Update on the PHA Pulmonary Hypertension Care Center Network: Early Experience With the National Accreditation Program

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World Health Organization (WHO) Group 1 pulmonary hypertension (PH) (PAH, pulmonary arterial hypertension) and WHO Group 4 PH (CTEPH, chronic thromboembolic pulmonary hypertension) are rare diseases of the pulmonary vascular system characterized by elevated pulmonary artery pressure and pulmonary vascular resistance in the absence of elevated left ventricular filling pressures, which may progress to right heart failure and death.[1] Left untreated, the median survival for idiopathic (IPAH) and heritable (HPAH) disease is about 2.8 years from diagnosis.[2] Adherence to expert consensus guidelines on PH diagnosis and management is of critical importance to correctly target therapy and improve patient outcomes.

In this journal, Chakinala et al have previously reviewed recently published observational studies highlighting challenges in PAH and CTEPH care delivery in United States, in both the academic and community settings.[3] These challenges specifically included underutilization of expert consensus guidelines regarding appropriate diagnostic studies leading to significant diagnostic error. Additionally, inaccurate prescribing of PAH-targeted therapies has been noted, including both overutilization of these medications in non-PAH patients and underutilization of parenteral prostacyclin therapy in functional class III and IV PAH patients.[4-6]

The Pulmonary Hypertension Association (PHA) is a patient advocacy organization based in Silver Spring, Maryland, with more than a 25-year history providing programs and services to patients, caregivers, and health care professionals impacted by PH. Its mission is to extend and improve the lives of those affected by PH. Global thought leaders working with PHA deliver PH disease state educational activities, highlighting the importance of seeking medical management with an expert PH clinician as a component of the expert consensus guidelines and a form of patient self-advocacy.[7] PHA-moderated electronic networking forums reveal this to be an effective message, as patients frequently recommend to new social media connections the importance of finding a "PH expert." In the past however, PHA noted an inability to provide objective recommendations to new patients regarding medical centers providing safe and effective PH care. In 2012, recognizing this gap, the PHA Scientific Leadership Council (SLC) worked with PHA to develop a national accreditation program to strengthen the resources available to PH patients, caregivers, and providers with the primary goal of improving PH care in the United States.

The PH Care Centers (PHCC) accreditation structure was developed over 2 years with the input of PH thought leaders, physicians, physician extenders, nurses, respiratory therapists, patients, and caregivers. External stakeholders were also involved throughout the process and provided important feedback on the selected criteria and implementation feasibility. This process included identification of the elements of skillful PH care, development of accreditation criteria, and the tools and methods for accurate, reproducible program assessment. The PHCC application supporting materials were developed along with processes for onsite program visits and objective review procedures. The financial structure to support the PHCC along with an observational patient registry (PHA Registry, PHAR) was developed in a parallel fashion. It was felt that the PHAR is an essential component to assist centers in individual quality improvement activities in addition to providing new insights into contemporary PAH and CTEPH diagnosis, management, and outcomes throughout the United States.

The PHCC program structure was developed as a tool for patient self-advocacy and a framework for medical professionals seeking to formalize a PH practice. This resulted in a pseudo-hub-and-spoke system of Centers of Comprehensive Care (CCC) and Regional Clinical Programs (RCP). Differences between the 2 PHCC accreditation types relate principally to the program size (often a feature of program age or geography), ability to provide all PAH therapeutic modalities, and the academic features of a program (including research capability and contributions to the pulmonary vascular literature). The PHCC program was rolled out systematically: assessing only CCC applicant programs for the first 3-year accred-

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itation period and followed by RCP applicants.

A pilot program involving "early adopter" volunteer PH programs selected for diversity in practice setting, patient volume, patient population, geography, and program history was instrumental to revise the application process and ensure the successful implementation of the final PHCC program. A period of process and protocol revisions was completed following feedback and the experience of the participating pilot centers' experiences. Applications for PHA-accredited CCCs were accepted from interested applicants beginning in September 2014, and from RCP applicants in the spring of 2018.

