PACO EDITORIAL

CONGENITAL HEART SURGERY

A DISCIPLINE ON ITS OWN

RODOLFO A. NEIROTTI M.D.
LUIZ F. CANEO M.D.

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Rodolfo Neirotti
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CONTENTS

PREFACE

This book, includes a compilation of 13 articles, previously published by us in the ***Brazilian Journal of Cardiovascular Surgery***, with the intention of producing a "mini book" with the support of the Journal that is interested in advancing this project.

Altogether, these papers have a variety of topics and concepts on our profession, complex systems, leadership, cardiovascular surgery in general, and pediatric cardiac surgery in particular.

However, due to the passage of time, in order to modernize and to make this collection more appealing, we thought it reasonable to add some up-to-date experts' comments to each article, with the help of several prestigious colleagues who were willing to cooperate. Additionally, a copy of the original article will be included to all of them— in an attempt to provide more information to the readers— before they move forward to understand the remarks and suggestions of these group of highly qualified experts.

INTRODUCTION AND GENERAL CONSIDERATIONS

Although there are common grounds with adult cardiac surgery, it is important to understand the differences in the business plan, paths, manpower, mindset, training, and infrastructure that are essential in those institutions where pediatric cardiac surgery can and should be performed. Time to start thinking, it is not what we can do, but should we do it?

Centers of excellence, with the necessary funds and manpower for research to generate new information and know-how, mainly in the field of rare congenital diseases, and adults with congenital heart diseases, are needed particularly in Latin America— an example of a framework with limited resources— for a more efficient treatment, cost benefit ratio, and sustainability of the care. These centers can then disseminate new knowledge, minimizing or even eliminating the learning curve and develop policies for the future of the specialty.

Pediatric cardiac surgery centers have much in common with other complex structures— that require faster decision making processes and more action-oriented— to generate complex services. However, it is important to keep in mind their unpredictable behavior and vulnerability— because they would not be strong if one of its components focus on its own immediate narrow interests. A union is usually better and stronger than the sum of its parts. Thus, in complex organizations is desirable to have a multidisciplinary team with mutually respectful and intensive interactions.

Along the same vein, the integrated approach suggested and successfully implemented a while ago by Aldo Castaneda (July 17, 1930-April 30 2021) and Patricia Hickey, at the Boston Children Hospital— in which all the components communicate among them and blend into a functioning or unified whole to ensure the quality of the final product— is an innovative and effective example of a way to preserve the function of complex systems, avoid or minimize failures, and reducing cost by improving their efficiency.

Unfortunately, the applicability of these modern concepts in low and middle income countries could be difficult due to cul-

tural and other barriers working against the close collaboration between doctors and nurses.

Needless to say, that societies where fixed roles are assigned on the basis of gender, where challenging of authority is culturally disapproved or where seniority supersedes any other form of expertise, will always have a hard time in converting complex systems— like a cardiac intensive care unit— into a high reliability organization.

All things considered, it is difficult to be optimistic about the future improvement of pediatric cardiac surgery in low and middle income countries without the resources for both— train enough qualified pediatric cardiologists, surgeons, anesthesiologists, nurses, pediatric cardiac intensivists and specialized perfusionists as well as providing the necessary equipment for them to work and produce satisfactory surgical results.

Although, Brazil is an exception the production is not enough according with the following numbers that compare the need and the production in the **year 2018: 54 centers are theoretically doing pediatric cardiac surgery; Need surgery 23,703 patients; Production only 7401 cases— a deficit of 16,302 that shows the reality**

While reading you will find some short excerpts in Portuguese, as well as in the final chapter entire appendices written in both languages. The apparent editorial misunderstanding was maintained to, first of all respect the authenticity of the Brazilian Journal of Cardiovascular Surgery (RBCCV), where the articles were originally published and, fundamentally, to allow a better understanding for those who, even though not perfectly fluent in English, that want to improve the protocols by using the knowledge transmitted here.

THE IMPORTANCE OF ASKING QUESTIONS AND DOING THINGS FOR A REASON

Rodolfo A. Neirotti

NB: Some of my thoughts expressed here have been shared in previous presentations.

Arts, artists and intellectuals, with their capacity of seeing with new eyes, sensing and perceiving mastery, finding beauty, meaning, elegance, rhythm, melody, harmony and composition— can help us to understand many aspects of our life, like:

> *The two most important days in your life are the day you are born and the day you find out why."*
>
> *Mark Twain. 1835-1910.*

> *"Whoever has a reason to live will almost always find how.*
>
> *Frederick Nietzsche*

> *"I keep six honest serving-men. They taught me all I knew. Their names are: WHY, HOW, WHAT, WHEN, WHERE, WHO."*

An exercise used as a problem analysis method based on Rudyard Kipling's poem, to ensure that all aspects were covered to improve interactions.

"*Stay away from difficult people* – they have a problem for every solution. Attributed to Albert Einstein. *How to handle them?* This is a common question of business people that encloses the assumption that they are dealing with abrasive, competitive, and unethical behavior that makes them think that they are right and the other party wrong. However, in a conflictive situation the other party can think that the other is difficult and obstinate!

Daily we ask many questions, WHY? WHAT? HOW? Why we do things in difficult contexts due to cultural, political and economic adversity? To learn, pay attention to details: every aspect of your

work, adopt an analytic mindset and ask *Why? How?* This Should be based on knowledge instead of feelings, habits and impulses. *What?* We all know what we do for a living—right or wrong.

Questions are useful tools, they open lines of communications; give us information; improve interactions, facilitate analysis and diagnostics of a situation; allow us to propose our own ideas; help to understand the priorities of others; stimulate motivation to learn; motivate creativity and more importantly scientific research, explanations and its applications happen in part through questions and answers.

Questioning everything helps to understand the world round us and *Why* we do what we do? How do we do that is about technical issues and *What* we do is usually known. *Why* reflects beliefs, reasons, purpose and objectives of an institution that eventually motivate its members to adopt them. *Caution*, failures of human psychology can induce people to consider a single factor. Responsible answers to questions can help to improve the quality of What we do. In addition, observations combined with curiosity and questions help us to learn WHY we do things. (3) *Modified from Marilee Adams; Berrett Koehler Publishers, San Francisco, CA. 2016.*

In general, people and societies know *what* they do and some are aware of *How* things are done but many of them ignore *why* they do *what* they do; that, in the end, has an impact on the outcomes. Please, if you do not know *Why* you do it, do not do it!

WHY Matters? *Because it is the question that every project team member should answer* to explain the reason they are pursuing a venture. A compelling "*WHY statement*" is a useful tool that aligns the efforts of the leaders, and team members, to improve the chances of success. It sounds simple, but it's not. Often, a good why requires work and debate.

In medicine, doing things without knowing *Why* is risky. Many of the things that doctors and nurses do continue simply because that is the way we have always done it. Still, if they do know why, it does not mean that it was done correctly! Unfortunately, it can also be due to lack of knowledge, attitude, or practices that eventually became automatic. Doing things for no reason—ignoring why— can involuntary harm institutions and patients. Abraar Karam. BMJ opinion January 17, 2019.

For doing things for a reason, start with *Why* because virtually, everything we do and think is generated by questions *that make you think*. Many projects fail because their members are functioning without a good reason for doing things. Failures are often due to not discussing, agreeing, or learning why workers do things. *K.A. Brown, N.L. Hyer and R. Ettenson. MIT Sloan Management Review. Fall 2013, Vol. 55 NO 1.*

Why do we work? It is an appeal to reasoning rather than to emotions. Generally speaking, we work for many reasons. We work to live and live to work. Therefore, understanding why we work should help to improve our attitude, motivation, efficiency, productivity, team work and quality of life.

How to reconcile with work? Start by thinking what you owe to work rather than what work owes to you. Will more money motivate us to work harder? Actually, not quite. The reasons people work hard are more fundamental than most realize. Simply, feeling like you are part of the team and made progress on a task can give you the boost you need to keep going. Work for it! *Modified from O. Kazhan, P Rosenfeld. The Atlantic Nov. 06, 2015.*

WHY education? Because the educational system does not fulfill its purposes. Therefore, new teaching and learning strategies are needed in this evolving, technologically saturated world. This doesn't mean teaching people to accept a set of beliefs without making a proper analysis! This is because education reduces inequality, social problems, improves quality of life — that includes physical and mental health, family, work, income and the environment. Furthermore, democracy doesn't work without people capable to elect honest and competent politicians. In a country with significant and increasing inequality that is divided by political ideas, religious belief, self-interest, income, and with a heterogeneous population, it does not come as a surprise that education is divided. Social scientists offer competing models of class structure, and most agree that society is stratified, among other factors, by educational attainment. Inequality, poverty, suboptimal education and inadequate health care are barriers to Maslow' Sets of Needs. *American Psychologist Abraham Maslow's Hierarchy of Needs Theory. 1943.* In addition, "No society can surely be flourishing and happy, if the greater part of the

numbers is poor and miserable" was the awkward phrase dropped by moral philosopher Adam Smith when he revised his thoughts for "*The Wealth of Nations"* published in 1776.

Altogether, this indicates that there is a need to modernize teaching techniques because there is a gap between what education systems provide and what is currently required by the society and employers. New technologies, have altered people's work and lives, pressing reformers to say that the traditional curriculum is not adequate.

Education and jobs can heal society. Authorities need to identify what skills are necessary for students to succeed in careers and personal lives, and then modernize their curriculums. Asking teachers to focus on a list of poorly defined skills is not enough. Interestingly, Angela Merkel during her address at the 2019 Harvard Graduation, address, stated "Nothing Has to Stay the Way It Is." Because the Berlin Wall limited peoples' opportunities, the German Chancellor invited the crowd to think with imagination about the possibility of precipitating what was previously an unimaginable change. "The Berlin Wall limited my opportunities but it couldn't impose limits on my inner thoughts… and that anything that seems to be set in stone or inalterable can, indeed, change."

Factors that can have either a positive or negative impact on the benefits of asking questions and doing things for a reason:

a) Attitude is the tendency to respond positively or negatively to work, ideas, persons, objects or situations. In addition, it also impacts the individual's selection of actions, responses to challenges, incentives and prizes. An optimistic attitude, avoids negative thinking, and helps with daily activities. Talent is natural, and attitude cannot be taught.

b) Motivation: the enthusiasm to do things, and a reason for people's actions, desires and needs. Inculcating motivation is not easy, but it's essential if you want your team to grow and stay satisfied with their jobs.

c) Complacency and false urgency: Complacency: people do little or nothing to grow and improve, justify why they cannot do, and are unaware of the self-damage. False urgency: when people act and look busy, without adding value to what they are currently doing.

d) Mental laziness -- a reluctance to doing something despite having the capability—due to a difficulty to put their brains to work. No matter how hard you work to get something done, mental laziness is when you stop midway because it is not easy. It is when you give up because you are tired or you feel that have done enough.

e) Perfectionist, someone who avoid errors on a personal crusade for flawlessness. A boss, colleague, or even a work friend whose values have almost nothing to do with reality. Studies have tended to focus on their output rather than the effect *they* might have on their team climate or interpersonal relationships.

Finally, if we know *Why*, think carefully about *What* we must preserve. *What* we must improve? And what we must transform? In order to progress.

Comments by: R. Neirotti MD, PhD. MPA Harvard University.

Altogether, the creation and initial goals of the Brazilian Academy of Cardiovascular Surgery, the incoming book and the importance of asking questions— that is the art of learning— have been a powerful incentive that invited us to think carefully and critically to reflex about our near and distant objectives— if we know *WHY – such as: What we must preserve? What we should improve? What we must transform and HOW?* Modified from Simon Sinek TED talk.*

This editorial is about a number of concepts and views outlined below, that also includes quotes of a group of intellectuals capable of articulating their wisdom in short sentences related to the different subjects. Furthermore, several aspects of life and practicing medicine— for us to remember and apply— are also mentioned with the hope that the incoming generations will improve on them by adding their new and creative ideas to promote progress and quality. **These entail**:

- ***Remembering that "The most important days in your life are the day you are born and the day you find out why"— Mark Twain*** (1835-1910). American writer, humorist, entrepreneur, publisher, and lecturer. However, to your surprise,

there may be several additional "days you find out why" throughout your lifetime. Make a good use of them, because sooner or later you may find road blocks on your way that require a paradigm shift or challenging a scientific dogma.

- ***Kipping in mind*** that leadership is not about *what* you say but *how* you say it and *what* you do. Leaders lead by example— then, honor your words and learn by spending more time listening. You do not learn anything while you are talking, but you do, while you are listening as it is nicely stated in the following recommendation*: **"Don't talk unless you can improve the silence**" by Jorge Luis Borges. Argentinian writer, poet, and Essayist 1899-1986.*
- ***Understanding that*** systematic rejection of compromise, is a problem because it biases the process in favor of the status quo and stands in the way of a desirable change.
- ***Managing anger at work-Aristotle's Way*: "Anyone can become angry— that is easy. But to be angry with the right person, to the right degree, at the right time, for the right purpose, and in the right way— that is not within everybody's power and is not easy" Aristotle, 384 BC - 322 BC.** Neca Smith**. Corporate Wellness Magazine.** Moreover, is it not one's duty to fight in a war you don't believe in? The answer to this question should help people's decision making process. **Therefore, keep in mind the option of "constructive anger" suggested by the Dalai Lama and his followers— that see ways that a well-guided anger can be useful.** "*A Force for God"; The Dalai Lama vision for our world. Daniel Goleman. Bantam Books, New York. 2015.*
- ***Patient empowerment***, based on ethic values by which we live, keeping in mind that one of the ethical standards of the Hippocratic Oath is to do no harm and a commitment to serving others rather than serving our self— the patient is the center of our practice— but we must understand ***"why"*.**
- ***A critical and honest analysis*** of *why* we do *what* we do, because in medicine doing things without knowing ***why*** is risky, particularly if you know where you are going, but

ignore how to get there and improvise— that requires good judgment and experience to deliver ***quality and precision,*** that are a must in our profession and specialty. Both are recognizable and can be measured.

Moreover, ***Precision is a part of quality*** — that requires appreciation to distinguish it— as reflected in the following equation: *Precision =precise diagnostic + doing what need to be done + doing it the first time (efficiency) to cut cost*. In sum, if we add the patient story— the humanistic demands of our profession— it is an ideal blend in which technical quality + service quality = quality of care. In order to achieve this goals we need the combination of change from the top— by influence or persuasion— as well as promoting bottom up involvement.

- ***A set of clear ideas and knowledge*** about our field of work, centered on improving business practices based on current knowledge, algorithms, solid data, curiosity and upward comparison that can diminish our success— we are no longer the best— but encourage us to learn by welcoming questions and criticism!
- ***Doing things for a reason***.: Recently, Professor Sir Magdi Yacoub MD, I*mperial College London, The Magdi Yacoub Institute, and London & The Aswan Heart Centre in Egypt, was the Key Note Speaker* on ***"Bridge to Recovery: from Flatlands to Complex Networks"*** at the University of Utah, Salt Lake City on March 18-19, 2021. In his thoughtful presentation and discussions with his disciples and colleagues, ***Sir Magdy repeatedly remained them about the importance of science, being humble, doing things for a reason and that there is no progress without theories and prove***. Science requires intellectual *humility for us to be open to the possibility of being wrong, that other people's ideas may be better than ours, and accepting our own* blind spots. *Fortunately, individuals with self-regulation are able to distinguish those that are free from pride, or disproportionate egocentricity. Altogether, a cluster of helpful assets that encourage most people to be humbly.*

- ***Unfortunately, the opposite is actual and real among those holding power in many countries around the world,*** *where people are dealing with difficult and authoritarian politicians – with an abrasive and unethical behavior that make them think that they are right. What is more, their initial denying and* down-playing *of the magnitude of the incoming catastrophe, together with their poor handling throughout the pandemic – had an enormous impact on the society, economy and health care systems. Altogether,* their behavior upturned pretty much everyone's definition of normal – *and are painful examples of their lack of knowledge and efficiency. How to handle them is a common and difficult question. Perhaps education can do it, as suggested in the following quote:* ***"Of the various instruments invented by man, the most astonishing is the book; all the others are extensions of his body... Only the book is an extension of the imagination and memory.*** Jorge Luis Borges. Argentinian, poet essayist and writer. (1899-1986)

In the same vein, *according with a rabbinic concept, cited by Peter Hotez*: ***"You are not obliged to complete the work, but neither are you free to desist from it".***

Subsequently, we feel that after *advocating doing things for a reason, discussing the importance of* science *and intellectual humility, we have the obligation to admit and report the existence of an active anti-science movement – that is escalating, going global, and killing thousands – with its negative and destructive impact*. Furthermore, a coordinated disinformation campaign is targeting prominent scientists and discrediting them by rejecting conventional science, medicine, scientific thinking views and methods, advocating replacing them with unproven or deliberately misleading theories – often for gains of the political right that use this artillery to attack the opposition. Interestingly, **Peter Hotez**, [1] in his recent article in the Scientific American" and **Jerome Groopman** [2] in the "New Yorker" – both with a broad vision that marries science with geopolitics – identified a group of non-medical drivers of deadly outbreaks, such as

wars, political instability, human migrations, racism, poverty, ignorance and anti-science.

References:

1. *Peter Hotez.*, "The Antiscience Movement is escalating". Scientific American, March 29. 2021.

2. Jerome Groopman. "The Politics of Stopping Pandemics". The New Yorker, April 29, 2021.

- The challenge to cope and comply with some or all the above mentioned suggestions and requests, demands the strength to look inwards with persistent honesty in order to manage our emotional life with intelligence— if we can learn how to bring the latter into motion— considering the daily news reporting the disintegration of civility and safety. ***"Emotional Intelligence. Why it can matter more than IQ" Modified from Daniel Goleman; A Bantam Book, 1995.***
- ***Last and but not least***, it is possible that before too long, an evolving technology, that is the application of science and data, will help us to make progress as well as bringing our specialty and practices into the 21st century— when the requirements would be generated by artificial intelligence and machine learning. For this reason, let's define both concepts, because ***"What is not defined cannot be measured. What is not measured cannot be improved. What is not improved always deteriorates." Lord Kelvin, Scottish mathematician, physicist and engineer, who profoundly influenced the scientific thinking and reasoning of his generation. (1824-1907)***

Artificial intelligence (AI) is the simulation of ***human intelligence*** in machines controlled by a computer, that are programmed to think like humans, with their ability to rationalize, and mimic their actions with the chance of achieving a goal— from the most simple to those that are even more complex. Therefore, some are afraid that

machines will have a negative impact on multiples human activities by pushing people out of the work force with the consequent increase of the number of individuals without a job. What is more, the term may also be applied to any machine with traits associated with a human mind such as learning and solving problems.

Machine learning: It is a branch of artificial intelligence based on the idea that systems can learn from data— that improves automatically through experience and algorithms— which identify patterns and make decisions with minimal human intervention (SAS.com.).

All in all, the prediction of ***Stephen Hawking. (1942-2018).*** "***Technology would eventually become self-aware and supersede humanity, as it developed faster than biological evolution***" might become a reality in the near future with the evolution, acceptance, and worldwide use of artificial intelligence, machine learning predictions, quantum computing and biotech. Interestingly, the ongoing and fast economic growth of China, is a good example of the impact of their heavy investment in the above mentioned advanced technologies— as well as other socio-political factors related to the stability strictly imposed by the authorities of the centralized Chinese government. However, "***Unthinking respect for authority is the greatest enemy of truth***". ***Albert Einstein, a German-born theoretical physicist, widely acknowledged to be one of the greatest physicists of all time. (1879-1955).***

THE IMPORTANCE OF THE PROPER DEFINITION OF ADULTHOOD: WHAT IS AND WHAT IS NOT INCLUDED IN A SCIENTIFIC PUBLICATION

Luiz Fernando Canêo
Rodolfo Neirotti

Dear Editor,

We have read with great interest the study by Khan *et al.*[1]: "Surgery for Tetralogy of Fallot in Adults: Early Outcomes", published in the Brazilian Journal of Cardiovascular Surgery, volume 31, issue 4, pages 300-3.

While the authors should be congratulated for their efforts to develop a pediatric cardiac surgery program in a difficult context, we have some comments, concerns, and questions around this article.

According to the references of this article, there are a few publications reporting the primary surgical treatment of Tetralogy of Fallot (TOF) during adulthood. In fact, only two publications about TOF in adults are enumerated in the references and some important reports are missing, including one from Brazil[2] .

This manuscript describes a single center experience in primary repair of adults with TOF in Pakistan during a two-year time-frame. They reported an impressive number of patients, but surprisingly they included patients between 12 and 43 years in this study.

The point at which a person progresses from childhood into adulthood may vary according to different cultures and the legal definition usually fluctuates between 16 and 21 years. Including younger patients increases the quantity, but using precise information is required in order to accurately evaluate surgical results and individualize risk factors.

As Lord Kelvin — an Irish mathematical physicist and engineer 1824-1907 — aptly put it, "What is not defined cannot be measured. What is not measured cannot be improved. What is not improved always deteriorates." Then, it is imperative to define the beginning of adulthood to avoid confounding and to facilitate the application of

methods for meaningful comparison of hospital mortality and morbidity for patients undergoing surgery for congenital heart disease.

According to the World Health Organization (WHO), an adult is a person older than 19 years of age unless national law delimits an earlier age, and an adolescent someone aged 10 to 19 years[3] . Additional literature retrieval about this issue, including those listed by the authors, shows that TOF in adults is commonly defined as subjects older than 18 years of age. Therefore, efforts should be made to embrace international parameters in our clinical practice.

In sum, it is not only a semantic issue, because there are potential errors in analyzing these data that include subjects younger than 18 years old named as "adults". For instance, transannular patches are required more often in children than in adults, due to the more favorable anatomy encountered in adulthood[2]. In table 1, Khan *et al*.[1] also showed a significant influence of age on the frequency in both right ventricular outflow tract and transannular patches.

Postoperative pulmonary valve insufficiency is a common sequela of transannular patches. Since pulmonary insufficiency is poorly tolerated in adults, some centers with experience in dealing with congenital heart disease in this age group are advocating placing a bioprosthetic valve in those patients requiring a transannular patch[4]. Khan *et al*.[1] reported 25% of moderate/severe postoperative pulmonary regurgitation in their study. In this context, how did they evaluate these patients? How did they follow them? What did they do with them?

Even though repairing TOF in adult patients is not a common procedure nowadays due to the movement of cardiac surgery to the very young, it is very important for all of us to understand the outcomes related to their treatment. How many of these patients were truly adults? Knowing the number of patients below 18 years of age would answer this important question.

Age definition is a central issue, thus it may not be appropriated to use adults both in the title and as a keyword for this publication. A word of caution for all of us, a proper review of the manuscript could have avoided observations like this.

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Comments by: Eugene Blackstone, MD.

Head, Clinical Investigations
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"I think your article has an ambiguity. There is a legal definition of an adult in the U.S: a person who has attained majority. The age of majority in the U.S. is defined by individual state laws, which vary from state to state, but in most states it is 18. This means that a person who is 18.00000 is considered an adult in most states. By the NIH for trials—we are asked if studies extend to subjects less than 18, but which they mean a subject age 17.9999… and under.

The WHO definition is also ambiguous. It says an adult is a person older than 19 years of age, and a child one that is 19 years and younger. This definition does not disambiguate what is meant by 19. Clearly 19.00000 is a child— actually an adolescent. It might seem to imply that a person who is 19.00001 is an adult although the person would say his or her age is 19. However, it could mean that adulthood starts at 20.0000.

Furthermore, from the perspective of drinking alcohol, adulthood in many states is 21 and it is generally understood to be 21.00000. From a health insurance perspective, the age is ever in-

creasing—I think it is now 26 or more. More importantly, there is a consternation with the STS registries. The "Adult Cardiac Surgery" registry is down to, I think, 18. But there is a congenital heart disease registry, too. So where do the bicuspid aortic valve patients go, with their root repairs, valve replacement, dissections, aneurysms, etc., up to any age? Same for ASDs, Ross operations, coarctations, etc., in adult patients. There are "adult cardiac surgery" but who gets to count the cases?" Then, how to address the ambiguity when governments, different states in the US, International organizations (WHO), professional societies (STS), the NIH— one of the world's foremost medical research centers, and most probably many others that might have a different criteria?"

Response of the authors:
Dear Dr Blackstone,

"Thank you for your response that as usual has thoughtful comments. Your points are well taken. In our letter, we emphasized the importance of definition and challenged the inclusion of 12 years old patients as adults, rather than trying to establish and exact age for someone becoming an adult. Nevertheless, we should have mentioned the ambiguity that you nicely described, and the lack of agreement on this important issue."

L.F Caneo, R. Neirotti.

BARRIERS TO DEVELOPMENT: PUSHING THE BOUNDARIES
BARREIRAS AO DESENVOLVIMENTO: EXPANDINDO AS FRONTEIRAS

Rodolfo A. Neirotti

> *Progress can change people's consciousness, and when you change people's consciousness, and then their awareness of what is possible changes as well — a virtuous circle.*
>
> *President Clinton*

Although this essay focuses on the situation in the emergent countries, "the less privileged parts of the world" can exist anywhere. To illustrate my point, consider the 42 million people living below the poverty level in the United States of America.

Lack of diversity due to social, intellectual, educational, and professional inbreeding, the latter representing cultural stagnation — doing the same thing repeatedly while expecting different results — can easily be responsible for the lack of scientific progress and development. It could be your problem! As Einstein reminds us: "The significant problems we face cannot be solved at the same level of thinking we were at when we created them".

The accumulation of mistakes combined with hubris, ignorance, hypocrisy, excess of diplomacy, bureaucracy and rampant corruption at all levels of the society are common findings in places where development is elusive. As a native of one of those countries, I experienced it; therefore, it is not without sorrow that I am making these observations. Easy to describe, hard to fix.

Because this eclectic article is based on realism – the practice of regarding things in their true nature and dealing with them as they are — rather than employing the primitive defense mechanism of refusing to accept reality, I have no judgment about this piece, nor control over it. Nonetheless, it is possible to transform reality by creatively doing something never completed before. Novelties are often the result of the disruption of reality.

As Dean Williams reminds us, "Fundamentally, the adaptive work of a creative challenge is group effort, and not to produce an individual psychological state of creativity… Anyone who has tried to exercise leadership in the face of a creative challenge soon realizes that creativity depends on the interaction among multiple people with different skills, perspectives, personalities, and attitudes. One individual may have a novel idea but not the ability to make it attractive or inspirational to others"[1]

The fight for the future now requires a different mind-set, one that includes a future that is struggling to be born, as former President Clinton put it: "Many of the world's greatest challenges today are modern expressions of our oldest demons. The future never had enough voters — those interested in present gain usually win out".

Our profession is immersed in the society and professionals are often absorbed in their daily activities without realizing that events beyond and around them have a significant impact in their lives and work. An intellectual revolution in performance, looking for ways to assess and apply the right changes to encourage ongoing growth in developing countries is required. Governments, the private sector and foundations working together in innovative ways can lead to greater advancements than any of those groups could do on their own[2].

Assault on the Senses: First, listen! Then Boo! Although in their own way, some may hear it and become a factor of change altering the course of the events.

Sometimes it is necessary to push audiences to the very limits of what they could understand or accept — and far beyond even if it sounds dissonant and that little immediate tradition lies behind it, as happened in Paris, in May 1913, during the premier of Stravinsky's "The Rite of Spring" ballet. Though it is now one of Stravinsky's most famous works, the inharmonic notes of the avant-garde music of his creation was first met with harsh criticism, negative reviews, and yes - a riot[1].

There is no easy time to say hard things. When to speak or not speak about pressing issues?

Michael Bloomberg, former mayor of New York City, said in his 2014 Harvard University Commencement dis- course "Do not feel reticent to speak what is right. Do not be complicit. Do not follow the crowd. Speak up and fight back." Supporting the free debate of opposing views is "a sacred trust" of universities and the basis of a democratic society. At the same event, Drew Faust, President of Harvard University, emphasized that universities owe the future answers to new questions that stimulate inquiry and debate, and the ability to understand answers to questions— about truth, justice, goodness, and our origin — and develop meaning from them.

In *Atlas Shrugged,* in which Ayn Rand expresses the advocacy of reason, individualism, capitalism, and the failures of governmental coercion, she aptly described what we find in many developing countries: "**When** you notice that to produce, you need to obtain authorization of those who produce nothing. **When** you see that the money flows to those who traffic not in goods, but favors. **When** you see that men get richer by graft and by pull rather than by work and your laws do not protect you against them, but protect them against you. **When** you see that corruption is rewarded and honesty becomes a self-sacrifice, then you will be able to claim without fear to be wrong, that your society is doomed"[4]. The drama unfolds between predator and victim. Altogether, it is the sanction of the victims defined by Leonard Peikoff as "the willingness of the good to suffer at the hands of the evil, to accept the role of sacrificial victim for the 'sin' of creating values"[5].

The driving forces of societies are Politics, Economics, and Culture

Politics: Governments can play great roles in their countries, regions, and cities facilitating or leading the resolution of festering problems and opening new pathways for progress. Good citizens generate good politicians that are eventually responsible for good

governance — the ability of a society's leaders to think long term, address their problems with the optimal legislation and attract capable and honest people into government. Collaborative political leaders would look very different from the ones we are used to. In the first place, they would do what they could to create a culture of cooperation, not competition. An educated population should know how to elect honest and competent politicians.

What is a True Democracy? Depending on the kind of political philosophy people are used to embracing, a true democracy is a society in which the citizens are not only electors, but also permanent actors in public affairs. When their participation is limited to elections, they lose their sovereignty soon after the vote. A true democracy is sustainable when people are committed to develop themselves intellectually, to expand their scientific knowledge, history, and making religious beliefs and erroneous beliefs a personal affair[6]. Faith must never be the final word when it comes to writing the law.

Ambiguous Democracy. Democracy vs. populism: Some believe that it is possible to achieve collective wisdom born out of individual ignorance. For others, democracy is self-correcting. Winston Churchill once said, "Democracy is a terrible thing — until you look at all the alternatives." However, it is eroding because corporations and finance capitalism are growing faster than democracy and influencing it for their own ends.

People spend their time "getting into politics" and too little time on why they want to be in politics, failing to ask:

- *First*, "What do I believe in and why do I believe it?"
- *Second*, "What do I want to do about giving effect to those beliefs, what policies would I want to change and what would I want to replace them with?"
- *Third*, "What can I do now to bring about those changes?"[7]

How could politicians that live in fear of mobilizing the "wrong" voters ever vote to change the system that keeps them comfortably in power and provides lucrative post-politics careers? In addition, politicians have no interest in projects promoted by their predecessors — a potential explanation for the political landscape littered with minefields to stop action from happening. Their intentions sound good but then the actions are like a snail, with wonderful

speeches not followed by coherent actions, using democracy for deco- ration rather than direction. The result is a loss of leadership and momentum, affecting the implementation of policies that assure sustainable growth for those living ten years from now. When blaming the politicians and showing your disrespect for the government, please remember that they are not aliens; they are elected members of your society with the same idiosyncrasy and values.

Economics: Man wishes are growing continuously.

***Maslow's Sets of Needs*:** As soon as needs on a lower level of the pyramid are fulfilled, those on the next level will emerge and demand satisfaction.

1. *Physiological needs.* The basic needs cannot be postponed for long. These are food, shelter, clothing, rest, air, water, sleep, etc.
2. *Safety needs.* The desire to be safe is connected with the psychological fear of loss of jobs, property, natural calamities or hazards.
3. *Social needs*. Our needs for love, friendship, and to stay in a group.
4. *Esteem needs*. Our needs for social recognition, status and respect.
5. *Self-actualization*. This is about fulfilment and the opportunity for personal growth, to become what one is capable of becoming[8].

Persistent Development Failure: The causes are multiple and the consequences have an enormous negative impact on people and society. Listing the problems may be easy; finding solutions is not, creating a capability trap that is responsible for the persistent development failure. Fundamental changes in the world's architecture and economy are needed.

Development is jeopardized by unique levels of daily interruptions that erode people's ability to identify their purpose, to focus their attention on it, eventually disrupting their efforts to achieve excellence[9]. In this complex environment, repeating history and failing

to form a direct path to destination is a common finding — circular progress — instead of a straight pathway to it — linear progress[10].

Restricted Resources: Leadership, patience, perseverance, dedication, the capacity to adapt, and the creativity that will come with having to work under adverse circumstances, can result in temporary achievements but do not necessarily ensure sustainability in a social order with limited wealth. Things happen thanks to the hard work and creative adaptation of individuals who are able to stretch the bounds of their abilities in spite of the restricted means. Inadequate funds are a constant problem forcing them to focus on short-term creativity and innovation about tomorrow's needs. A great deal of energy, in the form of leadership and negotiations, is required to insure that people surpass themselves and continue to work hard for a low pay continuously challenging themselves and those around them[11]. Altogether, contributing factors for emotional exhaustion, high level of depersonalization and a low level of personal accomplishment.

Culture:
Social ills in developing countries are blamable for the deterioration of the civil society.

Lower rankings on such measures as the Index of Eco- nomic Freedom and Transparency International government corruption index, plus a fragile judiciary with limited independence, and a cloudy legislative process, are manifestations of unaddressed institutional weakness[12]. Interestingly, the world's maps depicting corruption, health expenditures per capita, the burden of congenital heart disease and the absence of economic freedom clearly point to these countries.

Importance of Institutional Quality: Low quality institutions create "contaminated" incentives. Institutions are the site of many of our difficult moral problems, and the source for many of the solutions. Institutional quality requires quality people. They are the key to making quality products and making the best use of the ordinary distribution of human talent. Countries with a long history of incentivizing the development of strong political institutions (constitutions, regulatory authority, legal systems, and distribution of power)

are more likely to succeed. In contrast, those that fail to develop have weak institutions where the government violates property rights and concentrates wealth and power in a class of elites at the cost of the majority— frequently an undesirable side effect of populism[13].

Society, a complex system. Understanding Complexity: A system is a group of mutually supporting elements that are working together with a common objective. They are made up of individuals, activities, connections, and path- ways. Ideally, in complex systems, all members contribute to the quality of outcomes through an integrated manner in which communication, organization, interdependence and reciprocal supervision are crucial. Still, like in an orchestra, a conductor is vital.

The observations below describe the complexity and the difficulty in finding a way out:

Crime-Security expenditures are a drain on the economy: "Criminal activity acts like a tax on the entire economy: it discourages domestic and foreign direct investments; it reduces firms' competitiveness, and reallocates resources creating un- certainty and inefficiency"[14]. "Crime not only leads to material and immaterial costs for those who have become victimized, but crime also forces local and national authorities to spend billions on the prevention of crime and the detection, prosecution and punishment of criminals".

Unfortunately, some governments prioritize economic re- forms, and play down law and order, as the way to modernize their countries, without admitting that both are equally important.

Suboptimal education. Education of the underclass is a challenge with many unanswered questions: "When will we start to talk about practical ways of confronting the fact that many so-called at-risk children are in family situations that place them at a disadvantage at birth? What are both constitutionally acceptable and morally acceptable and practicable solutions to addressing this issue? How can we support families (single mothers) who lack the knowledge, motivation, and capability for preparing their children to benefit from education? These

are tough questions that are not being addressed. Without doing so, "education, education, and education" is a mere saying"[15].

"Unfortunately, the parents of these children are barely surviving and do not have the money and time to prepare them to learn in school. So where are the funds coming from? Our capitalist culture does not agree to provide these children with more services. We watch them fall behind because of their parents' lack the knowledge, motivation, and capability for preparing their children to benefit from education"[16].

There is a gap between what educational systems provide and what employers need. Universities should modernize their curriculum according to individual learning needs rather than the one-size-fits-all approach, adopting educational models that allow adaptation of resources to address local priorities. In today's economy, we need people who can take knowledge, apply it to new things and create new possibilities. Education is not a luxury; it is a necessity in this new century.

Lessons of the Finnish education system:

Purpose: to create a system that people are happy with — 90% in Finland vs. 29% in the USA when most of the ideas come from the USA!

Successful State: among the best in most of World Eco- nomic Forum indexes. Six percent of GDP invested in education.

Equal Society: Low-income inequality (child poverty rate 4%) and low Gini coefficient demonstrating that when you close the gap the bar will rise.

Cooperative Society: Teaching is a team effort. Schools ready for all children. Great schools for each child. Winners do not compete they collaborate.

Autonomy of the schools: over curricula and assessment to improve quality and to find your talent. Strong correlation between student's achievement and family background[17]

Knowledge gap: Latin America, with a low number of patents has not excelled at doing new things or at doing the same things in a new and better way — disruptive innovations. It has been slow to acquire, adopt and adapt technologies that exist in other places. Yet there is no

lack of talented and passionate people in this part of the world, nor of problems to solve. The bottleneck is in the support to let their innovative talents flourish. Talent and intelligence may be spread evenly across the planet, but opportunities are not. Regrettably, most of the requirements for innovation, including reforms in tertiary education are often not present in poor countries and in emerging economies.

Inequality and Poverty. Social Considerations: Growing income inequality affecting intergenerational mobility — even among advanced economies — is one of the biggest social, economic and political challenges of our time. "Should the improvement in the circumstances of the lower ranks of the people — Great Divide — be regarded as an advantage or as an inconvenience to society? The answer seems at first abundantly plain. What improves the situation of the greater part can never be regarded as problematic to the whole. No society can surely be flourishing and happy, if the greater part of the numbers are poor and miserable"[18].

