age < 37 0/7 weeks postmenstrual age (PMA) who has a requirement for O_2 past NICU discharge
(2) An infant that is diagnosed with BPD associated pulmonary hypertension (BPD-PH) and not PH-specific medication therapy (see BPD-PH section below for more specifics)

Exclusion Criteria:

(1) An infant with a syndrome or other diagnosis with known high risk for persistent hypoxia (cardiac disease, Trisomy 21, Pierre-Robin Sequence, etc.),
(2) Infant who has a requirement for O_2 flow rate > 1 L/min or tracheostomy
(3) Infants with conditions that may influence prolonged need for oxygen beyond lung disease of prematurity will be excluded

Care Coordination

The NICU Care Coordinator plays a critical role in home discharge planning and securing proper equipment necessary for safe discharge. The Care Coordinator/Case Manager at your site should be notified as soon as the decision is made to discharge on home oxygen. They then will attempt to identify a home care company that accepts the patient's insurance that has RAD-97's in their inventory and supply standardly to infants being discharged out of the NICU.

The Care Coordinator will notify the NICU Site Lead if unable to secure the Rad-97. If able, on the date when the oximeter is delivered, the Care Coordinator (or designee) will obtain the serial number for the specific Rad-97 assigned to the patient and relay this code to the Site Lead or DCC. Please refer to later section on notification of discharge and serial number to the DCC.

This is a vital role in ensuring proper discharge and management of HOT utilizing the RHO program. Proper communication between NICU, pulmonary, and case management and coordination are key and should be prioritized to ensure a smooth discharge process.

Parent Education of the RHO Program

Both the NICU clinical team and Pediatric Pulmonary teams at your center should educate parents on the utilization of home oxygen therapy, associated equipment, and weaning process utilizing RHO prior to NICU discharge.

Families or legal guardians of infants requiring HOT should receive program information and understand the reasoning behind the utilization of RHO to guide their child's oxygen management in the outpatient setting. The *RHO Program Parent Brochure* can help care teams point to the benefits of the technology and guidelines to safely and effectively manage their child's oxygen.

As RHO is being implemented as the standard of care management strategy at your center families will not have an option for an alternative management strategy if provided the proper equipment (i.e. Masimo RAD 97 oximeter). They do however have the choice of opting out of their child's data being shared as part of the ongoing implementation trial. Therefore, after parents receive the program information and are informed of the specific de-identified health information to be collected as part of the trial, they should make an informed decision to participate. If opting out of their child's data being shared, they should complete the opt-out section on the last page of the *program fact sheet*. The fact sheets should be kept at each local site for proper study management. Participating sites may be audited, and these forms serve in the place of formal written informed consent. Original copies should be stored in accordance to the most recent Common Rule (2018) regulations.

 **UMass Tip**: A CHILD Clinic Pulmonologist and RHO trained medical assistant meet with families several days before NICU discharge to review our plan for weaning their child's oxygen outpatient. Specifically, we review required oxygen equipment that they should receive from their home care company and if equipment is available, we will check to make sure all equipment was supplied (travel tank, regulator, and oximeter). Additionally, we review signs and symptoms of respiratory distress and when to contact our clinic. Prescribed outpatient pulmonary medications and any teaching will also be conducted at this consult. The RHO Program and management strategy is reviewed in full-detail with families and they are informed of the days to expect a call from the CHILD Clinic medical assistant with their child's oximetry results.

This encounter with the family is documented in the electronic medical record (EMR) and billed as an education and consult encounter by the pulmonologist. Please refer to the training document titled "NICU Pre-Discharge EMR Documentation" for additional guidance.

Notifying Data Coordinating Center of Discharge

Your sites designated Data Coordinating Center (DCC) will need to be notified of patients being discharged on home oxygen prior to discharge. Once the RAD 97 oximeter has been provided to the family by their home care company the serial number is required by the DCC to admit the oximeter into the Patient SafetyNET (PSN). Your sites designated coordinator or staff member should send an email to the DCC contact with the following information:

- Infants RHO ID Number
- RAD 97 Oximeter Serial Number
- Anticipated Discharge Date
- Specify Families Decision for Data Collection (opting in or out of data collection)
- If opting-out the diagnosis of BPD-associated pulmonary hypertension should be specified where this depicts the weaning algorithms utilization (see below guidance on BPD-PH management guidelines)

Please refer to the *DCC Discharge Notification Email Template* included in your sites Training Materials for more guidance. At this step, it is also recommended that the infant's demographic information be logged in the database.

NICU DISCHARGE AND SETTING UP PROPER EQUIPMENT

Home Care Set-Up and Parent Teach

As part of this program the home teaches on oxygen equipment by home care companies will not change. Each patient should receive a complete and thorough teach and education from a home care representative or respiratory therapist. Parents should be educated on equipment, alarm parameters and safety measures as outlined by the home care companies' procedures. If the child is receiving a RAD 97 as their clinical oximeter, the representative should also educate families on how to connect the device to their home WIFI. The document entitled *Home WIFI Parent Instructions* should be provided to the family by either the home care company representative or clinic staff. This workflow should be decided on at the individual site level and with each referring home care company.

The home care company representative will have to let your center's designated staff know of the oximeters serial number so that it can be relayed to the DCC for admission into the PSN for remote oximetry capture.

UMass Tip: Home care companies complete the home teach in the NICU on travel equipment (small portable tanks, regulator, and oximeter) in the NICU a few days prior (approximately 3-days) to NICU discharge. At this time, the oximeter is connected to the UMass network to ensure connectivity and communication with the PSN. The RHO medical assistant receives the oximeters serial number prior to the teach so that this demonstration can occur. Then day of discharge, the remaining home oxygen equipment (concentrator, MTanks etc.) is delivered to the home prior to the infant being discharged and family is re-educated on equipment by an RT once the baby is discharged. While in the home, the RT ensures the oximeter connects to the home WIFI network and is communicating with the DCC PSN (WIFI symbol is green on the oximeter).

