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Chair of the Joint Conference, Quality and Academic Affairs Committee
UNC Heath Care System Board of Directors
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Mr. Charles D. Owen
Chair, UNC Health Care System Board of Directors
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Dear Dr. Callaway and Mr. Owen,

We had the opportunity to participate in a site visit as part of a Pediatric Heart Surgery External Advisory Board on August 22, 2019. We are appreciative of the time and the honest feedback provided by the UNC faculty and leadership. It is clear that the culture of the program has significantly and fundamentally improved with the establishment of new leadership at both the divisional and departmental levels. Our comments are based on our interactions with faculty and departmental/hospital leadership during that visit as well as careful review of the programmatic structure and outcomes of the pediatric heart surgery program.

The pediatric heart surgery program and the UNC Health Care System are to be commended on their commitment to programmatic quality and improvement. There is clear alignment between the Board of Directors, the institutional and departmental leadership, and the pediatric cardiology and cardiothoracic surgical faculty in this commitment and a desire for outstanding outcomes. Significant investment and progress have been made, including new leadership as well as additional faculty and support staff within the pediatric heart surgical program, and surgical outcomes have improved over the last year. Team dynamics and interactions appear to be strong, with universal support for the current leadership team in the pediatric heart program.

The following will summarize our recommendations for continued programmatic growth and improvement.

A. Pediatric Cardiac Surgical Program

I. Surgical Leadership and Support

There is universal support from pediatric cardiology faculty, hospital administration and Pediatric and Surgical Departmental leadership for Dr. Sharma. While we cannot directly assess his operative skills, surgical outcomes for the past year have been very good and Dr. Sharma has the skills and training needed to lead the team. With a senior cardiac surgeon on leave, additional support for Dr. Sharma has been via a senior locum tenens surgeon who assists for complex surgical cases.

It is preferable that a pediatric cardiac program have, at minimum, two pediatric cardiac surgeons to provide optimal surgical coverage, including the ability to cover surgical needs 24/7/365, provide sufficient redundancy for vacations/conferences/other leaves, and allow collaborative management of very complex surgeries (which may include a second surgeon serving as assist). We acknowledge that this arrangement becomes challenging at smaller volume centers: the American Board of Thoracic Surgery (ABTS) requires at least 50 cases annually as the operative surgeon to maintain certification and technical competence (with 75 needed for initial certification) and most pediatric cardiac surgeons would place that number ideally in the 100-150 range. While the volume in the past has been a bit higher, UNC averaged just under 120 index pediatric cardiac surgeries in the last year. There is ongoing effort to improve market share in the highly competitive area around UNC and thus increase surgical volume, with a goal to support two full-time pediatric cardiac surgeons. While this concurrent effort is made to increase surgical referrals and volume, considerations to provide coverage might include: 1) A full-time senior pediatric cardiac surgeon willing to serve solely in an assist role to provide collaborative input as well as contribute to night/weekend/vacation coverage; 2) Continuation of locum tenens coverage to provide this assistance on an as-needed basis; or 3) Further exploration of a joint venture or collaborative agreement with another Congenital Heart Program (regional or national), to include surgical collaboration and coverage when needed.

II. Dedicated Pediatric Cardiac Surgical Team

The importance of a cohesive, dedicated surgical team cannot be overstated. We agree with the current plan to develop a dedicated pediatric cardiac surgical team (including scrub and circulating nurses, first assist, pediatric cardiac anesthesia, and perfusionists) who can provide coverage 24/7/365. This is similarly true for the pediatric cardiac catheterization lab, which must have dedicated trained staff available 24/7 to achieve optimal outcomes.

III. Surgical Volume

The current pediatric cardiac surgical volume presents challenges in a number of areas. While the volume places the program into the “medium” category, it is nevertheless borderline for optimally supporting and maintaining two full-time pediatric cardiac surgeons. Similarly, the number of high acuity (STAT level 4 or 5) cases are limited. Thus, exposure of the cardiac teams (surgical, intensive care, and inpatient) to complex cases and/or complications may be variable. Additionally, with small numbers, any complication or mortality will be magnified in percentages. While some smaller centers have been able to achieve excellent outcomes, in general larger programs have lower morbidity and mortality. We support continued efforts to increase surgical volumes and referrals. While this is ongoing, we have the following recommendations:

a. UNC may resume STAT 4 and 5 cases. These cases should be performed by Dr. Sharma as the primary surgeon with his core surgical team. At present, we would recommend that surgical assist for all of these cases be with a pediatric cardiac surgeon. In the future, if results dictate, consideration could be made for first assist by the surgical physician assistant (PA), based on individual risk profile and left to the discretion of Dr. Sharma.

b. We recognize that UNC must balance their role as a state hospital and thus an important resource for complex patients in North Carolina with a consideration for individual patient risk profiles. Complex patients with additional co-morbidities that place the patient at higher risk of poor outcome (either surgically or postoperatively) should continue to be carefully evaluated by the medical and surgical teams with referral to another center if deemed appropriate.

c. Education of all care providers on the pediatric heart surgery team (surgical, pediatric cardiac ICU, and inpatient) should continue on an on-going basis, with particular emphasis on maintaining the skills needed for emergency care, such as arrythmias, bleeding, cardiac arrest, emergent surgery, and ECMO cannulation. Simulation training may provide additional exposure to these events and may facilitate team work and a shared learning environment and is thus recommended for all team members on a routine annual basis.