Scarcity has many faces, changing from place to place and across time. Scarcity creates a similar psychology for everyone struggling to manage with less than they need. Just as busy people fail to manage their time efficiently for the same reasons, the poor fail to manage their money. Up to now, efforts to develop a unified field theory to solve the problem have inevitably fallen short[19].

- Poverty is hunger, is lack of shelter, and is being sick and not being able to see a doctor.
- Poverty is not having access to school and not knowing how to read.
- Poverty is not having a job, is fear for the future, and is living one day at a time.
- Poverty is losing a child to illness brought about by unclean water.
- Poverty is powerlessness, lack of representation and freedom.
- "Poverty is the most lethal weapon of mass destruction"[20]. "Nearly 164 million people live in poverty in Latin America (27.9% of the population), 68 million of whom are considered destitute. Since 2002, poverty in Latin America has

> fallen by 15% and destitution has dropped by 8%, but figures from a recent study by the Economic Commission for Latin America and the Caribbean (Elac) show that the rate of decrease is slowing. While poverty and destitution in this region decreased in 2012 in comparison with 2011, it remained unchanged in 2013. Countries in this region should push for more rapid structural changes in their economies to promote sustained growth with greater equality"[21].

Nonetheless, the middle class has grown in those countries with faster economic growth — in which center-left governments have adopted redistributive policies, spending the fruits of the now ending commodities boom on social programs, young people are more educated, empowered, and demanding better public services[22].

In addition to the economic inequality, there is often in- equality before the law — one law for the poor and disadvantaged and another for the rich and famous that can afford to hire the best lawyers and mount the best defense possible. When was the last time that a wealthy man was executed? A two-tiered criminal justice system discriminating based on socioeconomic status, race, and geography is morally unacceptable. Influence brings privilege, and privilege can plainly mean getting away with wrongdoing.

A further burden of poverty is inadequate health care: In emerging economies, low per capita expenditures and the inadequate allocation of funds explain the differences in success in the rich countries. Sixty percent of cancer cases and 70% of deaths from cancer happen in Africa, Asia, Central America and South America[23].

Unemployment: Although two thirds of the recent global economic growth happened in the developing world, a vast number of the young grew restless because of unemployment. Furthermore, the development of the infrastructure and professional skills has not kept pace with the surging demand for skilled workers despite the expanding economy[24]. Thanks to the electronic media, people are increasingly aware that these wrongs cannot be easily or rapidly put right and that those opportunities are more attractive in developed countries.

Corruption: What is happening in many countries today is not just a pathology, but a predictable pathology that arises whenever a society has no checks on behavior, no acceptance of any rule of law, and no respect for rules of procedure[25].

Does corruption arises from individuals' diminished personal integrity and misconduct or from institutional arrangements? Institutional corruption is the result of a guidance within an economy of influence that illegitimately weakens institutional effectiveness especially by weakening the public trust — "Crisis of Credibility"[26].

Interestingly, Aristotle in "Nicomachean Ethics", a compilation of lecture notes, emphasizes the role of an active condition in the moral search for ethical virtue, a state that consists in choosing "*the just one*" between the two ends. The *no* and the *yes* are always in our power. Both, virtue and corruption are in our control. It is in our power to do some- thing, as it is not to doing it[27].

In "Theory of Moral Sentiments", Adam Smith introduced a different explanation about the acquisition of moral values, suggesting that it is a process starting early in life and based on the approval or disapproval of what happens around us.

Are these concepts compatible in an era in which social, political, and financial systems are corrupted, elections and democracy manipulated by corporate interests, religious groups taking over governments, or charlatans dominating and controlling financial systems, and thereby influencing the legislative and judicial integrity? Corruption is not just a question of ethics, but also one of economics. As companies in rich nations push into poorer regions, illicit gains connected with politics or business go global.

The World Bank estimates that $1 trillion in bribes is paid annually to officials. An estimated $1 trillion a year is being taken out of poor countries and 3.6 million lives are lost be- cause of corruption. In Africa alone, $148 billion is siphoned off annually.

Not surprisingly, protective of their interests, corporations prefer settlements to the catastrophic financial penalties and the bad publicity if they lose in court. In the end, some of the people that are charged are extremely rich and powerful, and can afford great attorneys[28].

Corruption is a societal pathology closely related to blind spots and perception of legality: "Why do we often fail to do what is right? When confronted with an ethical di- lemma, most of us like to think we would stand up for our principles, but we may not be as ethical as we think we are, due to blind spots. We often overestimate our ability to do what is right and act unethically without meaning to. There is no good reason to believe that we would behave any differently from the agent, the auditor, the buyer, or the seller when we have conflicting motivations and interests. To avoid such unintended unethical behaviors, the first step is to recognize our own fallibility"[29]. Not surprisingly, ethical fading — the removal of ethics from the decision making process — can negatively affect our judgment by shifting our ethical values. "We can become more ethical by bridging the gap between who we are and who we want to be"[30]. Lack of integrity is the main obstacle. "Without integrity, there is no trust. With- out trust, there is no leadership, with everyone for himself. Without integrity, there is corruption, no respect for rule of law, and no true democracy. Unfortunately, once corruption becomes ingrained and an integral part of the society, it takes a miracle to change it"[31].

Tax evasion. Merits of taxes:

- "No one size fits all": An effective strategy to reduce tax evasion and avoidance that needs to be tailored to the specific country's environment.
- A strategy should involve both measures at the national as well as the international level. Actions at the international level can only be implemented successfully if specific prerequisites on the national level are guaranteed.
- Equally, measures undertaken at the international level have to be accompanied by adequate strategies at the national level. *Main Factors facilitating tax evasion and avoidance:*
- Low willingness to pay taxes by taxpayers usually re- sults from the tax rates and perception that they are unfair, or from the lack of transparency and accountability in the use of public funds, or the lack of service in return, or of the rule of law, as well as poor tax morale, and high compliance costs.

- Low ability to enforce tax law and tax collection due to low probability of detection, low penalties, high level of corruption, large informal sector, and incompetence of the tax administration[32].

Lack of independent and reliable justice. Checks and balances: In many developing countries, because of the lack of separation of powers, it is never easy and often im- possible to legislate against the will of the executive branch. Government systems that employ a separation of powers need a way to balance each of the branches to induce them to cooperate and to prevent one branch from becoming supreme. Typically, the latter is avoided through "checks and balances" — a system-based regulation that allows one branch to limit another, helping to ensure that no one branch becomes too powerful. Although it will not be an easy win, it is also necessary to balance the power of big money with the power of big ideas.

https://bit.ly/3vIFgQb

Unfortunately, regimes that violate these principles could survive a long time despite an economic crisis if the level of control over all government institutions, the press, education, and the business environment, is strong. Many perceive the job of the police and the courts as implementing political control, rather than investigating thugs.

Lack of long-term planning and a consistent model: Has the traditional approach of the *Big World Planners* found the solution to enrich the poor, to feed the hungry, and to save the dying? The answer is *No*, due to ineffective efforts, despite spending more than $ 2 trillion[33].

Outdated infrastructure. The recent Ebola epidemics is a clear example of the dismal infrastructure in the affected countries and the weaknesses of their health systems. The risks for volunteers is high. According to the WHO, a signif icant number of healthcare workers have been infected since the outbreak began and many of them have died[34]. "If there was a health care infrastructure able of rapidly identifying and isolating cases and providing adequate medical care and doing the proper contact tracing then this epidem-

ic might have been put under control a long time ago"[35]. As Paul Farmer, co-founder of Partners in Health put it, "Outbreaks are inevitable. Epidemics are optional."

A Coalition of Inaction: The inadequate and late response to the current epidemic stresses how little focus has been on the need of a strong global health set-up and making global health security a priority in individual countries. Alarmed by Ebola, the public is not reassured by what specialists say, and anxiety has soared about the potential for contagion. Lessons from this epidemic can be helpful for future outbreaks.

The absence of a social contract: an actual or hypothetical agreement among the members of an organized society or between a community and its rulers that defines and limits the rights and duties of each. The people agree to obey the ruler in all matters in return for a guarantee of peace and security. In surrendering their individual free- dom, they acquire limited agreed-upon political liberty and civil rights, a covenant for mutual benefit between an individual or group and the government or community as a whole. Regrettably, people often act slavishly by voting every few years and then passively accept what their representatives say[36].

Lack of solidarity and social responsibility. Participation: It is important that people take an active role in the social, political, and economic aspects of the society in order to defend the interests of those suffering. The time has come, to decide whether they will continue to be a part of the problem, or whether they will be part of the solution.

Modest philanthropic efforts: Philanthropy is suboptimal despite not everyone's being poor in the poor countries due to culture and/or interpretation, religion, lack of trust, and lack of tax incentives, as well as tax evasion. Philanthropy is not the solution for poverty. A combination of eco- nomic growth, higher human capital, social inclusion, and political will can help.

All of the above indicate that social and human capital as defined below, are low in developing countries:

Social Capital and Social Bonds: The levels of trust, tolerance, co-operation and reciprocity among individuals in a particular social environment is the base for team- work. The success of a society depends on the strength of its communities rather than on peer pressure. Bad things happen when good people do nothing.

Human Capital: This is the knowledge, skills, and expertise that individuals acquire through education and training, used to produce things, services or ideas. The greater quantity and quality of skilled workers in rich countries suggest that human capital is a central vessel for social and economic development. The quantity and quality of competent workers has a direct effect on the economic improvement of a society. The power is in the hands of each citizen[37].

Collaborative Rationality: Both social and human capital are complementary for getting better together, which is a different way of knowing, generating, making and justifying decisions based on diversity, interdependence, and authentic dialogue. The agents, facing a common problem, think logically and interact exchanging information in an open system, to identify a common solution for the benefit of all, avoiding the limitations of acting unilaterally. The culture of the group overcomes the culture of the superstar[38].

Raising the bar. Upward Comparison. Since we tend to overestimate where we stand in contrast to others, comparing our self to others is not bad if we avoid a twisting strategy to fit data — Pseudo Mathematics[39]. Upward comparison, as economists and psychologists call it, can diminish our success — we are not the best anymore — but also encourage us to learn. Although looking around us can be punishing, it is better to watch good players, and improve our performance, than bad ones and feel superior[40].

Why some nations are rich and others are poor and volatile. Order vs. Disorder

Regardless of the effort and brainpower that go into de- signing complex systems and their "system of work", it is impossible to do it perfectly and to predict the behavior of individuals under the conditions in which they must perform[41].

Order. Developed countries set themselves apart in how they deal with the unpredictable problems of complex systems. They manage to stay ahead because of their endurance, responsiveness, and their velocity in self-correction by bringing their modules together and making them better than the sum of their parts. Altogether bring about more capabilities, and the more capabilities they have the more likely they are to grow economically[42].

Disorder. Conversely, in emerging countries their parts come together through hard work, goodwill, and improvisation — a patchwork approach to fixing problems. Their com- ponents are managed as if they operated independently when in fact they are interdependent[41].

Are foreign advisors useful? Yes, when they are aware of the local context. International executives need "contextual intelligence" — the ability to recognize the limits of their knowledge and adapt it to different environments [43]. The link between leadership and culture is complex. It is not always easy to appreciate or understand that what people do, mean, and say, varies from one culture to the next. Understanding another part of the world better is an avenue for transcultural understanding. Without this understanding, it is impossible to lead in another culture. A style that would be effective in one culture might be dysfunctional in another. This is the case in the national culture as well as in the corporate culture. Furthermore, diplomacy is often necessary to pass the borders of ignorance, culture, and geography.

"Despite what we would like to believe, management practices — even the most effective ones — do not travel across borders"[43]. Notwithstanding the extensive use of foreign advisors in emergent

countries, there has been little examination of their roles. Outside consultants should not become insiders. One of the things necessary for them is to remain outsiders. Foreign technical advisers work by a different set of rules than nationals within the hierarchy. How do their roles differ from those of the host country? How do outsiders acquire influence? To whom are they accountable? These remain important questions since the advisors exercise vast influence with limited accountability and without organizational authority. Foreigners have the responsibility to consider the feasibility and broader context of their recommendations for moving people from dependency to self-sufficiency[44].

Useful Rules for Wise Advisors. Listening is an act of love:
-"*Encourage your advisee to tell their stories in order to understand the problems faced by locals.* First listen and let them tell you why they need your help, and then ask what help they feel they need."

-"*Do not talk too soon*. Avoid proving your value by offering advice before you know the problem fully."

-"*Avoid early judgment*. If the advisee senses that you are judgmental, he/she will probably become defensive and guarded. An open-minded understanding helps to gain trust and cooperation"[45].

The Power of Noticing: What Effective Leaders See. What are the critical threats and challenges that we are ignoring or denying? Why the leaders of some organizations fail to identify key problems and act before things turn catastrophic?

Cognitive dissonance: a pandemic phenomenon, where- by people do not want to see or cannot see because the group is not designed to see, and there are other people who are keeping us from seeing — motivated blindness, projecting an "Everything is just fine" attitude.

Adapting Development Models: Experiences from other global efforts may reveal the obstacles while providing valuable strategies for success[46]. However, as Lant Pritchett has noted, "models with proven effectiveness in other settings often fail to take hold in developing countries even despite having governments and international

support. The name for the practice behind the problem is *isomorphic mimicry*. This happens when consultants and public officials drop a replica of a proven model into an obsolete system. Unless resident agents work to give it a life of its own, it remains a replica"[47].

Recipient Responsibility. Impact of mindset: In the words of Robert G. Gard, "What cannot be taught, however, is motivation or incentive — morale or confidence in, and commitment to, the nation's institutions and leadership. This intangible element, essential to success, depends on the legitimacy of domestic governance. The legitimacy of the parent institutions is as necessary to success as well-trained personnel"[48]. People's self-theories about intelligence have an intense influence on their motivation to learn and subsequently on institutions. Those who hold a "fixed" theory are mainly concerned with how smart they are — they prefer tasks they can already do well and avoid ones on which they may make mistakes and not look smart. In contrast, people who believe in an "expandable" or "growth" theory of intelligence want to challenge themselves to increase their abilities, even if they fail at first[49].

Resistance to change. Ask what you can do and imagine what we can do together: Instinctively, people know that something is wrong but talk about change is often located in the near future, rarely in the present. Almost everybody accepts the idea of an out-of-date society or system trying to become a normal and modern developed country. The ability to see room for improvement, however, is not of much use unless one also has a strong desire to improve.

Agreement on a problem does not produce agreement on a solution. An early desire to look different can be abandoned when key supporters realize this means real changes and is against their interest — which produces a policy-implementation gap. Unfortunately, people appear to have the right to complain but do not believe that it is their duty to do something about it, fix what is broken, and to make the world a better place. Reinforcing a dysfunctional system strangles innovation and stifles the progress of organic adaptation.

Fundamental transformation of human nature is utopian, but partial transformations of human behavior occur all the time. Progress can change people's awareness of what is possible. Without failure, there is no innovation. Do not be afraid to explore what you could be! Change is in each of us[50]. "If we who have the talent and knowledge don't look after the problems ourselves, then others who are less talented and more ignorant of those problems will certainly do it for us"[51].

Business Model Innovation: a different way of generating change. A less radical and less expensive alternative is creating value through business model innovation — *how companies do business*; this can decrease resistance and simplify execution. It can be done by business model improvements, which can occur in a number of ways by adding and integrating novel activities and/or linking activities in a new way, changing one or more parties that perform any of the activities. "Who performs what? The *"whats"* are nonspecific, the "*hows"* are specific to you and the organization you are working with: going from *what* to *how* has to be understood through practice"[52].What they do will be less important pro- viding that quantitative evaluation of its impact follows the change. Countries and organizations can survive dramatic changes by deciding which parts of their business model to preserve and which to dump.

Real Leadership: Instead of looking for saviors, we should be calling for a leader that will challenge us to face difficulties for which there are no simple solutions, requiring us to learn new ways. Making progress on these problems demands not someone who provides answers from on high but changes in our attitudes, behavior, and values[1]. Successful leaders have the guts to marginalize radicals and nihilists who refuse to play by the rules of the institution.

Maladaptive practices exist everywhere and they eventually become adaptive challenges that do not subside with the ap- plication of technical skills provided by the professional. The frequency and persistence of maladaptive practices is related to the resistance of people to change and human nature's tendency to apply the "minimal risk" and "least effort" strategies that result in incomplete

adaptive work, allowing subsistence but no optimal result[1]. The principle-policy-implementation gap plays an additional roll.

Flexible adaptive leadership allows leaders to adjust, re- act and operate according to the needs of different contexts. The capacity to adapt enables both individual and business needs to be met through making changes to the time (when), location (where), and manner (how) in which people work[53].

Technology vs. Humans. Will technology assist individuals or limit them?

Advances in artificial intelligence will mean that computers rather than people will make more judgments and computers may not be able to explain their reasoning. All of us should ask ourselves what we could do now to improve the chances of gaining the benefits and avoiding the risks. In the near future access to information and new technology may make profits and privacy obsolete, and force us to redefine the boundaries between humanity and machines. These are advancing fast, and bring with them great hopes, but also great fears. Technology is neutral but people are not!

Hopes:

- Internet: communications, information, networking. "Exported knowledge fuels development. Tacit knowledge is spread through human interactions, which usually requires proximity. Bridges between people in different countries have increased, as global communications develop. This local diffusion of knowledge can help explain the well-known fact that rich and poor countries tend to be geographically clustered"[54]. Cluster: a geographically proximate group of interconnected companies and associated institutions in a particular field, linked by commonalities and complementarities[55].
- Education: free online education, classes, courses and degrees.
- Innovation: robotics, automation, energy, additive manufacturing and 3D bioprinting in which tissues containing blood

vessels and multiple cell types can now be assembled in architectures approaching the complexity of human tissues.
- Sciences: improving connectivity and removing barriers to cooperation, exchange of knowledge and interdisciplinary alliances.
- Health Care Quality

Fears to the downsides of advancing technology:

The only way to beat an existing technology is to bring in a disruptive and creative new technology that is a strong alternative. Just bad-mouthing it and stressing its handicaps do not go very far.

- Overuse/misuse
- Health Care Cost. "In every other sector of the economy, technology makes life cheaper, easier and better. In medicine, new treatments and devices usually do the last thing in that trio, sometime the second but rarely if ever the first"[56].
- Unemployment (youth): a time bomb!
- Inequality
- Cybercrime. National security. Many countries have nuclear materials in installations that are not safe. Sophisticated technology is not yet in the hands of terrorist organizations, but it might be one day in the future.
- Addiction, dependence, and distraction: today, all facets of the information age lead to overwhelmingly negative interruptions. In the end, a person requires a method. He must be able to distinguish between creative and destructive distractions by the sort of taste they have, whether they feel depleting or fulfilling. Moreover, this can work only if he is in good communication with himself — an artist of his own life.
- Quality of life, stress?

A Word of Caution: "Often people get what they could get, but getting the wrong thing is not necessarily the right thing to do. In medicine, for example, there is always a risk of being satisfied with delivering sub-standard care in resource-limited settings, assuming that offering some care is better than no care, or

that reaching a larger number of people with sub-optimal care is preferable to reaching fewer people with more sophisticated and therefore more expensive care"[57].

Quo Vadis? In developing countries, government officials and their population have to decide where they are heading:

> - "For the sailor who does not know where it goes, there is never a favorable wind"
> - "Para o marinheiro que não sabe para onde vai, nunca há um vento favorável"
> - "Para el navegante que no sabe adónde va, nunca hay vientos favorables"
>
> *Lucio Seneca (4 BC - 65 AD)*

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Our profession is deeply rooted in the social, political, and cultural realms in which we live. While it may be easier to stick our heads in the sand and "focus" only on our Profession i.e., surgery and patient care with its daily grind, that would be a disservice to our patients and community.

Furthermore, surgeons and physicians should take a broader perspective and advocate outside of the hospital setting in order to have the greatest impact in the care of patients with congenital heart disease globally.

Each year approximately 90% of more than 1,000,000 babies are born around the world with congenital heart disease and will receive suboptimal or no care at all.[1] [2] Successful treatment of most congenital heart defects results in a high quality of a life for patients who are important contributors to society.

There are ongoing efforts to address such a large burden, with recommendations for how international medical non-governmental organizations can effectively partner with local hospitals and medical providers, communities, and government officials in low and middle-income countries in order to impact change for these underserved areas [3]. All these efforts are critical and the involvement of physicians in broader societal, cultural, political, and traditional local hospital program educational initiatives can lead to progress and thereby improve the care of patients with congenital heart disease.

As physicians we are fortunate to command respect from other members of society and the healthcare system and, as such, our voice is influential at both to hospital administrators and govern-

ment officials. We should take advantage of this opportunity and advocate with decision-makers for the well-being of children and adults with congenital heart disease.

In this review, Dr. Rodolfo Neirotti details the various hindrances to progress to people groups around the world. He covers the key elements of society namely politics, economics, and culture— and discusses aspects within each of these realms that lead to impairment for large swaths of the population. While such impediments and these underprivileged groups are often thought as solely residing within low and middle income countries, developed nations such as the United States also contain pockets of populations facing similar challenges. Suboptimal education, poverty, corruption, and lack of social justice require examination of the roots of deep-seeded issues for solutions. Furthermore, advocacy, teamwork, cooperation, collaboration, and trust are required to achieve effective change. Strong institutions, reversing early disadvantages for at-risk children in certain home environments, strengthening educational opportunities, and addressing income inequality are some examples of the tasks at hand. Technology and innovation, when used appropriately, can also be instrumental in this regard.

Therefore, for the sake of our future, the sake of our society, and the sake of our patients, it is incumbent that the physician and healthcare workforces to be actively engaged in progressive development and improvements in the care of the marginalized patient communities with limited access—throughout the world and in our own backyard.

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CARDIAC SURGERY: COMPLEX INDIVIDUAL AND ORGANIZATIONAL FACTORS AND THEIR INTERACTIONS. CONCEPTS AND PRACTICES

Rodolfo A. Neirotti

"Inflexible mentality remains the biggest stumbling block to change."
Mikhail Gorbachev

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Invited Editorial: Personal View

Cardiac surgery has been available for many years in several developing countries, thanks to the creativity and hard work of individuals who were able to produce good work in spite of the limited resources. Leadership, patience, perseverance, dedication, and the capacity to adapt to adversity have been the keys to success. Limited resources were a constant problem forcing us to focus on short-term creativity about tomorrow's needs. A great deal of energy in the form of leadership and negotiations was used to convince people to continue to work hard for low pay. Our efficiency was suboptimal. Anyone watching migrating geese would discover that they fly in diagonal lines, or "V" formations, to save energy and allow them to fly longer distances. Most importantly, the leader rotates, and we often do not, attempting to solve the puzzle with a personal effort rather than a collective one, exercising leadership with a flexible multi-challenge approach.

Cardiac surgery is a high technology system in which performance and outcomes depend on complex individual and organizational factors and their interactions. Like in any complex system that involves a large number of individuals human errors are possible and can carry major consequences.

Technology and human capital. The general belief that buildings are important has resulted in new facilities spread around in many towns,

schools, universities, hospitals, research centers and convention centers, without realizing that the quality of the crew — less visible — is the real determining factor for progress. Economists call the belief that increasing buildings and machinery is the fundamental determinant of growth "*capital fundamentalism*." The conventional wisdom that investing in buildings and machinery is the key to long-run development is another panacea that has not met expectations unless it is combined with human capital — attributes gained by a worker through education and experience. Societies can grow rapidly by relying on a well-trained, educated, hardworking, and conscientious labor force that makes excellent use of modern technologies.

Institutional enabling support. Needless to say, it means enabling the faculty to do the work trough the active participation of those on the top in addressing and resolving other limiting factors which can eventually narrow down the number of the binding constraints—mutual benefit of changing for the better in a partnership with synergy. Institutional quality is required to achieve a better care in cardiac surgery.

Organizational factors. Team work in which all components of the cardiovascular services—a cluster of people with similar interests and focused on excellence— contributes, although in different degrees, to the quality of the final outcome with an integrated approach in which communication, organization, and mutual supervision are crucial. Using an orchestra as an example of team work, a conductor is needed — the chief cardiac surgeon in most centers — working out the problems these challenges pose collectively, with the individual orchestra members.

Individuals. Exchanges with highly qualified individuals concerning change often involve negotiations and compromise, since they would not comply with the instructions without adequate rationale. It is not a matter of who is right or who is wrong; the focus must be on what both professionals care about: the patient. Though silence is associated with many virtues, it can exact a high price on individuals, generating feelings of humiliation, paralysis, anger and resentment, and eventually, if unexpressed, seriously damage an organization.

Complexity. Although the accuracy and quality of the surgical procedure are the most important determinant of survival after

surgery, neonates and infants, in addition to early diagnosis, capabilities for transportation, and pre- operative resuscitation, require expensive sophisticated support, expertise, manpower, and advanced technology. Given that this cohort of patients has a limited physiologic reserve, complex cardiac lesions that often require technically demanding procedures, and are prone to complications and/or residual related to cardiopulmonary bypass, they are an example that complexity demands complexity.

Because individual medical leadership and skills are not enough to solve these problems—a puzzle with multiple challenges—neonatal cardiac surgery will linger last in most developing countries. I am mindful of the danger of being unjust to people who make choices in conditions of uncertainty and circumstances over which they often had little control. It will require efforts at multi-levels of the national government—leaders with a passion for reducing suffering, able of changing minds and mental models— and the civil society to face reality, adjust values and priorities addressing social exclusion, and the need to overhaul the health care. Institutionalizing change is not an easy task but it is probably the road to sustainability.

Interaction, negotiation and compromise. Ideally, after operation, patients stay in the intensive care unit where the physician on duty must synthesize information from multiple sources and personnel into a cogent plan of care for the patient. When another physician, such as the cardiovascular surgeon, collaborates with the critical care specialist to manage a patient, the relationship requires mutual respect and co-operation in order for optimal patient care to occur. Every interaction in the ICU involving two physicians is a negotiation as much as it is collaboration. Each party approaches the interaction with a preconceived idea of what they want to transpire and there is an urgent need to find common ground to achieve an agreement. I approach these discussions with a few ground rules in mind. *First*, there are certain basic principles of care I know to be true that should not be compromised. *Second,* both parties will learn something from the interaction. *Third,* there is much in medicine that is either uncertain or can be approached in more than one-way. And *finally*, the best plan for the patient usually results from honest

open communication between physicians and the melting of the best of both points of view. If both physicians enter into the negotiation with the understanding that give and take is essential to the process, then a well reasoned plan of care is achieved and the patient benefits greatly. A similar approach is applicable to the communications among surgeons, anesthesiologists and perfusionists.

Thoughts on Change. Resistance of people to change and human nature tendency to apply the "minimal risk" and "least effort" strategies that result in incomplete adaptive work allowing subsistence but no optimal result, explain the frequency and persistence of maladaptive practices. Maladaptive practices exist everywhere, and they eventually become permanent adaptive challenges that do not subside with the application of technical skills provided by a profession. Solutions often reside not in the executive suite but in the collective intelligence of employees at all levels, who need to use one another resources, and learn their way to those solutions. The answer is leadership, an important component of the leadership/management philosophy that fosters transformation by encouraging creative thinking, challenging the status quo, removing barriers and promoting "bottom up" changes. To think creatively means to think "outside the box." That kind of thinking needs role models, whom we count on to bring us new visions and possibilities.

Business intelligence. Because of the current demand for excellence and transparency, hospitals should start collecting and analyzing data — a method to evaluate future improvements — about outcomes calling for quality from their practitioners in preparation for a not too distant future. Implementing an independent measurement and a reporting system — business intelligence — focused on patient safety with a view to eventually making the information available to the public, will have an impact on quality and consumer and patient satisfaction. It requires good data and commitment of senior executives to fact-based and analytical decision- making as a way to learn rather that doing it *out of gut feel or intuition*. Information can also help those on the top to reflect critically on their own behavior, identify the ways they often *inadvertently* contribute to the organization's problems, and then change how they act.

Leadership and culture. Having worked in South America, Europe, and most recently in the United States, differences in culture, resources and technology has had a significant impact in my practice and interactions with colleagues, patients and the public. The link between leadership and culture is complex. It is not easy to appreciate or understand that what people do, mean, and say varies from one culture to the next, and without that understanding, it is impossible to lead in another culture. A leadership style that would be effective in one culture may be dysfunctional in another. We all have seen very bright people making mistakes because they didn't understand the environment in which they were operating.

Altogether, this essay reflects an array of personal views in an era with a tendency to rewards those who can accrue technical knowledge, a skill that is only marginally related to the ability of being sensitive to context. It is not linked at all to skills like empathy—an immeasurable variable of human capital. Sometimes diplomacy is necessary to pass the border of ignorance, culture and geography.

Comments by: Marcelo Cardarelli, MD, MPH
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In the second article of his series entitled "Cardiac surgery: the infinite quest II." Dr. Neirotti takes us into a completely unfamiliar universe. An untried realm for many surgeons, usually more comfortable reading about the clinical aspects of our work.

Initially this intricate article dives into the behavior of complex systems, attempting to extract the lessons learned and to compare the commonalities of our field with other complex systems, easier to understand and better studied. But soon enough this paper takes a dive into less explored realms. The human factors and the human relationships that can easily make a successful team, or a failure.

A particularly worth reading point is— Reasons people fail— as it takes us through a succinct description of personality issues such as poor people skills, negative attitude, unwillingness to change,

excessive confidence, anger and frustration. One can imagine, and remember, how many of us have been subjected to some, if not all of these traits during our training and early career. While not a clinical paper, reflection on these personality restrictions will only improve our team dynamics and ultimately our results. Dr. Neirotti' second installment of this series is definitely a significant contribution to some of the unexplored aspects of our complex field of practice and undoubtedly a worthwhile reading effort.

(1) Nota Bene Neirotti R. Cardiac surgery: the infinite quest. Part II **Braz. J. Cardiovasc. Surg**. 2013, v. 28, n. 1, p. 129-36 (1)

CARDIAC SURGERY: THE INFINITE QUEST
CIRURGIA CARDÍACA: A BUSCA INFINITA

Rodolfo A. Neirotti

Introduction

Man's Search for Meaning

> *"The secret of life is to have a task, something youdevote your whole life to, something you bring everything to every minute of the day for your whole life. And the most important thing is — it must be something you cannot possibly do!"*
>
> *Henry Moore*

What are these series of articles about? Hopefully the readers can find in them a series of concepts and their potential applications to daily practice — some borrowed from my previous work and some from others, in an attempt to expand the horizon of my knowledge. Although I have already presented and written on these subjects, the aim in returning to some of them, as well as adding new ones, is not just to offer new information but more importantly to propose some provocative viewpoints and theories for everyone involved with each and every encounter. I am challenging the reader in the belief that a continuous reassessment of our thoughts and convictions by defying reality can be helpful to verify the sustainability of previous judgments: "By studying how new observations led to the revision of important theories one can see that science is not about immutable laws but provisional explanations that get revised when a better one comes along." The repeated `trial` of a certain event is precisely what leads to new understandings — which in turn can instigate even newer understandings[1].

When Albert Einstein wrote "The significant problems we face cannot be solved at the same level of thinking we were at when we created them" he was suggesting that if we always think the way we have always thought, we will always do what we have always

done, and if we advocate and do what we have always done, we will get what we have always gotten — stagnation of thinking. In addition, his observation remains us of the need to reflect on the issues, challenges, and opportunities in front of the profession and specialty — a future that most likely will be quite different from the recent past. "History is where the future begins"[2]. "You only look to the past to create a solution for the future. If you look down, you can only see a few feet, but if you look up, the view is infinite"[3].

As J. Matloff put it, "The future of medicine would evolve almost entirely as a function of leadership and management capabilities. Beyond whether this evolution could happen, concern was expressed having to do with where that leadership would emerge from government, business, or medicine"[4]. Therefore, it is important that physicians and health professionals take an active role in the political, economic, and social aspects of society — social cure — in order to defend the interests of those suffering. The time has come when those involved have to decide if they will continue to be a part of the problem, or

Abbreviations, acronyms & symbols	
OECD	Organization for Economic Co-operation and Development

whether they will be part of the solution delving more into potential answers to improving their institutions and as a result the troubled health care system.

In recent visits to some leading centers I was able to perceive that they are already applying many of the concepts that will be discussed in the different sections. Like in the universe, in the world of pediatric cardiac surgery there are visible galaxies emitting light and five times as much dark matter. The purpose of introducing theories and ideas from other disciplines attempts to lighting up — if that is the appropriate word — the dark matter of our specialty and if possible contribute to diminish its size.

Because of its length, the manuscript will be divided in three parts that will be published in consecutive issues of the Journal, following the suggestion of the Editor.

PART I

Approaching our profession and specialty in new and different ways

Ultramini-abstract: *Thinking of the big picture matters because the health care is multidimensional and therefore it is affected by the economy, social issues and politics, particularly in the developing world. An array of topics will be discussed for the sake of a better understanding of subtleties and depths of the problem. The purpose of combining a mix of ideas and perspectives intended to avoid a piece structured around narrow fields of view.*

The challenge

How do we generate the necessary cohesion to implement reforms? We need to transform exogenous ideas into endogenous dreams through leadership, persuasion, and empowerment. By breaking down complexity into individuals, activities, connections, and pathways, it should be possible to act on the different levels, particularly on individuals to build the system of work required in successful organizations. Since institutions are defined not by buildings, endowments, or traditions but by people with vision, an effort should be made to attract the most talented people that can be found, never ending the pursuit of that perfect candidate. I invite the reader to share my vision rejecting the formalism that continuously hinders our perception and at the same time I encourage them to keep their eyes open.

In general, people with the ideas do not have the power to implement them, whereas the people with the power are so embedded in the system that they are unlikely to come up with new thoughts. In addition, it is important to bear in mind the principle-policy/implementation gap — an important barrier to modernization

nicely explained by the public choice theory, which results in fewer implementations — just 10% of good ideas. Often, people tend to agree when principles and policies are discussed but the support diminishes when those bearing the costs — interest groups, more influential than those who would benefit from action — have rational incentives to do precisely what they are doing even though the want of the greater part is differing. "The politician becomes a statesman when he thinks of the next generation and not in the next election." Winston Churchill (1874 – 1965)

Thoughts on changes brings possibilities - but also pains

"Inflexible mentality remains the biggest stumbling block to change"
Mikhail Gorbachev

In almost every system — country, government, community, organization — there is something broken, flawed or maladaptive. The diagnostic challenge of leadership is to establish what aspects of the system are broken, defective, or maladaptive and the extent to which those features exist in the values, habits, practices and priorities of the people[5].

What is it about how our brains are wired that resists change so tenaciously? Why do we fight even what we know to be in our own vital interests? Resistance of people to change and human nature's tendency to apply the "minimal risk" and "least effort" strategies that result in incomplete adaptive work allowing subsistence but no optimal result, explain the frequency and persistence of maladaptive practices. Maladaptive practices eventually become permanent adaptive challenges that do not subside with the application of technical skills provided by a profession because people are unwilling to probing their values, habits, practices and priorities. The values and practices that might be viewed as weaknesses are those values and practices that people adhere to and in doing so stay away from dealing with reality. Instead of scrutinizing these features, they prefer to look outside their structure for the cause of what is erroneous. Yet, solutions often reside not in the executive suite but in

the collective intelligenceof employees at all levels, who need to use one another's resources, and learn their way to those solutions. The answer is leadership, an important component of the leadership/ management philosophy that fosters transformation by encouraging creative thinking, challenging the status quo, removing barriers and promoting "bottom up" changes. To think creatively means to think "outside the box." That kind of thinking needs role models, whom we count on tobring us new visions and possibilities[5].

It is difficult to discuss the future with people wholive in the present, but even more so if they live in the past. Cultural stagnation, based on the sameness of world view caused by social, intellectual, educational, and professional inbreeding, is a real problem and a barrier to progress. These are people who travel in the same circles,go to the same parties, talk to the same people, compare their ideas to people with the same ideas, and develop a standard view on issues that make any deviation from them seem somehow marginal, or even weird. Everybody must believe the same things they do – thinking stagnation without diversity of thoughts – or their contributions will not be constructive. Opposite poles have always more to say to each other than people who share exactly the same views. "You don't make peace with friends. You make it with very unsavory enemies." *Isaac Rabin, former Prime Minister of Israel.*

Suggestion: be receptive to changes and new ideas — allow yourself to be changed!

Complex change requires vision, skills, incentives, resources, and an action plan. In addition, a framework for problem diagnostics may be necessary to identify the changes and adaptive work required according to context throughout the system. When goals and objectives have been achieved, and successful change has occurred, it is important for the institution to recognize, celebrate, and if possible reward these accomplishments.

In summary, "It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change" — *Charles Darwin*

The Health Care

Public health is a system of systems: The health care system goes beyond the care supply system which includes doctors, nurses and hospitals. It also brings in government infrastructure, business, university circles, society and media. It seems to be difficult to g*et al*l of those involved to agree on the best way to improve this intricate milieu. Reinventing ourselves can contribute to the reinvention of the public health domain. The "Fine Art of Reinvention" means specifically taking something that already exist and seeing what it can become. That is, what can happen when circumstances permit you to evolve or, perhaps, force you to evolve? In my end is my beginning, leading to constant redefinition: re-think, re-imagine, re-discover, and re- invent yourself and/or your institution.