Placing Infants on their RAD-97 Prior to Discharge

The RHO Program does not require patient's oximetry to be monitored prior to NICU discharge but it has been suggested as a recommendation. Oximeter averaging time varies across institutions. The RHO Program will utilize oximeters that are set to a 12-second averaging time and at this time maybe more sensitive than your units pre-determined averaging time on central monitors. This may cause the patient to be discharged on their existing flow rate and be found to require an increase immediately after discharge if having frequent intermittent hypoxia.

By placing the infant on their clinical monitor prior to NICU discharge, the parents or guardians can become familiar with the monitor, placing the oxygen probe, and alarm settings before going home. Additionally, it will allow for the clinical team to establish the infants baseline oxygen saturations prior to discharge. If utilizing this recommendation, the patient should be discharged home when their oximetry data shows a maintain or a wean and has stabilized. The DCC will also need to be notified prior to the placement inpatient to admit the oximeter into the PSN and analyze oximetry data prior to discharge upon request.

This option might not be suitable for all centers.

UPLOADING DATA TO THE TRIALS DATABASE

Record Numbering

When an infant has been identified as requiring HOT and the oxygen and pulse oximeter have been ordered, it is important to inform your site's respective DCC. This will allow for a smooth transition between NICU discharge and outpatient follow-up for continuous monitoring of recorded oximetry.

Your site should identify the appropriate team member to assign these RHO record identification numbers. As these are unique to each patient and no two patients can receive the same ID number and are important for tracking purposes.

Each infant eligible for the program will be assigned a unique RHO Implementation ID number. Record IDs will contain a total of 10 characters in the format XX-XX-XXXXXX. The first two characters are your assigned RHO site ID. The next two characters are the referring NICU ID, which will be unique to your individual site. The last six characters will be sequential for each referring NICU. As an example, the first subject from UMass' referring NICU 1 would be UM-01-000001 and the third subject from UMass' referring NICU 4 would be UM-04-000003. Please refer to the *Record ID Assignment Training* document included in your sites training materials. Assigning the correct record ID will be important when assessing your sites' referring NICUs' HOT utilization rate and allow the leadership team and site staff to identify barriers throughout the implementation period.

Communication between the clinical team and the DCC should only refer to patients by their unique RHO ID number and sites should keep a secure master list to track the infants enrolled in the program. A sample Master List has been included in your sites training materials and can be modified to fit your center's workflow.

Timing of Data Collection

The RHO Implementation Trials REDCap is comprised of 5 forms: Screening and Eligibility, Demographics, Home Oximetry Data Form, Adverse Events, and Implementation Discharge. Your site will be given access to a data access group (DAG) where you will have access to all your patients' data. The following section describes the timing of data collection.

Screening and Eligibility

This form should be completed for every infant potentially eligible (HOT requirement) to be followed by the RHO Program and should be completed after the infant is identified as requiring HOT by the NICU clinical team, but prior to NICU discharge. Ideally this form will be completed when the DCC is made aware of the upcoming discharge and provided with the patients provided oximeter serial number for admission into the PSN.

Demographics

This form can be completed after NICU discharge but should be completed very shortly after to maintain accuracy and provide pertinent information to the DCC (for example initial oxygen flow rate at discharge). Information to be collected includes discharge month and year, birth gestational age, sex, birthweight, maternal demographics, initial oxygen flow rate at discharge, and home care company.

Home Oximetry Data Form

This form will be completed by the DCC. When oximetry data is sent to your site, it is important that your site personnel replies to the email with the following information: whether the recommendation was followed and if the recommendation was not followed, the reason why.

UMass Tip: Some common reasons the recommendation has not been followed in the past have included growth concerns, recent or current illness, the provider felt comfortable maintaining the current flow rate, or the parent(s) felt uncomfortable changing the flow rate.

Adverse Events (AEs)

When an infant being followed by the RHO program has an AE, this form should be completed by implementation site personnel. An adverse event is defined as emergency department (ED) visit or hospital admission. Any serious adverse events (SAEs) will be evaluated by the Data Safety Monitoring Board (DSMB).

UMass Tip: Families are routinely asked whether the infant had an adverse event at their monthly outpatient clinic appointments that the team may not be aware of. If a family reports an AE during one of their bi-weekly check-ins calls the AE should be logged at that time if all information is provided by the family.

Implementation Discharge

This form will be completed by implementation site personnel once the patient is either successfully weaned off HOT or is determined to need continuous oxygen support, has a tracheostomy placed, or has died. This form should be completed when one of these endpoints has been reached. Similar to the demographics form, this can be filled out at any time, but should be completed in a timely fashion to maintain accuracy for monthly reporting and site implementation metrics.

OUTPATIENT FOLLOW-UP

All infants regardless of being followed by the RHO program should receive some type of follow-up at your clinic. The original RHO trial was designed and tested on the model that patients were seen monthly in clinic and recorded oximetry was analyzed between clinic visits to potentially decrease the duration of home oxygen.

If followed by the RHO Program and proper information has been supplied to the DCC prior to NICU discharge, an infant's recorded oximetry will start transmitting to the DCC the day of discharge. Their oximetry data will be analyzed on your sites next scheduled analysis day. If your site is on a Monday and Thursday downloading schedule and an infant is discharged on a Friday, then the first data download would be on Monday.

