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Ethical Considerations for Global Pediatric Cardiac Surgical Assistance Programs

William M. Novick

Abstract

Global health initiatives have expanded over the last 25 years and are no longer based solely on improving public health issues like clean water and childhood vaccination programs. Global healthcare assistance has grown into programs that provide specialty services and education today. Cardiovascular diseases are causing more deaths today in low and middle-income countries today as infectious diseases cease to be the number one cause of mortality in many of these countries. Growth in cardiovascular assistance has been substantial during the last 25 years and especially in the area of pediatric cardiac care. We discuss the ethical issues that can be found when visitors assist countries with different cultural values. The success of program development depends on navigating the ethical issues such that all stakeholders are satisfied with the project and the end result. The foundation of program development should be based upon medical ethics that are sensitive to cultural differences so that a capable sustainable program is developed upon completion.

Keywords: Ethics, short term global surgery programs, cardiac surgery, humanitarian assistance

1. Introduction

Global health programs have substantially increased in number and sophistication over the last 25 years. No longer do we see only primary care programs from upper-income countries (UIC) visiting lower and middle-income countries (LMIC). Today we have specialty global health care initiatives that include pediatrics, pediatric general and cardiac surgery, orthopedic and neurological surgery. Internal medicine programs specifically for endocrine and oncology, as well as singular issues with women's health. The increase in global health initiatives has sparked a discussion in the overall purpose and ethics of these efforts. The altruistic nature of these efforts cannot be overstated, but with the health care deficits in LMIC it is vitally important to consider building capacity at the local level and not fostering a dependency on the visiting team for a higher level of healthcare that is intermittent at best. Cardiovascular diseases are the number one cause of mortality world-wide [1]. However, there are deficiencies in cardiac care in almost 90% of the world, almost all in LMIC [2]. The result is that patients in these areas are poorly served and a significant healthcare in-equality continues to exist. The need to expand cardiac care to these parts of the world must be balanced with a beneficent approach to this problem since there are several ethical issues in providing medical

education, training, experience and optimal patient care which can be violated without adequate thought, preparation, and execution. Moreover, legal issues with the importation of medicines, supplies, equipment, and licensure must be considered on a country-by-country basis. Critics of surgical development assistance in general and cardiac specifically abound, some with relevant points. It is incumbent of those assisting to do so within the scope of ethical standards both from the visiting team's country and the country receiving assistance if success is to be assured.

2. Intentions of cardiac care development assistance

The overarching goal of cardiac assistance should be the development of an independent program of cardiac care capable of sustainability. Depending on the local situation such an endeavor may take only 2–3 years for a pre-existing program to as many as 7–10 years if you are building a program *de novo* [3, 4]. The timelines are not firm, as the major determinants of the speed of development are local leadership, visiting team commitment, consistent funding, and a supportive government. The key component to all the above is trust.

Good intentions without trust by all sides will result in a failure of development. Building relationships is critical to the success of advancement and attainment of the primary goal. Therefore it is important from the outset to create an environment that results in the delivery of the promise and goals. You cannot develop relationships and trust if you do not provide the opportunity for the local team to participate and grow through a program of mentored graduated responsibility. Those teams that provide services only and allowing only limited participation by the local team are not upholding the promise and as such trust will not be developed and a rapid disconnect will occur, thus dooming program development. There are few times and places where the local team cannot be developed, and the visiting team simply provides all the care without education [5]. Beneficence cannot be directed at only the children receiving operation at the time of a visit, this is only a part of truly doing good work. One must consider the local team and the children that are still waiting for surgery and those not yet born. The idea of assistance is to build a program that benefits many children for years to come.

3. Implementation of the development program

3.1 Direction and leadership

Before undertaking a program to develop pediatric cardiac services there must be an agreement between all stakeholders regarding what level of development is desired by the local team. Autonomy of choice by the local team is imperative, one should not approach this as *we know what is best for you and your country*, this is a form of neo-colonialism and is to be avoided [6]. You may be experts in pediatric cardiac care, but they are certainly the experts in the subtleties of politics and economics of their countries.