Improving the quality of health care and reducing its costs, requires real innovation with leaders focused lesson treating disease and more on systemic changes, i.e., considering health care as an integrated whole calling for revamping by means of innovation[6].

Innovations: Considering innovations in the health care is essential, as the technological opportunities for improved health, the search for better and more equitable services, and the ever swelling costs of health, threatenthe economic and social stability of nations worldwide."It is unlikely that the existing institutions will solve the current problems of the health care. They have to get people who actually know about public health in positions of power"[7].

Continuous Innovation Requires: As Persaud has so aptly put it, in order sciences to continue to improve, we must have 1) Knowledge development adding value by processing existing information to create new knowledge which could be used to define and solve problems. 2) Cross-fertilization of ideas – networking & physical proximity among well informed people. New knowledge comes from people with time and resources to discuss, think, and experiment. 3) Strong university-industry linkages. 4) Good governance – especially with regards to the legal protection of innovations[8].

A word of caution about expanding too far the lessons from the industry; hospitals do not manufacture anything and the raw

material – patients – are defective to start with. Although concepts from non-medical sources will be applicable – such as the business value added process, when a patient is admitted and discharged after a sequence of tests and/or procedures are performed— they should be patient centered.

Technology and human capital: The general belief that buildings are important has resulted in new facilities spread around in many towns, schools, universities, hospitals, research centers and even convention centers, without realizing that the quality of the crew — less visible — is the real determining factor for progress. The belief, that increasing buildings and machinery is the fundamental determinant of growth, is sometimes called "capital fundamentalism" by the economists. The conventional wisdom that investing in buildings and machinery is the key to long-run development is another panacea that has not met expectations unless it is combined with human capital — attributes gained by a worker through education and experience. As I have written elsewhere, societies can grow rapidly by relying on a well-trained, educated, hardworking, and conscientious labor force that makes excellent use of modern technologies[9].

Crossing Boundaries, Collaborating for Solutions: Improvement in health care performance requires stakeholders to understand the problems and the need of partnerships among hospitals and with business adopting pathways that can result in clinical solutions for the patient's well-being, as well as combining evidence-based standard medicine with complementary care. Translationalresearch and cooperation among sciences, establishing communication vessels, and removing barriers to inter- disciplinary alliances, can contribute to finding answers by the exchange of knowledge. The following examples show that medicine is not unique in benefiting from a multidisciplinary environment with its vast quantity of knowledge:

Network Science examines network representations and interconnections in complex systems, of physical, biological, and social phenomena, developing product space maps and analyzing structures of production. It seeks for common principles, and tools that govern network behavior, in order to increase collaboration

across disciplines by sharing knowledge. Research is searching for mathematical models to predict performance, according to network size, complexity, and environment[10]. Thereare several areas outside medicine that can contribute to solving our problems. For example the aviation and spaceindustry provide tools for safety in medicine and rescue operations, etc. Engineering and technology's contribution to the progress of precision medicine and its impact on quality is undeniable. In addition, "Clinical Economics" is a new approach, introducing diagnostic tools from Clinical Medicine for international aid to developing countries in the quests for improvements and grow[11]. And finally, economists, in the wake of the recent global financial crisis, are borrowing tools from other sciences — mathematics, biology, and medicine — in the search for certainty to explain and predict complex systems behavior. To prevent another meltdown, financial regulators may need to focuson the health of networks, not individual banks by thinkingmore like epidemiologists[12].

Innovative Reforms in Education

"The commonwealth requires the education of the people as the safeguard of order and liberty", inscription at the Boston Public Library emphasizing the value of education in society.

The Importance of Teaching, training and learning: Needless to say, the intellectual, cultural, and moral benefits of education for individuals and society are undeniable, particularly if it is based in quality rather than quantity. Formal advanced education does not by itself speak to success; it is always what one does with education (or lack thereof) that counts, not the degree itself. "Education is a substantial determinant of success — one of the most relevant — but it is less important than most people think. If everyone had the same education, the inequality of achievements would persist. The consequence of focusingon education alone is to neglect the myriad of other factorsthat determine people's future"[13].

It would be easy to give a list of many amous and influential people with basic schooling. With this truthin mind, it is important to judge people on the basis of their ability and if possible, with-

out bias. Nevertheless, to prosper, a nation needs a well educated workforce. Efforts to accomplish it should start early before students move forward to university. The countries that get excellent scores in reading, mathematics and science tests — OECD, a club of rich countries — are not necessarily those that spend more. "The variation in achievement cannot be explained by how much is spent but rather to how it is spent. High achieving countries have classes taught by great teachers. They have raised teacher's status by making it harder to become and remain one. Their salaries are according to their quality"[13]. When people are not properly paid, the workplace philosophy inspires: "they pretend to pay us, while we pretend to work."

Which are the industries, professions and professionals that will be needed in the 21st century? is a question that no one seems able to answer. It is important for societies to attempt to anticipate which sectors are expected to offer the best prospect for the future, therefore, it is the right time to work on the jobs yet to come and thinking seriously about how to prepare our institutions and professionals. This is a challenge not only for Medical Schools, Schools of Public Health and Medical Centers but also for many other disciplines since we are educating young people for jobs that do not even exist just yet with programs of study from the previous century.

Potential new path to success: "In America, only three in 10 young people earn a bachelor's degree by the age of 22, while 40 percent never attend a community college or university. In addition, high schools do not offer alternatives that prepare students to enter the working world. Therefore in a recent report called "Pathways to Prosperity" the authors reason that students could benefit from vocational training to learn the job skills they will need down the road. Just as high schools encourage students to consider college, they should also prepare their graduates to enter apprenticeships, certificate programs, or community colleges that can teach those jobs skills." This pathway could results in a better educated workforce in high-demand fields generating advances in science, health and society that benefit all of us[14].

Education of Health Care Professionals

Modernizing education even further may be needed at some point in time, moving to a competency based transformative learning. This approach in which knowledge objectives drives the curriculum — requires institutional design as well instructional design — curricula—individualizing the process according to specific contexts[15].

The implementation of "twinning programs" is a successful tool for improving training, quality, and access to care. Medical schools in all countries have benefited from twinning programs that foster exchange, share resources, and undertake collaborative work for mutual advance. Collaboration, a potent tool of academic systems, describes the opportunities to advance educational quality and output through sharing of information, academic exchange, quest of joint efforts, and synergies between institutions. It ultimately involves the relationship between individuals, but it can be structured and sustained through formalized institutional arrangements that promote, finance, and carry on relationships over time. The institutional objective in education, research, and service can be advanced through sharing of curricula, exchange of faculty, students, and joint research[15].

At the 2005 meeting of the American Board of Thoracic Surgery, a proposal to establish a subspecialty certificate in congenital heart surgery was unanimously approved by the Board of Directors. This proposal was prompted by the recognition that the discipline of congenital heart surgery requires unique skills and education that are not currently provided in a standard thoracic surgery residency. According to this concept, a curriculum is needed to define what skills are required to become an independent surgeon. In addition, education should not be limited to surgical trainees but should also include other related non medical patient caregivers and support services — all members of the health team — moving education beyond interaction only between surgeons to: 1) Attending physicians; 2) Charge nurses/leaders and bedside nurses; 3) Resident/ Fellows; 4) Community MDs; 5) Emergency Departments and Outpatient Clinics. Due to the lack of any formal educational process to prepare individuals for the administrative role of a division chief,

these efforts should also include those aspiring to these positions in order to promote scholarships in thoracic and cardiovascular surgery. To put it another way, the most important function of the system is the production of the producers.

The teaching-learning process can be improved by linking the matter being taught — whenever possible — to present-day situations in a non-punitive fashion learning oriented error reporting program. Doing so will make it much easier to understand the subject, in addition to making it more pertinent and effective as it relates to today's needs. Furthermore, institutions and professional organizations should be encouraged to use technology to considerably enhance the relevance and quality of education. Unfortunately, everybody gives lip service to education, but only a few are willing to funds it.

Potential Barriers: For many years physicians, and surgeons, have been able to implement new treatments with minimal oversight. As the general public becomes better informed about the inside working of hospitals, medical care, and their doctors, physicians have come under more scrutiny and monitoring than ever before. Society is more critical of the actions of the medical profession. The learning curve has changed, standards arestricter and the measuring sticks more exacting *(E. Bove. Seminars in Thoracic and Cardiovascular Surgery, 2003.)*. In addition, the impact of interventional cardiology and the shift to early repair have resulted in fewer straightforward cases. Furthermore, some common beliefs among surgeons such as, "observing is the best way of learning," "the real surgeon must do the entire case," and "not perceiving that the time spend helping a resident is part of the operation" worsen the situation[16].

Teaching Professionals How to Learn. Not so simple: "Professionals embody the learning dilemma: they are enthusiastic about continuous improvement — often the biggest obstacle to its success. For them, learning means solving problems by focusing on identifying and correcting errors in the external environment. Managers and employees must also look inward. They need to reflect critically on their own behavior, identify the ways they often inadvertently contribute to the organization's problems and then

change how they act." In order to be part of the solution they need to admit that they are part of the problem. For years, General Motors executives became practiced at the art of explaining their problems and attributing blame to everyone but themselves, rather than recognize their inability to admit mistakes[17].

Skilled professionals, almost always successful at what they do, often react defensively blaming others for their problems, in a closed single loop learning that shut down their ability to learn. Persistence of the problems and lack of progress are the consequences of failing backward. There's a difference between defending what you have done than being defensive[17].

Less commonly, smart people are able to learn from failure — "failing forward" by using critical thinking and productive reasoning — and this is called double loop learning. Continuous improvement is the result of how they think, design, and implement their actions combining a top down approach with a "bottom up" one[17] [18]. It would be hard to accept that maybe people do not want to learn?; Maybe people have not learned how to learn?; Maybe there is a fear of the unknown and therefore the amount and level of stimulation taken in must be inferior to one's own "wisdom"?

National/International Cooperation, Diagnosis and Recipient Selection: Because the world faces many formidable problems, we cannot expect to solve the mal- distribution and poor access to cardiac surgery through the regular channels for international aid. Currently, there are numerous groups around the world involved with structured international projects, but without coordination among them. In humanitarian medicine, there is room for cooperation rather than competition, because the people in need outnumber those able to provide assistance. Unfortunately, there are not humanitarian solutions for humanitarian problems. Answers that are more comprehensive are needed, in which humanitarianism would play only a part.

To avoid squandering energy and resources it is important to identify places, "fertile sites", and their needs, with receptive individuals where good work is being done. The majority of donor

programs focus on developing an on- going relationship with a host program. This relationship involves visiting teams, teaching, training, collaborative research, and donation of equipment. The "twinning process" results in a transfer of knowledge, ideas and skills and the visiting team usually includes: surgeon, anesthesiologist, cardiologist, perfusionist, critical care specialist, interventional cardiologist, and nurses. To maximize training effectiveness in other cultures, trainers need to understand how cultural differences may affect the expectations of their audiences. Volunteerism, a core value of many peer programs, eventually wears thin as volunteers have other obligations resulting in weakening of early successes. This approach will be most effective when local governments, doctors, and hospitals have a genuine learning interest. In those instances, eventually the host program becomes autonomous, with the donor program assuming a consultant role.

Professional Organizations: Professional organizations can be extremely helpful by coordinating the efforts, and taking maximum advantage of contemporary technology in communications and educational techniques for fostering the transfer of knowledge, skills, and ideas of its members beyond borders for the benefit of patients in lesser-developed countries. In addition to their role in education, lively and energetic local and international professional organizations can respond to the initiatives of the members, to the changes of the specialty and to the evolution of treatment modalities. Professional networks allow physicians to share insights with each other, almost on real time without enduring the unwieldy rules and delays involved in traditional academic publishing[7].

Accreditation: Evaluation of centers, surgeons, training programs and other health professionals: It is necessary to provide a formal recognition to the trainee that has completed the process. National accreditation systems should develop a criterion for assessment, define metrics of output, and shape the competencies of graduates to meet societal health needs. Probably the most difficult and at the same time the most important issue is how to evaluate the genuine technical skills of surgeons, which will not be reflect-

ed in references, written examinations and interviews. Professional organizations can arrangevisits of a group of experts to evaluate the function of the entire team as well as their training programs through interviews with residents and fellows. Although it is done in some countries it is not yet widely accepted.

Inferences

- To-date, particularly in developing countries, we have been unable to secure support from governments, professional organizations, philanthropists, patients, or peers for our specialty.
- The existing curriculum of medical schools, developed a century ago, need modernization to produce health care professionals that can adapt to the broad range of therapeutic options offered by the rapidly growing technology.
- Basic sciences may introduce an unthinkable scenario requiring redefinition of the regulatory bodies with a multidisciplinary approach in which innovation should be coupled to early evaluation in order to determine the value of new procedures[19][20].
- Many obstacles remain, but physicians and professional societies can and must play an important role in overcoming them.

Part II will be published in the next issue of the RBCCV Cardiac Surgery: issues around and beyond the operating room

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In this scintillating philosophical treatise, Neirotti presents a panoply of medical and scientific attitudinal and operational vignettes in the hope of illuminating a path forward for the next medical, and specifically cardiac surgical, generation. Quotes and aphorisms from such eminent luminaries as Einstein, Darwin, Churchill, and others lend credibility to an already articulate and prescient missive.

In the throes of the current pandemic of Covid-19, one can't resist reflecting back on the history of the 1918 influenza pandemic, and the relevance of many of the postulates and recommendations articulated here. It wasn't as if pandemics, influenza, and the impact of disease on the military were foreign concepts. But, despite the availability of "vaccines" for a variety of infectious conditions, science and public health were on their heels as the dreaded pandemic spread from the Midwest USA (possibly emanating from Kansas)

through the military vehicle of World War I to Europe and beyond. Many of Neirotti admonitions and challenges would have benefitted our health care and military leaders as the pandemic morphed from a relatively mild "flu" in the spring and summer of 1918 to the violent and lethal scourge by the fall of that year.

In the world of congenital heart disease and, in particular surgery, Neirotti suggests many operative principles in leadership and problem-solving. The challenges being considered in the US to set "standards" for congenital cardiac surgery "centers" will require wise and flexible approaches. The final calculus must seek solutions that account for widely disparate variables such as patient well-being, the relative rarity of certain operations and malformations, the highly mobile state of cardiac surgeons and intensivists in the US, patient cultural and socioeconomic impediments to long distance travel for care, political and financial incentives to both retain centers with inadequate volume and for larger centers to consume smaller but highly competent programs, and the challenges of identifying true quality in care. When this dilemma is expanded to the global stage of developing countries, the fabric of congenital heart surgery programs and regional needs presents a host of additional and very different imponderables. Much of Neirotti' messaging is entirely relevant to both of these important situations.

My congratulations to the author for this informative, useful, and stimulating article.

CARDIAC SURGERY: THE INFINITE QUEST. PART II
CIRURGIA CARDÍACA: A BUSCA INFINITA. PARTE II

Rodolfo A. Neirotti

Publicamos, abaixo, a segunda parte do artigo "Cardiac surgery – the infinte quest". Apesar de mais complexo que a anterior, este texto vai além das habilidades técnicas e tem conceitos modernos de como lidar com os sistemas complexos da atual prática da nossa profissão e especialidade.

Domingo Braile
Editor-Chefe/BJCVS/RBCCV

PART II

Cardiac surgery: issues around and beyond the operating room

Cardiac surgery: a complex system

Heart surgery has much in common with other high technology systems in which performance and outcomes depend on multifaceted interactions of individual, technical and organizational factors. In addition, our specialty often functions as a chaotic/emergent system since the initial circumstances vary in patients with the same medical condition resulting in uncertainty and lack of predictability[1]. ***Complexity***: The American Heritage Dictionary defines complex and complicated as "things whose parts are so interconnected or interwoven as to make the whole perplexing". If we add rarity and small numbers to complexity, the results is a distinctiveness that explains many aspects of our profession and specialty such as variability with institutional differences in outcomes; inconsistency

of results in treating rare diseases and uncertainty on any inference about results of complex rare lesions[2].

A system is a set of interdependent elements that are interacting, or working together, to accomplish a common goal. All systems, at the "atomic" level, consist of individuals, activities, connections, and pathways with the following characteristics, qualities or peculiarities in complex systems:

- Heterogeneity of the parties (diverse nature and multiple);
- Cause-and-effect relationships may be nonlinear and obvious only in retrospect;
- Richness of interaction between them (including their contradictory character);
- Multidimensional and multi-referential;
- Many variables commonly present;
- Provide information that by itself reveals the extent of its complexity;
- Under an apparent simplicity, they often hide the true dynamics of these processes and interactions between its parts
- Vulnerability — Are influenced by factors and surprising circumstances that may affect, cause, or facilitate a change in behavior and expected results, altering all or changed significantly

> "Complex business generates complex services. Regardless of how much effort and brain power go into designing their complex operations ('system of work'), it is impossible to do it perfectly and to predict how it will behave under every circumstance"[3].

Complex systems are rich in multiple and interdependent events that usually manifest unforeseen consequences that are nonlinear and often asymmetric — frequently called black swans. Why call big surprises black swans? It goes back to the second century when Roman poet Juvenal said that some events are "as rare as a black swan"[4] .

History is shaped by events that seem impossible until they occur changing predictions and planning. Surprises are by definition

unexpected and therefore well beyond the limit of our experience, not allowing us to pick the "next disaster". Why can't we foresee these events? Blame it on the way humans make sense of the world most of their experience falls within a tightly bounded range called "the norm". Focusing on that narrow array carries the risk of preparing us only for events we are familiar with[5].

Rare diseases rare as Black swans are a challenge for the Science of Cardiac Surgery because of their infrequency at any single institution, and thus the gaps in knowledge. Because of this, there is little chance that randomized comparison can be accomplished. In this setting, highly variable outcomes are predictable given the scarceness of skill-based, rule-based, and knowledge-based foundations for performance that avoids and compensates for human errors, the inevitable breakdowns due to complexity and uncertainty. Statistics to determine risk are not available; we just do not have them due to their rarity.

Complexity thus calls for experimentation. Once patterns become apparent, it is possible to attempt to destabilize undesirable interactions[6]. By contrast, in *chaotic* situations highly sensitive to initial conditions there are no trends to monitor. Sometimes complexity is at the "edge of chaos" without a pattern to differentiate.

Clayton Christensen reminds us that "Theory is often associated with the word theoretical, which, among practical people, has a connotation of impracticality. However, a well researched theory is practical because it allow us to know what cause what and why, and to predict the result of an action. The key to developing a theory that is valid internally and externally is to seek anomalies, to find instances in which the explanation of causality does not yield the result that the theory predicts. The scientific method requires to search for instances in which the theory does not work"[6]. *"As the circle of science grows larger, it touches paradox at more places" Nietzsche*.

Managing complexity: Steven Spear aptly describes the problem and manner of managing complexity: "There are *high velocity organizations* whom everyone chases but never catches that manage to stay ahead because of their endurance, responsiveness, and an exceptionally high velocity in self correction. They see and seize

opportunities and, by the time rivals responded, the leaders have raced on to further opportunities these systems pose both the capacity to retain their viability and the capacity to evolve"[3]

"These organizations complex adaptive, self- improvement systems — face a common problem and have identified a common solution, which keeps them performing way ahead of the pack and always getting better — the two go together. The solution has been used successfully by a wide variety of organizations indicating that the general theory is independent of any particular industry or activity"[3] [7]

"And this leads to collaborative rationality, of getting better together, which is a different way of knowing and generating, of making and justifying decisions based on *diversity, interdependence and authentic dialogue* — not always accepted by the chain of command despite of the limitations of acting unilaterally. The agents interact dynamically, exchanging information and the effects of these connections flow through the system. There are many direct and indirect feedback loops; the overall system is open. The behavior of the system is determined by these interactions, not the components; and the behavior of the system cannot be understood by looking only at the components" [7] [8].

Diversity: "Diversity implies that a collaboratively rational process must include not only agents who have power but also those who have needed information or could be affected by outcomes of the process". As in direct democracy, their success depends on the amount and quality of the information available to those involved in the decision making process[9] [10].

Interdependence: "Agents must depend to a significant degree on other agents, considering that each stakeholder has something that the others want. This condition ensures that participants maintain a level of interest and energy required to engaging each other and pushing for consensus — such interdependence means that players cannot achieve their interests on their own"[10]

Authentic dialogue: "Deliberations must be characterized by direct engagement so that the parties can test to be sure that claims are accurate, comprehensible, and sincere. Deliberations cannot be dominated by those with power outside the process, and everyone

involved must have equal access to all the relevant information and an equal ability to speak and be listened to. In authentic dialogue, nothing is off the table"[10]

Structure and dynamics of successful high velocity organizations

Structure: Managing and integrating the functions as part of the process.

Dynamics: "Continually Improving the Parts and the Process, by engaging those closest to *the work in the continual improvement, their speed of detecting and problem solving*, learning, and discovering better ways of how to produce. Any snapshot will reveal where they are today but not where they are headed determined by their DNA".

"These organizations, share four capabilities that can be adapted to medical situations: a) specifying design to capture existing knowledge and building in tests to reveal problems and improve a process; b) detecting and rapidly solving problems to build new knowledge avoiding memory perishability; c) sharing new knowledge throughout the organization; d) leading by developing the above mentioned capabilities by allowing enough time and resources for staff/team training, turning employees into problem solvers. Operations are designed to continually let them know that it does not know all there is to know.

When the operations speak, these organizations listen, learn, improve, and wait for the next lesson. The lesson learned here and now is spread throughout the organization. The high velocity set themselves apart in how they deal with the problem of unknowable unpredictable systems, understanding, learning and recovering from failures"[3].

How complex systems fail: in those systems that fail, their pieces come together through hard work, goodwill, and improvisation. Their components are managed as if they operated independently; in fact they are quite interdependent. Although it could be a "Sisyphean task" some of them fail wisely learning from their mistakes and try again. However, the choices are often both clear and stark: organizations must either modify their forms and structures (rein-

vent) in ways appropriated to the emergent environment or, over a period of time, cease to exist. Occasionally, disruptive innovations, creating new organizations are necessary rather than transformation of existing outdated institutions.

Like in our profession, the first step to treatment is diagnosis. If one considers that a system has an illness dysfunction the first step should be to make a diagnosis to uncover its root causes. Often, administrators and managers have a tendency to prescribe treatment without a proper diagnosis that would allow identifying the system-specific problems. Policies that work in some setting may not be effective in a different context. A chart constructed by combining a diagnostic tree with the National Diamond Model allows displaying the components of the system and pinpointing the potential binding constraints affecting performance and growth before implementing reforms. A similar approach, with different factors, can be used in program evaluations[11] [12].

There are many factors which contribute to failed or failing institutions[13].

Reasons people fail

- **Personal weakness** — failure to reach a minimum required performance;
- **Poor people skills** — inability to relate to others;
- **Deviance** — violating an agreed process or practice;
- **Negative attitude** — in reacting to adverse circumstances of life;
- **Bad fit** — mismatched abilities required to execute the job, interests, personality, values;
- **Lack of focus and attention** — priorities not well established leading to inadvertent departure from stipulations;
- **Weak commitment** — not giving the task our very best;
- **Unwillingness to change** — major enemy of success;
- **Shortcut mind-set** — take the shorter road to success;
- **Excessive confidence** — it is not beyond my scope or skills. I can do no wrong → Ego;
- **Relying on talent alone** — avoiding hard work to improve it;

- **Response to poor information** — not feeling you need more information;
- **No goals** — lack of a dream with a time limit;
- **Frustration** — not learning from failures;
- **Anger:** according to Aristotle, "*Anyone can become angry, that is easy — but to be angry with the right person, in the right degree, at the right time, for the right purpose, and in the right way — that is not easy*". Rationally speaking, it is a very important emotion and a huge driver of human behavior. In some cases it is even welcome; however, those that can control it — i.e., those who have emotional intelligence or are emotionally astute —avoid being an angry decision maker and may have an advantage in their daily life. In sum, showing your anger conveys a toughness that can help you get what you want. But beware: When your counterpart has better information than you do, your anger could work against you[14].

Human behavior and errors: Medical errors cause 90-120,000 preventable deaths per year in the USA *far more than in car crashes* — costing the industry somewhere between $9 billion and $15 billion a year.

Furthermore, only 50% of US patients receive adequate quality of care, altogether enough to take the necessary actions to reduce risk the factors. It is a basic principle of systems that every one of them is perfectly designed to achieve the results it attains. Academics, by studying these systems, could contribute to a better understanding of how the components relate to one another in designing a self improving process that prevents mistakes from occurring. In addition, medical schools should consider building up awareness of the importance of prevention of medical errors among students early on their career[6].

The fact that complexity makes errors inevitable should not be an excuse; we should to do our best to avoid them. Human factors research has been a major contributor to safety, enhanced reliability and error avoidance in those complex socio-technical systems such as the *aviation industry*. Their long used safety check list looks like a

simple and helpful tool to reduce errors, complications and deaths in medicine, as well as in other professions[15]. Unfortunately, industry and watchdogs often rely far too much on a patchwork of retroactive rules, with inspectors adding the negative event to their checklist each time a trouble is found in one of the components, decreasing its usefulness, particularly if thereafter the new norm is looked at with the old lenses.

Imperfect outcomes are caused not only by lack of knowledge — ignorance — but by imperfect selection of treatment, imperfect performance, and are too often caused by human errors. Mistakes are the result of either the misapplication of good rules — ineptitude — or the application of bad rules. Most mistakes can be traced back not just due to flawed execution but to flawed thinking of people trying to do a good work, and a tendency to make absurd decisions[16]. Team communication, organization, and mutual supervision are crucial to minimize the chance of making a mistake.

Technical failure and human error led to the loss of an Air France flight over the Atlantic in June 2009 and the deaths of 228 people, according to the final report of the French air accident investigation agency (*Pilot Linked to Air France Atlantic Plunge, BBC News, July 5, 2012*). Similarly, the Fukushima nuclear plant was "a profoundly man-made disaster that could and should have been foreseen and prevented" and its effects "mitigated by a more effective human response" according to the report of the Japanese parliamentary panel. The report catalogued serious deficiencies in both the government and plant operator response adding that regulators should "go through an essential transformation process" to ensure nuclear safety in Japan (*Japan panel: Fukushima nuclear disaster 'man-made'. BBC News, July 5, 2012*).

It is important to recognize that medicine is so complex that no human being can be in control of everything without some sort of compensation for bounded rationality or hyper rationality. Furthermore, over the last decades, science has filled in an enormous amount of knowledge, challenging even more the human mind's limited capacity to evaluate and process the information available, considering the time constraint to make some decisions. We have to achieve near

perfection in the shortest possible time avoiding the "let's-get-home-itis", a disease in judgment that has negative impacts on a number of surgeons who sing the praise of speed and quick operations.

It may be part of human nature to err, but it is also part of human nature to develop solutions, find better alternatives, and meet the challenges ahead. Rather than punishing those that make mistakes, it is more effective to find out why they made the mistakes in order to act on the system to diminish the odds of repetition[17] .

Negative events in complex systems

Minor Events are subtle, insidious, except to human factors observers, and many of them largely overlooked by the operator and the team members. As a result, no attempt to correct them is made. In isolation, they have little impact, but their multiplicative effect can lead to negative outcomes.

Near Misses can cause severe temporary or permanent complications. By paying attention to close calls, it is possible to recognize them, learn and eventually predict and prevent major events. Unfortunately, decision makers have often a tendency to view near-disasters as successes! *Major Events*, without compensation, are likely to lead to death. Because they are more obvious, they can be recognized, triggering rescue actions to avoid catastrophic consequences.

Risk Factors for Complications are more related to patient variables than to structural hospital characteristics. The highest quality, lowest risk hospitals have a higher prevalence of rescue from complications. It is the failure to compensate that leads to a negative outcome[18].

Individual and organizational factors and their interactions

Individuals: Exchanges with highly qualified individuals concerning change often involve negotiation and compromise, since they would not comply with the instructions without adequate rationale. It is not a matter of who is right or who is wrong; the focus must be on what professionals should care about: the patient.

Though silence is associated with many virtues, it can exact a high price on individuals, generating feelings of humiliation, paralysis, anger and resentment, and eventually, if unexpressed, can seriously damage an organization. Silence can also be the result of cultural conventions and a reluctance to question authority.

The message throughout the organization should be: STOP! Any question from the team? *"If you see something that concerns you please speak up"*. It is difficult to manage secrets! This approach thwarts the blame game, helping to build a culture that promotes participation, and encourages detecting, analyzing, and learning from failures[19] .

Organizational factors: Team work in which all components of the cardiovascular services — a cluster of people with similar interests, all focused on excellence contributes to the quality of the final outcome with an integrated approach.

Using an orchestra as a paradigm of team work, a conductor — the chief cardiac surgeon in most centers leading from the front and by example is *needed*, working out the problems collectively with the individual orchestra members. He does not produce the sound but he can inspire, teach, and persuade. It is about how to play rather than what, an excellent example of the importance of coaching something that surgeons seldom do.

After all, "Music fills a gap in life like nothing else — and brings serenity when other things cannot"[20] .

Interaction, negotiation and compromise: In an ideal world, after an operation, patients stay in the intensive care unit where the physician on duty must synthesize information from various sources and personnel into a sound plan of care. When another physician, such as the cardiovascular surgeon — when they participate, though often they do not — collaborates with the critical care specialist to manage a patient, the relationship requires mutual respect and cooperation, without patient ownership, in order for optimal patient care to occur. If the dialog starts with someone saying: this is my patient! It is a bad start. Every agreement in the ICU involving two physicians is a negotiation as much as it is collaboration. Each person concerned approaches the interaction with a defined (and possibly different) idea of what he wants to happen,

and therefore there is an urgent need to reach agreement on a plan of action. If you approach a negotiation thinking you know everything, you may not make the best decisions. You could be missing out on information, insight and suggestions that may be critical to the outcome. A leader who doesn't nurture an atmosphere where ideas are welcome is shortchanging his or her effectiveness. In addition, team members who are discouraged from giving opinions or input will be ineffective players.

It is prudent to approach these discussions with a few ground rules in mind. *First*, there are certain basic principles of care known to be true that should not be compromised. *Second*, both parties will learn something from the interaction. *Third*, there is much in medicine that is either uncertain or can be approached in more than one-way. *Ultimately*, the best plan more often than not results from honest open communication between physicians and the melding of the best of both points of view. If beyond winning, both physicians enter into the negotiation accepting that give and take is essential to the process, then a well reasoned design of care is achieved and the patient benefits greatly. An analogous approach is applicable to the interactions among surgeons, cardiologists, anesthesiologists and perfusionists. It is difficult to have a team unless every member has respect for people who have different skills[21] [22].

The power of a positive NO: "No is perhaps the most important and certainly the most powerful word in the language. Every day we find ourselves in situations where we need to say *No* — to people at work, at home, and in our communities — because *No* is the word we must use to protect ourselves and to stand up for everything and everyone that matters to us".

"Saying *No* the right way is crucial. A wrong one, a clear a resounding *NO*! can also destroy what we most value by angering and alienating people. The secret to saying *No*, clearly, respectfully, and effectively, without destroying relationships lies in the art of the Positive *No*, a technique that anyone can learn. The Positive *NO* can help you to get not just any *Yes* but to the right *yes* the one that truly serves your interests"[23] .

Quality: "An essential and distinguishing attribute of something or someone" (*Word Net Dictionary*). It is difficult to define, but you know it when you see it! Quality is measurable and requires appreciation to recognize the quality, its significance or magnitude and appreciation requires knowledge.

In medicine as in many other businesses *precision* equals precise diagnosis plus doing the right thing (effectiveness) plus doing it right the first time (efficiency). Precision in medicine not only improves outcomes but also can dramatically cut costs. In health care, cost is not a proof of high quality and low cost comes from focus. Value added procedures are possible only after a precise definitive diagnosis has been made[6] [24].

Quality comes from correct integration to get the job done. As we improve the technology of medicine, we also need to include the patient's story in the equation: ***Quality of care*** equals ***technical quality*** (precise diagnostic, doing the right thing and doing it correctly) plus ***service quality***, both throughout a process that cannot be turned off at five o'clock. Adopting the quality equation is a decision and a commitment one makes every day that never goes away, that needs to be sustained all year long to become a habit. Institutional quality and qualified people are the key to making quality products, with the best possible use of the ordinary distribution of human talent and a permanent awareness of personal and institutional limitations[25]

Service quality: The privilege to assist in preserving and improving life provides us with much professional satisfaction. But, do we have the necessary background to fulfill the humanistic demands of our profession? Often, one recognizes professionals who have mastered scientific facts and surgical techniques but who lack interpersonal skills and respect for the dignity of man, empathy, and humility. Remember that our attitude often trickles down to the entire team![26]

To achieve this, a combined approach is necessary, inducing change from the top, by influence or persuasion and commitment to education, and encouraging bottom- up grassroots involvement and cooperation. Promoting bottom-up chances is an important component of Edwards Deming's principles of total quality management. Both the top-down and the bottom-up approaches are

not mutually exclusive but rather complementary and are what is meant by **T**otal **Q**uality **M**anagement.

- Total Quality Management (TQM) is a business strategy aimed at embedding awareness of quality in all organizational processes making it the responsibility of all employees.
- TQM requires a re-organization of the work process and the workplace by application of principles of "teamwork" and work "teams" that are supposed to involve the workers and give them greater control in their work

Quality problems and categories of poor quality: Overuse, underuse and misuse of funds due to: defensive medicine, ignorance, the culture of money, poor attitude, lack of knowledge, resources, or technology, as well as corruption, greed, etc. Reforms such as revisions to the fee-for service reimbursement and the incentive it provides for overuse can result in significant savings[27] [28]. In other words, health care providers who ensure quality care, customer satisfaction, cost control, and efficient and appropriate use of resources, are preferred.

Reporting of quality

- *Lay media*: Anecdotal; substantiation not required; short-lived;
- *Professional literature/media*: Scientific process; scrutinized data; longer lasting;
- *Value of representation in both lay and professional media*: Credible evidence-based outcomes, that are recognized in the professional literature and attract the interest of the lay media provides the best of both worlds.

Quality of care: Using "network science", a method of analysis that examines webs of connections in complex systems, it is possible to map the "*Product Space*" by depicting clusters of capabilities/products grouping them according to their relatedness. The concept of "*proximity*" formalizes the intuitive idea that the ability of a center to generate an outcome depends on its ability to produce other ones "*structure of production*". When a center with many complex capabilities adds a new capability, it can create a range of new

possible products new complex procedures. Conversely, adding a single new capability in a center that has few to begin with won't leverage an existing matrix of capabilities in the same way, indeed it might not produce any new products at all[29] .

Systems of care, their impact on quality: Although the knowledge and practice of individual clinicians are important for high-quality care, today we realize that no health care professional can deliver high quality alone; therefore, health care professionals prefer to practice within groups — proximity — and systems of care. *Systems of Care equal institution plus staff partnership plus product space plus structure of production*[29] [30].

Institutional variations in hospital mortality associated with inpatient surgery

- Rates of death vary across hospitals, from 3.5% in low-mortality hospitals to 6.9% in high-mortality hospitals;
- High mortality hospitals have complications rates similar to those of low mortality hospitals (24.6% and 26.9%, respectively) and of major complications (18.2% and 16.2%, respectively);
- Mortality in patients with major complications was almost twice as high in hospitals with high mortality than in those with low mortality — high velocity organizations (21.4% *vs.* 12.5%, $P<0.001$). Hospitals with higher mortality rates the pack are less effective in rescuing patients from complications;
- Timely recognition and effective management of complications are important in reducing deaths after surgery;
- The value of avoiding complications is obvious. The quality of care once *complications have occurred is crucial for reducing mortality*[30].

Business intelligence: how are we doing?

Business intelligence the systematic use of information about one's business is vital to understand, report on, and to predict different aspects of performance. High quality intelligence capabilities

and analytic skills play crucial roles in the most competitive sectors of the global economy because it can avert bad events providing that the dots are properly linked.

How are we doing? Due to the current demand for excellence and transparency, hospitals should start collecting and analyzing data a method to evaluate future improvements about outcomes calling for quality from their practitioners in preparation for a not too distant future. Implementing an independent measurement and a reporting system business intelligence focused on patient safety with a view to eventually making the information available to the public, will have an impact on quality, as well as on consumer and patient satisfaction.

An accurate and unbiased statistical analysis of surgical outcomes allows for an intelligent search of the risk factors, continuous improvement through responsiveness of the parts and the course of actions, as well as for a valid comparison with other institutions. The truth is the truth wherever it is found and to dismiss it because it comes from people with different views is a mistake. Undoubtedly, gathering accurate information is vital also because politicians, bureaucrats and company officials are often wary about alarming citizens.

The systematic use of information requires good data and commitment of executives to fact-based and analytical decision-making as a way to learn rather that doing it out of gut feeling or intuition *cognitive illusions, illusion of validity*[31]. Gathering solid data, working analytically, and leaving emotions aside all help those on the top to reflect critically on their own behavior, and then change how they act to make better decisions. Efforts to develop fact-based decision-making capabilities are likely to fail unless they are closely supported by top management.

High performance organizations adapt and thrive by rapidly making choices that others do not by moving the decision making process down, close to the generation of information and around the needs of the user, instead of moving the information up to the executive suite.

The people who construct statistics are very often not the same kind of people needed to publicize them. An effective leader should be able to comprehend number- laden reports, evaluate the information provided to him, and draw conclusions from data, rather than be dependent on others to interpret for him.

