

Roadmap to Accreditation: Practical Aspects

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The Pulmonary Hypertension Care Center (PHCC) initiative began accrediting Centers of Comprehensive Care (CCC) in 2014, and Regional Clinical Programs (RCP) as part of a pilot program in 2017, in an effort to improve access to quality pulmonary hypertension (PH) care for patients throughout the United States. The purpose of this column is to present a roadmap to accreditation for PH coordinators and their PH teams. We will highlight the essential role that PH coordinators play in navigating all phases of the accreditation process. Figure 1 represents a recommended approach to the PHCC accreditation process.

DECISION TO PURSUE ACCREDITATION: ARE YOU READY?

The decision to apply for accreditation should be made by the medical director and the coordinator based on a careful evaluation of the PH program. The criterion of program volume helps to ensure that the program treats enough patients to maintain competency of all team members. While it is understood that most programs treat patients from all World Health Organization (WHO) diagnostic groups, only WHO Group 1 and 4 patients are included in this volume criterion. The first step to determine readiness for accreditation is to have an accurate assessment of patient volume using strict diagnostic criteria for WHO Groups 1 and 4. (See the following description of the Center Patient Roster.) Adherence to diagnostic and treatment evidence-based guidelines is required. To assess your program's adherence, you may refer to recently published guidelines¹⁻³ and the most recent reports from the WHO Symposium on Pulmonary Hypertension. The 2013 Symposium is reported in the *Journal of American Clinical Cardiology*, 2013, volume 62, D supplement.

The next most important criteria relate to the qualifications and tenure of the medical director and coordinator. Each should have served in their respective roles for at least one year at the current program. Even those with years of experience caring for PH patients require time to understand a new institution, its personnel, and organiza-