We recommend that infants on home oxygen receive monthly in-clinic visits while weaning off supplemental O_2. This is not required for infants followed by the RHO Program. Regardless of follow-up frequency at each visit the follow-up provider should ask parents of any AEs that the child may have had since their last visit. If the family reports an adverse event (emergency department visit or

hospitalization) the details of the event, diagnosis, treatment, and any changes in oxygen flow rate should be documented. The CHILD Clinic at UMMMC has provided their clinic documentation template as part of the programs training material and can be used as a guide or be modified to fit your site's clinic workflow.

THE RHO ALGORITHM

The RHO Program will utilize the same consensus-based guidelines for maintaining oxygen saturation targets above 93% and 96% SpO2 that were used in the original RHO trial. The guidelines are in agreement with national based guidelines that recommend weaning the current oxygen flow rate or discontinuing oxygen therapy if a child can maintain their oxygen saturations above 95% for greater than 95% of the recorded time.[18, 19] The consensus-based guidelines were originally criticized for being too strict and that they may actually prolong oxygen duration. The RHO trial resulted in shorter durations compared to the current described durations in the literature using the guidelines to manage oxygen weaning.

Examples of RHO Interpretations Utilizing the RHO Algorithm

The RHO Algorithm was developed for the original PCORI-funded trial by a consensus-panel of experts following national guidelines.

The algorithm utilized proved safe and effective for weaning premature infants off home oxygen.

Increase

Minutes Valid SpO2	Mean SpO2	Minimum SpO2	Maximum SpO2	Seconds below 93% SpO2	Seconds below 90% SpO2	Seconds below 96% SpO2
1802.8	95	74	100	9466	2238	60128
90.14*			Minutes	157.767	37.3	1002.133
			%time	8.751	2.069	55.588

Maintain

Minutes Valid SpO2	Mean SpO2	Minimum SpO2	Maximum SpO2	Seconds below 93% SpO2	Seconds below 90% SpO2	Seconds below 96% SpO2
1739.5	96.8	78	100	2997	1091	16951
86.975*			Minutes	49.95	18.183	282.517
			%time	2.872	1.045	16.241

Wean

Minutes Valid SpO2	Mean SpO2	Minimum SpO2	Maximum SpO2	Seconds below 93% SpO2	Seconds below 90% SpO2	Seconds below 96% SpO2
1922.2	98.6	79	100	225	86	4116
96.11*			Minutes	3.75	1.433	68.6
			%time	0.195	0.074	3.569

The RHO guidelines suggest weaning when an infant demonstrates the ability to maintain their oxygen saturation above 96% SpO2 for greater than or equal to 95% of the recorded time (minimum 1500 minutes recorded in data epoch). The WIFI enabled oximeters will be pre-set to an averaging time of 12-seconds for the purpose of implementation. The infant's current oxygen flow rate should be increased if they show the inability to maintain their oxygen saturations above 93% SpO2 for greater than 95% of the recorded time. For infants that demonstrate the inability to maintain oxygen saturations greater than 93% SpO2 for greater than 95% of the recorded time despite the minimum required minutes providers can increase to the next oxygen flow rate without a deviation for purposes of quality improvement metrics. The provider also has the discretion to not follow the guidelines recommendation to wean, maintain, or increase the infants current flow rate with appropriate justification.

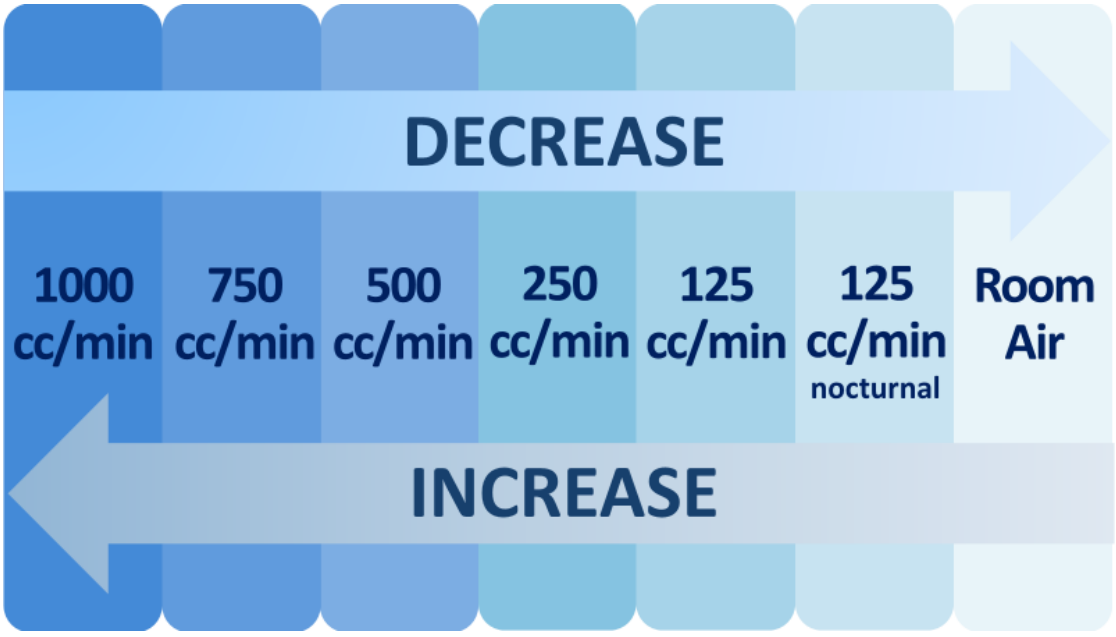
Examples of the RHO algorithm and suggestions to wean, maintain, or increase are included below and are also included as Appendix 1.