Once a decision is reached regarding the level of expertise the local team wishes to attain it is critical to identify clinical leaders in surgery, critical care, anesthesia, perfusion, and pediatrics. Once again, the autonomy of the local team is important here, they need to decide amongst themselves who will lead the various specialties involved in the care of children with heart disease. There is simply no justification for the visiting team to insist upon certain individuals being named to leadership positions. Such an attempt will lead to a fracture of trust and the development of

co-dependency. However, if during the program it becomes obvious that leadership needs to change, then it is incumbent upon the visiting team to address this issue. A failure of leadership is one of the most common factors in program disruption and failure to achieve the desired goals [7].

3.2 Infrastructure issues

One does not often relate ethics and infrastructure, but when considering the creation or improvement of an existing pediatric cardiac program you must be sure that the necessary elements for providing safe pediatric cardiac care are in place or will be before program initiation. The equitable treatment of the children receiving care in LMIC must be maintained within the constraints of economic reality. The deficiency in pediatric cardiac caregivers in LMIC has resulted in large waiting lists and the needs of the many outweigh the needs of the one. Although ECMO, artificial hearts and left ventricular assist devices can provide a few children in upper-income countries (UIC) with a survivable situation, but when costs are considered many more children could be saved in LMIC with a low-risk operation. Basic infrastructure needs for pediatric cardiac care include an echocardiogram machine, an operating theater (not a hybrid OR suite) adequately provided with climate control, oxygen, air and electrical sources in addition to anesthesia machine and routine open heart surgery equipment. A basic intensive care unit with invasive monitors, adequate oxygen and electrical sources and ventilators to provide routine care. The vast majority of children requiring surgical intervention will be adequately served with these essential elements [8]. A cardiac catheterization lab is a luxurious addition to the diagnostic equipment and justification for this is difficult in a number of LMIC. However, the possibility of acquiring a refurbished catheterization laboratory rather than a state-of-the-art device is a means of providing this diagnostic capability and creating an equitable situation. A donor who provides such sophisticated equipment must be prepared to continue to support the maintenance or the equitable situation they created in diagnostic capabilities can be short-lived. There is simply no justification for providing advanced diagnostic equipment, having the local team develop capacity with it, and then having it removed because of a breakdown and an absence of support for repair [9].

3.3 Human resources

Building a team or improving an existing team requires that the visiting team provide individuals that are specialists in pediatric cardiac care and education. Frequently the visiting team will have volunteers including medical students, residents and fellows who are wanting to explore global health initiatives. The team leader of the visiting team must remember that the purpose of the visit is to increase the experience and capacity of the local team. Members of both the visiting and the receiving teams can all benefit from the educational opportunities, but it is incumbent upon the team leader to mentor the recipient team members particularly. A trip to an LMIC is not a place for medical students to learn the intricacies of pediatric cardiac surgery, or cardiology or anesthesia; you are there to teach the local team and they should always be the primary recipient of training [10]. Upper-level residents and fellows should participate in all aspects of care as the children in LMIC are not the same as the infants that they care for at their home institution. The opportunity to see the ravages of chronic congenital heart disease on a child or adolescent is a lesson in natural history for them, but a daily occurrence for the local caregivers. Global cardiac surgical initiatives are first and foremost an opportunity to exchange knowledge in both directions between visitors and the local team.

However, one should not offer to provide or perform operations beyond the scope of your practice at your home institution [11]. Moreover, one must also maintain a sense of what is actually possible not just in the operating theater but, in the intensive care unit as well. Although the surgical expertise may exist to perform a complex operation flawlessly in the operating theater there must be adequate support for the recovery of these patients.

3.4 Medications and materials

Frequently the visiting team will provide donated products to carry out the surgery and care of the children. Several medical product and pharmaceutical companies in UIC support these efforts by providing product that may have a limited expiration date remaining. Additionally, hospitals in UIC often provide products which have had the external wrapping removed but remain in a secondary sterile packet and can be re-sterilized at the local site. Working in resource limited LMIC institutions one must be sure to understand the medical importation regulations before shipping nearly expired products. There are times when a non-governmental organization (NGO) may be offered expired products and medications from hospitals and manufacturers, when is it ethical to use such products? Clearly the expiration dates for medications are arbitrarily set and publications on potency after expiration are available [12, 13]. One must ask is it ethical to use a product or medication in order to provide life-saving cardiac surgery, this is an answer that will vary by site, culture and country. Implicit in this decision is input from the local team. Consultation with the local team over this issue is both respect and autonomy for and of the local team. Moreover, the family should be involved in this decision, as patient autonomy clearly must be preserved.