PHCC CRITERIA

Program Director

PHA-accredited PH Care Centers are expected to be led by a physician who has completed fellowship in pulmonary medicine, critical care medicine, and/or cardiovascular diseases (pediatric pulmonary medicine, critical care medicine, cardiology, or neonatology for pediatric programs), and should be certified in their specialty by the American Board of Internal Medicine (ABIM). The director is expected to have 2 years' experience (4 years for pediatric programs) in PH medical management following fellowship-level training. Engagement with other PH experts is expected through active participation in regional, national, or international PH-focused or cardiopulmonary meetings. The director is expected to contribute to the institutional or community education by broadly providing educational activities to hospital staff, trainees, or other community outreach activities. Additionally, the director is expected to participate in PH-specific continuing medical education (CME) activities to ensure patients are treated utilizing the most current recommendations.

Major differences between CCC and RCP program directors primarily involve the amount of time devoted specifically to PH clinical and research activities; the level of active participation in PH-specific regional, national, and international education; and the amount of PH-specific CME educational activities recently completed. Depending on local resources, RCP program directors are not required to manage patients on parenteral prostacyclin therapy; however, if they do not, they must demonstrate safe, appropriate, and effective collaboration with a larger center demonstrating competency in providing these therapies. If the RCP program director utilizes these advanced therapies in his or her practice, the program director and program staff must demonstrate competency equivalent to a PHA-accredited CCC.

Program Coordinator

PHA-accredited PH Care Centers are expected to include a program coordinator dedicated to PH clinical activities. For adult programs this professional can be a physician extender, registered nurse, respiratory therapist, or clinical pharmacist, but pediatric program standards require either a registered nurse or physician extender (nurse practitioner or physician assistant). The coordinator is expected to demonstrate disease state and therapeutic knowledge, including the approval, initiation, and maintenance of all therapies used in the practice. Integration with other clinicians in the practice, division, or institution should be demonstrated by the coordinator promoting or providing medical and general community disease state awareness activities, delivering education to the practice or institution's staff, or initiating or participating in PH support group activities. Individual professional development should also be prioritized for coordinators, through completing PH-focused CME/CE educational activities.

Significant differences in CCC and RCP center coordinator criteria include the amount of time devoted to PH clinical activities, as well as the level of participation in regional, national, or international PH or cardiopulmonary-focused meetings. Additionally, as medical management utilizing parenteral prostacyclin therapies is not required for RCP programs, RCP center coordinators are required to demonstrate proficiency in the approval, initiation, and maintenance of oral PH-targeted therapies. However, as above, if a center utilizes inhaled and parenteral prostacyclin therapies, competence in these therapeutic modalities must be demonstrated for successful accreditation.

Program and Support Services

As a multisystem condition, PAH and CTEPH require multidisciplinary management. PHA-accredited PH Care Centers are expected to have an appropriate total provider effort dedicated to PH clinical care, clinical research, and administrative duties, with a significant proportion of the total effort contributed by the program director. A substantial cohort of patients should be managed by the center, and the program must demonstrate consistent adherence to expert consensus diagnostic and treatment guidelines where possible. Programs utilizing parenteral prostacyclin therapies should have adequate experience with this modality, including at least 20 infusion patients over the preceding 3 years for adult CCC applicants and 16 infusion patients over the preceding 4 years for pediatric CCC applicants. The PH Care Center should have pulmonary and/or cardiology service on call 24 hours per day, 7 days per week, and established internal or external referral patterns with rheumatology, social work, nutritional services, cardiac anesthesia, pulmonary transplant, congenital heart disease, pulmonary thromboendarterectomy, coagulation, palliative medicine, and pulmonary/cardiac rehabilitation.

Significant differences exist in program and support services between CCC and RCP programs. Physician effort dedicated to PH clinical care and administrative duties should be appropriate to the demonstrated PAH and CTEPH patient volume, which is at least 25 patients for RCP programs and at least 75 patients for CCC programs. All program staff must demonstrate proficiency in the offered therapeutic modalities, which for an RCP must include all oral therapies at a minimum, and for a CCC must include oral, inhaled, and parental targeted therapies.