THE RHO PROGRAM'S HOME OXYGEN THERAPY WEANING PARAMETERS RHO ALGORITHM		
	STANDARD OXYGEN MANAGEMENT GROUP	**RHO OXYGEN MANAGEMENT GROUP**
CRITERIA FOR **INCREASING** O_2 FLOW RATE	INABILITY TO MAINTAIN **O_2 SAT >93%** AT PATIENT'S CURRENT O2 LEVEL FOR 20 MINUTES IN CLINIC VISIT CHALLENGE	INABILITY TO MAINTAIN **O_2 SAT >93%** FOR >95% OF RECORDED TIME
CRITERIA FOR **MAINTAINING** CURRENT O_2 FLOW RATE	ABILITY TO MAINTAIN **O_2 SAT >93%** AT PATIENT'S CURRENT O2 BUT UNABLE TO MAINTAIN **O_2 SAT >93%** AT WEANED FLOW RATE FOR 20 MINUTES IN CLINIC VISIT CHALLENGE	ABILITY TO MAINTAIN **O_2 SAT >93%** FOR >=95% OF RECORDED TIME BUT UNABLE TO MAINTAIN **O_2 SAT >96%** FOR >=95% OF RECORDED TIME
CRITERIA FOR **WEANING** O_2 FLOW RATE	ABILITY TO MAINTAIN **O_2** **SAT >96%** AT WEANED FLOW RATE FOR 20 MINUTES IN CLINIC VISIT CHALLENGE	ABILITY TO MAINTAIN **O_2 SAT > 96%** FOR >=95% OF RECORDED TIME
* RHO pass and fail will be determined by assessment of recorded oximetry. For each episode of transmitted data, a minimum of 1500 minutes (25 hours) of recorded data will be required for each data epoch to make any determination. **Infants are eligible to wean seen in clinic, a clinic pass (weaning) and fail (increasing or maintaining current flow rate) should be determined per clinic assessment of oximeter alarms.		

For infants in the RHO program, O_2 weaning will proceed, when allowable per weaning criteria in the guideline, in 50% decrements to a minimum flow rate of 125cc/min. For example, an initial flow rate of 500cc/min will be decreased to 250cc/min, and 250cc/min will be decreased to 125cc/min. From 125cc/min (the minimum continuous flow rate) the next weaning step will be to room air during the day and nocturnal O_2 only at a flow rate of 125cc/min. The final step will be from nocturnal oxygen to off supplemental O_2 entirely. At that point the infant's data will be downloaded twice more, and monitored for a total of one week, on room air to ensure they can properly maintain their oxygen saturations off oxygen therapy.

The recordings once off oxygen entirely will have to demonstrate either a maintain or wean of the current oxygen flow rate for both data epochs to be considered eligible to continue off supplemental O_2.

The weaning increment and decrement low-flow nasal cannula flow rates are presented below and are also included as Appendix 2.



Bi-weekly emails from the DCC will include the current flow rate of oxygen, the RHO algorithm report, and clinical suggestion to either maintain, increase, or wean the infants current supplemental flow rate. It is up to the infants' provider to determine if the RHO algorithm's determination should be followed. Compliance with the algorithms determination and providers decision to follow will be tracked as part of the implementation trial and quality improvement data collection to inform implementation evaluation.

Compliance with Recommendations

The RHO algorithm is a consensus-based guideline that follows national guidelines recommendations for weaning and managing home oxygen in infants with BPD. The twice weekly recommendations to wean, maintain, or increase your patient's oxygen flow rate is strictly a recommendation. You as the provider have the option to follow the recommendation or disregard.

As part of the RHO Implementation Trial we are tracking the compliance with the algorithm's recommendations. When you choose not to follow the algorithm's determination a reason should be included in your email response back to the DCC as they are inputting the data into the REDCap for that form. If information isn't provided, the DCC will ask for clarification and the reason at the time of the next data epoch interpretation.

Common reasons to not follow include but are not limited to: feeding concerns, recent illness, risk for aspiration, or poor growth.

As part of the RHO Program a total recorded time of 1500 minutes or 25 hours will be required for a recommendation to be made. If the infant is found to be spending more than 5% of the total recorded time below 93% SpO_2, which indicates an increase, the provider can choose to increase the infants current flow rate to the next increment of flow and still be within compliance.

Email Communication with Assigned Data Coordinating Center

As part of the implementation trial, a research coordinator at UMass has been assigned to this project's data collection. Therefore, to eliminate the potential increase in workload the research assistant at

UMass will collect all data for the "home oximetry" REDCap forms which include logging the algorithm's recommendation and associated data along with the changes made to the infant's oxygen flow rate. If a deviation occurs, they will also be responsible for tracking and logging compliance and deviations.

Therefore, it becomes essential that sites designees responsible for receiving the twice-weekly recommendations respond to the DCC with any changes made or reasons for not following the recommendation. This will ensure accuracy in the infants next recommendation and data collected as part of the overall trial.

FREQUENCY OF FAMILY AND PROVIDER CHECK-INS

Each site will receive twice-weekly data epoch recordings and recommendations to manage each active infant's current oxygen flow rate. Once the data and recommendation to either wean, increase, or maintain the current flow rate the parents or caregivers of the infant should be contacted by an RHO site member. Appropriate staff roles to contact a relay the recommendations could be an attending physician, NP/PA, clinic nurse, medical assistant or respiratory therapist. This role will vary by sites but should remain consistent as families and caregivers rely on this information once provided.

The contact method utilized to communicate results with families will be left to individual site and physician leads discretion, and the contact method may vary based on recommendation being made. Any changes made in supplemental O_2 flow rates should be documented in the patient's medical record.

For recommendations to increase, the RHO leadership team suggests a more formal check-in with the patient and parents/caregiver to uncover any potential causes for the increase in supplemental O_2. This could be done in the way of telemedicine or an in-person clinic visit.