Regulations for the importation of medications vary by country and similarly drugs which are registered for use vary. One must balance the good for the patient in deciding whether to adhere to local regulations but, beware of the consequences of violating such regulations [14]. A drug as beneficial as milrinone is not registered in several countries that we travel too, but we and our local colleagues know the benefits of this drug in pediatric cardiac surgery. We receive requests routinely to bring milrinone to countries where it is not registered for use and hand-carry sufficient quantities to carry-out the operative list. Clearly one must consider the ethical position of beneficence versus local regulations installed by a slowly moving bureaucracy.

3.5 Patient care

Providing safe, beneficial patient care is the first priority of the visiting team and is an excellent starting point for teaching the local team how to organize a pediatric cardiac care program [15]. We are all aware that it is not unusual for the local team to prepare a list of complex operative interventions for the visitors. Operations that the locals have never seen and certainly never performed are frequently on the list of the patient management conference. Once again it is important not to operate outside of your boundaries because you are not at home. Trust is important in developing relationships and can be eroded by an unwanted outcome as a result of operating outside normal boundaries, whether for the surgeon, perfusionist or ICU team's capabilities. Moreover, the unethical performance of an operation outside the limits of your capabilities can bring unwanted and complicating legal issues to bare as well. Teaching and reinforcing a patient-centric non-maleficence philosophy will lead to the development of a patient first approach by the locals.

Placing patient well-being above all other considerations must be balanced with your educational responsibilities to the local team. We have found that a frank conversation with the local team before the start of the surgical program is beneficial in understanding the local capabilities. A mentored program of having the local team serve as assistants first is patient-centric and provides the locals with an experience in how to perform safe surgery. The transition from assistant to primary surgeon for the local surgeon is graduated based upon the teacher's observations of progress. The principle of placing the patient's well-being first requires that the teaching surgeon have confidence that the local can provide the operation safely. Obviously if this is not the case then the teacher must take the place of the trainee as needed. Such a switch during an operation, induction of anesthesia or care in the ICU must be done in a diplomatic fashion as not to damage the confidence of the trainee.

One issue faced by all who are involved in assistance development is the presentation of a child with either a critical defect or in heart failure from the chronicity of their defect who needs an urgent operation at the end of a visit. We must consider the issue of non-maleficence and ask ourselves if there is a team prepared to care for the child after surgery that is capable of recovering the child. Agreeing to operate on this child and then have the visiting team depart when the child still needs complex care is providing false hope to the family and ethically questionable. We have faced this problem countless times in our history and have decided that if we are operating late in the trip on critically ill children, we will leave a team of ICU caregivers behind to provide 24-hour coverage until the child is discharged from the ICU. The decision to operate on such a child must be made in concert with the local team and family, autonomy of decision for both is critical for all stakeholders.

4. Database and research needs

4.1 Database

Developing a truly equitable program in an LMIC requires the encouragement of a clinical database and research projects. The benefits of a database need to be clearly communicated to the local team and then they must be left to make the decision to proceed with the establishment of one or not. Again, this highlights the autonomy of the local team and provides them with the opportunity to display complete commitment to program development, rather than simply intermittent surgical mission trips by the visitors. Program growth cannot be judged, and corrective actions taken unless a clinical database of outcomes is implemented. Furthermore, the establishment of a database and routine review and presentation of results provides the Ministry of Health with a realistic view of program growth and development, thus justifying the continuation of Ministry level support. Ideally the site will enroll in an international database that serves LMIC, examples include the IQIC [16] and WSPCHS registries [17]. Databases which only enroll UIC programs can be discouraging when results are compared, and the site should seek to compare itself to similar programs in LMIC.