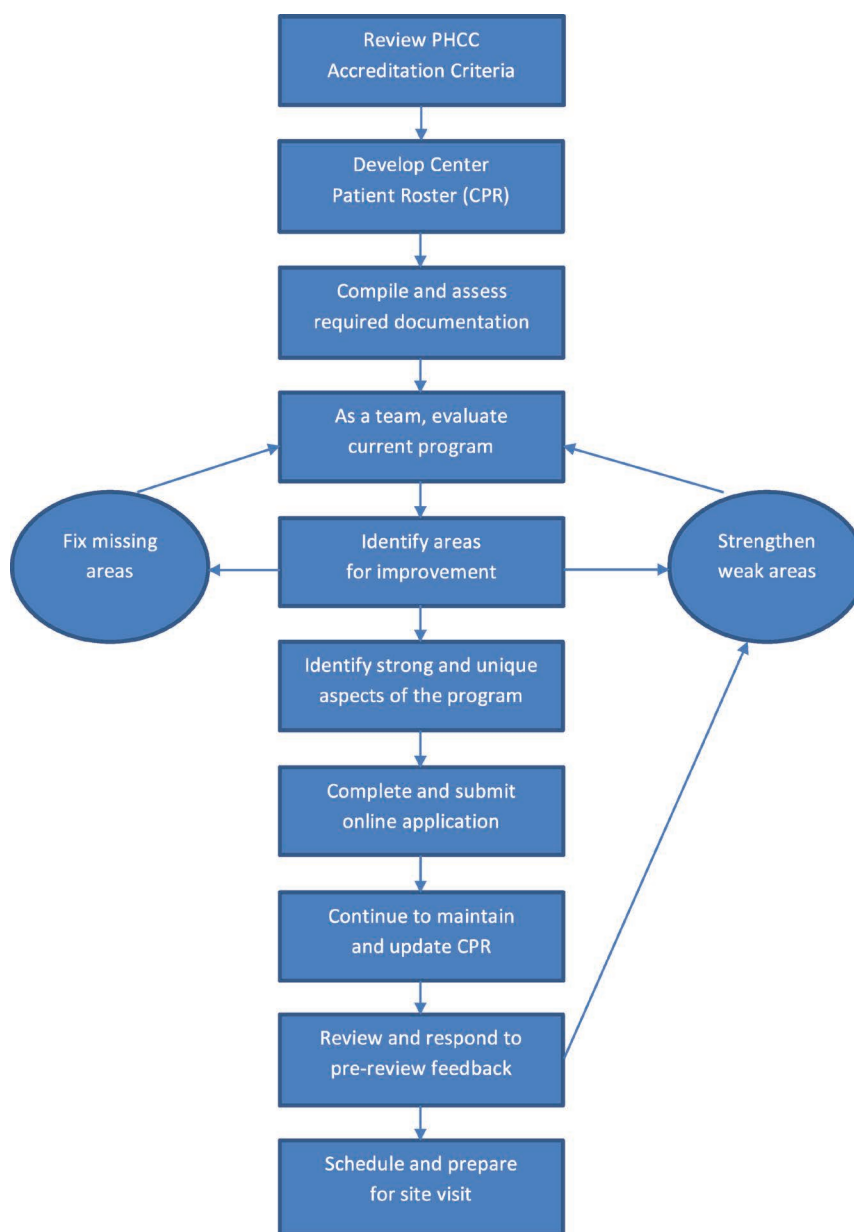


Figure 1: Organizing the PHCC accreditation process.

tional culture. The PHCC accreditation criteria require PH coordinators to demonstrate leadership and participation both within their institutions and as part of the larger PH community.

The third essential criterion is to have demonstrable institutional support. This goes beyond the payment of the accreditation fees and includes an observable commitment to the PH program and the team members. When performing this initial assessment, the appropriate level of accreditation (CCC vs RCP) is determined. Patient volume, program experience with parenteral therapy, and research experience should all be considered. If applying for RCP, referral networks should be in place when specialized PH care is required (to provide access to clinical trials, advanced therapies, or surgical interventions, including pulmonary thromboendarterectomy or transplantation).

The timing of application submission and the site visit should be based on when the PH program is able to put forth the strongest application possible. Once the decision to apply has been made, a timeline with delineated responsibilities should be developed. Each element should be described, noting the responsible person and the deadline for completion. Regular meetings of the PH team will help to keep the process on track. All team members should be involved in the application process, with the medical director and coordinator taking the lead roles. Smaller programs with limited clerical staff may need to request assistance to assemble documents and letters of support.

COMPONENTS OF THE APPLICATION PROCESS: GET SET TO APPLY

Online Application

Application for CCC and RCP is initiated through an online process. The application asks for narrative descriptions and explanations about the history and structure of the program, teaching and outreach activities, and how other health care providers, patients, and families are incorporated into the PH program. The rest of the application is divided into 5 sections for CCC accreditation: center director credentials and experience, center

coordinator credentials and experience, additional program staff and support services, medical facility services, and resources and research activities. RCP applications are not required to have research activities. The center PH coordinator plays an important role in organizing staff and documentation throughout the application and review process.

Documentation to support and expand on the application is required both prior to submission of the application and will be reviewed during the site visit day. A complete list of documents required is presented in the Required Documentation list. It is most efficient to include publications, educational, and outreach activities within the CV submitted with the application. Separate documentation of continuing education unit (CEU) completion is also required but can be maintained at the site.

The application requires letters of support (LOS) from departments that have regular or specialized interactions with PH patients. While there is a template on the PHCC website (<https://phassociation.org/phcarecenters/medical-professionals/application-process/>) that can be used for the multidisciplinary LOS, the program LOS are designed to highlight and specify the relationship between the PH program and the department. The institutional LOS should be specific about what the institution provides to PH program operations. Letters of support are uploaded with the original online application and must be included for the application to move forward. The coordinator can be helpful in distributing the template, identifying specific aspects of interdepartmental collaboration, tracking receipt of letters, and follow-up.

We have found that several institutions have staff dedicated to facilitating accreditation reviews and site visits regardless of the accrediting body. The coordinator should seek out the patient safety or quality of care departments early in the application process for assistance and expert advice in completing the application and conducting successful site visits.

Program Policies and Procedures

It is the expectation that PH programs have developed written policies, proce-

dures, and workflows for all aspects of PH evaluation and long-term management. As the guidelines for PH treatment have changed, these policies should be revised to follow current practice. The PH coordinator is able to review and revise current policies and identify areas where new policies should be created to enhance the quality and safety of patient care. These written policies will be reviewed by the PHCC Review Committee representatives during the site visit.