UMass Tip: The medical assistant (MA) in the CHILD Clinic at UMass is responsible for downloading and analyzing each patient recorded oximetry twice per week (Tuesday's and Friday's). Once the primary pulmonologist for each infant currently on HOT has reviewed and provided their management decision the MA then calls each family or caregiver with that day's recommendation to either wean, increase, or maintain their child's current oxygen flow rate. The recommendation and any clinically relevant details from the call are then documented in a telephone encounter in the child's EMR. Refer to the *RHO Telephone Encounter Template* in the training materials. Once every 30-days the primary pulmonologist will conduct the telephone encounter and bill for the appropriate telemedicine CPT codes for the program's services.

For any increases in oxygen flow rate the primary pulmonologist caring for the infant will schedule the infant within 24-hours for a video-telemedicine visit. This appointment is scheduled by the MA as they will still call to triage any emergent findings back to the CHILD Clinic team. In some cases the need for a telemedicine visit with the physician is found to be unnecessary, for example parents report an extended time off oxygen within that recording period.

BILLING FOR SERVICES ASSOCIATED WITH RHO

Patients with chronic diseases, such as BPD with a HOT requirement, can benefit from remote patient monitoring (RPM) programs that have the potential to decrease health care costs and utilization, promote family engagement, and increase satisfaction such as the RHO Program. The novel coronavirus pandemic has highlighted the need for expansion of RPMs and telemedicine services. Until recently, the

reimbursement for RPMs was limited and CPT codes did not exist or were widely covered by payer groups. In January 2020, CPT codes were implemented for use in RPMs similar to the RHO Program.

CPT code 99547 was made available in January 2020. It specifically covers "remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month."[24] This code must be billed and services rendered by a professional practitioner (MD, NP, PA) and not auxiliary staff.

Available CPT Codes for RPMs and Telemedicine Services

CODE	Definition and When to Use
CPT 99091	Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
CPT 99453	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
CPT 99454	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.
CPT 99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month
HCPCS G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion

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UMass Tip: CPT code 99547 is billed every 30-days after NICU discharge. This code has specific requirements in that it can not be billed within +/- 7 days of a clinic visit (telemedicine or in-person). Therefore, we use the NICU discharge date as the start date of this code and see the patient 1-2 weeks after discharge and complete a RPM encounter 4 weeks after discharge. The follow-up schedule of these visits is continued through the duration of supplemental O_2 weaning as patients are seen monthly. For example, if a patient is discharged on January 1st their first clinic visit would ideally be on January 15th and first billing encounter would be completed on January 29th.

On RPM encounter visits, the primary pediatric pulmonologist for that infant will contact the family/caregiver and use the "30-day Billing Encounter" template and document and bill within the EMR. The documentation covers the past 30-days of titrations made in the child's oxygen and refers to the twice-weekly telephone encounters documenting the changes that past month. On non-billing encounter days, a medical assistant contacts the family/caregiver with their oximetry results.

Masshealth (Medicaid) does not reimburse for CPT code 99547.

INFANTS ON HOME OXYGEN THERAPY AND DIAGNOSED WITH PULMONARY HYPERTENSION

For the purposes of this manual and telemedicine program, the presence of pulmonary hypertension will be defined as pulmonary hypertension as a diagnostic label for the study subject according to the discretion of local site team, supported at a minimum by one echocardiogram with echocardiographic evidence of pulmonary hypertension. Thus, the pulmonary hypertension diagnostic label will be applied at the discretion of each local site team (no central study oversight). Infants who are on PH-specific medication therapy will be excluded and recorded oximetry will not be obtained. PH-specific therapy will be defined as the following medications:

- phosphodiesterase-5 inhibitors (PDE5i) or riociguat
- endothelial receptor antagonists (ERA)
- prostacyclin or prostacyclin derivatives

Of note, the *RHO Program will follow infants on HOT diagnosed with pulmonary hypertension (pulm HTN) who are not on diuretic therapy*. Infants requiring HOT and diagnosed with pulmonary HTN will be identified prior to NICU discharge and follow the same procedures for obtaining proper equipment for the RHO program. Once discharged from the NICU, they will be followed by the RHO program and have recorded oximetry analyzed twice weekly.

Differences in RHO Program for Infants with Pulmonary BPD-PH

Unlike infants with BPD without PH, infants with BPD-PH will require three consecutive data epochs that meet weaning criteria in order to wean their current oxygen flow rate to the next decrement. Infants will follow the same RHO oxygen weaning algorithm as BPD infants with target saturations of 96% and 93% SpO_2 being analyzed and considered to either maintain, wean, or increase their oxygen flow rate. Flow rates will be weaned in 50% decrements. For example, an infant on 500cc/min would wean to 250cc/min, 250cc/min would be weaned to 125cc/min. Once an infant is tolerating 125cc/min and has three consecutive data epochs showing a wean the infant would be weaned to nocturnal oxygen at a flow rate of 125cc/min. Finally, nocturnal oxygen will be discontinued once the infant has another three consecutive data epochs with the recommendation to wean.

Email correspondence from the data coordinating center (DCC) responsible for maintaining your clinical site will keep track of the consecutive recommendations to wean. Patients' data will be downloaded and interpreted by the DCC with results being reported to the overseeing physician twice per week regardless of the algorithm's interpretation. Consecutive recommendations will be reported as and remaining weans required in order to decrease the patients flow rate. Due to the fragility of infants with BPD and pulmonary HTN if their recorded oximetry suggests an increase, despite the recorded time (minimum necessary to decide using the RHO algorithm is 1500 minutes) even below the minimum the DCC will recommend an increase.