Facility

Safe, effective PAH and CTEPH medical management requires knowledgeable, competent clinicians and coordination with institutional units outside the

outpatient setting. Each PHA-accredited PH Care Center is expected to have inpatient wards and intensive care unit (ICU) facilities with specially trained staff and specific protocols for managing PAH, including parenteral prostacyclin infusion. Members of the PH program staff must be directly involved with the care of their inpatients. Each program must have access to a cardiac catheterization laboratory with experience in acute vasodilator testing, and the PH program director or a designated physician must perform the diagnostic right heart catheterization and personally review tracings. Programs must have access to additional components of the diagnosis and risk stratification of PH patients, including an echocardiography laboratory, pulmonary function laboratory, and exercise testing protocols and facilities. As well, programs should have a pharmacy with access to, and proficiency with, parenteral prostacyclin therapies. Lastly, each program should have an established radiology department with experience in vascular access for chronic indwelling catheters, thoracic radiology, and nuclear medicine.

Clinical Research

Participation of the PHA-accredited PH Care Center in clinical research activities was considered a priority for accreditation by both the health care professional and patient leaders from the inception of the PHCC initiative. As both PAH and CTEPH patients are considered rare diseases epidemiologically, both constituent groups believed that cohorts of patients managed by high-volume centers should have access to clinical research opportunities.

Currently, CCC programs are expected to include the infrastructure required to participate in clinical research. These programs should have staff appropriately credentialed and certified in clinical research and be actively participating in at least 3 PH clinical investigations at the time of the application (within the prior 3 years). The program must be actively participating in at least one phase 2 or phase 3 interventional PH study (specifically within the prior 5 years for pediatric programs only). The center must have access to both an investigational drug service as well as a local or central institutional review board (IRB). Program staff must have published at least one PH-related publication within the last 5 years in a peer-reviewed journal. These research criteria are optional for RCP programs.

PROGRAM EVALUATION

Initial criteria selected to assess CCC and RCP accreditation status were designed to understand context, compliance, and competence of the applicant program.[8]

Each accreditation criterion ultimately included reflected expert consensus, had an objective evaluation method, and represented an opportunity for patient safety or quality of care improvement. The PHCC accreditation assessment reviews 209 individual items for CCC accreditation and 266 criteria for RCP accreditation at present. The PHCC Oversight Committee reviews these CCC and RCP accreditation criteria on an ongoing basis, ensuring that criteria included in the PHCC review process appropriately assess a patient safety or quality of care component necessary enough to justify the resources required from both the PHCC applicants and reviewers.

The PHCC staff and committees perform follow-up assessments of the successful and unsuccessful accreditation applicants, which help to inform changes in program evaluation including the accreditation criteria, application, and evaluation processes. This review has revealed common themes that programs seeking PHCC accreditation should consider in order to optimize their application.

APPLICATION PROCESS

Each applicant program assessment begins with an online application leading to an in-person site visit by 2 PHCC reviewers: one physician and one nonphysician clinician. Recognizing the diversity of PH programs in the United States, PHA has built a structure where centers can apply as a singular clinic within one division, a single program with multiple clinic sites, or as a collaborative program between divisions.

Elements of a Successful Program Application

Since initiating PH program reviews in 2014, the PHCC Oversight Committee and Review Committee have identified several common causes of delay in processing accreditation applications. In this issue of *Advances in Pulmonary Hypertension*, Housten et al provide a review of the role of the PH program coordinator and best practices to address some of these causes when preparing for application submission and site review.

