



Criteria also available in tabular format on the PHCC website (www.PHCareCenters.org)

Pediatric Center of Comprehensive Care (CCC) Criteria

1. CCC Director.

A CCC *must* have a Center Director who has the following attributes:

1.1 *Must* be Board Certified in Pediatric Pulmonary Medicine, Critical Care Medicine, Cardiology, or Neonatology.

- Documentation of specialty certification must be on file

1.2 *Must* have a minimum of 4 years of experience treating pediatric PAH and *actively* be managing a substantial cohort of PAH patients under the age of 18 (1 of the years may have been specialized fellowship training in pulmonary hypertension).

1.3 *Must* be an active participant in regional/national/international PH congresses (one or more of the following occurred within the preceding 3 years):

- Task Force membership
- Organizing/Steering Committee
- Presenting / Speaking (oral, poster, meet-the-expert, CME etc.)

1.4 *Must* be involved in PH-related education exemplified by *some* of the following endeavors

- Educating Center and hospital staff
- Mentoring trainees at the Center
- Involved in community outreach (patient support groups, schools, etc...)
- PH-related committee work

1.5 *Should* be a member of Pulmonary Hypertension Clinicians and Researchers (PHCR)



1.6 *Should* have completed 25 hours of CME related to PH over the past 3 years (attending and/or presenting)

2. CCC Coordinator

A CCC *must* have a designated **coordinator** who has the following attributes:

2.1 *Must* be either an RN, NP, or PA

- Coordinator must be employed by the PHCC, practice, or parent institution
- Coordinator's position within the Center should equal ≥ 1.0 FTE* -- see section 3.7 (Program Staff and Support Services) for additional support
 - *FTE requirement can be satisfied by more than one person, *but one individual must still be the Center's designated "Coordinator" and fulfill the remaining criteria outlined in section 2.*

2.2 *Must* be proficient in disease state and with all PAH therapies (oral, inhaled, parenteral) and delivery devices.

- *Must* also be knowledgeable about the approval, initiation, and maintenance of all PAH therapies.
- Reliance of the center on Specialty Pharmacy personnel to manage parenteral therapies in their PAH patients is **not** acceptable

2.3 *Must* be an active participant in regional/national/international PH congresses (one or more of the following occurred within the preceding 3 years):

- Task Force membership
- Organizing/steering Committee
- Presenting / Speaking (oral, poster, meet-the-expert, CME etc)



2.4 Should be involved in PH-related education exemplified by *some* of the following endeavors:

- Educating Institution's staff
- Educating Allied Health Care Practitioners
- Promotion of medical and general community disease awareness
- Involvement in PH Support Group activities

2.5 *Should* be a member of the Pulmonary Hypertension Professionals Network (PHPN)

2.6 *Must* have completed 12 hours of CME/CEU related to PH over the past 3 years (attending and/or presenting)

3. Program Staff and Support Services

Criteria 3.1 – 3.5 apply to all of the Program's physicians collectively

3.1 Physicians' effort towards PH program, including clinical care, clinical research, and administrative duties, should total at least 0.75 FTE

3.2 Should be *actively* managing a minimum of 75 patients with at least 50 patients classified as group 1 PAH and have experience with managing group 3 PH (e.g., BPD, CDH).

- A de-identified list of Group I (PAH) patients, their type of PAH and diagnostic workup, and the PAH therapy used (oral, inhaled, IV/SC) must be provided.
- If a Center's census falls outside this range, the accreditation decision could be impacted *positively* (if > 100 patients) or *negatively* (if < 75 patients). It is recognized that some Centers will have numbers outside this range and pertinent influential factors will be considered:
 - Duration of Center's existence



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- Tenure of Director at the Center
- Number and proximity of outside PH Centers near the candidate Center
- Regional population and Center's catchment area
- *Ultimate accreditation decision will rely on the Center's overall application.*

3.3 *Must* have proficiency and experience with all PAH therapies (oral, inhaled, and parenteral)

3.4 *Must* have adequate experience prescribing and managing *parenteral* prostanoid infusions.

- Center physicians are typically expected to have managed at least 16 different PAH patients on an outpatient parenteral prostanoid infusion over the preceding 4 years of which at least half included an intravenous prostanoid infusion.
- De-identified list of patients, which includes the PH diagnosis, the parenteral agent used, the period of infusion, and the most recent dose of medications must be provided.

3.5 *Should* follow available diagnosis and treatment consensus guidelines when possible, for example

- V/Q scans to exclude CTEPH if clinically suspect
- RHC to confirm PAH diagnosis
- Acute Vasodilator Testing in IPAH patients (or document valid reason for not performing)
- Parenteral prostacyclins for WHO FC IV patients (or document valid reason for not using)



3.6 Outpatient Nursing/Coordinator support *must* be commensurate with the Center's volume of patients

- Adequate nursing support to manage the Center's patients on parenteral therapies.