Additionally, patients can wean no more than two levels without obtaining an echocardiogram (ECHO) to confirm stability and improvement in pulmonary HTN. ECHOs should be obtained no less frequently than every three months while on oxygen and should be obtained within one-month after successful oxygen discontinuation.

INFANTS ON HOME OXYGEN THERAPY AND DIAGNOSED WITH CONGENITAL ANOMOLIES

As part of the current implementation trial we will not be following infants on home oxygen diagnosed with congenital anomalies or other diagnoses that put an infant at higher risk for hypoxia. Their data will not be collected as part of the implementation trial and their data will not be analyzed at the DCC.

If infants with congenital anomalies are discharged and provided a RAD 97 oximeter the DCC does not need to be provided with their oximeters serial number or information. Their eligibility form should still be completed within the database for tracking purposes with the appropriate exclusion criteria marked and noted.

If your center is participating and functioning as a DCC you can arrange with your pulmonary team to follow the infant at your institution using recorded oximetry as a guide for weaning per discretion, as they may potentially benefit from home oximetry. If the infant is followed, we ask that you don't collect their data as part of the trial where they likely have a condition that puts them at higher risk of hypoxia and longer durations of oxygen, but your site can track for internal purposes.

INFANTS ON HOME OXYGEN THERAPY WITHOUT HOME INTERNET

Infants who do not have home internet available should still qualify to receive a RAD 97 if available and able. Several sites using RAD 97s prior to implementing for various reasons have had luck writing letters of medical necessity to either (a) obtain home WIFI for a set period, or (b) to strengthen the internet signal within the home. Please refer to the letter of necessity template provided in the training materials.

If home internet is unable to be secured infants duration of home oxygen and adverse events should be collected as part of the trial.

Reach out to the RHO Leadership team for more guidance if this scenario arises and they can help in providing different options for the patient.

DISCONTINUING HOME OXYGEN AND IMPLEMENTATION DISCHARGE

Polysomnography

The current gold standard prior to discontinuing supplemental O_2 is to obtain a formal polysomnography (PSG) to determine eligibility.[10, 25, 26] The original RHO trial compared results of the clinical PSG to simultaneous recorded oximetry in the standard of care assigned group. Bland-Altman analysis showed a strong agreement of oxygen saturation time below 90% SpO_2 between PSG and the simultaneous recorded RHO results (slope= 1.014, p=0.24). Results of the PSG and RHO agreed in 96% of cases (White et al., in-print). In qualitative analysis of clinical findings found during the PSGs, 37 (80%) of infants who underwent a PSG had no relevant clinical findings. A total of 11 babies were found to have obstructive sleep apnea (OSA) but only 2 (4%) of these were found to be clinically significant. No infant was found to have abnormal carbon dioxide levels during their PSG. Concluding, RHO is not inferior to a formal PSG for evaluating an infant's readiness to discontinue home oxygen.

For purposes of implementing RHO as the standard management strategy of home oxygen in preterm infants with BPD, a formal PSG is not required to discontinue oxygen. As, for the purposes of determining eligibility to wean oxygen saturation is the only variable assessed in the PSG report. If you have a clinical concern for prolonged hypoxia, obstructed sleep apnea, hypercarbia or other and

determine a PSG necessary the test can be obtained. The clinical determination should be included in the infants' REDCap Discharge Form upon completion.

RHO Discharge and Data Collection

Infants will be considered "successfully weaned from HOT" after 2-oximetry epochs (1 week of recordings) are analyzed and either recommend a maintain or a wean. At this point, the DCC will stop analyzing the infant's data and their oximeter will be discharged from the PSN at the DCC.

For any infant followed by the RHO program and successfully weans but then requires home oxygen support after weaning can re-enter the program. At that time the pulmonologist caring for the infant should reach out to the RHO leadership team for more guidance on readmitting them into the program. If the requirement for supplemental oxygen is within 1-months of weaning this will be considered a severe adverse event and will be reported to the DSMB for review, but any new requirement for supplemental oxygen after weaning within 6-months should be reported as an adverse event.

Infants should continue to be followed according to your center's follow-up guidelines after successfully weaning from HOT.

The discharge data collection form should be completed for all infants followed by the RHO program regardless of weaning status. Infants will be considered "discharged" from the program when they successfully wean off supplemental oxygen, require a tracheostomy placement, or death.

GUIDANCE ON COMMON TROUBLESHOOTING CONCERNS OR PITFALLS

As with any real-world implementation of a health program there are some common barriers to overcome associated with the program, equipment, and overall participation. It is a goal of the RHO program that the program is generalizable to most if not all infants who require HOT. At this time, large in-part due to lack of consensus on best management, some infants will be excluded due to diagnoses related to higher rates of hypoxia, genetic abnormalities, or who are mechanically ventilated. These infants may share the same benefits as preterm infants diagnosed with BPD on HOT and their outcomes associated with the program will be studied at a later point in-time.

The most common associated troubleshooting concerns that arise are related to the required equipment. Where this program has been successfully implemented at UMass and more recently at Boston Children's Hospital, some common technical problems associated with the internet enabled oximeters have already been identified and properly solved.

Common troubleshooting solutions are included below.

Always reach out to the appropriate RHO Leadership team member or DCC staff member as they can help with any additional troubleshooting needs and provide necessary guidance. In some cases, it might be necessary to contact either the home care company or the oximeter manufacturer for additional guidance to solve the ongoing issue.