4.2 Research

Research is to be encouraged when assisting a site, whether it is pure clinical or translational, few LMIC sites will have opportunities for basic science research [18]. The research project requirements for overseas programs you are assisting are the same as those of your home institution. The project should be reviewed by the

Institutional Review Board, or Ethical Research Committee and approved before it is instituted. Moreover, it is necessary if your home institution is involved that approval from the relevant committee there is obtained. One should not be conducting research in LMIC that was not approved by the assisting team's home institution [19]. The claim of "*they are experimenting on our children*" can be a program downfall.

Research fits well with the maintenance of a database registry, providing the local team with an opportunity to publish their progress in development [20]. The presentation and publication of results builds confidence within the local team and is extremely beneficial to overall program development. Alternatively, when the visiting team publishes work that was performed at the assisted site it is beneficial to involve the local team and to invite them to contribute to the publication and therefor co-authorship [21]. Collaborative efforts like this build trust and confidence between the two teams and the benefit is program growth [22].

4.3 Parent interactions

The parents of the child with heart disease who live in LMIC and must deal with the day-by-day question of will their child live to see another day must be treated with utmost respect and clarity. Frequently local caregivers have limited understanding of the risks and complications of surgery and post-operative care and therefore should not be the sole descriptors of these risks [23]. The surgeon and anesthesiologist of the visiting team need to treat these families with the same type of informed consent as they would at home to be equitable [24]. A major difference is that a translator will frequently be needed and should be instructed to translate exactly rather than to interpret the information you are providing. Importantly the translator must be well versed in medical terminology and have an adequate understanding of the procedure and risks so they can provide a basic understanding to the parents. Similarly updates following surgery should be provided with the same level of respect and clarity by the surgeon performing the operation. Updates in the ICU should follow the same course with the Intensivist or nurse of the visiting team providing important information with a translator as needed. Once the local team becomes experienced these updates can be provided by them with the visitors available for questions from the family if needed. During all these talks it is critical that the visiting team members build confidence with the families for the local team. We have found over the years that the best approach is for the visiting and local surgeon are both present during both the pre-operative discussion as well as the post-surgical update. The format works well as the families can hear from both and it is an opportunity to build confidence in the local team in the eyes of the family.

4.4 Communications and media

The presence of a group of foreign experts in pediatric cardiac surgery in a LMIC frequently results in many media requests for access to the visitors, local caregivers, and parents [25]. The goal of the visiting team is to build confidence in the local team during these exchanges [23]. However, it is imperative that expectations be realistic so that the public clearly understands that this is a program in development and that the local team is building experience. Again, the autonomy of the local team is important, and the leaders of the local team must be included in any media interview so that they are viewed in a positive manner by the public. There is no better justification for program continuation than to have parent testimonials, but again this is a parental decision. You may request that they participate to tell their story, but you cannot coerce or demand they do so, this is not ethical, it removes parent autonomy, and the interview will not have the authenticity they need to convey.

4.5 Donors and volunteers

Donors (financial, material) and volunteers (medical, others) both contribute to the success of the program. The expectations of both groups should be known before they participate to avoid disappointment in the outcomes and program funding removed [26]. Donors should be briefed on the reality of the situation on the ground so that their expectations align with those of the visiting team. One should not make promises to donors that cannot be carried out given the local situation, this is disingenuous and not ethical. Conversely it is important to prepare volunteers for the cultural issues of the country being visited. Local medical ethics do not necessarily always coincide with those that the volunteers adhere to at home. A perfect example of this is the compassionate discontinuation of care practiced in many countries. Such medical decisions are not the norm in several countries around the world and it is important to brief the volunteers on this issue before the trip so they can decide if they can adhere to this cultural norm and refrain from inappropriate social media posts [27].

5. Summary

Pediatric cardiac global surgical initiatives have significantly increased in number and coverage over the last 25 years. The benefits to the children, their families and the local healthcare professionals are clear. However, it is possible to create discontent with the program if ethical pillars are violated. The result will be program failure. Providing autonomy for local stakeholders and parents is critical to promote confidence and trust, remembering that our primary concern is the patient and that one must practice non maleficence is important for perceptions within the local community and our first responsibility as physicians. The principle of justice runs throughout the development of pediatric cardiac programs in LMIC, it impacts all aspects from patient care to education of local healthcare professionals to allocation of resources. Following ethical principles will result in an independent locally driven program in pediatric cardiac care if all stakeholders adhere to these principles.

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