CCC must have the resources/consultants outlined in criteria 3.7 – 3.15 available

3.7 On call PH service 24/7 (should include PH doc, nurse, or PA)

3.8 Pediatric Rheumatology consultants

3.9 Pediatric Anesthesia with extensive PH experience.

3.10 Pulmonary/Cardiac Transplant Service or established referral process

3.11 Congenital Heart Disease Specialist

3.11A Congenital Heart Surgeon

3.12 Neonatal/Pediatric Critical Care Services for the management of infants and children with all forms of PH (includes PPHN, BPD, CLD, CDH)

3.13 Pediatric Pulmonary consultants

3.14 Pediatric Surgery consultants

3.15 Experienced central Line placement and repair personnel with PH experience

- e.g., pediatric surgery, cardiac catheterization, interventional radiology

CCC should have the resources/consultants outlined in criteria 3.16 – 3.19 available:

3.16 Social Work (SW)

- SW should be designated to the PH Program and be a consistent resource for the Center staff, but does NOT have to be exclusively assigned to the Center.
- SW or financial advisor should be capable of assisting PH Program staff and patients with insurance issues



3.17 Dietary/Nutrition Services

- Dietitian does not have to be dedicated to the PH Program

3.18 Coagulation Service, if not managed directly by the PH Program staff

3.19 Exercise test specialist (pediatric) (Either exercise physiologist or physician experienced in performing cardiopulmonary exercise testing in children)

4. Facility

4.1 Members of the PH Program *must* be directly involved with care of the Center's inpatients

4.2 Must have inpatient pediatric wards with specially trained staff and specific protocols for managing PAH, including chronic prostacyclin infusion

4.3 *Must* have ICU facilities including NICU and PICU (within the affiliated hospital) with specially trained staff and protocols for managing PAH, including chronic prostacyclin analogue infusion

4.4 *Must* have a cardiac catheterization laboratory

- *Must* have experience with acute vasodilator testing using inhaled nitric oxide, prostacyclin or adenosine
- Either the PH Program Director or a designated physician should be involved in the catheterization procedures (planning, performing and interpretation of data)

4.5 *Must* have an echocardiography laboratory with experience in PH (must provide letter of support)

- The echocardiography laboratory should have accreditation by the Intersocietal Accreditation Commission



4.6 *Must* have Pulmonary Function Laboratory (must provide letter of support, and display manual of procedures)

4.7 *Must* be able to perform Exercise Testing (e.g. 6 Minute Walk, CPET, treadmill test, or other; must display manual of procedures and provide report document)

- If the 6 Minute Walk test is used in routine clinical practice, the protocol must *approximate* ATS recommendations for its performance.

4.8 *Must* have a pharmacy with immediate access to parenteral prostacyclin agents

- Pharmacy staff proficient with preparation of prostacyclin infusions.

4.9 *Must* have an active Pediatric Radiology department with expertise in PH

4.10 *Must* have the ability to perform pulmonary thromboendarterectomy or refer for surgical treatment (must provide contact person)

4.11 *Must* have a system in place to assure patient confidentiality

4.12 *Must* have central line placement and repair service

4.13 Should accept patients insured by Medicaid and Medicare

4.14 *Should* have the ability to accept transfer of referred patients via an expedited route

4.15. On site ability to deliver inhaled Nitric Oxide

4.16 Institutional support for the PH Program (must provide letter of support)

5. Research Experience

CCC demonstrates a strong commitment to clinical research, as a part of the larger PH community's efforts to improve outcomes and find a cure

5.1 *Must* actively participate in PH clinical investigations in at least 1 phase 2 or 3 IRB-approved *human* study within previous 3 years..

- Active participation can be satisfied by any of the following type of investigations:



- All sponsored research
- Institutional initiated single or multi center therapeutic or non-therapeutic investigations (e.g . pharmacologic ,non-pharmacologic , genetic, epidemiologic, or mechanistic studies)
- Requirement cannot be satisfied by observational registries
- Program staff (physicians and coordinators) *must* show evidence of current human subjects research training (e.g. CITI modules and/or local institutional required training)

5.2 *Must* have research staff actively participating in PH research, with prior participation in at least one phase 2 or 3 PAH clinical trial and/or non-industry study in the past 5 years.

5.3 *Should* have access to an Investigational Drug Service that stores, prepares, and dispenses investigational medications

5.4 *Must* have institutional IRB or the ability to use outside (central) IRB

5.5 Center staff *must* have published in peer reviewed journals in the field of pulmonary vascular disease

- It is desirable that at least one publication will have been published within the prior 5 years

END of CCC Criteria