COMMON PITFALLS ASSOCIATED WITH THE RHO PROGRAM AND EQUIPMENT	
PROBLEM	SOLUTION
Patient does not receive RAD 97 through their home care company either (a) oximeter not available or (b) insurance doesn't cover referral to home care company providing RAD 97s	• Work with your care coordinator to see if any of the available home care companies take the patients insurance by reaching out to the home care company representatives directly (*be cautious that the prior authorization may take up to 10-days*) • As this method for weaning is proven safe and effective if a RAD 97 becomes available while the infant is weaning one should be provided, and at that time the infant enters the program • If insurance will not cover then the infant should be followed under your old method for weaning HOT
RAD 97 will not connect to the Patient SafetyNET (PSN) at DCC	• If the oximeter is connected to the patient's home WIFI and communicating with the PSN then the WIFI symbol on the oximeter should be green, if it is blue then the device is connected to WIFI but not the PSN • If that is the case, your home care company will have to re-license the device to the DCC's PSN (only home care companies have this capability)
RAD 97 will not connect to patients' home WIFI	• Have them check their home WIFI to ensure it is working and/or powered on • Try having them reboot their home network modem • If the family's home has two available networks one being 3G and the other 5G the oximeter should be connected to the 5G network to work efficiently • If problem continues and WIFI signal is not a concern the home care company should be contacted to switch out the device
Family doesn't have WIFI or signal quality is low preventing transmission of data	• Use the available template for a letter of medical necessity stating the argument that WIF or stronger connection is necessary for the patient's home oxygen management
Family is reporting low signal quality or inaccurate oxygen saturation or heart rates on monitor	• First, the RHO algorithm does not include time of low signal quality in the analysis report, these associated oxygen saturations are kicked out and are not included in the overall time • Check the white patient cable for any cracks, sometimes micro-cracks can occur and cause inaccurate readings • As with all oximeters, these are no exception that when the baby is upset or rapidly moving the signal quality will suffer
Short battery life	• The RAD 97s have only a 2-3-hour battery life compared to 10 hours on the older models. Patients should be advised to account for this battery life when traveling to appointments etc.

IMPLEMENTATION RESEARCH

At the site level, this project is first and foremost a quality improvement (QI) effort. Centrally, it is an implementation research project involving analyses of de-identified local QI data, as well as qualitative data from staff and families, that will go beyond the scope of local QI effort at the site level. Where this project is QI at the site level, the project is approved under the non-human subject exemption and written informed consent is not required. Families instead will receive the option to opt-out of their child's data being shared as part of the larger implementation research trial. All infants regardless of opt-in status will be followed by the RHO program if supplied a RAD 97 through their home care company.

The study across sites has been approved by the University of Massachusetts Medical School (UMMS) Institutional Review Board under a waiver of consent as it will analyze de-identified patient data.

Quality Improvement Procedures

Sites will be implementing the RHO Program as their standard method for weaning infants off supplemental oxygen in the outpatient setting. This is after the original RHO trial was the first to evaluate and establish effectiveness and safety of any home oxygen weaning strategy. All infants discharged home on supplemental O_2 are eligible to be followed by the RHO program as it is the standard method of weaning at your institution.

Oximeters will be provided to infants as standard equipment for home oxygen through their designated home care company. The monitors are to be provided to the patient, per clinical standards, standardly to all patients on home oxygen and not as "research" monitors.

MONTHLY SITE REPORTS

As part of the quality improvement initiative at each site and ongoing implementation evaluation, sites will receive monthly reports showing their progress in implementing the RHO program that will utilize QI run charts with statistical process control limits to demonstrate whether improvements are likely to be better than expected due to chance. For example, site compliance will be presented as the mean percent of eligible patients successfully managed by RHO, with upper control limits at 3 standard deviations from the mean.

Sites will receive monthly reports from the DCC at UMass with their sites implementation and QI progress included. Included QI run charts will include information on average NICU LOS for infants discharged on HOT, CGA at NICU discharge, HOT duration and adverse events while weaning. Reports will be reviewed on each monthly site call and will be used to guide the conversation on any identified barriers or facilitators in implementation.

The RHO leadership team will also compile the same graphs including all participating centers, masking each site, so that individual sites can compare their progress to others. This will later contribute to the evaluation of the overall large-scale implementation efforts.

PARENT FEEDBACK AND FOCUS GROUPS

A parent advisory board (PAB) will continue to provide guidance and feedback throughout all phases of the implementation project. We have solicited input through previous focus groups to inform the development of the guidelines and aims of the program's implementation. The PAB for this project includes former families of infants on HOT that utilized various methods of home oxygen weaning strategies, including one family that used RHO standardly. A goal of the programs is to recruit additional members from each participating site to reinforce widespread implementation of the RHO program. Family advisors will participate in monthly calls with the leadership council, and provide insight to program implementation, program adaptations, and determination of which outcomes should be prioritized. Each site will be asked to recommend potentially interested family members to join the board and participate in qualitative focus groups.

IMPLEMENTATION CENTER FEEDBACK AND FOCUS GROUPS

A separate IRB will be initiated in the 18-month intensive implementation phase which will occur after the 3-month initial implementation phase. At which time, we will ask site program staff to participate in focus groups and administer questionnaires that evaluate satisfaction with implementation. Families will also be invited to participate in the survey's as satisfaction is a goal of the program. The survey will capture detailed experiences with acceptability and perception of the RHO adoption at each site. A pre-post analysis will be conducted on the overall satisfaction scores to evaluate effectiveness and satisfaction.

Recorded Home Oximetry (RHO) Program Contact List

Name	Title	Email	Reasons to Contact
Lawrence Rhein, MD, MPH	Principal Investigator	Lawrence.Rhein@umassmemorial.org	Questions will be escalated to Dr. Rhein on an as needed basis.
Heather White, MPH	Program Director	Heather.White@umassmed.edu	Primary contact for questions regarding contracts, IRB & regulatory documents, and site trainings.
Lindsey Simoncini	Research Coordinator	Lindsey.Simoncini@umassmed.edu	Primary contact for questions regarding REDCap, data collection, and baseline data toolkit.
Maria Matoshi	Research Assistant	Maria.Matoshi@umassmed.edu	Primary contact for questions regarding monthly reports and oximetry data.