Altogether, evidence-based medicine improves patient care using metrics and evaluations as a tool for learning rather than accounting.

Two categories:

Reporting: Those providing services to the public, needs to report accurately on what is going on in their business. By getting a relatively early warning on their performance they can fix the problems and educate the team members encouraging their participation with a button up plus horizontal approach.

Analytics: This is more understanding-oriented in terms of knowing what factors are really driving your business performance, or prediction-oriented, looking forward instead of backward.

Inferences

- Cardiac Surgery is not immune to the waves of innovations — Kondratieff waves — sweeping the world at large over the past fifty years starting with disruptive new technologies that have tranformed industries, societies and economies beyond recognition. Developing economies have been spared this technological onslaught, but they might soon have this same problem[32]. As President J. F. Kennedy put it, “Great change dominates the world, and unless we move with change, we will become its victims”.
- An innovative partnership among the government, the private sector and foundations can led to major advancement of the health system.
- Listening to customers is in general a good idea, but it is not the whole story; in order to innovate smart companies

should sometimes ignore what the market says it wants today, relying on inspiration and even distorting reality for the genesis of new products.

- We should be prepared for changes in the patient population requiring surgery. Conventional surgical procedures are expected to diminish. Hybrid procedures, requiring special facilities and team work with the participation of people with different skills will be more often adopted.

Part III will be published in the next issue of the RBCCV Pediatric Cardiac Surgery: a discipline on its own

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Comments by: **Marcelo Cardarelli, MD, MPH**
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In his 2010 editorial essay titled "Cardiac Surgery: complex individual and organizational factors and their interactions. Concepts and Practices" [1], Dr. Neirotti delivers a personal essay on the desirable conditions and challenges found in the development process for pediatric cardiac surgical programs in limited resources environments. In his brief but well thought analysis, based on his own personal experiences, he reminds us of the minimum set of personal virtues

needed to survive these difficult environments. Leadership, patience, perseverance, dedication and the capacity to adapt to adversity.

Our own experience in helping build pediatric cardiac surgery programs in low and middle income countries (LMIC) worldwide would suggest that Dr. Neirotti' observations have not lost validity 10 years later. Perhaps, one of the most interesting point about this essay is that, while the writing was intended for audiences based in LMICs, its conclusions are equally applicable today to pediatric cardiac programs in the developed world as well.

The goal of our commentary would be expand on some concepts expressed in Dr. Neirotti' original piece. Our intent is the addition of intelligible models, easy to grasp by the younger generations of specialists and administrators familiar with current business language and practices.

The last decade has witnessed the development of concepts in the business and engineering world that could and should be embraced and adopted by those interested in the successful development of pediatric congenital heart programs in any area of the world, but particularly in countries with limited resources. Among the many concepts we could elicit for discussion, we have chosen to expand on three of the original ones cited by Dr. Neirotti' in his essay: Leadership; the use of data to improve results, and achieving a patient safe environment.

Inspiring Leadership: Leadership is different from -Inspiring Leadership-. Every Country, every organization, every company, has leaders. Very few of them are subjected to inspiring leadership.

In his widely viewed TED-Talk titled "How Great Leaders Inspire Action" [2], business guru Simon Sinek, describes the phenomenon by which only some companies, groups or special people achieve great things while others who could have achieved exceptional success did not. In his presentation he uses Apple, Martin Luther-King or the Wright brothers as examples.

He simplifies for us the special leadership characteristics of these companies, groups or individuals in what he denominates the "Golden Circle". Describing the mission and values of a person, group or company in three concentric circles. These circles are named from the outermost inward: What, How and Why.

While everyone involved in any collective effort (in our case, the development of a pediatric cardiac surgery center) should, hopefully, be able to describe "What they do" and "How they do it", very often we find team members unable to elaborate on "Why they do it", unless they have, or they are themselves, inspiring leaders. As an example and drawing from our own experience working to develop sustainable pediatric heart surgery centers in underserved areas of the world, we could simply answer the What question by saying we do pediatric cardiac surgery in poor countries. And we could articulate the How question by explaining that we bring teams of experts to work together with local specialists. Both answers, may be somewhat satisfying for ***What*** we do and How we do it, but these are not inspiring answers, since many people, groups, foundations do the same thing to a varying degree of success. Inspiration will only come by answering the Why question. An example of an inspiring answer to the Why question could be: We are trying to change the natural history of congenital heart disease around the world.

It is very difficult to mobilize a team working towards a common goal, if the goal itself can be simply defined by a *What* question or a How question. It would seem that the significance of the ***Why*** question is almost a constant among business and industry leaders and should be adopted by healthcare leaders as well. Among many opinions on the subject, we would like to rescue a publication by Brown et al [3]. We share their vision that "a project without a clear and compelling why can lead to wasted effort, missed project objectives (limited surgical complexity), dissatisfied clients (patients), poor business performance (high mortality and morbidity), demoralized team members and damage to the reputations of the team leader and the project."

Using data to improve results: We live in the age of information and data is just another name for it. The New York Stock Exchange generates about one terabyte of data per day, Facebook spawns about 500+terabytes per day and a Jet engine produces 10 terabytes of data every 30 minutes of flight [4].

In his essay, Dr. Neirotti reminds us of the importance of data collection and analysis. While data generated from a single open heart patient dwarfs in comparison to the above giant data producers, the value

of all the data on all the patients compiled over time into the available databases reaches size significance and unquestionable clinical value.

It is only through data collection that retrospective critical analysis is possible, therefore contributing our patient's data to a database helps the improvement of our results by providing risk-adjusted results hence facilitating the comparison of safety indices among different centers and benchmarking against international standards [5].

The reluctance of some pediatric heart centers in low and middle income countries to contribute data to international databases may be based, at least partially, on the fear that their data, and consequently their results, could be benchmarked against centers located in industrialized nations. To that purpose a number of databases provide benchmarking among centers in the developing world have been developed. The International Quality Improvement Collaborative (IQIC) for Congenital Heart Disease is based at Boston Children Hospital [6] and launched in 2008 while the World Database for Pediatric Congenital Heart Surgery (WDPCHS) was inaugurated in 2017 and it is based at University of Alabama at Birmingham [7].

At last review, membership in the WDPCHS included up to 68 hospitals in 22 countries, while membership in the IQIC Database included 64 sites in 25 countries.

Every current and future pediatric cardiac centers in LMICs should be enthusiastically encouraged to contribute their data to these registries.

Patient Safety: Twenty years have passed since the "To Err is Human"[8] report, yet the goal of absolute inpatient safety, while significantly improved, continues to be elusive in medical centers in the Western Hemisphere and it is unlikely better in countries with limited resources.

Hospitals, although hard to accept, are high risk complex organizations where inpatient safety may not always be guaranteed. In order to optimize the transformation of hospitals into a place where patients cannot be harmed, many healthcare facilities in the western world have begun an attempt to transform themselves into *"High Reliability Organizations"* (HRO) [9].

The HRO concept is one of "constant improvement and failure avoidance" and applies to industries that cannot afford unwant-

ed events. Among the many examples of industries successfully transforming into HROs the most commonly cited are the airline industry, nuclear plants, nuclear submarines, major military operations, and others.

The HRO culture is based in a number of principles [10] and while not always applicable to hospitals without a change in culture, significant portions of these principles could and should be implemented to improve on patient safety.

A central tenet of the HRO philosophy is the serious preoccupation with failure or the occurrence of unwanted events. This preoccupation should lead to a prospective search for built-in conditions within the system that unless modified will eventually lead to an unwanted event.

Another principle is the tendency to avoid over-simplification. Complex operations (flying a commercial jet, running a nuclear plant, treating a complex heart malformation, etc.) have an infinite number of details that may go wrong and if over-simplified, mistakes could be overlooked. Breaking down complex processes into simpler ones may prevent a minor mistake from becoming an irrecoverable failure.

Among the HRO thinking process there is a high sensitivity to the operations processes. Everyone involved in a process or operation must understand the principles behind and report any deviation from normal, even (especially) when no harm results from it. This is perhaps one of the most difficult principles to adapt to hospital environments (particularly heart surgery centers) where intimidation by hierarchy, seniority or rank are culturally ingrained.

Likewise, HROs have a commitment to resilience which is best summarized by Weick et al. [11] as "The hallmark of an HRO is not that it is error-free but that errors don't disable it"

Finally, High reliability Organizations carry the culture of deferring to expertise. When a problem rises, the team member with the most expertise on the subject, not necessarily the one in charge, takes over. Again, seniority and hierarchies need to become obsolete since they present a serious obstacle for implementation of this principle in cardiac surgical teams

In summary, Dr. Neirotti' essay contributed to our knowledge base a valuable roadmap that would greatly benefit those interest-

ed in developing a sustainable pediatric cardiac centers in limited resource environments. We have just emphasized some of the landmarks on that map, with the believe that will likely continue to be current for years to come.

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CARDIAC SURGERY: THE INFINITE QUEST. PART III - PEDIATRIC CARDIAC SURGERY: A DISCIPLINE ON ITS OWN

CIRURGIA CARDÍACA: A BUSCA INFINITA PARTE III - CIRURGIA CARDÍACA PEDIÁTRICA: UMA DISCIPLINA POR SI SÓ

Rodolfo A. Neirotti

O último dos três tópicos deste ensaio enfatiza as particularidades da cirurgia cardíaca pediátrica. Espero que a série de textos possa ter levado à reflexão sobre como lidamos com vários aspectos ligados à nossa especialidade e sirva de impulso para adoção de novas medidas, a fim de elevar o nível de excelência da cirurgia cardiovascular, proporcionando o bem-estar do paciente, que é nosso objetivo maior.

Domingo Braile
Editor-Chefe/RBCCV/BJCVS

Pediatric cardiac surgery

Pediatric cardiac surgery has been available for many years in several developing countries, thanks to the creative adaptation of individuals who were able to stretch the limits of their abilities in spite of the restricted resources that forced them to work harder but not allowing them to work smarter. In this context, economic constraint is a constant problem forcing those involved to focus on short-term solutions for tomorrow's needs. It was sometimes tougher to deal with the multiple stumbling blocks than with the patient condition. After all, we were trying to keep our feet on the ground and our heads in the clouds.

Leadership, patience, reflection, self-discipline, perseverance, dedication, the capacity to adapt, and the creativity that comes with

having to work under adverse circumstances were the keys to success but do not necessarily ensure sustainability[1]. Still, worldwide we have islands of excellence in an ocean where millions of people living outside North America, Australia, and Europe have limited or no access to pediatric cardiac surgery.

Making the impossible possible: The most conspicuous advantage of the human mind is its remarkable ability to simplify complex tasks, but due to the limitations of simplification it is both a strength and a weakness. The escalating costs and the lack of money required to simplify the surgical process led to implementing an ingenious multi- principle *adaptive work* —the Kiss (**K**eep **I**t **S**imple and **S**afe) approach — in order to help more patients with the available funds, equipment and manpower. However, the danger of oversimplification of the complex process of policy formulation is substantial. Solutions often reside not in the executive suite but in the collective intelligence of people at all levels, who need to use each other's resources and learn their way to those solutions[1] .

The road to successful development and change in a program depends on numerous variables that include government and hospital administration support, consistent medical staff leadership, and a medical staff that is receptive and committed to protocolizing peri-operative diagnosis and management algorithms, data acquisition, and implementation of a quality assurance program.

Abbreviations, acronyms & symbols	
CPB	Cardiopulmonary by-pass
HLHS	Hypoplastic left heart syndrome
KISS	Keep It Simple and Safe
PCCC	Pediatric Cardiac Care Consortium
RACHS	Risk Adjustment for Congenital Heart Disease
TGA	Transposition of the great arteries

International/National Cooperation: Because the world faces many formidable problems, we cannot expect to solve the mal-distribution and poor access to cardiac surgery through the regular channels for international aid. Currently, there are numerous groups

around the world involved with structured international projects with the support of non- governmental organizations together with other members of civil society, but without coordination among them. In humanitarian medicine, there is room for cooperation rather than competition, because the people in need outnumber those able to provide assistance. In those countries where mal-distribution of access is the main problem, the existing centers of excellence can contribute to the creation and support of new centers – "national twinning programs" – an alternative model to be explored.

Recipient selection: Although some of the following recommendations were included in PART I of this article, it is pertinent to reiterate them:

- To avoid squandering energy and resources it is important to identify places, "fertile sites", and their needs, with receptive individuals where good work is already being done.
- The majority of donor programs focus on developing an on-going relationship with a host program. This relationship involves visiting teams, teaching, training, collaborative research, and donation of equipment.
- Twining programs in Pediatric Cardiac Surgery. These "*twinning processes*" result in a transfer of knowledge, ideas and skills. A visiting team usually includes: surgeon, anesthesiologist, cardiologist, perfusionist, critical care specialist, interventional cardiologist, and nurses.
- Do they work? Yes, in selective places with the potential of eventually becoming autonomous, with the donor program assuming a consultant role.
- This strategy is based on a long-term educational and technical support model.
- This approach will be most effective when local governments, doctors, and hospitals have a genuine learning interest.
- It is important to using metrics and evaluations as a tool for learning and sensing the feasibility of the project.

Domestic Philanthropic Endeavors

Philanthropy in the developing countries is suboptimal and has no solid tradition. Latin America, predominantly Catholic, the world's most unequal region, is a good example of relatively modest philanthropic efforts with many opportunities for leadership.

Culture and/or interpretation of the concept of philanthropy may be responsible for weak philanthropic efforts. In the United States philanthropy is mainly the donation of money for a good cause. In other parts of the world where money is scarce, people donate their time and skills to help other persons without expecting personal benefits.

Lack of tax incentives and tax evasion also has a negative impact on philanthropy and charitable donations. Even when tax incentives are available, deductions are only possible for the minority that pays taxes. In addition, lack of trust and accountability are powerful deterrents.

However, not everybody is poor in the emerging countries. There are often people with enough education and resources to organize and participate in local philanthropic efforts, to help their own "have nots". The philanthropic leadership will come once the elites have the opportunity to cross the physical and psychological barriers that make it difficult to get to know the poor, recognizing them as fellow citizens. Philanthropy can also add to the total sum of efforts necessary to rescue the education systems.

Basic Requirements: After analyzing concepts and theories, we can now move to the practices required in our daily work such as:

- ***Institutional enabling support:*** Needless to say, this means enabling the faculty to do the work through the active participation of those on the top in addressing and resolving other limiting factors which can eventually reduce the number of binding constraints — thereby, with synergy, creating the mutual benefit of changing for the better in a partnership. High quality institutions provide the required enabling support to achieve better care in cardiac surgery.
- ***Integrated approach:*** Team work exist when all members of the cardiovascular services — a cluster of people with similar interests and focused on excellence — contribute,

although in different degrees, to the quality of the final outcome; in another words, the members of the team show the willingness to face reality and agree to do adaptive work throughout the organization.

- ***Volume for a safe and sustainable care:*** Many hospitals want to have a pediatric cardiac surgery program. It might be that this is a specialty that has to be done only in centers with enough volume[2] . A minimum of approximately 100 surgical cases per year, with the potential to increase to 300 cases per year or more over an approximate 5-year period, is needed to ensure that heart surgery is not being carried out on children where the low volume of patients or other factors makes it unsafe to perform such surgery. National standards should be developed, as a matter of priority, for all aspects of the care and treatment of children with congenital heart disease.
- ***Diagnosis and Treatment:*** 1) Pediatric cardiologists and related specialties; 2) Congenital cardiac surgery, 24/7, with 100 pediatric cardiac surgery procedures per year/surgeon as a minimum; 3) Congenital cardiac anesthesia 24/7; 4) Nursing (24/7; 4) Interventional cardiology 24/7; 6) Other allied health services such as perfusion, social work, pharmacy, blood bank 24/7.
- ***Pediatric Intensive Care:*** Preoperative evaluation and optimization of patient condition; postoperative care 24/7.
- ***Follow-up and application of methods for meaningful comparisons of in-hospital mortality for groups of children undergoing surgery for congenital heart disease:*** such as the Risk Adjustment for Congenital Heart Surgery (RACHS-1) methodology or the Aristotle Basic Complexity Score (ABC Score) and Aristotle Basic Complexity Levels (ABC Levels).
- ***Utilization of the clinical material:*** for contributions to professional society's national and international journals. Make the best and most effective use of their organization's resources.
- ***Open mindedness:*** Institutional sclerosis is a major obstacle to progress. In those institutions with rigid structures, all of

their tenured staff should cooperate, be prepare to compromise and agree to work toward these basic requirements, using the method of self criticism and rectification to address not only technical issues but also dysfunctional behaviors. Human factors — especially those affecting interpersonal relationships, interactions and collaboration — are frequent causes of lasting problems[3] . *"Minds are like parachutes. They only function when they are open." Sir James Dewar*

Rethinking the Adult and Pediatric Cardiac Surgery under one roof

An outdated model at a crossroad: Up to the late seventies, most of the new developments in cardiac surgery were coming out of centers doing both adult and pediatric work. By 1975, ten percent of the patients coming to operation were within the first 6 months of life and 19% were within the first 12 months of life. Currently, around 60% of the patients are operated on their first year of life, and 30 % in the first month of life[4]. This trend — the movement of pediatric cardiac surgery to the very young — has developed because of the numerous biological and socio-economic benefits of early repairs, as well as the excellent outcomes that are being obtained particularly in pediatric cardiac surgery centers as a result of an ongoing generation of knowledge.

"In some specialties, such as pediatric cardiac surgery, clinical practice has become so sophisticated and the technology has become so advanced that those patients who would otherwise have died only 10 years ago can now be safely treated with confidence"[5]. In addition, hospital admissions for adults with congenital heart disease are increasing at a higher rate than for children, supporting the need for optimizing health delivery for adults, as the drift in increased hospitalization is expected to persist into the near future. We need to flex new muscles as the demands of the business environment are changing.

One size does not fit all: In the current era, it is an artificial construct cemented together by an elite that ignores the increasing trend for sub-specialization in both fields and the challenges around the safety and sustainability of these services in the future. Rather

than artificially repressing them, those institutions in which pediatric cardiac surgery is combined with the adults program need to understand the differences in the business plan, paths, manpower, mindset, training, and infrastructure of both disciplines.

It is possible to modernize the structural needs of outdated institutions by applying the concept of *spatial thinking*, a cognitive skill that can help in understanding the world around us by using the properties of space in everyday life, the workplace, and science, to structure problems, find answers, and express solutions. In a case of co-habitation, it is helpful for *analytic* purposes, to develop a modern *vision* based in a constructive co-existence — to exist in peace with others at the same time or in the same place despite differences preserving the necessary connectivity to solve common problems.[1]

Furthermore, spatial thinking is also a *tool* to consider for designing a structure with core groups of dedicated specialists — human capital — covering critical areas in which different practices and protocols are required, such as surgery, anesthesia, intensive care, and perfusion.

While preserving their identity, this approach can improve the quality and the efficiency of the services by finding paths to allow synergies among all disciplines involved, thus avoiding a "perfect storm", an event where a rare combination of circumstances will aggravate a situation drastically. Such a significant change can only succeed with a strong bottom up leadership, involvement, and cooperation. Open governance should facilitate the integration. Closed means a small non- responsive and non-expandable number of decision makers.

The context should determine the strategies and processes to address these issues, and what parts of the professionals, administration, and professional societies should be engaged in planning, setting and articulating the goals and participating in the negotiations.

As Charlene Barshefsky, Great Negotiator Award Winner, reminds us: *"The goal tells you what you need to know. It informs who should be at the table, and which parties are extraneous…. If the goal is framed too broadly, the results are likely to be ambiguous and unenforceable."*

1. Karen Lee Bar-Sinai, *"The role of architects in negotiations"* Harvard School of Education. Cambridge, November 20, 2012.

In other words, critical thinking is fundamental to understand the limitations of the current model and to address creatively and effectively the needs of the users with a long term objective. Then there should be a path to execute and reach that objective that can be frequently evaluated and adjusted accordingly.

Compromise can minimize the resistance that might be encountered in implementing the recommended strategies, and help to reach an agreement with a smooth transition, allowing differentiation with advantages for the various components of the system. Work groups ought to consider what should be the design of each program and how this should be enacted all at once, phased-in, etc. The majority adult cardiac surgeons (number of cases) need to learn how to make their minority pediatric colleagues feel that they are a pillar of the governing structure. Minority pediatric surgeons must embrace their place in the new structure by becoming fully contributing partners while leaving behind any ill sentiments.

Because things always change it is important to take measurements to know what the differences are.

"This institutional decision needs to be made in a framework of deep reflection, commitment to the well-being of each individual patient and requires considerable study and integrity"[4].

Neonatal Surgery: an example of complexity

The frequent advances in the diagnosis and treatment of congenital heart disease during the last two decades have changed the way these patients are currently managed. Neonatal heart surgery aims at the prompt anatomical and physiological restoration of the anatomy and physiology, or seeks the best feasible palliation, in order to improve functional capacity and life expectancy. In this particular field, the progress in multiple medical and technological areas allows successful early surgical approach to complex pathologies that carried a devastating mortality not long ago. In order to obtain the best possible results and minimize the multiple risks involved in this practice, various considerations have to be taken into account. These are related to the institution where the surgery takes

place, the human resources available, and the particular characteristics of the new born patient that presents distinctive critical issues that deserve a few words of caution, including:

- Preoperative circumstances requiring a preoperative management according to the anatomic and physiological variants.
- Limited physiologic reserve — organ immaturity — lungs, liver, kidneys.
- Transient organ dysfunction: cardiac, respiratory, renal.
- Known complications and/or consequences related to cardiopulmonary by-pass (CPB) that is unique because of immaturity.
- Diverse and complex physiopathology of the cardiac lesions.
- Prematurity and low birth weight (2.5 kg or less).
- Complex surgical procedures and risks of residual problems. For example, poor cerebral protection can have catastrophic consequences for the patient, the family and the society, such as poor outcomes in learning, behavior, and both physical and mental health. As Shonkoff has made clear, "Every second, a baby's brain makes 700 new synapses. These connections can be strong or faulty and once made, they cannot be rewired. Early events shape the architecture of the developing brain"[6].

In spite of these particular handicaps an early approach to the initial phase of repair should be attempted whenever possible, since leaving these patients untreated or unnecessarily delaying surgery, contributes to high mortality. To mention only two important neonatal heart problems, for both transposition of the great arteries (TGA) and hypoplastic left heart syndrome (HLHS), a surgical repair performed in the first days after birth has dramatically modified the natural history of these malformations. This progress is well explained in Brooks' definition of path dependence which refers to the notion that often "something that seems normal or inevitable today began with a choice that made sense at a particular time in the past, but survived despite the eclipse of the justification for that choice"[7]. The operative mortality of HLHS was as high as 40% in the 1990s and has dropped to less than 10% recently[8].

Although the accuracy and quality of the surgical procedure are the most important determinants of survival after surgery for neonates and infants, in addition to early diagnosis, capabilities for transportation and pre-operative resuscitation, require expensive sophisticated support, expertise, manpower, and advanced technology. Given that this cohort of patients has a limited physiologic reserve, complex cardiac lesions that often require technically demanding procedures, and are prone to complications and/or residual related to cardiopulmonary bypass, they are an example in which complexity demands complexity. In all fields there is a residue of anomalies unexplained by the dominant theory. Unsolved observable facts do not necessarily nullify good theories. It just means that more work needs to be done to bring those anomalies into the accepted paradigm.

Neonates face unique incremental risk factors related to the patient's variables and to structural hospital characteristics that should be properly individualized and addressed in a timely fashion in order to improve surgical results. The development of a successful neonatal heart surgery program requires institutional quality, medical expertise and resources an integrated approach – in which every component of this complex system (individuals, activities, connections, and pathways) should be activated. In other words, a meaningful institutional commitment and staff partnership is necessary to meet the current demand for excellence.

Because individual medical leadership and skills are not enough to solve these problems – a puzzle with multiple challenges – neonatal cardiac surgery will linger last in most developing countries. Well-trained and skillful surgeons, while being able to generate excellent results in children, have difficulties reproducing the same kind of outcomes with neonates and infants. I am mindful of the danger of being unjust to people who make choices in conditions of uncertainty and circumstances over which they often had little control. It will require efforts at multi-levels of national governments – leaders with a passion for reducing suffering, capable of changing minds and mental models – and civil society to face reality, adjust values and priorities causing social exclusion, and the need to overhaul the health care system. Institutionalizing change is not an easy task but it is probably the road to sustainability[1].

Ethics, experience, decision making for children, and risks

Recognition of institutional and individual limitations is imperative for ethical pediatric cardiac care. "When confronted with an ethical dilemma, most of us like to think we would stand up for our principles. But we are not as ethical as we think we are. We overestimate our ability to do what is right and how we act unethically without meaning to. We can become more ethical by bridging the gap between who we are and who we want to be"[9] [10].

Experience matters: The more experience physicians and teams have in treating patients with a particular disease or condition, the more likely they are to create better outcomes – and ultimately realize lower cost. By performing particular procedures over and over, teams increase their learning opportunities and thereby reduce mortality rates. Having to think about everything each time leads to imperfect performances. Although procedure volume is relevant, other institutional factors can also contribute to the quality of outcomes. Recognition of institutional limitations is imperative for ethical patient care[11].

Decision making for children: At the beginning and at the end of life, children and elders are not part of the decision- making process regarding procedures, risks, or by whom, and where the care should take place. Therefore, adults, parents, and doctors making decisions for them should be aware of their responsibility by including in their considerations the information available regarding risks, prognosis, suffering, quantitative improvement, and long term quality of life.

Talking about medical risks, the uncomfortable truths: What duties and responsibilities arise with regard to the physician-patient/parents relationship? Should patients and parents be told of better care elsewhere?[11]. Notwithstanding that some people prefer to be treated close to home even if the risks are higher there, patients are not often told during the informed-consent process that the results of treatment can vary among hospitals and the volume-outcome relationships, particularly for those requiring complex risky procedures. Often, patients and families get some numbers from the literature, but very few physicians sit down and tell them what their own complications and success rates are. The question of what the doctor's obligation is remains unresolved.

Statistical evaluation and comparison of results:

"No human investigation can claim to be scientific if it doesn't pass the test of mathematical proof"

Leonardo Da Vinci

Repair of congenital heart anomalies involves an enormous anatomic variety and offers a diversity of surgical procedures of different complexity that makes a comparative analysis of mortality and quality of results very difficult, even within the same center or among different centers or regions. Often, comparison it is not about how bad you are, but rather about how good others are. Meaningful quality of care evaluation needs to take into consideration the variations of the population the so called "case mix". This concept is less important in the adult population due to significant differences in the size of the samples and the diversity of operations[12]. The statistical analysis of crude mortality without taking into consideration case mix complexity is inadequate for comparison and erroneous in itself. Neonatal evaluation carries an additional challenge due to the small numbers and the larger diversity of the procedures.

In January 2002, Jenkins & Gauvreau[13] reported a new and original consensus-based method called RACHS-1 (Risk Adjustment for Congenital Heart Disease) which permits a meaningful and adjusted comparison of mortality in children undergoing surgery for congenital heart disease. Two years later, Lacour-Gayet et al.[14] reported another method called "The Aristotle Score": a complexity-adjusted method to evaluate surgical results.

Risk Adjustment for Congenital Heart Disease (RACHS-1): This method was developed to adjust for baseline case mix differences in comparisons to discharge mortality among pediatric patients less than 18 years old. The surgical procedures were classified by a panel of 11 experts (pediatric cardiologists and cardiovascular surgeons) into six categories, 1 being the lowest and 6 the highest risk of expected

in-hospital mortality, based on information obtained from the Pediatric Cardiac Care Consortium (PCCC) with 4,370 surgical procedures done in 32 hospitals and the American Hospital Discharge data.

This classification is based on the type of surgery rather than on the anatomical diagnosis; for example, in the sequential surgical approach of the HLHS, the first surgical intervention (Norwood procedure) has a risk 6; the second step, the connection of the superior vena cava to the pulmonary artery (bidirectional Glenn) carries a risk 2, and the final surgical intervention (total cavo-pulmonary connection) a risk 3.

This system, used to predict mortality and risk adjustment in pediatric cardiovascular surgery constitutes a valid tool to compare the results between different health centers and has been statistically validated worldwide by several authors[15] [18]. There is a vast literature referring to the benefits and limitations of both methods, which are at present being used in many institutions all over the world. Moreover, there are currently studies in progress to improve them, adding new elements such as standardization of morbidity measurements and a new development of complexity stratification system based on objective data (the sum of mortality, and morbidity) and subjective technical difficulty[19] [21]. Understandable data and analytic leaders individuals who are at ease with numbers and able to explore solutions based on a rational analysis of complex issues are needed.

Risk stratification for adult congenital heart surgery: This is a large and growing group of patients that require different business models, mindsets, and pathways than the one in use for the pediatric population. Currently no risk stratification score is available for adult congenital cardiac surgery. The discriminatory power of the pediatric risk scores are suboptimal for the adult population, but improve when adding age as a score component. A best performance can be achieved by the combination of age and the Comprehensive Aristotle Score, for both 30-day and 1-year mortality. Proper risk stratification scores for this cohort of patients will be useful to decide who should treat them and where[22] [23].

Leadership and culture

Leaders are individuals who significantly affect others, transforming the way the individuals with whom they come in contact think and go about doing things. They lead by their example; therefore, it is important to recognize that no matter how good you are, you are only as good as the people who are working for you and how good you are developing them. If leaders tell one story but lead contradictory lives, they are hypocrites. A leader is best when people barely know he exists. He is not so good when people obey and acclaim him. But he is worst when they despise him. But of a good leader who talks little, when his work is done and his aim fulfilled, they will say: "We did it ourselves." (*Lao-tzu, 6th Century B.C., Chinese Philosopher*)

It is important to understand medicine, health care, illness and disease from a socio-cultural perspective. What is medically obvious in one culture might be incomprehensible in another. What is possible in a rich country might be almost impossible in the developing world regardless of authority, leadership and technical competence.

Having worked in South America, Europe, and most recently in the United States, I have found that the differences in culture, resources and technology have had a significant impact in my practice and interactions with colleagues, patients and the public. In complex cross-boundary interactions, it is difficult to assess risks and make decisions requiring the calculation of the probability of outcomes and the prediction of people's behavior. It is difficult to judge anything at all without walking a few miles in the other person's boots.

My leadership challenges in my home country and abroad where I always tried to lead from the middle resulted in a mix of successes and failures. Like everybody else, I have made my share of mistakes, related at time to insufficient resources, my personality, my emotional intelligence, the feasibility of the task, the limitations in my authority and sometimes not enough knowledge of the local cultural narrative. Effective leadership from the middle is possible but can be extremely difficult and even impossible when

those holding the platforms of power at the top are not receptive. This means that a good leader in the right place at the right time still might not necessarily save the day.

Politics is about leadership and the ability to get things done. Actions in addition to words! The elasticity of reality describes the relative size of the principle/rhetorical- implementation/reality gap, resulting in poor implementation of good ideas a concern about the growing skepticism of future rhetoric. Yet as the gap between reality and rhetoric expands, the risk increases that the public will grow skeptical of future oratory.

Challenges facing cardiac surgeons and the science of cardiac surgery

"Together, as it was the case in the recent past during which enormous progress was made — the list of achievements is long — we need to bring our specialty into a brighter future, it must be something we cannot possibly do!"[24]. We have been able to see so far because we stood on the shoulder of giants. Therefore, we need to nurture our youth in order to give rise to a new generations of giants that will prolong the path to success. Their tools being commitment, technology, creativity, and learning how to learn by cultivating their ability to ask questions that include cause and effect, the cornerstone of critical thinking. In addition, collaboration with other sciences by breaking down the boundaries around academic disciplines, and by strengthening the capacity to adapt, can play a role in finding answers for a future that seems to have no limits. In other words, we must continue to be a resilient system in the face of the inevitable new stumbling blocks — problems or difficulties that stop one from achieving something. However, the history of complexity research indicates that our can-do optimism should always be tempered by caution[25].

Inferences

- Talking directly about problems is risky because most people do not like it.

- Enumerating the problems may be easy, finding the solution is proving increasingly difficult in settings without political stability and sustainable economic growth.
- We do not have yet the clout due to lack of cohesion to advocate successfully for our "orphan" pediatric cardiovascular services particularly in the developing world.
- It is important to determine what should be preserved, what needs improvement, how it can be done, by whom, and what we must transform[26].
- Those institutions in which pediatric cardiac surgery is combined with the adult program need to understand the differences in the business plan, paths, manpower, mindset, training, and infrastructure of both disciplines. Each group's bosses should have a clear understanding of what they want from the alliance before signing up. Most important is gaining support at all levels of each discipline for working together.
- We need to improve the quality of the decisions we make. How we decide often determines what we decide.[2] Ask yourselves, what strategies and processes would you advise to overcome these problems, and what parts of society and other professionals would you want to engage to aid the process? What problems do you expect might be encountered in implementing the recommended strategies?[27].
- Centers of development with the necessary funds and manpower for research to generate new knowledge, particularly in the field of rare diseases, and adults with congenital heart diseases, may be needed for a more efficient treatment, cost benefit ratio, and sustainability of the care. These centers can then disseminate the new knowledge, minimizing or even eliminating the learning curve and develop policies for the future of the specialty[28].
- These centers, can improve their analytic capabilities through adding estimative intelligence to gauge uncertainty and make assumptions about different scenarios, to anticipate the consequences and probabilities[29].

2. Iris Bohnet. Institute of Politics. Harvard Kennedy School.

Final thoughts

Some readers may consider this paper "philosophical". If we accept that philosophy — the base of critical thinking is "*The critical analysis of fundamental assumptions or beliefs*"; "*A set of ideas or beliefs relating to a particular field or activity*" or "*A system of values by which one lives*", it could be rightly regarded as philosophical. However, I thought that the title of "Philosophy of Cardiac Surgery" may not sound attractive to the surgeons' mindset[30].

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Comments by: James S. Tweddell, MD.
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In a series of special articles, Dr. Rodolfo A. Neirotti identifies the characteristics, the promise and goals of congenital heart surgery [1-3]. In the third of his series of special articles on pediatric cardiac surgery, Dr. Neirotti summarizes the challenges of pediatric cardiac surgery in developing countries.

Congenital heart surgery in limited resources environments will require visionary, fostered and encouraged with a leadership/administrative culture that recognizes the importance and potential of congenital heart surgery to both save lives and prevent suffering.

Even in the developed world there are challenges with allocation of healthcare resources and socioeconomic disparity and Dr. Neirotti is realistic in recognizing that allocation of healthcare

resources is an even greater challenge in the developing world. These resources are precious and decisions need to be made to distribute the resources so they can achieve the greatest overall good. Success will require the judgement to select patients that can be managed within the available resources in order to maximum success, achieve the best outcome for the most patients at the lowest cost and create a track record of success.

Resources for pediatric cardiac surgery in the developed world might reasonably include typical support through whatever payer or governmental support mechanisms are already in place but also domestic philanthropic support and international cooperation. Dr. Neirotti outlines the challenges of philanthropic efforts in the developing world where income is low. It is difficult to develop a culture of giving when those in need far outweigh those with means. He further outlines the challenges of congenital heart surgeons working either within programs with adult cardiac surgeons or having to compete with adult cardiac surgery for limited resources. While international cooperation is clearly beneficial, these efforts are most effective if they are coordinated and sustained. There is a role for coordinating these international efforts to provide sustained support and education to all providers in the program.

Ultimately, each country will need to identify that level of congenital heart surgery they can provide. While it might be appropriate to provide certain simple, neonatal procedures such as coarctation repair, aortic and pulmonary valvotomy etc., that relieve suffering and provide excellent long term outcome, complex neonatal cardiac surgery requires specially trained surgeons and additional highly qualified specialists and this will only fit into the budget of the wealthier countries. Neonatal cardiac surgery will be the last to develop in emerging countries.

In order to ensure the best outcomes and quality there is an ongoing need for both education and outcomes assessment. In the last year, during the COVID-19 pandemic, global travel including teams of pediatric cardiac teams visiting developing countries has been severely curtailed. Nevertheless, despite the inability

to interact face-to-face we have seen incredible growth in virtual meetings, and conferences. This may be the silver lining of the pandemic and provide a way to support pediatric cardiac surgery in developing countries in a more sustained and less expansive ways. In addition to being an opportunity for low-cost educational exchange, virtual conferences could provide more regular interaction. We might envision regular joint patient care conferences between programs rather than only an annual on-site visit of a week or two. Ultimately we might see remote viewing and interaction in the operating room. Another opportunity in our new, electronically smaller world is the opportunity for programs from developing countries to track their outcomes in a global database. The recent development of the World Database, sponsored by the World Society of Pediatric and Congenital Heart Surgery provides a low cost option for programs wishing to track their outcomes, especially benchmark operations [4].

Ultimately the goal of the achieving the best outcome for patients with congenital heart disease across the globe will depend on the willingness of governments and physician leaders to work together with the best aims of the patients and families in mind while balancing the overall health care needs and the resources necessary for a congenital heart surgery.

Dr. Neirotti has worked as a pediatric cardiac surgeon in South America, Europe and the North America in both the wealthiest countries and economically challenged countries. He is a student of both congenital heart disease public health. He has a remarkable perspective on this challenging problem. I would recommend these series of special articles and in particular the final one Cardiac surgery: the infinite quest. Part III--pediatric cardiac surgery: a discipline on its own as it provides an outstanding framework of the challenges and potential solutions to extending pediatric cardiac surgery to the developing world [3].