Development and Maintenance of the Center Patient Roster

The Center Patient Roster (CPR) is a list of patients actively managed by the program during the previous 3 years that carry a diagnosis of Group 1 pulmonary arterial hypertension (PAH) and Group 4 chronic thromboembolic pulmonary hypertension (CTEPH) only (Table 1). Within Group 1, patients should be identified further as idiopathic or other Group 1 diagnoses. The date of first visit to the program, current status, and the specific therapies the patients have been treated with is also required. The CPR plays a crucial role in multiple aspects of the review process. The roster is used to satisfy overall patient volume criteria requirements as well as treatment volume requirements for oral, inhaled, and parenteral therapies.

In our experience, the coordinator plays a vital role in the development and maintenance of the CPR throughout the planning and review process. Creating an accurate list requires careful and significant review and editing since historically structured coding systems (International Classification of Diseases [ICD] 9 and 10) have lacked the ability to clearly and consistently delineate all PH classification subgroups. Particularly in programs with multiple physicians, the coordinators may have a more robust perspective on the entire program population and easier access to information about treatment start dates.

Once drafted, the entire list should be reviewed by both the physician and coordinator to confirm that the list accurately reflects patient volumes during

Table 1a. CPR Format for CCCs

All PAH (Group 1) and CTEPH (Group 4) patients seen and managed within the prior 3 calendar years.

Patients who are included but don't meet traditional hemodynamic definition of PAH [Hoepfer MM, et al. *J Am Coll Cardiol.* 2013;62(25 Suppl):D42-50] may need justification to site reviewers for inclusion in the roster.

ID #	INI-TIALS	SEX	DOB (DD/MM/YY)	DATE OF FIRST Encounter (MM/YY)	DIAGNOSIS			MEDICATIONS Current PAH medications (may be multiple)					PAST TREATMENTS	VITAL STATUS (may be multiple)
					IPAH	Non-IPAH PAH	CTEPH	PO	IH	IV	SQ	Date of parenteral drug initiation, if applicable (MM/YY)		
__1													Been on IV/SQ therapy within last 3 years	A = Alive T = Transplanted P = PTE D = Dead L = Lost to follow-up
__2														
__3														
__4														
__5														

Table 1b. CPR Format for RCPs

ID #	INI- TIALS	SEX	DOB (DD/MM/YY)	DATE OF FIRST Encounter (MM/YY)	DIAGNOSIS			MEDICATIONS								COLLABORA- TIVE CARE		VITAL STATUS (may be multiple)
								Current PAH medications (may be multiple)										
					IPAH	Non-IPAH PAH	CTEPH	ERA	PDE5 inhibitor	SGC agonist	Oral PG	Inhaled PG	SC PG	IV PG	Date of parenteral drug initiation, <i>if applicable</i> (MM/YY)	Clinical Care	Clinical Research	A = Alive T = Transplanted P = PTE D = Dead L = Lost to follow-up
__1																		
__2																		
__3																		
__4																		
__5																		
__6																		
__7																		
__8																		
__9																		
__0																		

REQUIRED DOCUMENTATION

Submit Electronically With Application:

- PHCC director CV
- PHCC coordinator CV and license
- PH program after-hours call schedule
- Letters of support (LOS)
 - Rheumatology service
 - Cardiac anesthesia service
 - Transplantation program
 - Congenital heart disease service
 - Palliative care service
 - Rehabilitation service
 - Institutional/administration
 - Cardiac catheterization laboratory director
 - Pulmonary function laboratory director
 - Echocardiography laboratory director
- Exercise testing (6MWT) report document
- Echocardiography laboratory accreditation certificate
- Institutional review board approval or renewal letters demonstrating the program's PH investigations (prior 3 years only) if CCC application
- Copy of investigator and clinical research coordinator's completion of human investigation training (eg, Clinical Investigator Training Initiative, "CITI," or equivalent)

Reviewed at Site Visit:

- PAH/CTEPH patient roster
- PH clinical and scientific meeting participation by program director (organizing/steering committee assignments, lectures, poster presentations, continuing medical education [CME] certificates, etc)
- PH educational activities by program director (educating center and hospital staff, mentoring/teaching trainees, community outreach, PH-related committee work, etc)
- PH clinical and scientific meeting participation by coordinator (participation with organizing/steering committee, lectures, poster presentations, CME, etc)
- PH educational activities by coordinator (educating center and hospital staff, mentoring/teaching trainees, community outreach, PH-related committee work, etc)
- PH patient-related safety activities by coordinator
- PH-related hospital RN and RT staff training materials, competencies, and inpatient management protocols
- Cardiac catheterization laboratory PH-related protocols
- Pulmonary function test (PFT) laboratory PH-related procedural manuals and protocols (eg, 6-minute walk distance and cardiopulmonary exercise testing)
- Inpatient pharmacy PH staff training materials, competencies, and inpatient medication protocols
- Program publications (please list peer-reviewed publications within the prior 5 years only)

changes to an existing database to collect more comprehensive patient data over time.

Pre-review of Application

The PHCC Review Committee has established a formal pre-review process for applications. During pre-review, the application and documents uploaded to the Pulmonary Hypertension Association (PHA) website are reviewed by PHA staff and selected members of the larger PHCC Review Committee. The application is screened for components that may be missing or need clarification prior to moving forward with scheduling the site visit. The feedback given to the site during this pre-review process should be carefully considered by the PH coordinator and lead to discussion with the entire PH team about what aspects of the program should be enhanced prior to moving forward with an onsite visit.

PREPARING FOR THE SITE VISIT DAY: GO!

The goal of an onsite visit by PHCC reviewers is to verify and expand on the information provided in the application. A physician and coordinator representative from the PHCC Review Committee will conduct the site visit. The entire written application is provided to the reviewers.

Site reviewers evaluate objective data (program volume and resources) and are also interested in learning about features of the program that make it unique and progressive. The coordinator is essential in identifying inpatient and outpatient staff who can best showcase the PH program and discuss the day-to-day care of patients with the reviewers. This includes the cardiac catheterization lab, pulmonary function lab, pharmacy and research staff, as well as a representative from the institution's administration.

The PHCC accreditation site visit requires the institution to develop a PHCC Business Associates Agreement (BAA) and PHCC Statement of Work (SOW). The purpose of these formal agreements is to allow site reviewers as representatives of PHCC access to

the 3-year time period and adherence to published guidelines for diagnostic evaluation and treatment. While data from the initial CPR is needed to complete the application, the CPR should be maintained by the coordina-

tor and updated routinely throughout the review process. The PHCC Review Committee has received feedback from sites that creating the CPR either became the basis for the development of a PH center database or prompted

POTENTIAL SITE VISIT INTERVIEW QUESTIONS

1. Please provide an overview of your PH experience and how you obtain and maintain proficiency in the field.
2. Describe how you make decisions about therapy initiation with patients/families.
3. How do patients contact their PH physician, nurse, or coordinator during normal working hours? After hours or on weekends/holidays? Is this process any different for patients enrolled in research projects?
4. Discuss your written PH catheterization protocol and indications for vasoreactivity and provocative testing.
5. What safety protocols are in place for ordering and monitoring blood test results for risk evaluation and mitigation strategies (REMS) required monthly testing?
6. Discuss your community outreach activities for both patients and providers.
7. Who provides staff education in your specific clinical area and how is competency measured?
8. Which PAH medications are on your hospital formulary? What is the process for ordering nonformulary medication? Which PAH medications are stocked in the pharmacy? Which supplies are stocked for device therapy and how do hospital staff obtain them?
9. If prescribing parenteral therapy:
 - When chronic parenteral therapy patients are admitted to the hospital, what infusion device is used?
 - What safety measures are in place to assure the correct dose is maintained?
 - What happens if there is a problem with a pump or delivery device?
10. In what ways is the PH program supported by the institution?
11. What are your unmet needs or resources?

future. These preparatory sessions may reduce staff anxiety and identify areas of the program that can be improved prior to the site visit. The PH coordinator should make note of any performance improvement projects that have been completed or are ongoing as well as patient safety initiatives. Outcomes and quality measures, evidence of staff competency assessment, and staff education documents are all evidence of the PH program's commitment to quality PH care.