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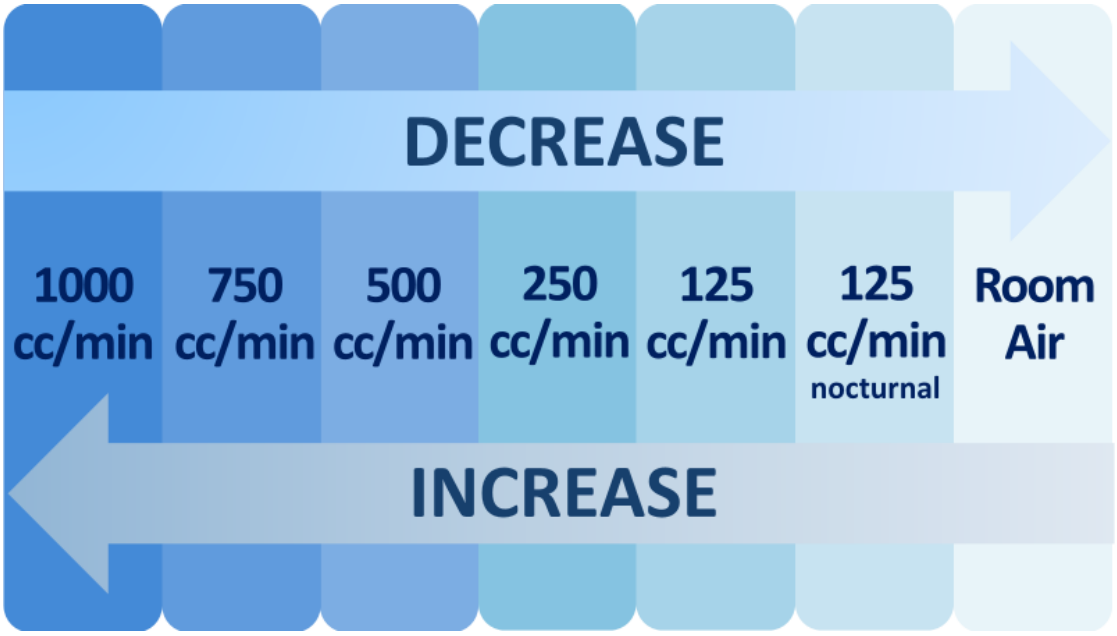
Appendix

Appendix 1: RHO Program Algorithm for Determining a Wean, Increase, or Maintenance of Current Oxygen Flow Rate

THE RHO PROGRAM'S HOME OXYGEN THERAPY WEANING PARAMETERS RHO ALGORITHM		
	STANDARD OXYGEN MANAGEMENT GROUP	**RHO OXYGEN MANAGEMENT GROUP**
CRITERIA FOR **INCREASING** O_2 FLOW RATE	INABILITY TO MAINTAIN **O_2 SAT >93%** AT PATIENT'S CURRENT O2 LEVEL FOR 20 MINUTES IN CLINIC VISIT CHALLENGE	INABILITY TO MAINTAIN **O_2 SAT >93%** FOR >95% OF RECORDED TIME
CRITERIA FOR **MAINTAINING** CURRENT O_2 FLOW RATE	ABILITY TO MAINTAIN **O_2 SAT >93%** AT PATIENT'S CURRENT O2 BUT UNABLE TO MAINTAIN **O_2 SAT >93%** AT WEANED FLOW RATE FOR 20 MINUTES IN CLINIC VISIT CHALLENGE	ABILITY TO MAINTAIN **O_2 SAT >93%** FOR >=95% OF RECORDED TIME BUT UNABLE TO MAINTAIN **O_2 SAT >96%** FOR >=95% OF RECORDED TIME
CRITERIA FOR **WEANING** O_2 FLOW RATE	ABILITY TO MAINTAIN **O_2** **SAT >96%** AT WEANED FLOW RATE FOR 20 MINUTES IN CLINIC VISIT CHALLENGE	ABILITY TO MAINTAIN **O_2 SAT > 96%** FOR >=95% OF RECORDED TIME
* RHO pass and fail will be determined by assessment of recorded oximetry. For each episode of transmitted data, a minimum of 1500 minutes (25 hours) of recorded data will be required for each data epoch to make any determination. **Infants are eligible to wean seen in clinic, a clinic pass (weaning) and fail (increasing or maintaining current flow rate) should be determined per clinic assessment of oximeter alarms.		

Appendix 2: Oxygen Flow Rate Decrements and Increments for Managing Home Oxygen Therapy.



Available Training Documents

NICU Related Materials

- Baseline Data Collection Training Slides
- VON Baseline Data Collection Instruction Sheet
- Additional Baseline Data RHO Implementation REDCap Form
- Outpatient Baseline Data Operational Definition List and Data Collection Template
- Parent WIFI Connection Instructions
- RHO Program Parent Brochure
- RHO Program Fact Sheet (V.3)
- NICU Pre-Discharge EMR Documentation Template
- Record ID Assignment Template
- NICU Pre-Discharge Email Template
- Sample Master List Template

Outpatient Follow-up Related Materials

- Clinic Documentation Template
- 30-Day Billing Encounter Template
- Telephone Encounter Template (to be used bi-weekly)
- Letter of Medical Necessity Template

Regulatory

- Institutional Review Board (IRB) Study Plan (V.3)
- RHO Program Parent Brochure
- RHO Program Fact Sheet (V.3)
- UMass REDCap Account Request Instruction Sheet