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NEW TECHNOLOGY: VALVE REPAIR USING BIODEGRADABLE RINGS
NOVA TECNOLOGIA: VALVULOPLASTIAS COM ANÉIS BIODEGRADÁVEIS

Rodolfo Neirotti
Mustafa Cikirikcioglu
Alberto Della Martina
Philippe Le Goff
Afksendiyos Kalangos

Abstract

Objective: To introduce a new concept in the annuloplasty technology. Although rigid and flexible rings meet the basic needs of adults, they do not preserve the changes in shape and size occurring during the cardiac cycle. If implanted in children, such materials do not allow growth of the native annulus.

Methods: From March 2003 to March 2007, 207 patients underwent mitral and/or tricuspid valve repair implanting polidioxanone biodegradable rings - Bioring®. Patients were divided into two groups: Group 1, Adults: n=121. Mean age: 48 years (+- 19.2). Oldest 85 years. Group 2, Pediatric: n=86. Mean age: 9.6 years (+- 4.4). Youngest 0.5 years.

Results: Group 1, Hospital mortality: 3.3%. Mean follow- up: 26.4 months ± 15.4. Four patients underwent mitral valve replacement 1, 2, 2 and 4 months post repair. Group 2, Hospital mortality: 1.2%. Mean follow-up: 26.7 months±13.4. Seven mitral reoperations within 1 to 24 months, 2 for valve re-repair, 5 for valve replacement.

Conclusions: Biodegradable rings remodel the shape, reinforce the repair, restore the function of the atrioventricular valves and maintain the three dimensional dynamic motion and geometry of the mitral and tricuspid valves annulus. Growth potential is preserved in children. Although the biodegradable annuloplasty ring was first designed and developed for a pediatric population, it is currently applied to adult cases. Children with single ventricle and

AV valve incompetence are an additional indication. The mid-term results showed that degradation of the device occurred without negative observable consequences. Long-term results should confirm these findings.

Descriptors: Heart valves. Absorbable implants. Heart valve prosthesis Mitral valve/surgery. Tricuspid valve/ surgery.

Resumo

Objetivo: Introduzir um novo conceito na tecnologia de anuloplastia. Embora anéis rígidos e flexíveis cumpram com as necessidades básicas em adultos, não preservam mudanças na forma e no tamanho ocorridos durante o ciclo cardíaco. Se implantado em crianças, eles não permitem o crescimento do anel nativo.

Métodos: De março de 2003 a março de 2007, 207 pacientes submeteram-se ao reparo da valva mitral e/ou tricúspide implantando anéis biodegradáveis de polidioxanona Bioring®. Pacientes foram separados em dois grupos: Grupo 1, Adultos n=121. Idade média: 48 anos ($\pm$ 19,2). Mais velho 85 anos. Grupo 2, Pediátrico: n=86. Idade média: 9,6 anos ($\pm$ 4,4). Mais novo 0,5 anos.

Resultados: Grupo 1 - mortalidade hospitalar: 3,3%; seguimento médio: 26,4 meses $\pm$ 15,4. Quatro pacientes submetidos à substituição da valva mitral 1,2,2 e 4 meses pós- reparo. Grupo 2 - mortalidade hospitalar: 1,2%; seguimento médio: 26,7 meses, $\pm$ 13,4. Sete reoperações mitrais entre 1 a 24 meses, duas para novo reparo da válvula, cinco para substituição valvar.

Conclusões: Anéis biodegradáveis remodelam a forma, reforçam o reparo, devolvem a função das valvas átrio-ventriculares, mantendo a dinâmica tridimensional e geometria dos anéis valvares mitrais e tricuspídeos. Além disso, estes anéis preservam o crescimento potencial em crianças. Embora o anel de anuloplastia biodegradável tenha sido inicialmente desenvolvido para população pediátrica, é atualmente aplicado em adultos. Crianças com ventrículo- único e incompetências valvares A-V são indicações adicionais. Resultados a médio prazo mostraram que a degradação

do produto ocorreu sem consequências negativas observáveis. Resultados a longo termo deverão comprovar estes achados.

Descritores: Valvas cardíacas. Implantes absorvíveis. Próteses valvulares cardíacas. Valva mitral/cirurgia. Valva tricúspide/cirurgia.

Introduction

Biotechnology has made significant contributions to medicine and surgery in general and to cardiac surgery in particular. To develop the biodegradable rings, it was necessary to adjust the degradation time by hydrolysis of polydioxanone, a biocompatible polymer. Polydioxanone, like many biodegradable polymers, is a polyester. Ester is a bond with polar nature-less stable-hence more reactive that can be broken down by hydrolysis. Hydrolysis of the ester bond results in formation of an alcohol and an acid, (2-Hydroxyethoxy) acetic acid[1]. The latter, triggers an inflammation inducing the formation of fibrous tissue[2] [3].

The use of biodegradable rings is a new concept in the evolving annuloplasty technology- from the rigid ring to the biodegradable one. While rigid and flexible rings meet the needs of adults, they do not allow growth of the native annulus in children. Biodegradable rings induce fibrous tissue with structural function which preserves the growth potential of the annulus in the pediatric population maintaining the three- dimensional dynamic geometry of the mitral and tricuspid valves. The mitral orifice undergoes striking changes in its size and shape during different parts of the cardiac cycle[4]. The annulus changes its shape both in the horizontal plane and in the vertical plane, where it changes from a saddle shape to a more flat structure[5]. Preserving them can improve the result and durability of the repair[4].

Although the biodegradable annuloplasty ring was first designed and developed for a pediatric population, it is currently applied to adult cases as well.

Methods

From March 2003 to March 2007, 207 patients underwent mitral and/or tricuspid valve repair implanting 222 biodegradable rings (Kalangos' ring, Bioring®, Lonay. Switzerland). Patients were divided in two groups: Group 1, (Adults, n=121). Mean age: 48 years (± 19.2). Oldest 85 years. Group 2, (Pediatric, ≤ 16, n=86). Mean age: 9.6 years (± 4.4). Youngest 0.5 years (Table 1). The preoperative functional status for the adult and pediatric population is disclosed in Figures 1A and 1B, respectively. The etiology of the mitral valve pathology in the adult and the pediatric population is shown on Figures 2A and 2B.

Group	Patients n=207	Mean age	Mitral	Tricuspid	Both
I Adults II Pediatric	121	48 years (+19.2) Oldest: 85 years	91	19	11
II Pediatric	86	9.6 years (+ 4.4) Youngest: 5 months	57	23	6

Table 1. Distribution of the atrioventricular valves requiring repair

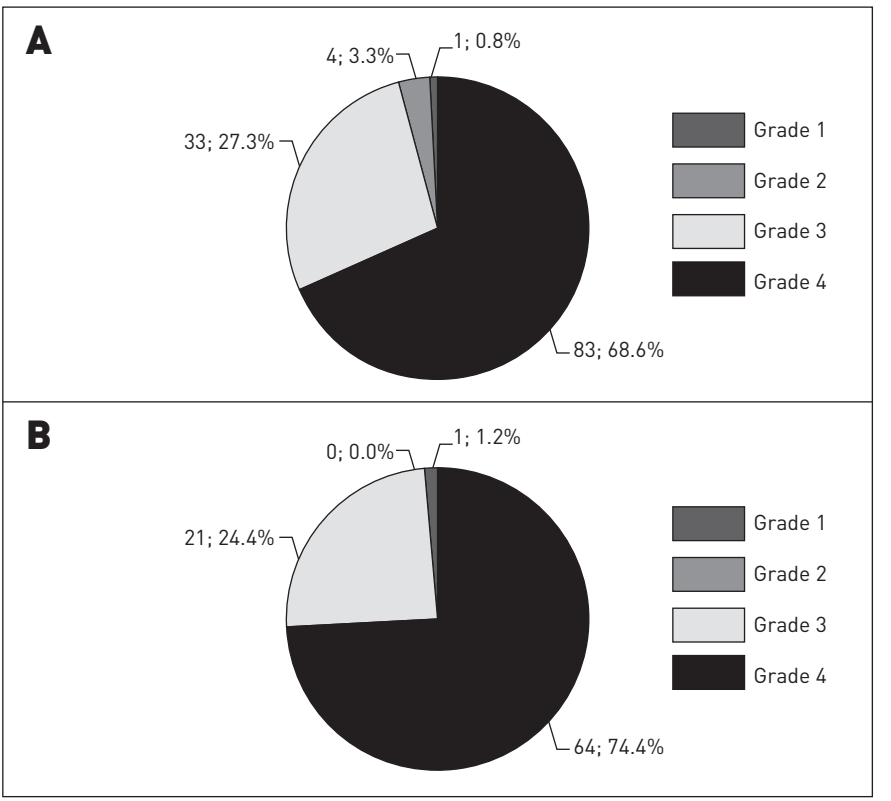

Fig. 1. A) Chart showing the preoperative the New York Heart Association functional class (NYHA) of the Adult population. B) Table showing the preoperative New York Heart Association functional class (NYHA) of the pediatric population

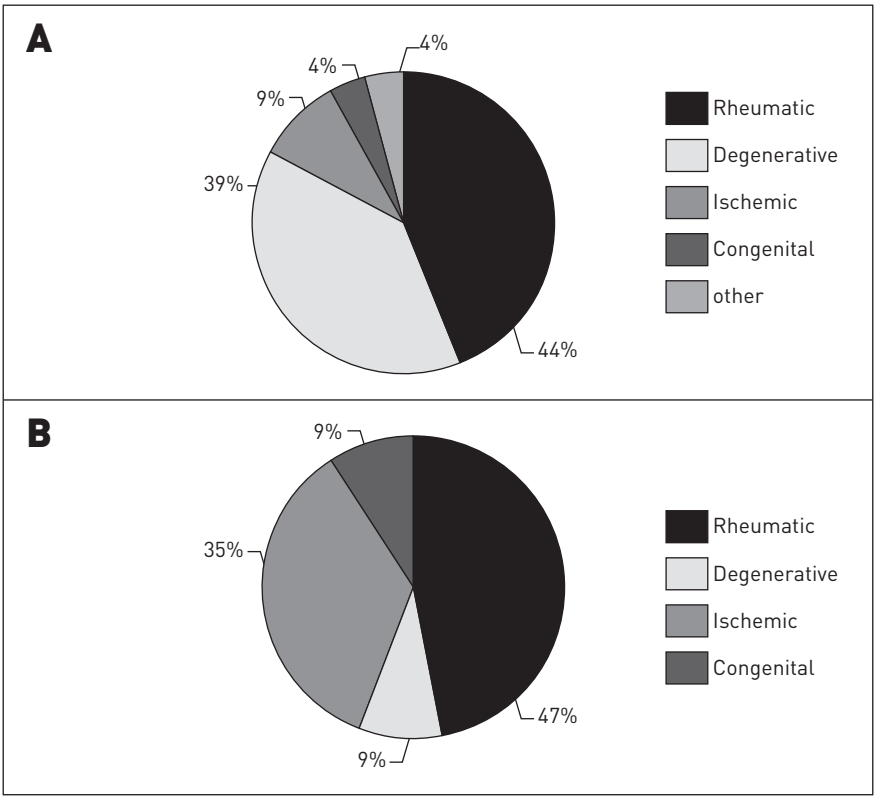

Fig. 2. A) Chart disclosing the mitral valve pathologies in the adult population. B) Table showing the mitral valve pathologies in the pediatric population

In both groups, the repair was evaluated in surgery by trans-esophageal echocardiography and after discharge by trans-thoracic echocardiography.

The mitral and tricuspid models include a re-absorbable polymeric 'C'curved segment of a poly-1, 4-dioxanone polymer, prolonged by a 2/0 monofilament polyvinylidene fluoride (PVDF) suture-in continuity over the entire biodegradable ring- with a swaged stainless steel needle in each end. The specific molecular weight of the ring provides a structural memory that protects it from subsequent deformity.

Operative technique for the mitral implantation (Figure 3)

The anterior leaflet of the mitral valve was unfurled and the ring was chosen according to the sizer that matched the leaflet's surface area.

The sub-endocardial insertion started at the level of the posterior commissure, 2 mm away from the hinge point and 3 mm in depth, *taking always the same exit point* to move forward around the posterior annulus.

The implantation was completed by fixation of the extremities to the anterior and posterior trigones, respectively. Altogether, the time of implantation and ischemia was significantly shorter than with the traditional rings. This was particularly important in complex valve repairs or in concomitant procedures.

Alternative technique: the suture extensions were tied in the middle of the anterior annulus when this segment is dilated in: Ischemic mitral insufficiency; Barlow disease (5%); Idiopathic cardiomyopathy.

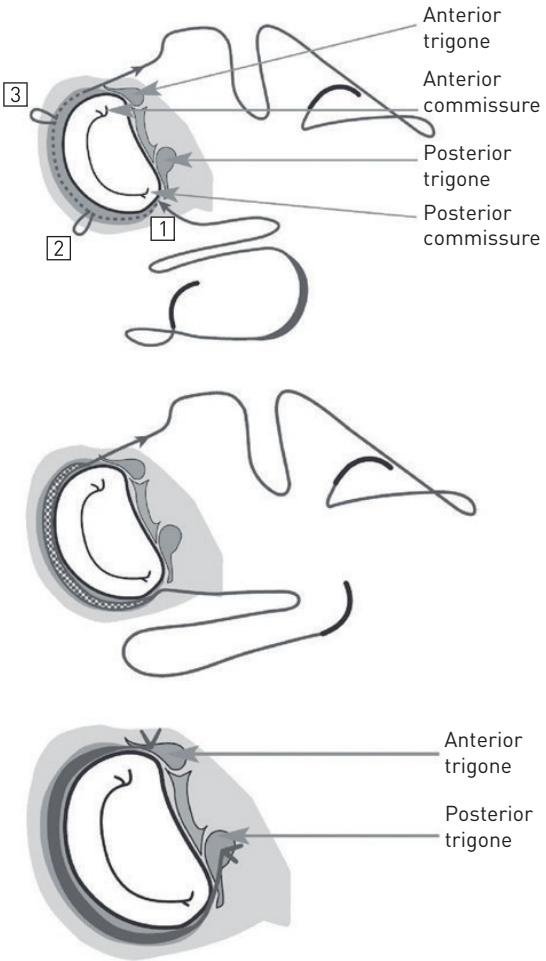

Fig. 3. Showing of technique for mitral annuloplasty with subendocardial insertion of a mitral biodegradable ring

Operative Technique for the Tricuspid Implantation (Figure 4)

- The anterior leaflet of the tricuspid valve was sized to select the appropriate ring;
- With the heart beating, the sub-endocardial insertion
- started at the level of the postero-septal commissure, with the shortest end of the ring, 2 mm away from the hinge point

and 3 mm in depth, *taking always the same exit point* to move forward around the anterior annulus;

- The implantation was completed by fixation of the anterior and the posterior extremities, respectively;
- Careful attention was paid to rhythm changes due to
- the vicinity of the sinus node to the posterior fixation point.

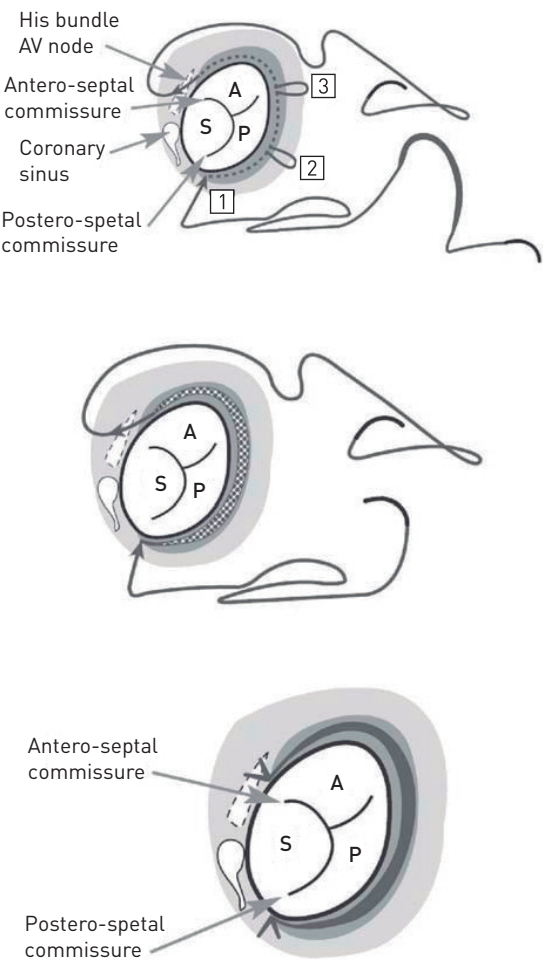

Fig. 4. Surgical technique for tricuspid annuloplasty with subendocardial insertion of a tricuspid biodegradable ring

Results

Group 1 (Adults n= 121)

Hospital mortality (four patients) was 3.3%. Mean follow- up was 26.4 months ± 15.4. The surgical techniques for both valves were: annuloplasty + repair in113; ring alone in

18. Concomitant procedures: five patients had an aortic valve replacement and 17 a Maze operation. Intra-operative trans-esophageal echocardiography showed no regurgitation in 71 patients, trivial incompetence in 37 and mild regurgitation in 13. The mean mitral gradient was 2.9 ±

3.1 mmHg. Re-operations: four patients underwent mitral valve replacement 1, 2, 2 and 4 months post repair. There was one late death, 2 months after operation, due to gastrointestinal bleeding (Figure 5A).

Group 2 (Pediatric n= 86)

Hospital mortality (one patient) was 1.2%. Mean follow- up was 26.7 months±13.4. The surgical techniques for both valves were: Annuloplasty + repair 77 cases; ring alone in nine patients. Concomitant procedures: aortic valve repair (n=5); repair of congenital cardiac anomalies (n=15). Intra- operative trans-esophageal echocardiography showed no regurgitation in 47 cases; there was trivial incompetence in 24 patients and mild reflux in 15. The mean mitral gradient was 2.7 ± 2.7 mmHg. Seven patients required re-operation within 1 to 24 months, two for mitral valve re-repair and five for mitral valve replacement (Figure 5B).

In both groups, the incidence of rheumatic valve disease was higher than expected due to the inclusion of patients referred from developing countries.

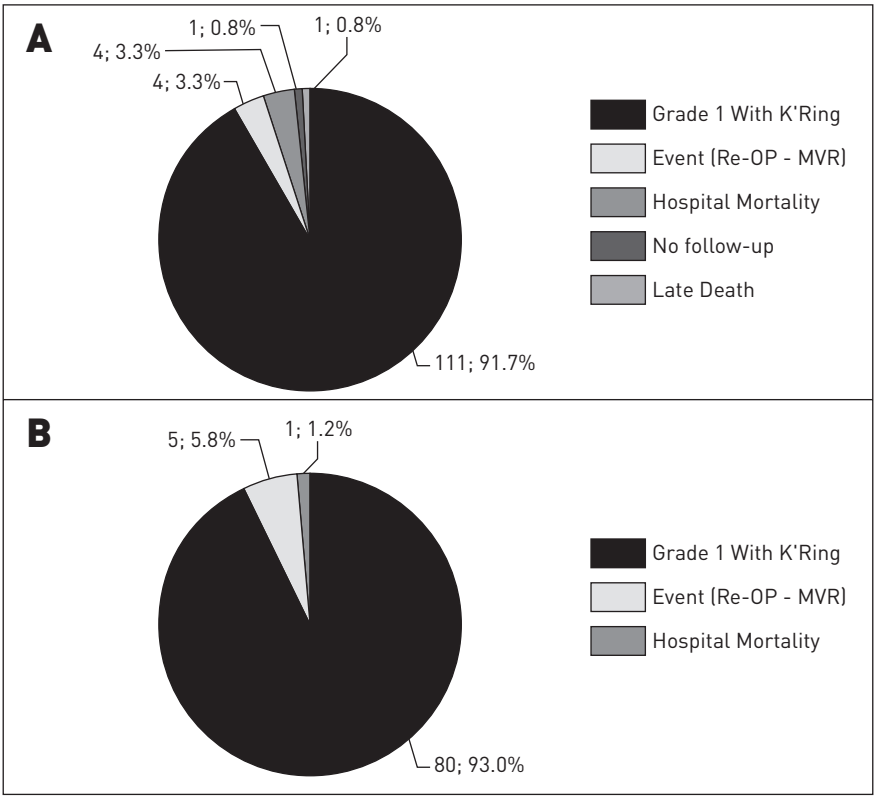

Fig 5. A) Showing of postoperative outcomes in the adult group. K'Ring : Kalangos' ring; Re-op: reoperations; MVR: mitral valve replacement. There was one late death, 2 months after surgery, due to gastrointestinal bleeding. B) Showing of the postoperative outcomes in the pediatric population. K'Ring: Kalangos' ring. Re- op: reoperations; MVR: mitral valve replacement. Among the 7 patients that required reoperations, 2 continue with a ring. MVR: mitral valve replacement

Discussion

The good functioning of the native or repaired heart valve depends on the coaptation capacity of its leaflets. Annuloplasty rings are artificial prosthesis sutured to the native mitral or tricuspid valve annulus that have been used since 1968, to remodel the shape, correct the dilatation and consolidate the repair of the valve and improve coaptation of the valves leaflets during systole[6]. In systole, in the normal mitral valve, the transverse diameter is longer than the anteroposterior diameter. When the annulus is dilated, the transverse diameter is shorter than the anteroposterior diameter.

The dilatation affects mainly both commissures and the posterior segment. The use of incomplete 'C'-curved rings to remodel the dilated segment is based on this concept.

A better understanding of the three-dimensional geometry and the dynamic of the native valve annulus during the normal cardiac cycle lead to the evolution of the rings from the first rigid planar stainless steel-based Carpentier's ring to the flexible Duran ring and to the more recent Cosgrove-Edwards bands. While these conventional devices respond to the needs of the adult population, they do not allow for the further growth of the native annulus- an important issue for the long term results if implanted in children. Indeed, their implantation in growing hearts could result in a stenotic effect which could worsen with time.

These considerations were the driving force for the development of a new concept in annuloplasty valve repair- a device that allows for growth of the native annulus. Encouraging results were reported in annuloplasties, performed mainly in the pediatric population, using different techniques and different biodegradable materials[7-10]. However, even though those trials were based on a good rational approach and gave promising results, techniques required some degree of craftsmanship and therefore were less predictable. For this reason, it was decided to develop a biodegradable ring that was not only applicable to the pediatric population but also easier to implant than the available devices[11].

The following characteristics of biodegradable implants were considered:

- Promote/accelerate body self-repair;
- Provide a gradual transition to regain a normal organ function;
- Do not interfere with organ growth in children;
- No need for operations to remove them;
- Low risk of infection.

The biodegradable ring is also a partial ring with a 'C' curved shape that allows a homogeneous remodeling of the dilated annular segments using different pre-designed sizes.

An experimental animal trial was conducted to assess the histo biocompatibility of the biodegradable ring and orifice area growth in

a porcine model. The smallest (size 16) biodegradable ring was implanted into the tricuspid annulus of 16 juvenile pigs (30 kg - 43 kg). Transthoracic echocardiography controls performed at monthly intervals showed no signs of tricuspid valve dysfunction, a preserved ventricular contractility, and physiological growth of the tricuspid valve orifice without significant transvalvular gradients. This was confirmed by macroscopic measurements of the valve orifices on the sacrificed pigs which had increased their body weights from 30-43 to 190-200 Kg (average of more than 500%) over a year. Histological sections in all dissected hearts, at different time points after surgery, showed that a fibrous autologous tissue was developed in replacement of the implanted polydioxanone device, reabsorbed by hydrolysis, six months or more following implantation. Moreover, it was found that the fibrous tissue continues to growing for a few months after complete re-absorption of the device[11].

In addition, in a series of 20 patients operated on between 1994 and 2003-mean follow-up of 62 + months- who had mitral valve repair implanting biodegradable rings that were smaller than the commercially available ring sizes (<26), there were no evidence of mitral stenosis[12]. The newly grown fibrous tissue remodels the annulus, prevents further stretching preserving its physiological dynamical motion without interfering with growth[13].

Biodegradable rings are new solutions and undoubtedly contribute to today's emerging advances in annuloplasty technology[11].

A recent retrospective echo-cardiographic study performed in our institution in 213 patients-Carpentier's rings (n=173); biodegradable rings (n=40)-showed that when compared with rigid rings, biodegradable rings have:

1. less gradient, measured at 3 months, 6 months and 1 year. While the rigid showed a steady increase the biodegradable increase was significantly lower;
2. better posterior leaflet mobility: it was significantly decreased in the rigids and only mildly reduced in the biodegradable;
3. faster recovery of the shortening fraction after surgery. It was initially reduced in both but the recovery to preoperative values was 3 months for the rigids and 3 weeks for the biodegradable;

Altogether, when compared with rigid rings, biodegradable rings have less gradient, better posterior leaflet mobility and faster recovery of the shortening fraction after surgery-important features for the short, medium and long term results of valve repairs[14].

Persistence and progression of tricuspid valve incompetence after the repair of functional mitral regurgitation and the significant risk associated with re- operation has triggered the interest on a more aggressive policy of performing a tricuspid annuloplasty at the time of the initial mitral valve surgery[15]. Because considerable tricuspid dilatation can be present even in the absence of substantial tricuspid regurgitation, surgical repair of the tricuspid valve based on tricuspid dilatation rather than regurgitation-if the tricuspid annular diameter is greater than twice the normal size-can lead to potential benefits[16]. The short time of implantation and ischemia required for the biodegradable rings, make them attractive in cases needing repair of both valves and/or concomitant procedures.

There is an increasing trend to recommends early surgery for patients with mitral valve regurgitation. This approach is justified only in patients undergoing repair by surgeons who routinely perform mitral valves repair, no replacement. Because the number of patients currently undergoing valve repair is not sufficient, there is a need to train more surgeons capable to repair valves[17].

Atrioventricular valve repair with this new technology is feasible with good early and mid term results. Its intra-annular implantation prevents the device from coming into contact with blood, thus avoiding thromboembolic complications and systemic anticoagulation therapy unlike the traditional rings-sutured on the native annulus-until they are covered with tissue. It also diminishes the risk of infection if used in the presence of infective endocarditis[18].

Altogether, biodegradable rings enhance the well known benefits of valve repair and improve the access to these procedures because of its use in the pediatric population.

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Although rigid and flexible rings meet the basic needs of adults, they do not accommodate the changes in shape and size occurring during the cardiac cycle. In addition, if implanted in children, they do not allow growth of the native annulus.

Our article is quite clear about the material that was used, as well as the advantages of using this device, particularly in patients that are still growing— such as children and young adolescents. Other functional features like maintaining the three-dimensional dynamic geometry of the mitral and tricuspid valves that change in size and shape during the cardiac cycle are also important.

After giving some thoughts, we decided to focus on the reasons why these devices were not more widely used despite the advantages of this technology, particularly for the pediatric patients as mentioned above.

There were several factors that prevented the general acceptance and wider clinical use of this novel device, such as the short shelf life of the rings, the lack of trust on the duration of the annulus support because the ring was absorbable, disregarding that it will be replaced by fibrous tissue that takes up the reinforcement function while

preserving the growth potential of the annulus. Furthermore, the resistance of several important and busy European surgeons to use the rings, probably due to their financial connections with the manufacturers of other types of bands and rings for valve annuloplasties was another obstacle. Altogether, these were the main causes of the commercial failure of the Kalangos'-Ring. In addition, the company that produced the devices went bankrupt just before the FDA was about to grant a "humanitarian device exemption" to the pediatric sizes of the ring for some particular indications, which would have opened a new chapter in the recognition of the device.

A recent review of the literature led us to the conclusion that there were no new biodegradable materials introduced for such

applications and available on the market after the Kalangos' ring— only some fundamental research-stage experimental singularities have been seen on articles since our publication.

We are aware that new attempts will be made in near future to revive the production of biodegradable rings with polydioxanone— the same biocompatible polymer described in the article by us. The good results described in our series of adults and pediatric patients, encourage us to welcome such initiatives. In addition, the references 11, 12, 13, 14, and 18 of our paper provide further information about our experience with the technology being discussed.

SCREENING OF FETAL CONGENITAL HEART DISEASE: THE CHALLENGE CONTINUES - LETTER TO THE EDITOR

RASTREAMENTO DAS DOENÇAS CARDÍACAS CONGÊNITAS FETAIS: O DESAFIO CONTINUA - CARTA AO EDITOR

Dear Editor,

The initiative of inviting a group of obstetricians to write an editorial for a cardiovascular surgery journal emphasizing the need of an adequate prenatal diagnosis of congenital heart diseases should be commended. The authors provide a comprehensive summary of the recent advances and advantages of intrauterine diagnosis, encouraging obstetricians not to limit the screening to those known to be at risk of developing a cardiac malformation. They also recognize the value and the limitations of the four chambers view with which the obstetricians feel comfortable. Furthermore, the authors stress the fact that there are a number of cases, particularly the cono-troncal anomalies, where the visualization of the great arteries is difficult and the pitfalls important. They also underline the importance of expanding the training, knowledge and abilities of those performing the studies to allow a broader detection of cardiac anomalies[1].

As in other specialties, there is an increasing interest in the newly developed technologies which will certainly improve the images and facilitate a precise detection and diagnosis. However, the key for an accurate screening continues to be the operator's knowledge of the cardiac anatomy and a proper understanding of the unique and complex spatial arrangement of the cardiovascular system. The concept of spatial thinking - a cognitive skill used by architects and urban planners - can help in understanding the world around us by using the properties of space in everyday life, the workplace, as well as in science, to structure problems, find answers and articulate solutions[2].

While we firmly believe that a proper utilization of the present tools should enable us to improve detections, we recognize the importance of a conscientious labor force that makes excellent use of modern technologies as they become widely available and affordable. Whether we liked it or not, technology will continue to shape our practices.

Although it is not our intention to write a paper within a letter to the Editor, there are important concepts such as proximity, product space, structure of production, collaborative rationality, and team work that should be at least mentioned. Their application will improve our understanding of the complexity of the cardiovascular services and thereby enhance performance.

Proximity formalizes the idea that the ability of a center to generate a product depends on its ability to produce other ones - structure of production. When a center with many complex capabilities adds a new one, this can create a range of new, possible complex procedures. Conversely, adding a single new capability in a center that has few to begin with won't leverage an existing matrix of capabilities in the same way - it might not produce any new procedures at all[3].

As a pediatric cardiologist and a cardiovascular surgeon we strongly advocate the need of an inclusive team approach for the proper management of the neonate with congenital heart disease: a work structure in which all components of the cardiovascular services - a cluster of people focused on excellence according to their relatedness and interests - contributes to the quality of the final outcome with an integrated approach[4]. This leads to collaborative rationality, of getting better together, which is a different way of knowing and generating, of making and justifying decisions based on diversity, interdependence and dialogue[5] [6].

It is a team integrated by pediatric cardiologists, neonatologists, cardiovascular surgeons, anesthesiologists, nurses and specialized critical care units in which obstetricians with imaging expertise have a place. The role of the latter should not be limited to the image detection but also to participate in the decision making process: that is, diagnosis, intrauterine treatment, time, type and place of delivery, etc. In other words, an effort centered in the fetus' health, encouraging collaboration among professionals and sharing knowledge that contributes to reciprocal medical education in a multidisciplinary environment.

How are we doing?

The use of information about one's business is vital to understand, report on, and predict different aspects of performance. After making theoretical considerations, which, among practical people, has a con-

notation of impracticality, we feel compelled to include information about our policies as well as unpublished data on our experience.

Recently, we reviewed our findings on early detection of congenital cardiac anomalies in a group of 49 neonates under 30 days of life that underwent surgery[7]. Interestingly, in this cohort of the patients, 40% had prenatal diagnosis and 90% of them had severe forms of univentricular heart - the majority with hipoplastic left heart syndrome. In all cases, the malformations were detected by an obstetrician specialized in images and confirmed by a pediatric cardiologist, both aware of the importance of visualizing the outflow tracts and the great vessels, using a conventional four chambers view.

It is our policy to discuss all patients with prenatal diagnosis of heart disease by a group formed of general obstetricians, obstetricians specialized in images, pediatric cardiologists, neonatologists and cardiovascular surgeons. This team decides the management of the patient - that includes consulting the mother - with special consideration to the need of prenatal intervention, the time, type and place of delivery, and the timing for surgery. We strongly believe that a joint management benefits the patients and improves surgical results by diminishing morbidity and mortality. However, the findings disclosed in the Editorial as well as ours clearly indicate that there is room for improvement by training those involved in the screening process, realizing the need of a team approach, and the adoption of modern technologies. It is, among other things, the ability to recognize where there is room for improvement that allows an expert operator to reach great heights. "The ability to see room for improvement, however, is not of much use unless one also has a strong and continuing desire to improve"[8].

Neonates face unique incremental risk factors related to the patient's variables and to structural hospital characteristics that should be properly individualized and addressed in a timely fashion in order to improve surgical outcomes. An accurate prenatal diagnosis can make a significant contribution to accomplishing this goal.

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Although the letter to the editor written in 2013[1] and the editorial of Rocha LA et al, published in the same journal [2] entail modern concepts on the multidisciplinary approach of fetal diagnosis

and early treatment of Congenital Heart diseases, it is important to admit that new information may be available as shown in an excellent recent review by Lindsey Hunter and Anna N. Seale [3].

Even though we understand that only few of the topics need to be updated, emphasized or completed, they should be analyzed according to the role of the different disciplines implicated in the subject.

Recent advances in the diagnosis and treatment of congenital heart diseases have changed their natural history permitting early treatment of the most severe heart defects. A frequently cited classical example is the D Transposition of the Great Arteries, in which an appropriate fetal diagnosis and early care carries more than 98% survival rate in an adequate medical center [4].

Because each patient with CHD requires a distinctive and individual management according to the diagnosis and risk of the anomaly, a prenatal judgment permits a selective conduct according to the patient´s pathology. Furthermore, correct information allows proper transfer for delivery in time and form to a center with a multidisciplinary team that can provide optimal care [5].

This transversal multi specialist's team approach includes pediatric cardiologists, obstetricians, geneticists, neonatologists, ICU specialists and surgeons that together play an important role in the modern organization of perinatal care.

Role of the Obstetrician: The obstetrician has an active involvement in the whole process that goes beyond his specific task. This combined vision includes his/her participation in the decision making process of selecting the location and timing of delivery, thus assuring a standard of care.

This approach can avoid unnecessary cesareans as well as preterm deliveries. [6] In addition, it is important to remember that beside obstetric indications, there are multiple reasons related to fetal maturity and the necessity of early surgical interventions where delivery at 39 to 40 weeks is preferred.

Congenital Heart Disease (CHD) by itself is a rare indication of cesarean section as almost all fetuses affected by it benefit from vaginal delivery. Therefore, term partum is absolutely crucial to improve surgical results in the neonates with critical CHD.

It is also well known that both, prematurity as well as late preterm, constitute an incremental risk in which minor complications may delay vital surgical procedures and jeopardize proper management.

There is however a small number of indications for preterm or late preterm delivery, mostly in fetuses with signs of in uterus heart failure, mainly due to primary myocardial disease or severe arrhythmias with an inappropriate response to pharmacological treatment. In those patients a close relationship with the cardiologist specialized in arrhythmias becomes essential in order to provide accurate care.

Role of the Obstetric Sonographer: The role of the obstetrician specialized in images is vital in the initial prenatal screening for congenital heart disease of a larger population where detection starts with preconception assessment of risk factors that can be identified and prevented.

When obstetricians manage patients with other congenital defects, such as twin pregnancies, polyhydramnios, pregestational diabetes pregnancies, hydrops, alcoholics, autoimmune diseases, fetal arrhythmias, early intrauterine growth retardation, etc. a more detailed fetal echocardiogram must be done.

If the sonographer is able to detect a fetal congenital heart disease, this task could be performed with a lower cost-benefit ratio in a single inclusive procedure between 18 and 22 weeks of gestation [3] [7]. In addition, the incidence of CHD of 5 per 1000 live born infants, clearly indicates the inappropriateness of leaving this search exclusively to the pediatric cardiologist.

The incorporation of different echocardiography views added to the classical four chambers view is important for a proper assessment of the outflow tract and blood vessels.

Furthermore, others views recently incorporated to the UK screening— such as the three vessels and tracheal (3VT), increase further detection of major CHD[9]. The awareness of these specific views are crucial in the recognition of cono-truncal anomalies increasing detections as high as 45 % [10].

There is no doubt that congenital heart defects are often difficult to detect by the obstetric sonographer, so it is quite obvious that in order to increase the prenatal detection an adequate training and

continuous education is decisive [11]. This is accomplished by implementing regular multidisciplinary prenatal meetings in which all patients can be systematically discussed.

Role of the Pediatric Cardiologist: Although fetal cardiac evaluation made by a pediatric cardiologist includes an echocardiogram that will usually lead to a precise anatomical and physiological diagnosis, a multidisciplinary team should evaluate the diagnosis and determine the final approach.

The anatomical diagnosis, however important, gives us a static picture of the moment in which it is taken. Therefore, an ongoing fetal follow up becomes essential, particularly in those patients with either pulmonary or aortic valve stenosis, diseases that often present progressive anatomical and physiological changes that may end up requiring a different clinical or surgical approach.