- Complete a Comprehensive Review of CCC and RCP Criteria: Several fundamental differences exist between programs successfully receiving CCC and RCP accreditation status, including a PH program director dedicated full-time equivalent to PH medical

Table 1. Criteria Framework

Criteria Name	Assessment
Context Criteria	Assess integration of components considered necessary for successful operation of a practice or program (eg, center director and center coordinator employed by the institution or practice with dedicated time to PH medical care and research)
Compliance Criteria	Assess the extent to which protocols and practice guidelines utilized by the program are constructed from evidence-based interventions
Competence Criteria	Assess the ability of the individual practitioner in utilization of evidence-based interventions

management, patient volumes, utilization of parenteral prostacyclin targeted therapy, clinical research infrastructure and participation, and peer-reviewed publications by program staff. Prospective PHCC applicants are encouraged to contact PHA prior to application initiation to discuss their program and to receive feedback on which application type might be best initially.

- Business Associate Agreement (BAA)/Statement of Work (SOW) Contract Completion: The BAA and SOW between PHA and the applicant site allows for complete review and completion of the full site review process. Applicant sites are encouraged to utilize template documents available on the PHA website and are advised to begin this contract process as early as possible, preferably prior to the submission of a completed application. Many applicant PH programs initiate this process by connecting the institution's legal, compliance, or accreditation offices with PHA staff.
- PAH/CTEPH Patient Roster: Applicant and accredited programs are expected to complete and maintain a roster of PAH and CTEPH patients managed by the PH program in the previous 3 years. It is necessary to complete the PAH/CTEPH Patient Roster prior to completing the PHCC accreditation application, to ensure that volume and adherence data are reported accurately. This roster should be restricted to patients meeting WHO Group 1 PH (PAH) and WHO Group 4 PH (CTEPH) diagnostic criteria. The "PH Diagnostic Guidelines" section of the PHCC application contains questions on patient volume, adherence to diagnostic guidelines, and patient volumes on specific therapies that can be best answered directly from the patient roster. Many sites begin the PAH/CTEPH Patient Roster process by contacting their specialty pharmacies for a list of patients on PH-targeted therapies.
- CME/CEU Requirements: Applicant and current PH center directors and coordinators are expected to meet thresholds of PH-specific education activities. Several applicant programs have cited "cost of attendance" as a factor for not being able to complete these educational activities. PHA offers many free CME/CE educational resources, with global thought leaders serving as faculty. Applicants are encouraged to review opportunities such as in-person *PHA Medical Education On-Demand* and electronic *PHA Online University* for CME/CE educational hours.
- Publications: As a rare disease, patient advisors and leaders in PHCC development valued academic contributions to the field. Applicant CCC programs are expected to have published at least one publication in a peer-reviewed journal in the field of pulmonary vascular disease in the last 5 years. Authorship on publications meeting this criterion can be completed by any member of the PH program staff.
- Research: Applicant CCC programs are expected to have both the infrastructure and evidence of active participation in IRB-approved PH clinical investigations. There should be supporting evidence of at least 3 separate clinical studies within the past 3 years and at least 2 of these studies must be interventional in nature. One of the studies may be a multicenter, observational registry.

Site Visit

- Document Checklists: Prior to the PHCC site visit, applicant programs will be provided document checklists that should be reviewed carefully, and the referenced guidelines, protocols, and essential materials assembled. These documents will need to be available for immediate review by the onsite reviewers during the site visit. In addition, the checklist will outline documents that applicant programs should be prepared to send to PHA upon completion of the site review.
- Chart Review Instructions: This document provides an overview of components to be assessed during the onsite chart review. The PHCC reviewers will use the PAH/CTEPH Patient Roster completed prior to application submission to randomly select patients meeting prespecified characteristics. During the onsite chart review, the applicant program director and coordinator should be prepared to access the medical records of the randomly selected patients to find clinical information requested by the site reviewers. Examples include evidence of appropriate chest imaging, pulmonary function tests, overnight oximetry, ventilation/perfusion scintigraphy, right heart catheterization results, and acute vasodilatory testing; exercise testing; functional class assessments; appropriate utilization of PH-targeted therapies, including therapeutic decisions documented in clinical notes; and referral to services such as palliative care and transplant when appropriate. Groups of patients reviewed during the onsite chart review include:

  - PAH patients on oral therapy
  - PAH patients on inhaled therapy
  - PAH patients on parenteral prostacyclin therapy
  - CTEPH patients
  - Recently deceased patients

The PH Care Centers program has previously reported on the site visit performance, most recently at the American College of Chest Physicians' 2016 annual congress.[9] This analysis of the first 41 accredited programs demonstrated strong adherence to expert consensus guidelines in the diagnosis and treatment of PAH and CTEPH selected for chart review. However, several opportunities for improvement were identified, and consistent with previous reports in the peer-reviewed literature, through significant variability in utilization of overnight oximetry/polysomnography

testing and slight variability in ventilation/perfusion scintigraphy and acute vasodilatory testing during right heart catheterization of PAH patients.[10]

ACCREDITED PHCC NETWORK

The First 4 Years of the PHCC Network

Development of the PHCC structure, policies, and procedures was completed over a 3-year period by 3 task forces involving more than 19 committee members (Online Supplement 1). These task forces led an iterative process that defined specific program criteria, developed a business model to create a financially sustainable system, and implemented objective and reproducible review processes to evaluate each applicant program.

Since 2014, a total of 67 PH programs have completed the review process; the PHCC initiative has accredited 57 US PH programs, including 46 adult CCCs, 8 pediatric CCCs, and 3 adult RCPs, which have collectively managed an estimated 12,500 PAH and CTEPH patients (Figure 1).

Expectedly, the PHCC initiative has noted significant diversity in the structure of PH programs successfully completing the accreditation process.

Practice Setting

PHA-accredited adult PHCCs are most frequently (70.2%) affiliated with a division of pulmonary diseases, with the remaining practices (29.8%) within a division of cardiology. As expected, most (62.5%) pediatric-accredited PHCCs are affiliated with a pediatric cardiology division of the applicant institutions.

Center Director

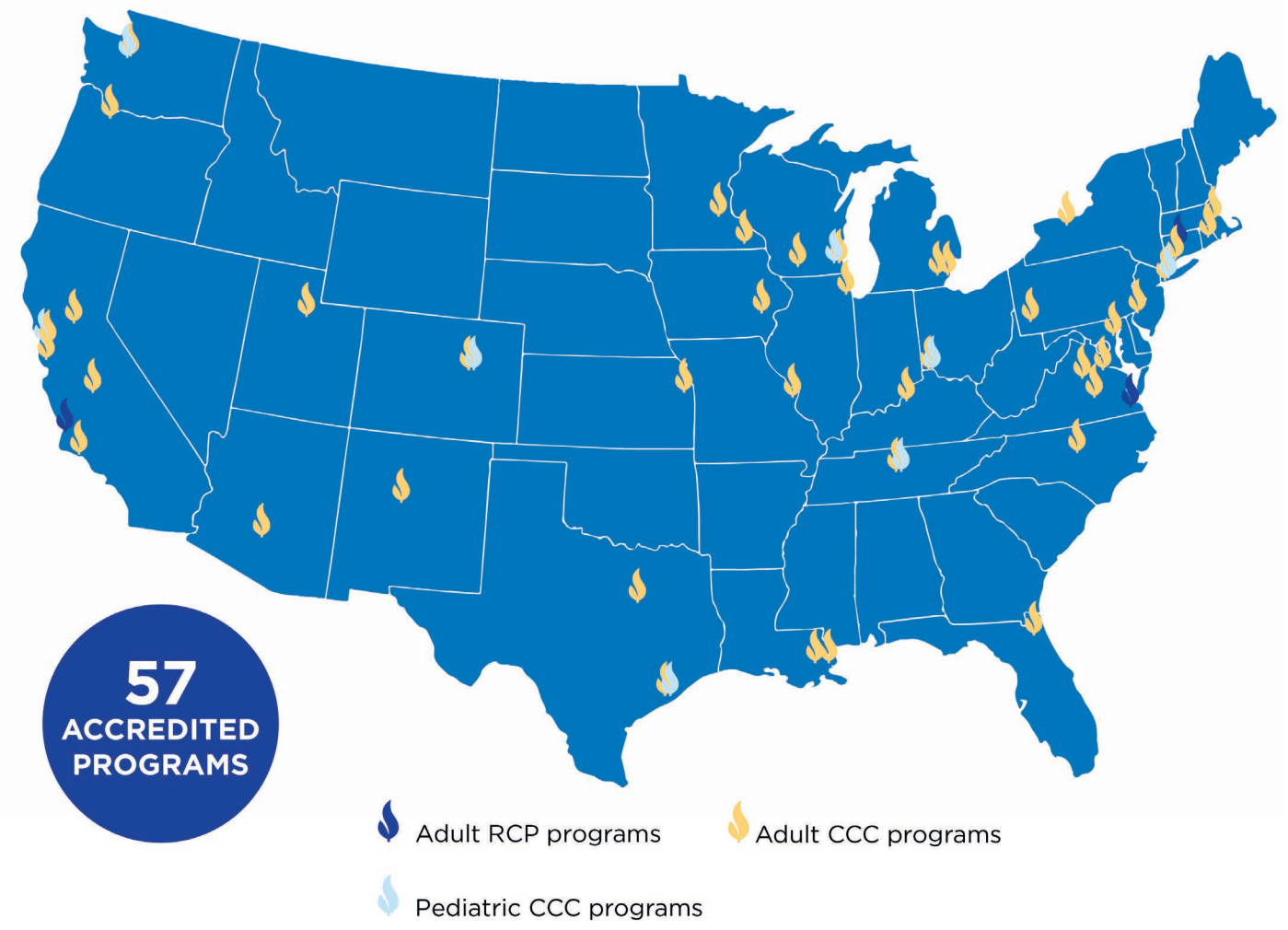
Center directors of adult CCCs have served as the director of their program for an average 10 years (IQR 9, 14.5) at the time of application; pediatric CCC center directors have served in this role for an average of 11 (IQR 5, 15) years. Adult RCP center directors report a similar length of tenure in their role, serving as the program director for an average of 7 years prior to program application (IQR 7, 15).