RESOURCES

Preparing for a PHCC accreditation visit is similar to other accreditation visits (ie, The Joint Commission). Contact the people at your institution who prepare staff for those accreditation visits for their help and advice, particularly to prepare inpatient and outpatient staff caring for PH patients for the site visit. Evaluating your program in terms of collaborative practice may be helpful in identifying personnel and implementing roles to improve your program's performance.^{4,5} The rationale for the development of the PHCC initiative and its goals has been outlined in previous issues of *Advances in Pulmonary Hypertension*.^{6,7} Other resources include the PHCC website (<https://phassociation.org/phcarecenters/medical-professionals>) and PHA and PHCC staff. The application and materials that you upload to the PHA website are reviewed prior to scheduling your site visit. During this review process, many suggestions or requests for clarification may be made by the pre-reviewers. Use this opportunity to ask questions and refine and improve your application. As you embark on the accreditation process, you may find it helpful to work with a mentor through the PHPN Mentor Program. There are now PH coordinators available to mentor PHPN members in the accreditation process. Mentee applications are available through the PHPN website (<https://phassociation.org/medicalmembershipnetworks/phpn/mentor-program/>).

CONCLUSION

Guiding your PH program through the accreditation process is an experience

the site and confidential records. This process is often new to sites, and the coordinator can work with PHA staff and hospital administration to ensure their execution prior to the site visit day. In addition, the coordinator should clarify the institution's policy for visitors.

On the day of the site visit, time will be devoted to reviewing the CPR and identifying select patients for medical record review. Electronic medical records as well as paper records will be reviewed. The goal of this review is to assess treatment patterns and adherence to diagnosis and treatment guidelines.¹⁻³ Most commonly, the site physician and coordinator will each be reviewing charts with one of the site reviewers at separate computers. Clarification may be requested if questions regarding adherence to published guidelines are raised during the review. It is beneficial to conduct a mock chart review before the

site visit so clinical documents can be located quickly.

It is helpful for the PH coordinator to prepare staff for these meetings. Ahead of the site visit, the coordinator should meet with staff to review the goals of the PHCC accreditation process and the purpose of the site review. The coordinator can also perform mock interview sessions with potential questions that may be asked by the reviewers to fully prepare staff for the types of conversations the reviewers will initiate. The Potential Site Visit Interview Questions list identifies possible discussion topics and questions that may be asked of department staff during the site visit.

The PH coordinator, in collaboration with the medical director, should elicit and identify challenges that the PH program or associated departments encounter in PH care along with plans for how to resolve these issues in the

SUMMARY OF RECOMMENDATIONS

Application:

- All members of the team should understand and agree on the rationale for applying for accreditation.
- The tasks associated with the process should be clearly divided among the PH team.
- When in doubt, wait to apply until the application is as strong as possible.

Before the Site Visit Day:

- Identify institution staff who have experience organizing accreditation site reviews.
- Plan the day to highlight both what is required and unique about your program.
- BAA and SOW must be fully executed.
- Conduct a mock chart review so you can quickly find diagnostic tests and chart documents on the day of the site visit.
- Check institutional policies for requirements for visitors.
- Prep staff by holding information sessions and mock interviews.
- Make sure the patient to be interviewed understands the rationale for accreditation and that the interviewers are all health care providers experienced in PH care.
- Identify who will travel with reviewers to all patient care areas.
- Frequently review and revise the Center Patient Roster.
- Make required supporting documents readily available onsite to reviewers. Consider printing out documents and organizing them in a binder.
- Identify current challenges and strategies to improve for discussion.

Site Visit Day:

- Establish a time keeper.
- Have contact numbers for all participants in one place for adjustments and have a few backup plans if institution staff become delayed or unavailable.
- Chart review
 - Two computers (for electronic medical records) and staff to assist finding data if needed
 - Pull any paper charts when the chart review list is made
 - Familiarize yourself with charts before afternoon review time

that will promote program growth and improvement, build a stronger PH team, and contribute to quality care for PH patients in your region and the broader PH community. We encourage you to participate in the PHCC initiative to advance these goals and obtain recognition for your PH program.

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