This complete and continuous assessment provides the required information to plan a management for each patient. It is also important to individualize those patients in which a ductus patency is essential for survival in the immediate neonatal period. An anatomical impediment for an adequate pulmonary or systemic circulation requires prompt flow restitution via prostaglandins infusion to allow a repair in improved clinical conditions.

Obviously, there are some congenital heart diseases that may not require early treatment and the delivery could be planned in hospitals of lesser complexity. On the other hand, for those in need of a more sophisticated management, an institution with a multidisciplinary team able to provide a modern and appropriate care becomes mandatory.

This transversal approach is essential in those patients that may require fetal intervention [12]. This group encompasses fetal arrhythmias as well as the less common invasive fetal procedures on severe aortic or pulmonary valve stenosis.

In severe fetal tachyarrhythmia's the trans-placental pharmacological treatment given through the mother has nowadays become common practice requiring the close collaboration of cardiologists and obstetricians, considering that both, mother and fetus, are involved and both require close monitoring to detect potential adverse effects[13].

What´s new?

1. A team approach with a partnership of an obstetrician and a pediatric cardiologist is currently accepted as the best option for prenatal detection of congenital cardiac malformations.

2. An ongoing screening in hands of obstetric sonographer is advisable

3. The active participation of a properly trained obstetrician during the whole pregnancy and follow up is accepted and recommended.

4. A close cardiology participation in the follow-up of particular lesions that may eventually require fetal intervention.

Conclusion: The implementation of the above mentioned advances is an effort to avoid or minimize the potential adverse impact of a pregnancy associated with a congenital heart disease.

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CARDIOPULMONARY BYPASS: A FORGOTTEN AREA OF SEARCHING FOR NEW KNOWLEDGE IN BRAZIL AND THE IMPORTANCE OF TRANSLATIONAL RESEARCH

Rodolfo Neirotti

The first heart transplantation in Latin America was performed less than six months after the pioneering work of Christian Barnard in this field[1]. As impressive as the fact that this procedure was the 17th heart transplant done in the world, is that this surgery was performed with a cardiopulmonary (CPB) machine made in Brazil.

At that time, the homegrown cardiac surgery was side by side with the cardiac surgery of the developed world due to the capabilities of the bioengineering industry and the remarkable surgical skills and dedication of the local pioneers[2]. However, nowadays, there is an industry stagnation with low technology incorporation in the country and a gap in this field with the international technological development due to multiple factors. The diminished number of publications by Brazilian authors — less than 0.9% of total worldwide publications — registered in PubMed (US National Library of Medicine National Institutes of Health) database ratify the scientific stagnation in the knowledge of CPB.

Translational research, a "bench-to-bedside and beyond" approach, aims to improve individual and public health by generating multicenter and multidisciplinary collaboration to pull discoveries from basic science arising from laboratory, clinical, or population studies into clinical applications[3].

The importance of testing the devices used in our clinical practice

Recently, driven by the need of introducing translational research in CPB, the Heart Institute of University of São Paulo (Instituto do Coração da Universidade de São Paulo) began collaborative

studies in pediatric CPB with the Penn State University Health Center for Pediatric Cardiovascular Research.

Brazil has a large number of medical devices manufactured and available only in this region that are approved by the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – Anvisa) without further clinical data or benchmarking with other similar devices. Moreover, only FDA approved or widespread used products in the developed countries are object of research by the international scientific community.

Monitoring pressure, blood and water temperature, use of bubble detectors and blood level sensors devices are not incorporated neither in the clinical perfusion guidelines, nor in the training school curriculum and clinical practice. Furthermore, despite that some imported CPB machines equipped with all these safety devices are available for use in a great number of cardiac centers, only less than 5% of them are used with the servo control mode turned on. In other words, the majority of the clinical perfusions are conducted without any automatic safety device control, thus making impossible to identify, explain and document undesirable events. Building a stronger knowledge about CPB through basic research and clinical trials, and the incorporation of the new information in the perfusion curriculum, will help the management of children with congenital heart defects (CHD).

Altogether, a better understanding of the hemodynamics characteristics and differences among these devices, as well the interaction between them and the patients, will help to improve clinical outcomes in pediatric cardiovascular surgery in Brazil and other Latin American countries using them.

The manuscript entitled "*In-vitro* evaluation of two types of neonatal oxygenators in handling gaseous microemboli and maintaining optimal hemodynamic stability during cardiopulmonary bypass", published as an original article in this issue of the Brazilian Journal of Cardiovascular Surgery, represents an important initiative of an international multicenter and multidisciplinary collaboration. This study was conducted at the Pediatric Cardiovascular Research Center at the Penn State Milton S. Hershey Medical Center, under the supervision and mentorship of Prof. Akif Undar[4]. The purpose of

this joint venture was to understand the characteristics of a Brazilian oxygenator byusing an internationally used oxygenator as a benchmark rather than to determine the superiority of one of them.

It is well known that only FDA approved devices are used in large clinical trials published by the international scientific community. Thus, this study represents the first published evaluation of the hemodynamics and handling capabilities of microemboli in a Brazilian made oxygenator, using a FDA approved oxygenator as a point of reference. Both oxygenators are clinically used for the same population and although with different characteristics regarding maximum flow and prime volume, they have a very similar hemodynamic performance. The undesirable passage of microemboli from the venous side of the oxygenator to the patient is sometimes forgotten, as well that the capability of capturing them by the oxygenator may be different and dependent on the membrane area/maximum flow rate ratio.

Clinically, rather than the existence of microemboli in the arterial side of the oxygenator, the most important issue is to diminish the passage of air to the patient by placing an arterial filter in the circuit. Unfortunately, this practice is not yet part of the routine.

I am aware that another study was done recently, in order to further understand the role of an arterial filter — to be published soon — testing the Braile pediatric oxygenator with and without an arterial filter in the CPB circuit, using another FDA approved oxygenator as a benchmark.

The knowledge acquired with these and other experiments in CPB should enable the authors and others to improve the outcomes for their CHD patients. They should be congratulated for their initiative and efforts to embrace international parameters in their clinical practice.

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The editorial by Dr Neirotti in the Brazilian Journal of Cardiovascular Surgery [1] was a poignant reminder of times which have passed and the need for cardiac surgery clinicians to continue to move towards the future of pediatric cardiac surgery in Brazil. This path requires Brazilian surgeons, perfusionists, nurses and anesthesiologists to integrate standards utilized in other countries to evaluate disposables, such as oxygenators and tubing packs [2][3], as well as standards for the conduct of bypass during surgery for congenital heart defects [4]. Translational research is an optimal approach to bridge the divide which has grown over the past decades. Paired with Brazilian research and development, it will allow Brazil to improve public health by leveraging knowledge and techniques utilized at other international centers with a staged approach to change domestically [4]. The key question in my mind is how to promote maximal engagement among Brazilian clinicians for this endeavor. Who will be the change agents to improve outcomes in cardiac surgery in Brazil by helping the current healthcare system evolve? Certainly, cooperative projects between the University of Sao Paulo and the Pennsylvania State University teams showcases that several change agents are already cooperatively working towards the goal.

More change agents are needed. Efforts including the International Quality Improvement Collaborative for Cardiac Surgery should be fully taken advantage of as they have been shown to improve outcomes through education [5] and have parallel endeavors which may help specific professions through unique offerings funded by charitable organizations [6]. This author looks forward to following the change already taking place in Brazil, commends those currently leading the way, and encourages more Brazilian clinicians to consider how to move their respective professions forward for the greater good of Brazil.

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ECMO: IMPROVING OUR RESULTS BY CHASING THE RABBITS

Luiz Fernando Canêo
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Abstract

As Marcelo Giugale published in the Financial Times, Latin America, on the whole, has not excelled at innovation – doing the same things in a new and better way or at doing new things. It has been slow to acquire, adopt and adapt technologies by this time available in other places[1]. Although extracorporeal membrane oxygenation (ECMO) is not a new technology, its use in Latin America is not widespread as needed. Furthermore, we still have a number centers doing ECMO, not reporting their cases, lacking a structured training program and not registered with the extracorporeal life support organization (ELSO). With this scenario, and accepting that ECMO is the first step in any circulatory support program, it is difficult to anticipate the incorporation of new and more complex devices as the technologically advanced world is currently doing. However, the good news is that with the support of experts from USA, Europe and Canada the results in Latin America ELSO'S centers are improving by following its guidelines for training, and using a standard educational process. There is no doubt that we can learn a great deal from the high velocity organizations – the rabbits – whom everyone chases but never catches, that manage to stay ahead because of their endurance, responsiveness, and their velocity in self-correction[2].

Abbreviations, acronyms & symbols	
ECMO	= Extracorporeal membrane oxygenation
ELSO	= Extracorporeal life support organization
PMP	= Poly-methylpentene

"Insanity is doing something over and over again and expecting a different result."

Albert Einstein

Concepts and practices

Since its beginning 37 years ago, the use of extracorporeal membrane oxygenation as an advanced life support therapy has evolved from the complex circuit with a roller pump and a silicon membrane to the simplified circuit with a centrifugal pump and a polymethylpentene membrane in use nowadays.

Although, Extracorporeal Membrane Oxygenation (ECMO) could be regarded as an "old dog" in the developed countries, its current form is still considered a new technology in Latin America. The Extracorporeal Life Support Organization (ELSO) was founded in 1978, as an international consortium with the mission of maintaining a registry of the use of extracorporeal membrane oxygenation in the registered centers. Nevertheless, looking at the map of the centers registered in ELSO, in Latin America there were centers only in Chile and Colombia. In fact, the Pontificia Universidad Católica de Chile, located in Santiago, was the first center to join ELSO, in 2003. Then, we can say that 37 years after the first successful case reported in USA, ECMO was not a usual procedure in most of the Latin American countries. A survey, made 3 years ago and presented during the 25th ELSO meeting in Ann Harbor, Michigan, USA[3], showed that there is a gap between the starting of using ECMO, the registration of the center in ELSO, and sending their data to the international registry. ELSOs' international consortium is nucleating an important number of health care professionals and scientists dedicated to develop and to evaluate ECMO as a support of the failing cardiopulmonary system. In addition, the organization provides educational programs for active centers as well as for the broader medical and lay communities. Therefore, it is fair to say that those that are not part of this society are most probably

not following its guidelines and principles, and possibly not doing ECMO in the correct way.[1]

Historically, in Latin America, ECMO was strongly related to cardiac surgery. In countries like Brazil, it was often considered an extension of the regular cardiopulmonary bypass that is transferring the patient to the intensive care unit connected to the pump with the usual hollow fiber oxygenator. Due this misconception, the results with ECMO were not good for many of us, and for some, it is still a way to postpone death.

After the H1N1 outbreak, others specialties, especially clinical intensivists working in non-cardiac centers, showed a great interest in learning how to use this therapy in their daily practice. Moreover, the new demand for V-V ECMO for respiratory support stimulated the interest in training people not previously familiar with this technology. Following ELSO's guidelines for training, centers from Chile, Colombia and Brazil started a standard education process, with the support of experts from USA, Europe and Canada. Furthermore, the foundation of the Latin America chapter, in 2012, facilitated the partnership with specialists of the developed world – the rabbits – as well as to bring trainers to our recently joined ELSO centers, to reproduce the same courses they used to have in their countries.

The first ECMO Specialist Training Course[4] was held 3 years ago in Brazil at the Heart Institute, University of Sao Paulo Medical School, with a similar format of those courses offered in every center in the USA and Canada. It combined lectures with hands on, as well as high fidelity simulation teaching focused on the ECMO circuit and its clinical applications.

Although, our experience initiated in the late 90's, only very few members of the multidisciplinary team – particularly the direct patient caregivers – demonstrated familiarity with the materials and resources. This scenario has completely changed with the continued training of these professionals and the subsequent improvement of the results showed in a recently published paper of our center[5]. Our outcomes improved by

1. This study was carried out in Instituto do Coração of Faculdade de Medicina of Universidade de São Paulo (InCor - FMUSP), São Paulo, SP, Brazil.

using a 1:1 ratio model, where patient and ECMO are both handled by a single bedside nurse without a dedicated core team. Before training, the probability of weaning and survival after post-cardiotomy ECMO was 25% with only 5.5% discharge rate. After training, the therapy was used in 20 patients, and weaning was possible in 17 (85%), with 9 (45%) hospital discharges (P<0.01). Similar improvements, mainly related to training, occurred in 4 centers in Chile, 6 in Argentina, 2 in Colombia, 2 in Mexico, 3 in Peru and 1 in Costa Rica. These centers joined ELSO, they are following the organization's guidelines and they are reporting their data to the organization's database. In our continent, we find 3 times more papers in the last four years when we compare the number of publications by Latin American authors with the time we had no registered centers in ELSO. Altogether, training is improving the quality and safety demonstrating the importance of doing ECMO in the right way. Clinica las Condes, in Santiago, Chile, received the award of Center of Excellence[6]for their high quality standard, and became the first one recognized by ELSO in Latin America. They have done more than 53 transports in patients on ECMO – among of the largest volumes in the world. Centers of development, with the necessary funds and manpower for research to generate and accumulate know-how can advance a diversity of new procedures requiring their use for a more efficient treatment, cost benefit ratio, and sustainability of care. These centers, can then disseminate the new knowledge, minimizing or even eliminating the learning curve as well as producing policies for the future of the specialty[7].

Even though, we are seeing a reorganization of the people around us and some are following these principles, trying to achieve excellence in the multiple centers and contexts around the world will require time and hard work. As an example, nowadays there are nine ELSO centers in Brazil that are supposed to report their data and results. However, the ELSO's data and the numbers of poly-methylpentene (PMP) membrane sold in the country show a huge decentralization and a great number of unreported procedures, probably conducted by non- trained personnel. It is estimated that the number of ECMO runs reported to ELSO represents only 10% of the PMP membranes sold, clearly reflecting that we have main centers not registered in the organization, not reporting their data, not follow-

ing the guidelines, and without an established training program. In this scenario, is understandable and even acceptable to assume that many consider this therapy "experimental", without proven results, not cost-effective and closely related to death.

ECMO requires a high-level of technical and non-technical skills, associated with an interdisciplinary teamwork, with the difficulties to accomplish the latter in the Latin American context. Looking to the future and talking about an advanced circulatory support program, ECMO is the first step, the kindergarten. Since the beginning, when we debate about ECMO, or even other complex technologies, the blame always goes to our economic situation – they are too expensive!

WHERE ARE WE GOING?

Unfortunately, in our health system, it is often preferable to reach a large number of people with sub-optimal care than to reach fewer people with a more sophisticated, and therefore more expensive care. Cardiac and respiratory support will evolve with the incorporation the new devices, and will need centers of excellence with a well-trained people and the best possible basic education working as a team. Because the adoption of new technology should be followed by good results and cost- effectiveness, the health priorities in developing countries, and the status of their health systems are likely to be the limiting factors in accomplishing a widely available care. International partnership is important to train people and to achieve better results with new tools. "Nonetheless, foreign assistance should be adjusted to the local context avoiding dropping a replica of a proven model into an obsolete system – the name for the practice behind the problem is isomorphic mimicry. Unless resident agents work to give it a life of its own, it remains a replica"[8].

What concerns us most is that there is still a lot more to come, demanding major changes in the society, the economy and the health care. The best way to predict the future is to invent it – this is our real challenge!

Authors' roles & responsibilities	
LFC	Final manuscript approval; manuscript writing or critical review of its content
RAN	Final manuscript approval; manuscript writing or critical review of its content

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ECMO has been proven to be a solid rescue devise in disease processed that result in refractory cardiorespiratory failure unresponsive to conventional medical therapies, in many patient populations, as we have seen recently highlighted in past and current pandemics [1] [2] [3]. While ECMO is known worldwide, the level of training, techniques, reporting and technology differ leading to inconsistent outcomes. This paper defines the challenges of broad coverage care in developing countries, mostly due to the necessity to provide the same level of care to all without escalating cost. Training is essential and must be conducted with a mindset to start small and standardize practice to decrease variability in ECMO care so as not to deliver sub-optimal care to masses from the outset— expansion of practice must be stepwise and gradual. Moving forward, it is our hope that devises and technology will became more available and cost effective to broaden the reach, delivering high-quality ECMO and provide resources to aid training and outreach.

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FUNCTIONAL PERFORMANCE OF DIFFERENT VENOUS LIMB OPTIONS IN SIMULATED NEONATAL/PEDIATRIC CARDIOPULMONARY BYPASS CIRCUITS

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Abstract

Objective: Hemodilution is a concern in cardiopulmonary bypass (CPB). Using a smaller dual tubing rather than a single larger inner diameter (ID) tubing in the venous limb to decrease prime volume has been a standard practice. The purpose of this study is to evaluate these tubing options.

Methods: Four different CPB circuits primed with blood (hematocrit 30%) were investigated. Two setups were used with two circuits for each one. In Setup I, a neonatal oxygenator was connected to dual 3/16" ID venous limbs (Circuit A) or to a single 1/4" ID venous limb (Circuit B); and in Setup II, a pediatric oxygenator was connected to dual 1/4" ID venous limbs (Circuit C) or a single 3/8" ID venous limb (Circuit D). Trials were conducted at arterial flow rates of 500 ml/min up to 1500 ml/min (Setup I) and up to 3000 ml/min (Setup II), at 36°C and 28°C.

Results: Circuit B exhibited a higher venous flow rate than Circuit A, and Circuit D exhibited a higher venous flow rate than Circuit C, at

both temperatures. Flow resistance was significantly higher in Circuits A and C than in Circuits B (P<0.001) and D (P<0.001), respectively.

Conclusion: A single 1/4" venous limb is better than dual 3/16" venous limbs at all flow rates, up to 1500 ml/min. Moreover, a single 3/8" venous limb is better than dual 1/4" venous limbs, up to 3000 ml/min. Our findings strongly suggest a revision of perfusion practice to include single venous limb circuits for CPB.

Abbreviations, acronyms & symbols	
A-V	= Arterio-venous
ALF	= Arterial line filter
CPB	= Cardiopulmonary bypass
CVR	= Cardiotomy venous reservoir
GME	= Gaseous microemboli
GSD	= Gravity siphon drainage
ID	= Inner diameter
IVC	= Inferior vena cava
OR	= Operating room
USB	= Universal serial bus
VAVD	= Vacuum-assisted venous drainage

Introduction

Cardiopulmonary bypass (CPB) is commonly utilized during surgical repair for congenital heart defects. The CPB circuit prime hemodilutes the patient once CPB is initiated. Limited hemodilution is known to provide the benefits of decreasing blood viscosity and improving microcirculatory flow[1]. However, hemodilution is also associated with a number of adverse side effects, including decreased plasma colloidal oncotic pressure, increased total body water, and coagulation abnormalities[2] [3]. In consideration of these issues, perfusionists typically minimize the CPB circuit prime volume so as not to cause excessive hemodilution[4] [6]. Other intraoperative techniques such as conventional ultrafiltration during CPB and modified ultrafiltration at the end of CPB are also important to minimize hemodilution and reduce the requirement for transfusions[7]. These are central concerns in pediatric cardiac surgeries since the bypass circuit prime volume tends to be larger than the pa-

tient's own circulating blood volume. In neonates, the CPB circuit prime may be as much as 200-300% of the patient's blood volume[8].

The bypass circuit prime volume comprises the prime volume of primary components, including the oxygenator, cardiotomy venous reservoir (CVR), arterial pump head, arterio-venous (A-V) loop, arterial line filter (ALF), hemoconcentrator, and sampling lines[7]. The prime volume of most disposable components is constant when devising a CPB circuit. However, some aspects of the circuit are less standardized: the length, the inner diameter (ID), and at some centers, the number of venous lines utilized when bicaval cannulation is required. In addition to the number of venous lines used, the bypass circuit venous component can further vary with the drainage technique employed – gravity siphon drainage (GSD) *versus* vacuum-assisted venous drainage (VAVD)[7]. The use of VAVD is quite common as it can provide adequate venous drainage with smaller ID tubing, but it does not come without a downside risk. In fact, VAVD has been shown to increase the potential for gaseous microemboli (GME)[9] [10]. While the effect of GME on overall pediatric patient outcomes is unclear[11], most clinicians agree that, intuitively, we should minimize GME on bypass since the adult literature supports their negative impact on patient outcomes after cardiac surgery[12] [13]. Therefore, while minimizing venous line tubing ID and maximizing the use of VAVD would decrease bypass circuit prime volume, other important considerations must be taken into account.

Finally, the selection of a venous line tubing has an important impact on venous drainage during bypass. Venous limb tubing is typically upsized compared with the patient's size owing to the increased kinetic potential of tubing sizes with larger internal diameters. Specific flow limitations for each size, dual or single limb venous circuits, are not well defined since table height relative to reservoir height, venous limb length, and reservoir construction vary across institutions[7]. Adequate venous drainage is essential for the optimal conduct of perfusion and this is, in large part, a function of the flow specifications for the venous limb. Inadequate venous drainage can result in edema and organ dysfunction[14] [15].

We currently employ three different circuits at the Heart Institute, University of São Paulo Medical School, Brazil. We categorize our circuits according to the sizes of the single arterial limb and the dual venous limbs, in this order. They are defined as neonatal (3/16" x 3/16" x 3/16"), pediatric (1/4" x 1/4" x 1/4") and adult (3/8" x 3/8" x 3/8"), since it is common practice in Brazil to provide individual venous drainage lines to each cava for bicaval cannulation. This has been a unique standard clinical practice for decades which deserved an evaluation.

The objective of this study was to evaluate venous limb options currently in use and to compare resistance and maximum flow rate capacity on thevenous side of simulated CPB circuits in order to better qualify a current practice for anticipated bypass flow rates up to 3000 ml/min. A prime volume comparison of the different circuits was also done.

Methods

Experimental Circuits

Circuit designs employed in this study simulated pediatric CPB and utilized the standard equipment in clinical use at the Heart Institute, University of São Paulo Medical School. The experimental circuit included Maquet (Maquet Cardiopulmonary AG, Rastatt, Germany) hardware, with a Jostra HL-20 roller pump and an HCU-20 heater-cooler system. The pseudopatient consisted of a 2000 ml capacity hardshell reservoir (Maquet Cardiopulmonary AG, Rastatt, Germany). The pseudopatient reservoir level was located 80 cm above the CVR and it was connected to options for venous tubing. Setup I included two 3/16" venous limbs and one 1/4" venous limb running from the pseudopatient to the CVR (Figure 1, Setup I). Setup II included two 1/4" venous limbs and one 3/8" venous limb running from the pseudopatient to the CVR (Figure 1, Setup II). Venous limb lengths were standardized to 120 cm. Maquet disposable oxygenator-reservoirs included either their Neonatal or Pediatric options. The arterial pump head for all test conditions included 150

cm of 1/4" ID tubing. A Hoffman clamp was placed at the distal end (just before the pseudopatient reservoir) of the arterial limb to maintain a constant post arterial cannula pressure during all trials. The CPB circuit was first primed with lactated Ringer's solution (Baxter, São Paulo, Brazil) and then packed red blood cells were added to achieve a circuit hematocrit of 30%. The venous reservoir level was kept at 200 mL for both oxygenators- reservoirs in use.

Experimental Design

Table 1 lists the four circuits tested: A) two 3/16" ID venous limbs, B) a single 1/4" ID venous limb, C) two 1/4" ID venous limbs, and D) a single 3/8" ID venous limb. Circuits A, B and C included 1/4" arterial limbs whereas Circuit D included a 3/8" arterial limb.

To evaluate the performance of these circuits we used two different setups as shown in Figure 1 (Setups I and II).

Setup I was used to test circuits A and B at flow rates of 500 ml/min to 1500 ml/min in 500 ml/min increments, with Maquet Neonatal oxygenator-reservoir. We adjusted the Hoffman clamp for position A or B to test each venous option independently. Setup II was used for circuits C and D at flow rates between 1500 ml/min and 3000 ml/min in 500 ml/min increments, with Maquet Pediatric oxygenator-reservoir. We adjusted the Hoffman clamp for position C or D to test each venous option independently. The blood level of the pseudopatient was kept at 80 cm above the CVR in all experiments. Arterial line pressure (P3) was maintained at 50 mmHg during all trials. Experiments were conducted at 36°C and 28°C. Data were electronically collected.

A second experiment was done using a 1600 ml capacity soft bag (Medtronic, Minneapolis, MN, USA) simulating the pseudopatient to test Circuits C and D in a different condition (Figure 2, Setup III). Setup III was used to test Circuits C and D with controlled venous pressure at flow rates between 1500 ml/ min and 3000 ml/min in 500 ml/min increments, with Maquet Pediatric oxygenator-reservoir. A Hoffman clamp was placed near the distal end of the arterial line to maintain an arterial line pressure (P3) of 50 mmHg during all trials. The CPB circuit

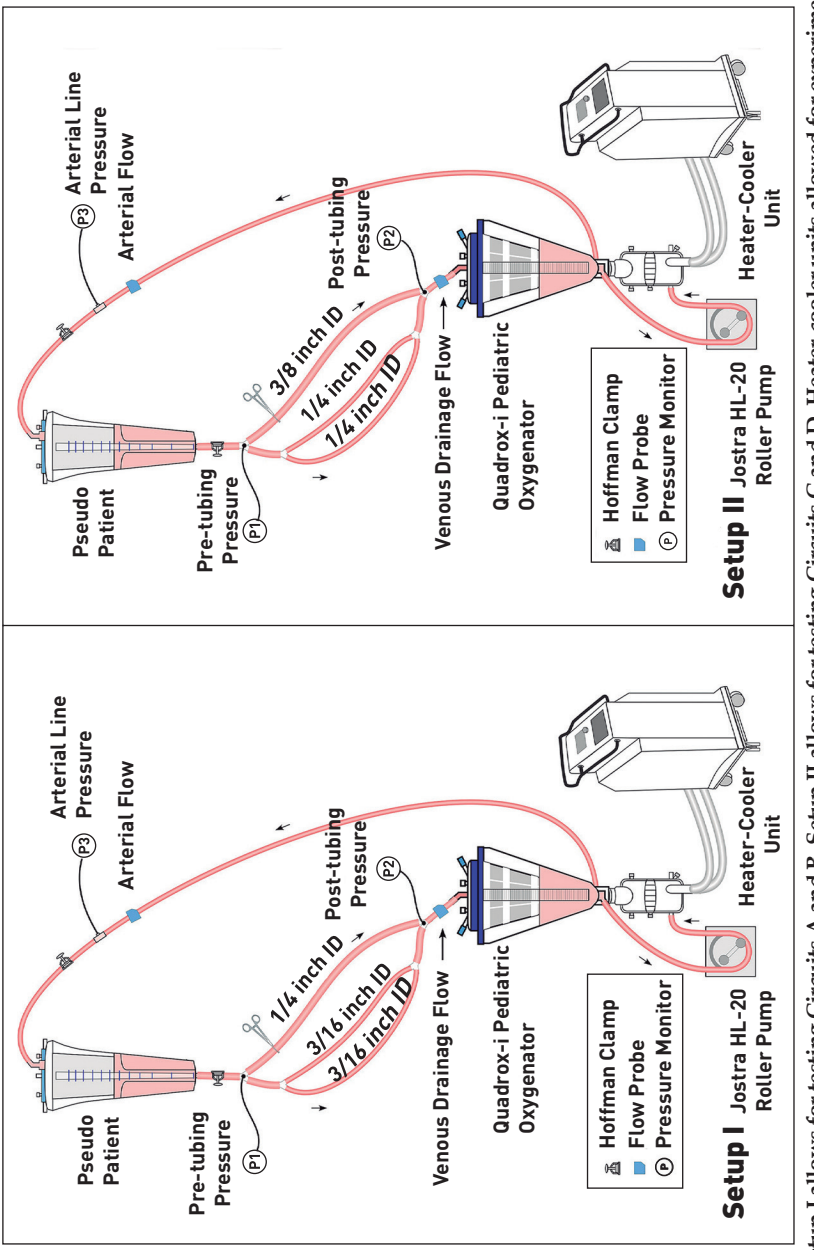

Fig. 1. Setup I allows for testing Circuits A and B. Setup II allows for testing Circuits C and D. Heater-cooler units allowed for experiments to be done at 35°C and 28°C. Hoffman clamp on the circuit arterial limb allowed for a constant post-cannula pressure

Circuit tested	Venous Limb Size (ID)	Venous Limb Length (cm)	Total Venous LimbPrime Volume (ml)	Difference between Circuits
A	Two 3/16″	120	42	A-B = 5 ml
B	One 1/4″	120	37	
C	Two 1/4″	120	74	C-D = - 10 ml
D	One 3/8″	120	84	

Table 1. Venous limb circuit test specifications. Volume was measured using the circuit tubing tested in Setups I, II, and III

was primed with lactated Ringer's solution, and then packed red blood cells were added into the circuit to maintain the blood hematocrit at 30%. The reservoir venous pressure was kept at 3 to 4 mmHg, simulating the pseudopatient's venous pressure. The venous pressure was controlled using an open hardshell reservoir and a Hoffman clamp at the experimental venous limb. The total priming volume of the circuit was 2600 mL (Circuits C and D), including the pseudopatient's volume. We adjusted the Hoffman clamp for Setup D, then we repeated the experiment without any adjustments to Setup C. Experiments were conducted under normothermia (36°C) and hypothermia (28°C), separately. The entire process was repeated six times for each unique combination.

Data Acquisition

Two Transonic ultrasound flow probes (Transonic Systems, Inc., Ithaca, NY, USA) were used for each set of test conditions. One flow probe was located at the venous inlet to the CVR and the other was located before arterial cannula, as shown in Figure 1. Three Edwards TruWave disposable pressure transducers (Edwards Lifesciences Corp., Irvine, CA, USA) were placed. The first transducer was located at the beginning of the venous limb (P1), the second was at the venous limb insertion to the CVR (P2), and the third was at the pre-arterial cannula site (P3). Pressure transducers were connected to pressure monitors CPB-100 (Bioengineering Division, InCor, São Paulo, Brazil). Pressure monitors and flowmeter outputs were connected to a DataQ DI-710 data acquisition device (DataQ, Akron, OH, USA) and then connected to a computer via universal serial bus (USB) port. WinDaq

data acquisitions software (DataQ, Akron, OH, USA) was used to record real-time data at 1000 samples per second per channel. A 30 s segment of pressure and flow waveforms was recorded at all sites.

Calculating Venous Line Resistance

Venous line resistance of each tubing set was calculated using the following equation (Tables 2, 3, and 4).

$$Venous\ line\ resistance\ (wood\ units) = \frac{(P2 - P1)\ (mmHg)}{Venous\ flow\ (L/m\ in)}$$

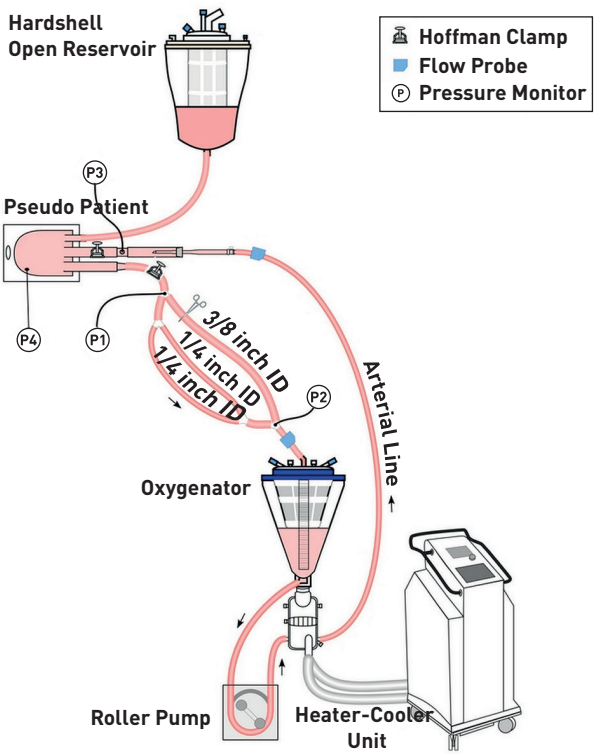

Fig. 2. Setup III for testing Circuits C and D using a soft bag as pseudopatient. During this experiment, venous pressure was kept at a constant range of 3 to 4 mmHg, simulating a controlled venous pressure more similar to a clinical scenario. Heater-cooler units allowed for experiments to be done at 35°C and 28°C. Hoffman clamp on the circuit arterial limb allowed for a constant post-cannula pressure of 50 mmHg.

Statistical Analysis

A linear mixed-effects model was fit to continuous hemodynamic outcomes to compare tubing sizes (*e.g.*, 1/4″ and 3/16″) and temperatures (*e.g.*, 28°C and 36°C) within specific flow rates. The linear mixed-effects model is an extension of linear regression that accounts for the within-subject variability inherent in repeated measures designs. In this study, the repeated factor is the location in the simulated system. For each outcome, P values were adjusted for multiple comparisons testing using Tukey-Kramer procedure. All hypotheses tests were two-sided and all analyses were performed using SAS software, version 23 (SAS Institute, Inc., Cary, NC, USA).

Results

Venous Limb Prime Volumes

The total volume necessary to fill 120 cm tubing of the venous limb was measured for each circuit option with results shown in Table 1.

Venous Line Resistance and Flow Rate

The results for Circuits A and B using Setup I are shown in Table 2. Results for Circuits C and D using Setups II and III are shown, respectively, in Tables 3 and 4.

Circuits A and B

Setup I compared dual 3/16″ venous limbs (Circuit A) *versus* a single 1/4″ venous limb (Circuit B) as shown in Table 2. The resistance across the circuit venous limb was assessed as well as the set pump flow rate *versus* the measured venous flow rate. Venous drainage was better with a single 1/4″ venous line than with dual 3/16″ venous lines, as indicated by a higher venous flow rate and

a lower venous resistance at flow rates of 500 ml/min to 1500 ml/ min, for both sets of temperature condition. Though, finding that the dual 3/16" circuit was less favorable at 1500 ml/ min may be academic, as most clinicians would not limit inferior vena cava (IVC) flow to a single 3/16" venous line at such flow rate with a dual venous limb circuit. The IVC flow is typically thought to provide two-thirds of the return to the heart and this experimental design doesn't account for that. The 1/4" venous circuit had an advantage over the dual 3/16" venous limb, with small savings in prime volume (Circuit B has 5 ml less than Circuit A).