Center Coordinator

A majority (53.1%) of adult PHCCs have identified a physician extender (DNP, NP, or PA) as the program coordinator. A registered nurse (RN) serves as the program coordinator for 42.6% of adult PHCCs, and a registered respiratory therapist serves in this role for 4.2% of adult programs. One hundred percent of pediatric PHCCs have identified a physician extender serving as the coordinator for their program.

Patient Population

Accredited adult CCCs manage an average of 185 (IQR 139, 319), adult RCPs an average of 40 (IQR 26,55), and



pediatric CCCs an average of 136 (IQR 73, 189) PAH/CTEPH patients.

PHCC RE-ACCREDITATION

Sites successfully accredited through the PHCC initiative receive an initial accreditation term of 4 years before completing the re-accreditation process. Accredited PHCCs are provided the opportunity to participate in the PHAR: a US-based, multisite, prospective, observational registry of PAH and CTEPH patients incident to the accredited PHCC. Though initially conceived as 3-year accreditation periods, in order to accommodate the re-accreditation process, the initial accreditation period has been extended to 4 years to provide time for sites choosing to participate in PHAR to complete the IRB approval and onboarding process. Subsequent accreditation periods will remain 3-year cycles.

By design, each accredited PHCC is expected to assess quality of care, identifying and implementing improvement activities that will be assessed during re-accreditation. These specific re-accreditation processes are currently being finalized to assess adherence to current PH evidence-based guidelines, review staff competencies in the medical management of PAH and CTEPH, and examine program improvements made based on initial accreditation feedback from the previous accreditation cycle. A goal is to minimize the administrative burden for the sites without sacrificing objectivity. The PHCC program seeks to provide accredited centers with tools and platforms that can be used to complete quality of care improvement activities. Additional benefits to each participating site are projected to include individual comprehensive site reviews; performance benchmarking of each site relative to other accredited centers; opportunities to participate in the PHAR with annual program and individual site reports with real-time dashboards.

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