B. Pediatric Cardiology

I. Faculty Expansion

There has been ongoing recruitment of faculty into the division of Pediatric Cardiology; three faculty have been added in July 2019 and there is support from the hospital to continue recruitment up to a total of 12 faculty. We are supportive of this expansion as well as a desire for each current and future faculty to have a "core" area of interest and expertise, moving away from a generalist model. In particular, additional expertise in fetal cardiology and adult congenital heart disease is recommended, as these areas are important targets for programmatic expansion.

Consideration should also be made for development of programs that may differentiate UNC from regional competitors. Some examples are: a comprehensive multi-disciplinary single ventricle care (including cardiac, liver, kidney, and neurodevelopmental specialists), an accredited adult congenital heart program, a pulmonary hypertension program, and a cardiogenetics program.

II. Pediatric Cardiac Intensive Care

In the past six months, a dedicated pediatric cardiac intensive care unit (PCICU) has been created, with a separate staffing model. Additionally, two pediatric cardiac intensivists with advanced cardiac critical care training have been hired. The PCICU has in-house faculty coverage 24/7 with current night coverage by pediatric intensive care (PICU) faculty. While the lower cardiac surgical volume again impacts staffing needs, a core, specially-trained pediatric cardiac intensive care team is fundamental in the care of complex patients. As such, we have the following recommendations:

a. We believe the ideal faculty staffing model in a PCICU is with dedicated, advanced-trained pediatric cardiac intensivists (either 4th year advanced pediatric cardiac ICU fellowship or dual pediatric cardiology/critical care fellowship training). We support ongoing efforts to recruit an experienced medical director for the PCICU. In particular, we would encourage pursuit of faculty with pediatric cardiology training (with additional

advanced pediatric cardiac ICU training or with dual training in pediatric critical care medicine), to provide additional breadth of knowledge on the team.

b. A review of the pediatric cardiology faculty who provide consultative cardiology care in the PCICU should occur, with consideration made for creation of a small "core" team to provide this coverage and consultation, based on individual skill set and experience.
c. A core nursing and RT team should support the PCICU and take part in cardiac education and yearly simulation training with the entire PCICU team (including faculty and fellows) to maintain skills and optimize team dynamics.
d. While we acknowledge that different models of care exist and have also been successful, there are several advantages to having cardiac critical care faculty as part of the pediatric cardiology division. These advantages include, but are not limited to, participation in all aspects of cardiac care, from quality improvement to surgical planning, including regular participation in surgical care conference.
e. We support admission of most cardiac neonates with critical heart disease to the PCICU (except when non-cardiac morbidities supersede cardiac concerns). Neonatology consultation and co-management should occur for any non-cardiac neonatal needs.

III. Advanced Practice Providers

The addition of Advanced Practice Providers (either advanced practice nurses or physician assistants) to both the inpatient and outpatient pediatric cardiology service as well as procedural areas (such as pediatric catheterization lab) is recommended. In the PCICU in particular, the presence of trained dedicated APPs as front-line providers would provide expertise in management as well as consistency of coverage and care.

C. Establishment of Service Line

The establishment of a Pediatric Heart Center Service Line is recommended to facilitate the needs of the cardiac program. This program should be multi-disciplinary, consisting of physicians and staff in pediatric cardiothoracic surgery, pediatric cardiac anesthesia, and pediatric cardiology, and may include nurses, advanced practice providers, sonographers, technicians, dieticians, pharmacists, perioperative staff, perfusionists, etc. In some institutions service lines incorporate financial aspects; while this may be helpful in some respects, it is not absolutely necessary. Rather, it is more important that a service line be a functional cohesive group, with shared mission and goals. It is also important for Heart Center leadership to have a direct communication line to the hospital and departmental leadership to quickly assess and address needs of the service line.

D. Enhanced Quality Monitoring

i. UNC has a clear commitment to quality outcomes and monitoring, and we encourage continued investment in quality and process improvement in the pediatric cardiac surgical program. Scheduled review of complex cases, morbidities and mortalities should continue at regular monthly intervals and be attended by all pediatric cardiac surgery and pediatric cardiology faculty as well as pediatric critical care medicine and PCICU faculty. We recommend enhancing this to include reviewof

volume metrics (surgical, procedural, and medical) including STS data (and other registry data when available) at least twice yearly.

ii. While participation may not directly impact patient outcomes, there are multiple benefits from participation in national quality collaboratives, such as access to comparative data amongst centers, allowing "best practices" learning from high achieving institutions, involvement in national or regional quality improvement projects, and shared resources among programs. As such, we recommend participation in the Pediatric Cardiac Critical Care Consortium (PC4), the Pediatric Acute Care Cardiology Collaborative (PAC3), the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC), and the Cardiac Neurodevelopmental Outcomes Collaborative (CNOC).

iii. We support transparency in outcomes to the public and participation in public reporting of outcomes. We encourage UNC to continue to participate in the STS database and to report up-to-date program results on the UNC website so that patients and families may have the most accurate and most current data to make informed decisions. We recognize that there are clear and justifiable criticisms of the current STS congenital heart program public report, in particular the star system, and acknowledge that improvements in a system may not be identifiable for several years in a report that provides cumulative 4-year averaged data.

Conclusion

It is clear to us that significant investment in the pediatric cardiac program has been made with positive results. UNC has an excellent foundation for continued success and ongoing improvement. To continue the move forward, this new collaborative culture should be fostered and encouraged. Open, honest, and respectful discussion of outcomes, care issues, and disagreements in care are to continue to be welcomed. We support the ongoing work to increase patient referrals and surgical volume, recognizing that the overarching goal is outstanding outcomes and not merely program growth.

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