Circuits C and D

Setup II compared dual 1/4" venous limbs (Circuit C) *versus* a single 3/8" venous limb (Circuit D) as shown in Table 3. The single 3/8" venous circuit had a higher flow at both temperature conditions with a slightly increased limitation at 28°C. The single

Temperature (°C)	Group	Circuit	Venous flow (ml/min)	B-A (ml/min)	P1 (mmHg)	P2 (mmHg)	P2-P1 (mmHg)	Resistance (Wood unit)
36	500 ml/min	A	515.0±0.3		-15.5±0.0	-6.2±0.0	9.3±0.0	18.1
		B	538.9±0.6	23.9±0.9	-15.6±0.0	-8.7±0.0	6.9±0.0	12.7
	1000 ml/min	A	1013.9±1.0		-15.3±0.0	5.7±0.0	21.0±0.0	20.7
		B	1087.8±0.6	73.9±0.7	-15.1±0.0	1.2±0.0	16.2±0.0	14.9
	1500 ml/min	A	1516.5±1.4		-15.0±0.0	21.1±0.0	36.1±0.0	23.8
		B	1728.5±0.6	211.9±1.4	-14.7±0.0	15.9±0.0	30.6±0.0	17.7
28	500 ml/min	A	523.0±0.2		-15.7±0.0	-4.9±0.0	10.9±0.0	20.8
		B	548.1±0.3	25.1±0.3	-15.8±0.0	-7.6±0.0	8.2±0.0	14.9
	1000 ml/min	A	1014.0±0.7		-15.3±0.0	8.1±0.0	23.5±0.0	23.1
		B	1125.8±0.8	111.8±1.0	-15.1±0.0	3.3±0.0	18.4±0.0	16.3
	1500 ml/min	A	1518.2±0.8		-15.0±0.0	24.4±0.0	39.3±0.0	25.9
		B	1768.4±1.4	250.2±1.4	-14.6±0.0	19.0±0.0	33.6±0.0	19.0

Table 2. Flow rate, pressure, and resistance of Setup I (Circuits A: two 3/16" and B: one 1/4")

Temperature (°C)	Group	Circuit	Venous flow (ml/min)	D-C (ml/min)	P1 (mmHg)	P2 (mmHg)	P2-P1 (mmHg)	Resistance (Wood unit)
36	1500 ml/min	C	1525.7±1.5		-14.5±0.0	0.1±0.0	14.6±0.0	9.6
		D	1681.4±2.1	155.7±0.8	-14.3±0.0	-7.5±0.0	6.8±0.0	4.1
	2000 ml/min	C	2022.6±1.4		-13.3±0.1	8.8±0.0	22.1±0.0	10.9
		D	2328.0±0.4	305.4±1.2	-12.3±0.0	-2.0±0.0	10.3±0.0	4.4
	2500 ml/min	C	2516.0±0.6		-11.9±0.0	19.1±0.0	30.9±0.0	12.3
		D	3152.9±0.8	636.9±0.7	-9.8±0.0	6.0±0.0	15.8±0.0	5.0
	3000 ml/min	C	3054.7±0.6		-10.4±0.0	31.8±0.0	42.2±0.0	13.8
		D	4393.3±11.4	1338.6±11.6	-5.3±0.1	20.5±0.1	25.8±0.2	5.9
28	1500 ml/min	C	1528.4±2.0		-14.1±0.0	1.2±0.0	15.2±0.0	10.0
		D	1714.3±0.5	185.9±2.4	-13.8±0.0	-6.9±0.0	6.9±0.0	4.0
	2000 ml/min	C	2008.7±0.2		-13.0±0.0	9.7±0.0	22.8±0.0	11.3
		D	2354.2±0.9	345.5±0.8	-11.9±0.0	-1.2±0.0	10.7±0.0	4.5
	2500 ml/min	C	2506.2±0.6		-11.3±0.0	21.2±0.0	32.5±0.0	13.0
		D	3217.0±4.5	710.8±4.4	-8.6±0.0	8.2±0.0	16.8±0.0	5.2
	3000 ml/min	C	3021.4±2.8		-9.5±0.0	34.2±0.0	43.7±0.1	14.5
		D	4505.3±10.6	1483.9±12.6	-3.5±0.0	24.8±0.1	28.3±0.1	6.3

Table 3. Flow rate, pressure, and resistance of Setup II (Circuits C: two 1/4″ and D: one 3/8″)

Temperature (°C)	Group	Circuit	Venous flow (ml/min)	D-C (ml/min)	P1 (mmHg)	P2 (mmHg)	P2-P1 (mmHg)	Resistance (Wood unit)
36	1500 ml/min	C	1418.3±0.4		-14.8±0.0	-1.6±0.0	13.2±0.0	9.3
		D	1537.4±1.0	119.0±1.0	-14.5±0.0	-8.3±0.0	6.2±0.0	4.0
	2000 ml/min	C	1804.5±0.6		-13.9±0.0	4.9±0.0	18.8±0.0	10.4
		D	2033.7±1.6	229.2±2.0	-13.2±0.1	-4.5±0.1	8.8±0.0	4.3
	2500 ml/min	C	2140.4±1.4		-13.0±0.0	11.4±0.0	24.4±0.0	11.4
		D	2508.6±0.2	368.3±1.4	-11.7±0.0	-0.1±0.0	11.6±0.0	4.6
	3000 ml/min	C	2451.2±1.2		-12.0±0.0	18.0±0.0	30.1±0.0	12.3
		D	3031.6±0.7	580.5±1.6	-10.1±0.0	5.0±0.0	15.1±0.0	5.0
28	1500 ml/min	C	1394.4±0.5		-14.5±0.0	-1.0±0.0	13.5±0.0	9.7
		D	1534.1±0.7	139.7±0.9	-14.4±0.0	-8.3±0.0	6.1±0.0	4.0
	2000 ml/min	C	1772.0±1.8		-13.7±0.0	5.5±0.0	19.2±0.0	10.8
		D	2015.9±0.4	243.9±2.1	-13.1±0.0	-4.2±0.0	8.8±0.0	4.4
	2500 ml/min	C	2116.2±1.4		-12.9±0.0	12.4±0.0	25.3±0.0	11.9
		D	2515.1±1.3	398.9±2.6	-11.3±0.0	0.7±0.0	12.0±0.0	4.8
	3000 ml/min	C	2397.9±0.8		-11.8±0.0	18.7±0.0	30.6±0.0	12.8
		D	3000.9±1.4	603.0±1.0	-9.6±0.0	5.8±0.0	15.4±0.0	5.1

Table 4. Flow rate, pressure, and resistance of Setup III (test from Circuit D to C)

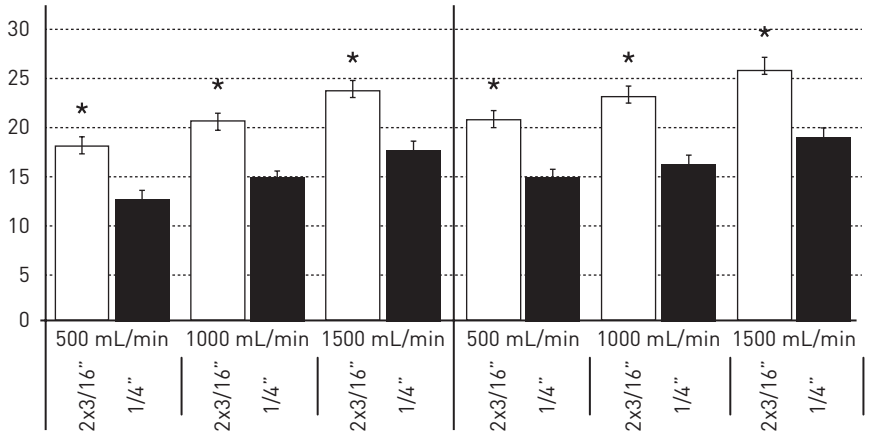

Fig. 3. Venous line resistance according to the arterial flow rate observed in Circuits A and B, in both normothermia and hypothermia (setup I), showing significant difference between them (*P<0.001)

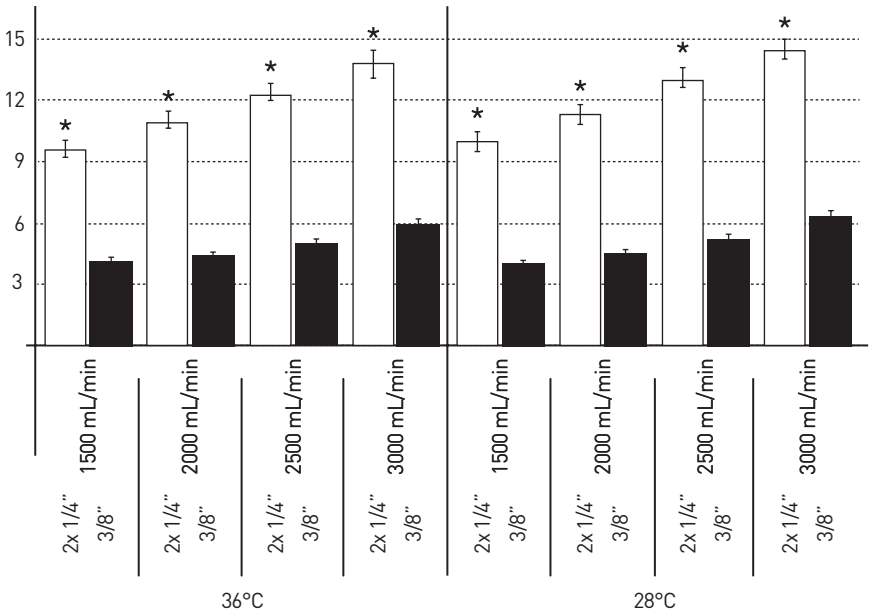

Fig. 4. Venous line resistance according to the arterial flow rate observed in Circuits C and D, in both normothermia and hypothermia (setup I), showing significant difference between them (*P<0.001)

3/8″ venous circuit had an apparent advantage over the dual 1/4″ venous limb with a clinically insignificant 10 ml (Circuit C has 10 ml of prime volume less than Circuit D) prime volume increase.

The results of using Setup III to test Circuits C and D with controlled venous pressure and flow up to 3000 ml are shown in Table 4. A higher achievable flow rate was also evident, although less marked, with a single 3/8″ tubing in the venous limb compared with the dual 1/4″ venous limb.

Venous Line Resistance

The venous line resistance of both Circuits A and B is shown in Figure 3. Arterial line (P3) pressures were maintained at 50 mmHg by a Hoffman clamp during all trials, pre-reservoir pressures increased (became less desirable) at higher flow rates and hypothermia. The difference between the venous line resistance of both Circuits A and B was statistically significant ($P<0.001$). Venous line resistance of both Circuits C and D is shown in Figure 4. The venous line resistance in Circuit C was significantly higher — less desirable — than in Circuit D at higher flow rates and hypothermia; the difference was also statistically significant ($P<0.001$).

Discussion

All of the CPB circuit components — oxygenator with or without an integrated ALF, venous and cardiotomy reservoirs, A-V cannulae, and tubing — should be evaluated *in vitro* to determine their hydrodynamic performance before they are used in clinical practice[16 - 18]. Brazil has a large number of medical devices manufactured and available only in this region which are approved by the National Health Surveillance Agency. These devices commonly do not have large clinical studies comparing clinical data or doing benchmarking of similar devices[19 - 21]. In this context, cultural issues associated withthe widespread clinical use of devices without any scientific evidence could be responsible for suboptimal outcomes

related to perfusion practice. Brazilian manufacturers and international distributors only offer three types of pre-mounted and pre-connected circuits — neonatal, pediatric and adult. There's not the possibility of customizing these circuits for each heart center. Furthermore, oxygenators are sold with a bypass tubing circuit to nearly all cardiac centers around the country. In this framework, the market dictates clinical practice with the common perception that smaller tubing ID is the most important feature when choosing a circuit for small patients. As a point of reference, the neonatal circuit has a dual 3/16" ID venous limb and a single 3/16" ID arterial limb. The pediatric circuit has a dual 1/4" ID venous limb and a single 1/4" ID arterial limb. Furthermore, the adult circuit commonly has a dual 3/8" ID venous limb — even in cases that this might not be needed — and a single 3/8" ID arterial limb.

The use of smaller ID A-V tubing for neonates and infants undergoing CPB procedures is a common perfusion practice in order to minimize the priming volume. However, it is important to remember that smaller ID tubing affects the hemodynamic profiles of CPB circuits, especially when combined with small- sized A-V cannulae for neonates and infants[4]. Adequate venous return is essential to provide the prescribed arterial flow to the patient during CPB. Gravity drainage allows for the movement of blood through the circuit (cannulae and venous limb of bypass circuit), from a higher area (patient on operating room [OR] table) to a lower area (venous reservoir), as long as the fluid column is not interrupted by air. Gravity drainage is dependent on the relative heights of the patient *versus* the venous reservoir, the length and diameters of the venous limb(s), the maintenance of a continuous fluid column, the patient volume status, and CVR characteristics[7]. Smaller CPB circuits may reduce blood bank transfusions at the beginning of CPB run, but if the drainage is suboptimal due to small ID tubing, an extra volume may need to be added to the reservoir to achieve the prearranged pump flow rate. Volume required to keep the venous reservoir volume above the minimum operating level is "dynamic" and may differ from the initial "static" priming volume. Our study

shows that there is an insignificant difference in the prime volume of dual venous limb circuits versus a single venous limb circuit. Therefore, the primary consideration becomes the ability to achieve the calculated flow rate with the selected circuit. The findings of this study indicate that the pressure drop in venous limb related to the tubing ID was the main resistance in the venous side of these simulated pediatric CPB circuits. A high resistance in the venous limb (pre-reservoir pressure) may result in insufficient venous return, limiting the perfusionist's ability of maintaining an adequate and safe minimum operating level in the venous reservoir. A higher venous pressure with siphon drainage — less negative-pressure — may require volume addition during CPB which eliminates the initial advantage of a decreased prime volume. As pointed out in our findings, this is the case for dual 3/16" venous limbs when compared to a single 1/4" venous circuit, as well as when comparing dual 1/4" venous limbs to a single 3/8" venous limb. Our results also showed that hypothermia could increase circuit resistance across CPB circuits most probably by increasing the blood viscosity of the perfusate and vascular resistance, which further elevates circuit pressure. Unfortunately, the latter effect cannot be seen in an *in vitro* study due to the fixed compliance of the tubing. Although there was higher (less desirable) pre- reservoir pressure under hypothermia than normothermia, the arterial flow delivered to the pseudopatient was similar.

We intentionally evaluated the circuits at routine CPB pump flow rates along with lower flow rates because the latter may be used during hypothermic CPB and CPB weaning. To be clear, we do not suggest using low flow rates for routine normothermic CPB procedures. For instance, pump flow rates of 500 mL/min can be used during weaning but not during a normothermic full-flow CPB. However, with the same circuit it is possible and it is not uncommon to use high-flow rates during rewarming.

Our data support that a dual 3/16" venous limb may be acceptable but not necessarily practical for venous drainage at a flow up to 1500 ml/min. Ultimately though, a single lower resistance 1/4"

venous limb is preferable when compared to a dual 3/16" venous limb at the same arterial flow rate. Finally, a single 3/8" venous limb circuit may be acceptable with gravity drainage at a flow rate up to 3000 ml/min. It is important to note that this experimental design measured overall flow and that clinicians must consider the flow differential between the upper body and lower body when using bicaval cannulation connected independently to dual venous limbs in the pump circuit. It is our hope that these data support a change towards single limb venous circuits which allow for improved achievable flow rates while, at the same time, does not introduce the variable of a limiting dual venous line, which can negatively impact lower body drainage when one limb is connected to the IVC cannula.

Limitations

Our results can be affected by the fact that this experiment was performed under *in vitro* conditions that may not represent all clinical CPB scenarios. Cannulae selection, table height relative to CVR level, gravity *versus* VAVD, and CVR design impact achievable venous flow rates. Temperatures and flows utilized during congenital heart surgery also vary significantly. Further, individual caval flow may vary considerably in this patient population based on patient's cardiac anatomy.

Conclusion

There was an insignificant difference in priming volume between dual venous and single venous limb circuits. Smaller dual limb venous circuits exhibited a higher venous resistance that was associated with reduced achievable flow and would likely result in impaired venous return during CPB. In addition, impaired venous return with smaller dual limb venous circuits could impose a volume penalty increasing hemodilution in order to keep a safe minimum operating level in the reservoir, which is contrary to the accepted rationale for using smaller ID tubing. Our data indicate that using

a single 1/4" venous limb is better than using a dual 3/16" venous limb at all flow rates up to 1500 ml/min flow rate. Moreover, a single 3/8" venous limb is better than a dual 1/4" venous limb up to 3000 ml/min. Assisted venous drainage would improve all values for all circuits, but without any clear benefit since priming volumes are nearly identical.

Our findings strongly suggest a revision of the perfusion practice in Brazil and justify the use of single venous limb circuits for CPB.

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Authors' roles & responsibilities	
LFC	**Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; drafting the work or revising it critically for important intellectual content; final approval of the version to be published**
GSM	**Drafting the work or revising it critically for important intellectual content; final approval of the version to be published**
DPG	**Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; final approval of the version to be published**
GV	**Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; final approval of the version to be published**
MM	**Substantial contributions to the conception or design of thework; or the acquisition, analysis, or interpretation of data forthe work; final approval of the version to be published**
IC	**Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; final approval of the version to be published**
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Thank you for the opportunity to contribute comments to this paper. About fifteen years ago when I traveled to INCOR hospital in São Paulo Brazil, I never thought there would be work devoted to determining the benefits of one venous line in a cardiopulmonary bypass circuit. As this study has shown, there is increased venous drainage utilizing a larger diameter single venous line versus two venous lines of half the diameter.

Poiseuille's law states that out of length, viscosity, pressure drop, and radius. Radius by far affects the resistance of blood flow through tubing by the power of 4. This means that when comparing two smaller venous lines versus one venous line of double the diameter, the larger venous line will have a statistically significant decrease in resistance, which increases blood flow through the tubing.

The pediatric population suffers from dramatic hemodilution during cardiopulmonary bypass. While the authors of this study mention that the difference in prime volume between the smaller double venous lines and larger single venous line is clinically insignificant, there is still an added benefit that is not addressed in this paper. As documented by Pintar and Collard, there is a direct relationship between foreign surface contact with blood and the body's systemic inflammatory response[1]. Reducing the number of venous limbs in the bypass circuit will decrease the surface area thus reducing the inflammatory response to a foreign surface. This is particularly beneficial to the pediatric population who are simultaneously battling deeper hypothermia, and increased donor exposures.

For all the reasons mentioned above, this paper very strongly supports single venous line utilization as standard practice not only here in the US, but also many other countries around the globe.

Thank you Professor Neirotti for continuing to support evidence-based changes to improve pediatric cardiac surgery!

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THE BRAZILIAN SOCIETY FOR CARDIOVASCULAR SURGERY (SBCCV) AND BRAZILIAN SOCIETY FOR EXTRACORPOREAL CIRCULATION (SBCEC) STANDARDS AND GUIDELINES FOR PERFUSION PRACTICE

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A primary role for clinical medicine societies is to develop standards and guidelines for practice as an instrument to promote safe and effective patient care. The Brazilian Society for Cardiovascular Surgery (SBCCV) represented by its Department for Mechanical Circulatory Assistance (Decam) and the the Brazilian Society for Extracorporeal Circulation (SBCEC) conducted a careful critical review of current clinical perfusion practices in Brazil. In addition, a literature review focused on patient safety and surgical outcomes in cardiac surgery was performed. This is the first joint initiative of these two societies (SBCCV/SBCEC) to provide a framework for safe and effective clinical perfusion practice for our cardiac surgery patients. The purpose of this pioneering work was to develop guidelines for the perfusion profession and for those involved in cardiopulmonary bypass (CPB) technology in our country. Both

the SBCCV and the SBCEC recommend that institutions and clinical teams adopt the standards and guidelines outlined in this text. The standards and guidelines we recommend are based on those published bythe published American Society for Extracorporeal Technology (AmSECT) with a phased adoption recommendation set as an achievable goal. Further, we recommend that cardiac surgery programs develop institution-specific protocols to support the clinical use of these guidelines.

The Pioneering Era of Cardiac Surgery

Open heart surgery has developed considerably over the past several decades including numerous pioneering efforts in Brazil regarding biomedical engineering and circulatory support[1]. Pioneer surgeons, such as John Kirklin, Francis Fontan, Euryclides Zerbini, Adib Jatene, and Denton Cooley were part of our lives and we were able to study their papers, witness their presentations and participate in professional discussions. They are passing away one after another but their work, techniques, experience and wisdom stays with us as their legacy. The impact of their methods profoundly changed the lives of our patients with congenital heart defects, giving them the chance of enjoying a better quality of life. Now, the pioneering era of cardiac surgery has essentially ended in Brazil.

Congenital cardiac surgery is markedly changing and surgeon-centered outcomes are being replaced by team- based efforts with new paradigms requiring an adaptive work environment in institutions where cardiac surgery is performed.

As William Norwood aptly put in his paper, *Our Roots, Our Future* [1] [2], "Institutions are not what they are by historical prerogative: the people walking the halls are responsible for maintaining the legacy and creating new vistas." That being said, we need to continue the initial work of our pioneers and press on upgrading their achievements to ever higher standards. The era we have now entered is no longer about quantity, it is about achieving excellent whole-patient quality outcomes including optimized neurologic outcomes. We must dig deep into issues

that impact the quality of outcomes, teamwork and overall transparency in our respective professions.

Reviewing Perfusion Practice: Time to Stop Living in the Past

Brazil has a strong history of innovation that extends back to the earliest days of cardiac surgery when our centers pioneered advances in heart-lung machines (HLMs), cardiac valves, conduit implants, and surgical techniques. Brazil started to produce their own HLMs in 1959 and indeed used one of them to perform the first heart transplantation in South America. These innovations highlighted the teamwork primarily of surgeons and biomedical engineers. This was natural since surgeons and other physicians were the first 'perfusionists'. Additionally, perfusion products, including a series of oxygenators, were developed and manufactured domestically. While we fondly remember these great achievements, we also need to focus on the future. Unfortunately, there are still people living in the past and not adapting to evolving cardiac surgery and perfusion practices. We continue to blame our economic burden for the stagnation of our practice while paying little to no attention to the need for cultural change in the operating room.

Furthermore, clinical perfusion has not been recognized by the government as a distinctive profession until quite recently. Currently, only five professional councils recognize Perfusion as a specialty for their undergraduates: Biology, Biomedicine, Nursing, Pharmacy, and Physiotherapy. These professions do not have a standardized perfusion-specific curriculum. Consequently, perfusionist education and training is heterogenous. Furthermore, it is still the case in Brazil that perfusionists must follow the instructions of surgeons and anesthesiologists. In fact, the conduct of perfusion is only considered a medical act once the perfusion record is signed by the surgeon. This practice risks perfusionists not taking full ownership for the conduct of CPB and that raises serious safety concerns since the surgeon and anesthesiologist have much to attend to during cardiac surgery and the perfusionist is the individual who can best manage extracorporeal support with all of its nuances. These facts support the outdated

paradigm whereby perfusionists are essentially asked to follow the instructions of surgeons and anesthesiologists during CPB instead of working collaboratively within a famework of well-developed perfusion practice guidelines. Currently, the SBCEC and the SBCCV are in discussion with the Federal Councils regarding ways for this activity to be uniformly recognized by the Professions and subsequently legalized with a federal law regulating perfusion activities. Brazilian perfusionists must have the education, tools and authority to perform their job and to become active and respected members of the multidisciplinary cardiac surgery team. Several limitations currently exist which impair the advancement of perfusion practice, including educational gaps, a lack of case ownership, and a lack of tools to assess the adequacy of perfusion in real time during surgery. This is a vicious cycle which impacts outcomes and patient safety.

On a positive note, it is important to highlight the progress made by the Brazilian Society of Extracorporeal Circulation. Supported and stimulated by their society, a significant number of Brazilian perfusionists have had the opportunity to attend symposium-based perfusion related courses, exchange experiences with more advanced international programs and to discuss current techniques of extracorporeal circulation with local perfusionists and those from abroad.

In more developed countries, perfusionists have the freedom to choose perfusion products according their performance, their patient population's needs, and the information available in the literature. Each component is selected via an independent decision with the ideal components used to build the circuit. Alternatively, in Brazilian perfusion practice, it is difficult to be objective since product decisions are almost exclusively based on price and subjective preferences due to the lack of scientific publications comparing Brazilian perfusion products with those available in other markets. In our country, oxygenator manufacturers typically provide complimentary HLMs with an agreement that their oxygenator can only be guaranteed on their HLM. There is an obvious conflict of interest with such an agreement. This implied agreement has no scientific basis and, to our knowledge, is not practiced elsewhere which speaks to the need for change in Brazilian cardiac surgery. Again,

our culture needs to adapt to end such practices for the benefit of our patients. This is even more of a concern when one notes that the majority of HLMs made and used in Brazil do not have servoregulating safety devices incorporated for arterial flow, cardioplegia delivery, level sensing, and bubble detectors. Servoregulation for HLM functions is not enough. Perfusionists must also be trained to operate the devices. Standards for perfusion practice, including the use of safety devices, must be established and adhered to.

Why are Clinical Perfusion Standards so Important?

The Gritten Report[3] published by the University Hospitals of Bristol National Health Service (NHS) Foundation Trust of Great Britain described the death of a five-month-old infant undergoing complex cardiac surgery and was released May 25, 2005. The Root Cause Analysis (RCA) report was led by Mark Gritten, an independent and nationally known NHS senior professional. A police investigation and coroner's inquest labeled the case 'unlawful killing'. In English law, unlawful killing means that the killing was made without lawful excuse and in violation of criminal law including murder, manslaughter, and infanticide. The finding of unlawful killing must be beyond reasonable doubt; that is, the evidence must be overwhelminglyobvious that death would result from the act when all factors are taken into account. Otherwise, a verdict of accidental death or death by misadventure would apply. The death was the result of a calcium overdose by a perfusionist that caused irreversible brain damage and subsequent death the day after surgery. The hospital put safeguards into place immediately to minimize any similar incidents happening again. Also, the National Society of Perfusionists perhaps carried some responsibility for this incident because it does not appear to have disseminated other perfusion incidents between its members.

The report concluded that this was a unique but avoidable incident that resulted in an indictment not just to the perfusionist involved in the accident, but to all perfusionists and the perfusion profession as a whole in Great Britain. Had a similar incident hap-

pened in São Paulo or Rio or elsewhere in Brazil, would the SBCEC or SBCCV also be held responsible?

Perfusion practice during cardiovascular surgery is recognized in the international literature as a critical component to successful patient outcomes. Therefore, as medical societies, we have the responsibility to change our culture, our commercial practices, legislation, regulations and whatever else which involves our specialty which can improve patient outcomes[4][5]. The intent of our proposed standards and guidelines document is to provide a modern framework for the practice of cardiopulmonary bypass in Brazil that can maximize patient safety and outcomes.

The standards and guidelines document we developed for perfusion practice in Brazil is based on publications from AmSECT [6] [7]. It focuses on the role of written institutional protocols to dictate clinical practice. We worked on four main subjects:

a. empowerment of perfusion as profession with a focus on professional qualification and education standards
b. standardization of perfusion practices
c. mandatory safety devices
d. importance of non-technical skills and patient centered team work

Professional Constraints:

Although perfusion is considered a medical act, Perfusion as a profession is still not fully regulated in Brazil. Consequently, the legal responsibility for what happens at the pump is unclear. The surgeon's knowledge of what is actually happening on the pump at all times during an operation depends upon their communications with the perfusionist. The surgeon's signature on the perfusion record is a formality which does not ensure proper care during CPB. This practice jeopardizes the development of a new generation of perfusionists who should be taking ownership for their individual perfusion cases and, of course, introducing the necessary changes to modernize existing clinical practices. The Perfusionist must be responsible for the whole

procedure of extracorporeal circulation and be an active member of the cardiac surgery team, as is the case with most enters abroad.

According to the SBCEC, perfusionists are expected to have:

a. Dedication to the patient
b. Full integration with the team in which they work
c. Professional competence
d. Personal ethical and professional conduct, as well as being zealous, affable, aware and observant.

Considering our context, the effort of publishing this document by the societies SBCCV and SBCEC should be considered as one of most important steps for the future of cardiopulmonary bypass practice in Brazil.

The"holy trinity" for the cardiac surgey patient— perfusionist, surgeon and anesthesist— is a critical issue for optimal outcomes in cardiac surgery. Therefore, publication in Brazil of the Standards and Guidelines for Perfusion Practice aims not only to improve CPB but also to improve overall surgical outcomes as an important quality improvment initiative.

Perfusion and the Pediatric Cardiac Surgery:

In the early 1950s, the pioneers of congenital cardiac surgery, among them— Bigelow, Lewis, Kirklin, Gibbon and others— realized that the time available with hypothermia and inflow occlusion would not be sufficient to safely perform lenghty intracardiac operations and that an extracorporeal support system would be needed. In 1954, Lillehei introduced the technique of controlled cross-circulation, in which a patient's parent functioned as the extracorporeal pump and oxygenator— a system that put both the parent and the child at risk. Therefore, the development of mechanical cardiopulmonary bypass circuits in the late 1950s was an important step for the progress of congenital cardiac surgery. Since then, extracorporeal perfusion circuits have come a long way to the current low prime membrane oxygenators, the use of centrifugal pumps, vacuum-assisted venous drainage, electronic gas blenders, in-line oxygen analyzers and other important devices.

The array and complexity of the equipment, the perfusion techniques to manage a wide variety of patient's age and size along with the broad spectrum of surgical procedures are real challenges that require properly trained and knowledgeable perfusionists.

Because one size does not fit all, the need for a standalone Standards and Guidelines document to perform perfusion for congenital heart surgery is unquestionable and it will in many ways be unique as compared to the one used for the correction of acquired heart disease in adults.

Providing cardiopulmonary support for repair of congenital heart lesions has become a specialty standing on its own. This context should determine the strategies and processes to address these issues; the professionals, administrators, and professional societies should be engaged in planning, setting and articulating the goals of robust pediatric perfusion standards and guidelines to improve the outcomes in pediatric cardiac surgery.

The Brazilian Society for Cardiovascular Surgery (SBCCV) and the Brazilian Society for Extracorporeal Circulation (SBCEC) Standards and Guidelines for Perfusion Practice address perfusion in general. We believe that developing a specific Brazilian Pediatric Perfusion Standards and Guidelines document is essential and that it should be published in the near future to complement this document.

Development of this Document

The Standards and Guidelines for Perfusion Practice will serve as a useful guide for Brazilian cardiac surgical teams to developinstitution-specific protocols aimed at improving the reliability, safety, and effectiveness of cardiopulmonary bypass. We are aware that the development of a Standards and Guidelines for Perfusion document alone will not change patient care or outcomes. Safe, reliable, and effective care will be best served through the implementation of institutional protocols based on these standards. SBCCV/SBCEC's Standards and Guidelines for Perfusion Practice reflect the changing landscape for perfusion leading to the safe and optimal provision

of cardiopulmonary bypass for our patients as well as a working team-based environment that is supportive of these policies.

We preferred to name this document "Standards and Guidelines for Perfusion Practice" because this terminology is contemporary and coincides with the language used by other professional medical societies, including AmSECT[8].

The SBCCV/SBCEC Standards and Guidelines for Perfusion Practice: 2018 is primarily based on a previous document developed by AmSECT, through its Perfusion Quality Committee. Initially, AmSECT developed a draft standard for perfusion entitled the "Essentials for Perfusion Practice, Clinical Function: Conduct of Extracorporeal Circulation," which was originally endorsed by the membership in 1993[9], and then reviewed and revised on a number of occasions[10-12]. In 2011, the AmSECT Board of Directors (BOD) asked the International Consortium for Evidence-Based Perfusion (ICEBP) subcommittee to review and update the "Essentials and Guidelines" document. The ICEBP conducted a careful review and critique of the document as well as its relevance and purpose, given the focus on patient safety and surgical outcomes. This initiative resulted in a revised joint document entitled, the Report from AmSECT's, International Consortium for Evidence-Based Perfusion American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice: 2013[13]. It was developed as an outgrowth of marrying evidence-based practices from the literature with an understanding of the context in which care is currently provided. Quite notably at the same time, the Minimum Standards for Perfusion Practice in Brazil document was developed as an outgrowth of ongoing collaboration with the International Quality Improvement Collaborative for Congenital Heart Surgery (IQIC) which is managed from Boston Children's Hospital and overseen by an international steering committee. Adoption of the Minimum Standards for Perfusion Practice in Brazil document will empower perfusionists to effect change at their institution by working towards practice standards endorsed by their national organizations including minimum safety devices for all cardiopulmonary bypass cases, monitoring devices to help assess the adequacy of perfusion,

and promotion of a team- based appoach for the care of cardiac surgical patients. Our vision to improve perfusion practice, and thus patient outcomes, is for the minimum standards to be adopted as soon as possible by Brazilian cardiac surgery teams with the comprehensive list of AmSECT standards phased in as soon as practial given the constraints discussed previously.

Following translation to Portuguese and critical review by colleagues, this final document was presented to the SBCCV and SBCEC for their steering commitiee aproval. A majority of the members of the steering commities of both societies voted to accept this document as an official position for the Standards and Guidelines for Perfusion Practice in Brazil. Both documents are included in this manuscript. The SBCCV and SBCEC endorse this comprehensive report and strongly recommend implementation.

Minimum Standards for Perfusion Practice in Brazil:

Seven standards were identified as the minimum recomendation for perfusion practice. The SBCCV and SBCEC considers these seven standards as mandatory for all cardiac surgical centers (Appendix 1).

SBCCV/SBCEC Comprehensive Standards and Guidelines for Perfusion Practice in Brazil:

The Perfusion Standards listed in Appendix 2 have been modified and adapted to the Brazilian regulatoy agencies' policies and recommendations, by taking The American Society of Extra-Corporeal Technology (AmSECT) Standards and Guidelines as a model[7] and translated to Portuguese. The final document consists of 15 areas of practice including 50 Standards and 38 Guidelines (Appendix 1) with the first standard focusing on the development of institutional protocols to support their implementation and use. Each institution must commit to working towards implementing all standards for patients undergoing cardiovascular surgery.

Terminology

The SBCCV and SBCEC would like to point out that cardiac surgery clinicians must understand the terminology used in this report. The meanings of these words, as described in the AmSECT publications, are listed below in order to facilitate understanding and adoption of the Standards and Guidelines[7] :

Standards: practices, technology, and/or conduct of care that institutions shall meet to fulfill the minimum requirements for cardiopulmonary bypass

Guidelines: recommendation that should be considered and may assist in the development and implementation of protocols

Protocols: an institution-specific written document, derived from professional standards and guidelines, which contains decision and treatment algorithms

In this document, the word **shall** is used to indicate a **mandatory** requirement

In this document, the word **should** is used to indicate a **recommendation**

In this document, the term **surgical care team** is used to indicate the components of the system: surgeon, anesthesiologist, perfusionist, nurse, and technicians

Conclusion

The SBCCV and SBCEC both recognize the vital need for cultural and clinical changes in the application of cardiopulmonary bypass in Brazil. Cardiac surgery enters must adopt the MinimumStandards For Perfusion Practice in Brazil as soon as possible and work towards adopting the Comprehensive Standards and Guidelines for Perfusion Practice in Brazil moving forward. Ultimately, a team-based approach utilizing nationally endorsed standards will help ensure safe and optimal cardiopulmonary bypass for all our patients and improve outcomes for the complex population we serve.

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Appendix 1

Minimum Standards for Perfusion Practice in Brazil

Minimum Standard 1: Perfusion practice must be guided by a written set of policies developed within the institution and approved by physician leadership. (See also Comprehensive Standard 1).

Minimum Standard 2: Each perfusionist must be adequately trained through a defined education process. Staff must participate in annual continuing education activities and institutional based quality improvement programs. (See also Comprehensive Standards 2 and 13).

Minimum Standard 3: The care team must discuss the bypass plan before incision; anticoagulation plan and target ACT values, pump flows, hematocrit management, target temperature, myocardial protection plan, blood gas management, blood pressure goals, etc. Closed-loop communication must be used during the procedure. The care team must have real- time multidisciplinary discussion regarding all concerns during bypass (*i.e.*, blood pressure too low, poor venous drainage, falling NIRS, need for blood product transfusion, etc.). (See also Comprehensive Standards 1, 3, 5, 8 and 12).

Minimum Standard 4: Perfusion equipment must be maintained by qualified personnel. An appropriately sized selection of equipment and standardized disposables must be used for each patient with back-up equipment available. Back-up supplies of cannulae and connectors, etc., must be located next to the primary perfusionist in the OR. The bypass circuit must be set-up on the heart-lung machine before the patient arrives in the operating room. (See also Comprehensive Standards 6 and 14).

Minimum Standard 5: The perfusion record must include sufficient timed data to reconstruct a bypass run, include the prebypass checklist and list the products used for the case. The perfusion record must be part of part of the patient's medical record. (See also Comprehensive Standards 3,4, 5, 7, 8, 9 and 12).

Minimum Standard 6: The follow monitoring and safety devices must be used for all patients; patient and circuit temperature probes, reservoir level sensor, bypass system and cardioplegia temperature and pressure, an arterial line filter, flow probe, one-way valve on the vent line, back-up oxygen supply, SvO2 monitoring and a hand crank. The following items should be considered for every case: NIRS monitoring and bubble detection. Servoregulation must be utilized where available. Blood gases must be verified on a defined schedule. (See also Comprehensive Standards 6, 7, 10 and 11).

Minimum Standard 7: The perfusion team must have adequate storage space near the operating theater for back-up and emergency supplies. A comfortable chair which allows for close monitoring of the perfusion circuit should be available to the perfusoinist during bypass. (See also Comprehensive Standard 14).

Appendix 2

SBCCV/SBCEC Comprehensive Standards and Guidelines for Perfusion Practice in Brazil[1]

Standard 1: Development of Institutionally based Protocols

Standard 1.1: As a mechanism for applying each standard to clinical practice, an institution or service provider shall develop and implement an operating procedure (protocol) for each of the standards.

Standard 1.2: The protocol shall be:

- Approved by the Chairman of Cardiac Surgery, or his or her designee, Director of Perfusion or equivalent, and other relevant clinical governance committees if available.
- Reviewed and revised annually or more frequently when deemed necessary.

1. "The SBCCV/SBCEC Comprehensive Standards and Guidelines for Perfusion Practice in Brazil have been modified and adapted, following Brazilian regulatory agencies' policies and recommendation, from The American Society of Extracorporeal Technology (AmSECT) Standards and Guidelines[2] and translated to Portuguese"

Guideline 1.1: Deviation from protocol may be at the discretion of the Surgical Care Team and should be documented in the perfusion record.

Standard 2: Qualification, Competency, and Support Staff

Standard 2.1: Extracorporeal circulation should only be performed by a professional trained among the professions recognized by SBCEC and SBCCV as competent to carry out the procedure; have a post-graduate degree recognized by the Brazilian Ministry of Education (MEC) with minimum workload described in article 12 of the Brazilian Standards for the Exercise of the Specialty of Perfusionist in Extracorporeal Circulation or SBCEC Specialist Degree[1], validated by this society; or professionals who fall within the sole paragraph of Article 2 of the aforementioned Standard.

Standard 2.2: Perfusionist competency shall be assessed annually to evaluate compliance with departmental protocols.

Standard 2.3: The perfusionist shall attend, participate, and engage in perfusion-related continuing education courses on an annual basis.

Standard 2.4: Support staff shall be available on-site to assist the primary perfusionist during CPB procedures.

Guideline 2.1: An individual graduating from an accredited perfusion education program should complete all requirements for the Sociedade Brasileira de Circulação Extracorpórea (SBCEC) certification.

Guideline 2.2: A standardized process should be developed and followed to identify, orient, and educate support staff to ensure they have general knowledge of the duties performed by the perfusionist, flow of the operation, and location of primary and ancillary items required during CPB. Support staff may include a perfusionist, nursing, technical, or nontechnical staff.

Guideline 2.3: A standardized process to educate, train, and to evaluate annually perfusion staff should be developed and followed.

Guideline 2.4: It is recommended any perfusion procedure be conducted by two perfusionists, ensuring a better procedural safety.

Guideline 2.5: Use of Personal Protective Equipment: The perfusionist should use Personal Protective Equipment (PPE), such as masks, goggles and procedure gloves while conducting CPB. Gloves should be changed after drawing a blood sample, blood products administrtion and manipulation (blood bag) or whenever exposed to a blood splash[3].

Standard 3: Perfusion Record

Standard 3.1: The perfusion record (written and/or electronic) for each CPB procedure shall be included as part of the patient's permanent medical record. The perfusion record shall be maintained and stored according to institution policy for retaining patient medical records.

Standard 3.2: The record shall include:

- Patient information including demographics and preoperative risk factors (Appendix A)
- Information sufficient to accurately describe the procedure, personnel, and equipment (Appendix B).
- Patient physiological parameters documented at a frequency determined by institutional protocol (Appendix C).
- Blood gas and anticoagulation monitoring results (Appendix D).
- Signature of the perfusionist (and all relief perfusionists) performing the procedure.

Guideline 3.1: There should be perfusion (writing and/or electronic) record for each performed CPB procedure. The perfusion record must include a free text space for recording comments, including verbal orders given by the medical staff, including verbal orders given by the supervising physician.

Guideline 3.2: The perfusion record should include the signatures of the physician(s) providing oversight for the CPB procedure.

Guideline 3.3: Raw data (*e.g.*, blood flow, pressure, and temperature values) contained in electronic perfusion databases should be stored for a time period in accordance with your institution's policy for retaining electronic patient medical records.

Standard 4: Checklist

Standard 4.1: The perfusionist shall use a checklist for each CPB procedure[4].

Standard 4.2: Checklists shall be included as part of the patient's permanent medical record.

Guideline 4.1: The perfusionist should use checklists in a read-verify manner where critical steps that should have been performed are confirmed[4]. Completion of the check- list should be performed by two people, one person being the primary perfusionist responsible for operation of the heart lung machine during the intraoperative period. In services where there is no availability of another professional perfusionist, a systematic routine of checking the items contained in the checklist should be adopted, in order to minimize the occurrence of adverse events.

Guideline 4.2: The perfusionist should use a checklist throughout the entire perioperative period (*e.g.*, setup, pre- bypass, initial onset of bypass, before cessation of bypass, postbypass, and/or any return to bypass).

Guideline 4.3: The perfusionist should use a checklist for other ancillary perfusion services (*e.g.*, cell salvage, intra-aortic balloon pump, extracorporeal membrane oxygenation).

Standard 5: Communication

Standard 5.1: A patient-specific management plan for the CPB procedure shall be prepared and communicated to the surgical team either during the preoperative briefing or before beginning the procedure[5].

Guideline 5.1: The use of cellular telephone technology in the operating room should be avoided, since it is a distracting factor and predispose the patient to the risk of contamination by potentially infectious bacteria, compromising the quality and safety of the health assistance. When their use is unavoidable, the devices must be pre-sanitized according to the institution protocol for infection control[6-8].

Guideline 5.2: Protocol-driven communication (*e.g.*, closed-loop) should be used to acknowledge verbal commands, verify the content, and reduce ambiguity[9-11].

Guideline 5.3: The primary perfusionist should participate in the postprocedure debrief with the surgical team.

Standard 6: Safety Devices

Standard 6.1: Pressure monitoring of the arterial line, cardioplegia delivery systems, and venous reservoir (when vacuum assisted venous drainage is used) shall be used during CPB procedures.

- The pressure monitor shall be either servoregulated to control the arterial/cardioplegia pump or to allow interruption to the arterial/cardioplegia flow.
- The pressure monitor shall include an audible and visual alarm.

Standard 6.2: A bubble detector shall be used during CPB procedures.

- The gross/macrobubble detector shall be used to control the arterial pump or to allow interruption of the arterial blood flow.
- The detector system shall include an audible and visual alarm and be positioned according to manufacturer instructions for use to enable timely identification and action.

Standard 6.3: A level sensor shall be used during CPB procedures using a (hard-shell) reservoir.

- The level sensor shall be either servo-regulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor shall include an audible and visual alarm and be positioned according to the manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.

Standard 6.4: Temperature monitoring of the arterial outflow from the oxygenator shall be used during CPB procedures.

- The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures.

Standard 6.5: An arterial-line filter shall be used during CPB procedures.

Standard 6.6: A one-way valve in the vent line shall be used during CPB procedures.

Standard 6.7: A method for retrograde flow avoid- ance when using a centrifugal pump shall be used during CPB procedures.

- At least one method to prevent retrograde flow shall be used for systems using centrifugal pumps for systemic circulation. Examples of retrograde avoidance systems may include the following:
- One-way flow valves;
- Hard-stop detent controls to prevent accidental
- reduction in pump speed;
- Electronically activated arterial line clamps; or
- A low-speed visual and audible alarm.

Standard 6.8: An anesthetic gas scavenge line shall be used whenever inhalation agents are introduced into the circuit during CPB procedures.

Standard 6.9: Hand cranks shall be readily available during CPB procedures.

Standard 6.10: A back-up gas supply shall be available during CPB procedures.

Standard 6.11: A back-up battery supply for the CPB machine shall be available during CPB procedures.

Guideline 6.1: A ventilating gas oxygen analyzer should be used during CPB procedures.

Guideline 6.2: A level sensor should be used during CPB procedures using a soft-shell reservoir.

- The level sensor should be either servo-regulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor should include an audible and visual alarm and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.
- The use of an air bubble detector distal to the outlet can be used as a surrogate level detector.

Guideline 6.3: The tubing pack should be provided by the manufacturer "pre-assembled", pre-connected and in a sterile tray sepa-

rating the circuit that will be used in the surgical field of the one that will be mounted in the heart- lung machine (HLM), offering more safety to the perfusion itsef and granting faster circuit assembly.

Standard 7: Monitoring
(Obs: to be performed in conjunction with Standard 3)

Standard 7.1: Patient arterial blood pressure shall be monitored continually during CPB.

Standard 7.2: Arterial line pressure shall be monitored continually during CPB.

Standard 7.3: Arterial blood flow shall be monitored continually during CPB.

Standard 7.4: Cardioplegia dose, delivery method, line pressure (antegrade), coronary sinus pressure (retrograde), and ischemic intervals shall be monitored continually during CPB.

Standard 7.5: Patient and device temperatures shall be monitored continually during CPB.

- Patient (*e.g.*, nasopharyngeal, rectal, bladder, esophageal).
- Heart–lung machine (arterial, venous and cardioplegia).
- Heater cooler (H_2O temperature).

Standard 7.6: Blood gas analyses shall be monitored con- tinually or at regular intervals during CPB (Appendix D).

Standard 7.7: Hematocrit (or hemoglobin) shall be monitored continually during CPB.

Standard 7.8: Oxygen fraction and gas flow rates shall be monitored continually during CPB (Appendix D).

Standard 7.9: The percentage of venous line occlusion of the venous occluder shall be monitored continually during CPB.

Standard 7.10: Venous oxygen saturation shall be monitored continually during CPB.

Guideline 7.1: Carbon dioxide removal should be monitored continually during CPB.

Guideline 7.2: Arterial oxygen saturation should be monitored continually during CPB.

Guideline 7.3: The following patient pressures should be monitored during CPB:

- Central venous pressure; and/or Pulmonary artery blood pressure.

Guideline 7.4: Continuous in-line blood gas monitoring should be used during CPB.

Guideline 7.5: Cerebral oximetry should be used during CPB.

Guideline 7.6: Arterial blood flow should be monitored continually at a point in the CPB circuit where it accurately reflects the flow delivered to the patient during CPB (*e.g.*, distal to intracircuit shunts).

Standard 8: Anticoagulation

Standard 8.1: The perfusionist, in collaboration with the physician-in-charge, shall define the intended treatment algorithm for anticoagulation management (heparin) and an alternative algorithm for when heparin is not suitable, including acceptable ranges for activated clotting time (ACT).

Standard 8.2: The perfusionist shall work closely with the surgical care team to monitor and treat the patient's anti- coagulation status before, during, and after the CPB period.

Guideline 8.1: The surgical care team should determine the target ACT by considering relevant factors, including variability in the measurement of ACT attributed to the device's performance characteristics.

Guideline 8.2: Patient-specific initial heparin dose should be determined by one of the following methods:

- Weight;
- Dose–response curve (automated or manual);
- Blood volume; or
- Body surface area.

Guideline 8.3: Anticoagulation monitoring should include the testing of ACT. Additional monitoring tests may include:

- Heparin level measurement, *e.g.*, heparin/protamine titration or unfractionated heparin level;
- Partial thromboplastin time;
- Thromboelastograph;

- Thrombin time; and/or
- Anti-Xa.

Any point-of-care (POC) device should be used under the hospital clinical laboratory policies. The Clinical Laboratory Director is responsible for all POCs tests performed within the institution. The clinical laboratory should provide documented standard procedures to all sites using POC devices for guidance on its pre-analytical, analytical and post-analytical phases, including:

a. systematic recording and release of interim results;
b. procedure for potentially critical lab test results;
c. systematic review of results and release of reports by qualified professional.

The clinical laboratory should keep records for the quality control program as well as the standards procedures to perform them. The clinical laboratory should promote and maintain records of its ongoing users' education process for POC equipments[12].

Guideline 8.4: Additional doses of heparin during CPB should be determined by using an ACT and/or heparin/ protamine titration. Note: in patients requiring longer CPB times (>2 to 3 hours), maintenance of higher and/or patient-specific heparin concentrations during CPB may be considered to reduce hemostatic system activation, reduce consumption of platelets and coagulation proteins, and to reduce blood transfusion (Class IIb, Level of evidence B)[13].

Guideline 8.5: Heparin reversal should be confirmed by ACT and/or heparin/protamine titration.

Standard 9: Blood Management

Standard 9.1: The perfusionist shall participate in efforts to minimize hemodilution and avoid unnecessary blood transfusions[13].

Standard 9.2: The perfusionist shall minimize the CPB circuit size to reduce prime volume[13].

Standard 9.3: The perfusionist shall calculate and communicate to the surgical team before initiating CPB a patient's predicted post-dilutional hemoglobin or hematocrit.

Guideline 9.1: Blood management efforts should include the following[13]:

- Participate in preoperative briefings (discussions) with the surgical care team (Standard 5.1) regarding transfusion strategies and target hematocrit values.
- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
- Matching the size of the CPB circuit to the size of the patient;
- Autologous priming of CPB circuit, including retrograde arterial and venous antegrade priming;
- Biocompatible coating on the surface of all CPB components;
- Perioperative blood cell recovery and reinfusion after being appropriately processed; and CPB circuit blood salvage at the end of the procedure.

Guideline 9.2: Point-of-care hemostasis monitoring should be used to minimize blood loss.

Monitoring may include:

- International normalized ratio;
- Partial thromboplastin time;
- Prothrombin time;
- Thrombin time;
- Thromboelastography/thromboelastometry;
- Platelet count; and/or
- Platelet function analysis.

Standard 10: Gas Exchange

Standard 10.1: Gas exchange shall be maintained during CPB according to protocol accounting for:

- The individual patient characteristics/risk profile;
- Oxygenator type, design, and instructions for use; and
- Blood flow, temperature, and metabolic demand.

Standard 10.2: Devices used to measure gas exchange shall be calibrated according to the manufacturer's instructions for use.

Standard 10.3: Blood gas analysis shall be performed and recorded according to protocol.

Guideline 10.1: Point-of-care testing should be considered to provide accurate and timely information for blood gas analysis[14].

Guideline 10.2: Oxygen delivery and consumption calculations should be used to evaluate and optimize gas exchange[15]:

Oxygen delivery: $DO_2 = 10\ CI\ CaO_2$

Oxygen consumption: $VO_2 = 10\ CI\ (CaO_2 - CvO_2)$

Where:

CaO_2 (arterial oxygen content) = $(Hb \times 1.36 \times SaO_2) + (0.0031 \times PaO_2)$

and

CvO2 (mixed venous oxygen content) = $(Hb \times 1.36 \times SvO_2) + (0.0031 \times PvO_2)$

CI = cardiac index HB = hemoglobin

PaO_2 = partial pressure of oxygen in arterial blood PvO_2 = partial pressure of oxygen in venous blood SaO_2 = arterial oxygen saturation

SvO_2 = venous oxygen saturation

Guideline 11.1: Variance from intended and targeted blood flow should be communicated to the physician-in-charge.

Guideline 11.2: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
- Base excess;
- Anesthetic level;
- Arterial blood pressure;
- Cerebral oximetry;
- Lactate burden; and
- Oxygen delivery and consumption (refer to Guideline 10.2 for formulae).
- Venous pO_2
- Arterial pO_2
- Hemoglobin concentration
- Arterial oxygen saturation
- Systemic vascular resistance (SVR);

- Temperature; and
- Venous oxygen saturation.

Standard 12: Blood Pressure

Standard 12.1: The perfusionist, in collaboration with the physician-in-charge, shall define and communicate the intended treatment algorithm for blood pressure management before CPB, including acceptable ranges for blood pressure. Obs: in many circumstances, the physician- in-charge may direct the perfusionist to modify the intendedblood pressure management to address circumstances occurring during the CPB procedure.

Standard 12.2: The perfusionist shall work closely with the surgical care team to maintain blood pressure according to protocol during CPB.

Guideline 12.1: Variance from intended and targeted blood pressure should be documented and communicated to the physician-in-charge to allow for changes in the blood pressure management plan.

Standard 13: Quality Assurance and Improvement

Standard 13.1: The perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs.

Guideline 13.1: The perfusionist should collect data regarding conduction of the perfusion through a clinical registry or database.

Guideline 13.2: The perfusionist should use this data for quality control and improvement projects[16] [17].

Guideline13.3: The perfusionist should evaluate the postoperative period of the patient in a standard form (Appendix E), storing data for periodic evaluation of perfusion in his service[18].

Guideline 13.4: Specific and periodic meetings should be held in his service for the review of avoidable errors occurring in his daily practice.

Guideline 13.5: Any adverse events shall be notified in writing to the responsible sector, which shall forward them to the regulatory agencies and other competent areas after their verification. The service should encourage notifications to be always carried out, establishing a direct line of communication between the team and the risk management department, guaranteeing their confidentiality[19].

Standard 14: Maintenance

Standard 14.1: The perfusionist shall assure that properly maintained and functioning equipment is used in the conduct of CPB, including (but not limited to):

- Heart–lung machine Pumps
- Timers
- Pressure monitors
- Temperature monitors
- Low-level alarm
- Air bubble detector(s)
- Blood flow sensors
- Heater/cooler
- Anesthetic vaporizer
- Oxygen blender/flow meter
- Oxygen analyzer
- Ancillary equipment
- Intra-arterial blood pressure
- Vascular assist device
- Cell salvage device

Standard 14.2: Preventive maintenance on perfusion equipment shall be performed and documented on a regularly scheduled basis by the perfusion team and/or appropriately trained and qualified biomedical engineering staff. Any or all of the following may determine the interval of such maintenance:

- Manufacturer recommendations;
- External accrediting agency guidelines; and/or
- Institutional requirements.

Note: In the case of consigned equipment, the owner of the CPB machine is responsible for maintaining the perfusion set, and all liabilities and legal issues will be assigned to it. In the case of an adverse event resulting from the use of this equipment, even if the equipment is proven to be defective, even with adequate maintenance and not related to improper use by the perfusionist, the owner of the equipment and not the institution shall be held liable.

Therefore, there should be an updated document for each of the equipment used, with dates and details of preventive and corrective maintenance and that should be filed in the perfusion service/department or clinical engineering unit of the institution[20].

Standard 14.3: The organization shall have a written procedure for perfusion equipment failures[21].

Standard 14.4: Appropriate back-up perfusion supplies shall be readily available. Obs: when CPB machine is not property of the institution, the equipement's owner will be responsible for the replacement, and has legal responsibility for this action.

Standard 15: Duty Hours

Standard 15.1: The perfusionist can be hired by the hospital or through a medical services company, respecting the labor laws according to the signed agreement.

Standard 15.2: It is briefly forbidden for the perfusionist to be engaged to perform perfusion and perform another function in the service with the same labor contract.

Guideline 15.1 The perfusionist should receive a minimum of 8 hours of rest period for each consecutive 16-hour work period [22-24].

Appendix A
Patient Information

1. Medical record number
2. Patient surname, first name
3. Demographics
    a. Age (date of birth)
    b. Gender
    c. Height
    d. Weight
    e. Body surface area (BSA)
4. Blood type
5. Laboratory data
    a. Hemoglobin/hematocrit
    b. Predicted hematocrit on bypass
    c. White blood cell count
    d. Platelet count
    e. Activated partial prothrombin time
    f. Sodium
    g. K+
    h. Blood urea nitrogen/creatine
    i. Glucose
    j. Other relevant laboratory values
6. Patient allergies
7. Planned procedure
8. Medical history/risk factors (recommended)
    a. Cardiovascular
    b. Pulmonary
    c. Renal
    d. Neurologic
    e. Gastrointestinal/endocrine

Appendix B
Information Sufficient to Accurately Describe the Procedure, Personnel, and Equipment

1. Date of procedure
2. Type of procedure
3. Perfusionist(s) names
4. Surgeon(s) name
5. Anesthesiologist(s) name
6. Nurse(s) name
7. Operating room number
8. Comments/events (recommended)
9. Equipment
    a. Heart–lung machine
    b. Cell salvage (autotransfusion) device
    c. Heater/cooler

Note: Items A–C are often uniquely identified (*e.g.*, Pump 1, 2, 3, etc.) The related serial numbers for each component (*e.g.*, roller pumps, vaporizer, blender, etc.) are documented and stored locally.

10. Disposables
    a. Oxygenator
    b. Cardiotomy reservoir
    c. Tubing pack/arterial line filter
    d. Centrifugal pump head
    e. Cardioplegia delivery system
    f. Cell salvage (autotransfusion)
    g. Ultrafiltration device
    h. Arterial cannula
    i. Venous cannula
    j. Cardioplegia cannulae
    k. Sump/vent(s)

Note: Manufacturer, model, serial, and/or lot numbers should be documented with items a–k.

Appendix C
Patient Physiological and Perfusionist Practice Parameters Documented at a Frequency Determined by Institutional Protocol

1. Blood flow rates (RPM)
2. Arterial blood pressure
3. Arterial line pressure
4. Central venous/pulmonary artery pressure
5. Vacuum assist venous return (VAVR)
    a. VAVR pressure
    b. Venous inlet pressure (VIP)
6. Arterial/venous blood gases
7. Venous oxygen saturation
8. Patient temperatures, including:
    a. .Patient core (at least one)
        I. Nasopharyngeal
        II. Bladder
        III. Esophageal
        IV. Rectal
        V. Tympanic
        VI. Myocardium (optional)
9. Cardiopulmonary bypass temperatures:
    I. Venous return blood
    II. Arterial blood inflow
    III. Water bath(s) (optional)
10. Oxygenator gases including gas flow rate and concentration(s)
11. Input fluid volumes including:
    a. Prime
    b. Blood products
    c. Asanguineous fluids
    d. Cardioplegic solution
    e. Autologous components
12. Cardioplegia
    I. Solution (ratio)
    II. Route

III. Flow
IV. Pressure
V. Temperature
VI. Volume

13. Output fluid volumes, including:
    a. Urine output
    b. Ultrafiltrate

Medications and/or inhalational anesthetic agents administered through extracorporeal circuit

Appendix D
Blood Gas, Electrolyte, and Anticoagulation Monitoring Results

1. Blood gases
    a. pO_2
    b. pCO_2
    c. pH
    d. Base excess
    e. Bicarbonate concentration
    f. Saturation
    g. Potassium concentration
    h. Ionized calcium concentration i. Sodium concentration
    i. Lactate
    j. Glucose
    k. Hemoglobin/hematocrit
2. Activated clotting times (ACTs) and/or heparin/ protamine assay results and/or thromboelastography results.

Appendix E
Postoperative Evaluation of Patients Submitted to Extracorporeal Circulation

1. Name
2. Patient's hospital identification number
3. Date of surgery
4. Date/Time of ICU admission

5. Values of CK, CKMB and Troponin at 6hs, 12hs and 24hs
6. Ejection fraction in the postoperative period.
7. Vasoactive drugs dose used at 6hs, 12hs and 24hs
8. Water balance every 6 hours until completing 48 hours of ICU
9. Central venous pressure every 6 hours, until completing 48 hours of ICU
10. Use of blood products
11. Extubation Time
12. Date of ICU discharge

Appendix F
Checklist

The checklist should check, at least:

- Integrity and operation of the CEC machine and heat exchanger.
- Operation of gas systems and connections to the oxygenator.
- Correct identification of the patient.
- Availability of blood products.
- Composition of the perfusate.
- Composition and preparation of cardioplegia.
- Cannulas that will be used.
- All circuit connections.
- Calibration and direction of the rollers.
- Calibration of pressure, flow and bubble sensors and alarms.
- Calibration of cardioplegia pressure sensors.
- Calibration and connection of the gas monitor.
- Availability of disposable materials and emergency equipment (hand crank, emergency light, etc.)
- Dose and administration of heparin.
- Outcome of ACT before starting ECC.
- Availability of drugs, needles, syringes, and serum and blood infusion kits for use during CPB.

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Appendix 1 (Portuguese version)

Padrões Mínimos para a Prática de Perfusão no Brasil

Minimum Standard 1: As práticas de perfusão devem ser orientadas por um conjunto de políticas desenvolvidas dentro da instituição, disponíveis na forma escrita e aprovadas pelo)a) chefe da equipe cirúrgica (para mais detalhes, veja Comprehensive Standard 1).

Minimum Standard 2: Cada perfusionista deve ser treinado adequadamente em um processo de formação definido. Toda a equipe de perfusionistas deve participar das atividades anuais de educação continuada e dos programas de melhoria de qualidade da instituição (para mais detalhes, veja Comprehensive Standards 2 e 13).

Minimum Standard 3: A equipe cirúrgica deve discutir o plano de perfusão antes da incisão na pele, assim como anticoagulação e valores de TCA alvo, fluxos de perfusão, hematócrito alvo e política transfusional, temperatura alvo, estratégia de proteção miocárdica e manuseio da pressão arterial. A comunicação em alça fechada (*closed loop*) deve ser usada durante todo o procedimento. A equipe deve promover uma discussão multidisciplinar em tempo real sobre todas as preocupações durante a circulação extracorpórea (ou seja, pressão arterial muito baixa, dificuldade com a drenagem venosa, queda dos valores da oximetria cerebral não invasiva – near-infrared spectroscopy – NIRS, necessidade de hemoderivados, dentre outras) (para mais detalhes, veja Comprehensive Standards 1, 3, 5, 8 e 12).

Minimum Standard 4: A manutenção do equipamento de perfusão deve ser realizada por pessoal qualificado. A escolha adequada dos equipamentos necessários e dos descartáveis padronizados em protocolo institucional deve ser realizada para cada paciente, assim como um equipamento de reserva deve estar disponível para a perfusão. Os suprimentos e componentes descartáveis do circuito (cânulas e conectores etc.) em duplicidade devem estar localizados o mais próximo possível do perfusionista responsável pelo caso, preferencialmente na sala de cirurgia. O circuito de circulação extracorpórea (CEC) deve ser montado na máquina de CEC antes que o paciente chegue à sala de operação (para mais detalhes, veja Comprehensive Standards 6 e 14).

Minimum Standard 5: A ficha (registro) de perfusão deve incluir dados suficientes para reconstruir a perfusão por inteiro, incluindo um

checklist pré-CEC e contendo todas as drogas e descartáveis utilizados para a condução do caso. A ficha de perfusão deve ser parte do prontuário médico do paciente e deve ser anexada a ele. Uma cópia deve ser mantida com a equipe de perfusão (para mais detalhes, veja Comprehensive Standards 3, 4, 5, 7, 8, 9 e 12).

Minimum Standard 6: Os seguintes dispositivos de monitoração e segurança devem ser utilizados para todos os pacientes: sensores de temperatura no paciente, no circuito venoso e arterial e na cardioplegia; sensor de nível de reservatório; sensor de bolhas; sistema de pressão na linha arterial e na linha de infusão da cardioplegia; filtro de linha arterial; fluxômetro na linha arterial; válvula unidirecional na linha aspiração da aorta/ átrio esquerdo; cilindro de oxigênio de reserva; equipamento de monitoração da SvO2; monitor de oximetria cerebral contínua (NIRS); detector de bolhas e "*hand cranck*" para manuseio manual da bomba arterial. A servorregulação deve ser utilizada sempre que disponível. Os gases no sangue devem ser verificados em uma rotina predefinida em protocolo (para mais detalhes, veja Comprehensive Standards 6, 7, 10 e 11).

Minimum Standard 7: A equipe de perfusão deve ter espaço de armazenamento adequado perto da sala de cirurgia para suprimentos de emergência. Uma cadeira confortável quepermita um monitoramento próximo do circuito de perfusão deve estar disponível durante a perfusão (para mais detalhes, veja Comprehensive Standard 14).

Appendix 2 (Portuguese version)

SBCCV/SBCEC Padrões e Diretrizes Abrangentes para a Prática de Perfusão no Brasil[2]

Standard 1: Desenvolvimento de um protocolo institucional próprio

Standard 1.1: A instituição ou o provedor de serviços de perfusão deve desenvolver e implementar os procedimentos opera-

2. "SBCCV/SBCEC Padrões e Diretrizes Abrangentes para a Prática de Perfusão no Brasil" foram baseados e adaptados da publi- cação "The American Society of ExtraCorporeal Technology (AmSECT) Standards and Guidelines[2] e traduzidos para o português.

cionais padrão (protocolo, POP) para cada um dos procedimentos realizados como um mecanismo de aplicação das recomendações desse documento para a prática clínica.

Standard 1.2: O protocolo deverá ser:

- Aprovado pelo(a) chefe da cirurgia cardíaca ou seu/ sua designado(a), diretor(a) da perfusão ou equivalente ou outra pessoa ou comitê de relevância hierárquica de decisão das práticas clínicas institucionais.
- Revisto e reavaliado, ao menos anualmente ou com maior
- frequência quando necessário.

Guideline 1.1: Mudanças no protocolo podem ser feitas a critério da Equipe Cirúrgica e devem ser documentadas na ficha de perfusão.

Standard 2: Qualificação, Competência e Pessoal de Apoio

Standard 2.1: A circulação extracorpórea só deve ser ralizada por profissional formado nas profissões reconhecidas pela Sociedade Brasileira de Circulação Extracorpórea (SBCEC) e pela Sociedade Brasileira de Cirurgia Cardiovasccular (SBCCV) como competentes para realizar o procedimento; ter pós-graduação reconhecida pelo MEC com carga horária mínima descrita no artigo 12 das Normas Brasileiras para o Exercício da Especialidade de Perfusionista em Circulação Extracorpórea ou Título de Especialista da SBCEC[1], validado por esta Sociedade; ou profissionais que se enquadram no parágrafo único do artigo 2º da Norma acima citada.

Standard 2.2: As competências do perfusionista devem ser avaliadas anualmente com o intuito de averiguar se estão em conformidade com os protocolos departamentais.

Standard 2.3: O perfusionista deve assistir, participar e se envolver em cursos de educação continuada relacionados à perfusão ao menos uma vez ao ano.

Standard 2.4: O pessoal de apoio deve estar disponível no local para auxiliar o perfusionista durante os procedimentos necessários na condução da CEC.

Guideline 2.1: Um indivíduo que se formar em um programa credenciado de educação em perfusão deve preencher todos os requisitos para a certificação da SBCEC.

Guideline 2.2: Um processo padronizado deve ser desenvolvido e seguido para identificar, orientar e educar a equipe de suporte de forma a garantir que todos tenham conhecimento geral das funções desempenhadas pelo perfusionista, fluxo cirúrgico e localização dos itens essenciais e auxiliares necessários durante a CEC. A equipe de apoio inclui equipes de perfusionistas, enfermagem, técnicos e pessoal administrativo.

Guideline 2.3: Um programa estruturado para educar, treinar e avaliar a equipe de perfusão, ao menos anualmente, deve ser desenvolvido e seguido.

Guideline 2.4: É recomendada a existência de dois perfusionistas por procedimento, garantindo maior segurança ao procedimento.

Guideline 2.5: Utilização de equipamentos de proteção individual. Durante a condução da CEC o perfusionista deve utilizar equipamentos de proteção individual (EPI), como máscaras, óculos e luvas de procedimento. As luvas devem ser trocadas após a coleta de amostra, após a troca de solução (bolsa de sangue) do equipo ou sempre que estiver com respingo de sangue[2].

Standard 3: Ficha (Registro) de Perfusão

Standard 3.1: A ficha (registro) de perfusão (escrita e/ou eletrônica) para cada procedimento de CEC deve ser incluída como parte do prontuário médico do paciente. O registro de perfusão deve ser mantido e armazenado de acordo com a política da instituição para a retenção de registros médicos (prontuário) do paciente.

Standard 3.2: A ficha (registro) deve incluir:

- Informações do paciente, incluindo dados demográficos e fatores de risco pré-operatório (Appendix A).
- Informações necessárias para descrever com precisão o procedimento, pessoal e equipamento utilizado (Appendix B).
- Parâmetros fisiológicos do paciente documentados de
- acordo com a frequência determinada pelo protocolo institucional (Appendix C).
- Gases sanguíneos e resultados da monitoração da
- anticoagulação (Appendix D).

- o Assinatura e carimbo do perfusionista (e de todos os demais perfusionistas de apoio) que participaram do procedimento.

Guideline 3.1: Deverá haver uma ficha (registro) de perfusão (escrita e/ou eletrônica) para cada procedimento de CEC. A ficha de perfusão deve incluir um espaço de texto livre para registro de comentários, incluindo ordens verbais dadas pela equipe médica pertinentes à perfusão realizada.

Guideline 3.2: O registro de perfusão deve incluir as assinaturas do(s) médico(s) responsável(is) pela supervisão da CEC.

Guideline 3.3: Os dados brutos (por exemplo, fluxo sanguíneo, pressão e valores de temperatura) contidos em bancos de dados de perfusão eletrônica devem ser armazenados por um período de tempo definido pela política institucional referente à retenção de registros médicos eletrônicos de pacientes.

Standard 4: Checklist

Standard 4.1: O perfusionista deve utilizar um *checklist* para cada perfusão realizada[4].

Standard 4.2: O *checklist* deve ser preenchido, incluído e anexado ao prontuário do paciente.

Guideline 4.1: O perfusionista deve fazer o *checklist* lendo-o em voz alta a outro perfusionista e marcando cada um dos itens após a confirmação de que aquela ação, definida item a item, foi realizada[4]. O preenchimento do *cheklist* deve ser realizado por duas pessoas, sendo uma delas o perfusionista principal responsável pela condução da CEC durante o período intraoperatório. Nos serviços em que não há a disponibilidade de outro profissional perfusionista, deve ser adotada uma rotina sistemática de verificação dos itens contidos no *checklist*, com o objetivo de minimizar a ocorrência de eventos adversos.

Guideline 4.2: O perfusionista deve utilizar o *checklist* ao longo de todo o período perioperatório (p. ex., montagem da máquina de CEC, pré-CEC, fase inicial da perfusão, antes da saída da perfusão, após a perfusão e/ou qualquer retorno à CEC).

Guideline 4.3: O perfusionista deve utilizar o *checklist* para os demais serviços auxiliares à perfusão (isto é, recuperação sanguí-

nea através de "*cell salvage*", balão intra-aórtico, oxigenação por membrana extracorpórea – *extracorporeal membrane oxygenation* – ECMO, entre outros).

Standard 5: Comunicação

Standard 5.1: Um plano de perfusão individualizado e específico ao paciente deve ser preparado e comunicado à equipe cirúrgica tanto no "*briefing*" quanto antes do início do procedimento[5].

Guideline 5.1: O uso de aparelhos de telefone celular em sala cirúrgica deve ser evitado e em CEC deve ser proibido, visto que é um fator de distração e predisponente para riscos ao paciente. Além disso, a grande maioria está contaminada por bactérias potencialmente infectantes, comprometendo a qualidade e segurança da assistência. Quando seu uso for inevitável, os aparelhos devem ser higienizados previamente, conforme protocolo de antissepsia da instituição[6-8].

Guideline 5.2: A comunicação padronizada por meio de protocolos específicos (p. ex., *closedloopcommunication*) deve ser utilizada para o reconhecimento dos comandos verbais, verificação de conteúdo e redução de ambiguidade[9-11].

Guideline 5.3: O perfusionista principal deverá participar do "*debrief*" pós-operatório com toda a equipe cirúrgica

.

Standard 6: Dispositivos de Segurança

Standard 6.1: O monitoramento de pressão da linha arterial, do sistema de administração de cardioplegia e do reservatório venoso (quando a drenagem venosa assistida por vácuo for utilizada) deve ser realizado e documentado durante a CEC.

- O monitor de pressão deve ser servorregulado para o controle do rolete arterial e de cardioplegia de acordo com a pressão da linha arterial e da linha de cardioplegia, permitindo a interrupção do fluxo de ambas.
- O monitor de pressão deve incluir um alarme audiovisual.

Standard 6.2: Detector de bolhas deve ser utilizado durante a CEC.

- O detector de macrobolhas deve ser usado para controlar a bomba arterial ou para permitir a interrupção do fluxo sanguíneo arterial.
- O sistema detector deve incluir um alarme audível e visual e ser posicionado de acordo com as instruções do fabricante para uso do oxigenador, ligado e testado antes de cada procedimento, de forma a permitir a identificação e ação a tempo de evitar sua passagem para o paciente.

Standard 6.3: Um sensor de nível deve ser utilizado durante a CEC quando utilizado um reservatório rígido (*hard-shell venous reservoir*) no circuito.

- O sensor de nível deve ser servorregulado para controlar a bomba arterial ou para permitir a interrupção do fluxo sanguíneo arterial.
- O sensor de nível deve incluir um alarme audível e visual e ser posicionado de acordo com as instruções do fabricante para permitir um tempo de reação apropriado e um volume operacional seguro.

Standard 6.4: O monitoramento da temperatura da saída arterial do oxigenador deve ser utilizado durante os procedimentos de CEC.

- O sensor de temperatura deve incluir um alarme audível e visual para a prevenção de temperaturas elevada na saída arterial do oxigenador.

Standard 6.5: Um filtro arterial isolado ou acoplado ao oxigenador deve ser utilizado em todo o circuito de CEC. Quando usado de forma isolada do oxigenador, deve ser utilizado no circuito depois do oxigenador e deve contar com uma linha de recirculação conectada ao reservatório de cardiotomia ou venoso. Deve dispor de um "*bypass*" que permita ao perfusionista anular o filtro em caso de obstrução ou rupture.

Standard 6.6: Uma válvula "*one-way*" deve ser utilizada na linha de aspiração da aorta/átrio esquerdo durante a perfusão.

Standard 6.7: Deve ser utilizado pelo menos um método para evitar o fluxo retrógrado para a circulação sistêmica em circuitos com bombas centrífugas. Exemplos de sistemas de evasão retrógrada podem incluir:

- Válvulas de fluxo unidirecional (*one-way flow valves*);
- Controles de redução de velocidade da bomba com
- mecanismos de prevenção de acionamento acidental (*hard-stop detent controls*);
- Pinças de acionamento eletrônico na linha arterial; ou
- Alarme audiovisual em caso de baixa velocidade da bomba.

Standard 6.8: Uma linha de eliminação de gases deve ser utilizada sempre que anestésicos inalatórios forem utilizados diretamente no circuito durante a perfusão.

Standard 6.9: Manivelas manuais (*hand cranks*) devem estar prontamente disponíveis durante a perfusão.

Standard 6.10: *Backups* (alternativas de segurança) de fonte de gás (p. ex., cilindro de oxigênio/ar comprimido) devem estar prontamente disponíveis durante a CEC.

Standard 6.11: A máquina de CEC deve possuir bateria incorporada ou outra fonte de energia suplementar disponível durante toda a perfusão.

Guideline 6.1: Um analisador de oxigênio da mistura de gás (*sweep flow*) antes da entrada de gás da membrana deve ser utilizado durante a perfusão.

Guideline 6.2: Um sensor de nível deve ser usado durante os procedimentos de CPB com um reservatório fechado (*soft-shell reservoir*).

- O sensor de nível deve ser servorregulado para controlar a bomba arterial ou para permitir a interrupção do fluxo sanguíneo arterial.
- O sensor de nível deve incluir um alarme sonoro e visual e ser posicionado de acordo com as instruções do fabricante para permitir um tempo de reação apropriado e um volume operacional seguro.
- O uso de um detector de bolhas de ar distal à saída do reservatório pode ser utilizado em substituição ao detector de nível.

Guideline 6.3: A bandeja de tubos disponibilizados para montagem do circuito deve ser disponibilizada "pré- montada", pré-conectada e em bandeja estéril separando o circuito que ficará no campo cirúrgico daquele que ficará na máquina de CEC,

ofertando mais segurança ao procedimento e gerando mais rapidez na montagem do circuito.

Standard 7: Monitoração
(Obs.: para ser realizado em conjunto com Standard 3)

Standard 7.1: A pressão arterial do paciente deve ser monitorada de forma contínua durante toda a CEC.

Standard 7.2: A pressão da linha arterial do circuito de CEC deve ser monitorada durante toda a perfusão.

Standard 7.3: O fluxo arterial deve ser monitorado continuamente durante toda a perfusão.

Standard 7.4: A dose de cardioplegia, o método de infusão, a pressão de linha (cardioplegia anterógrada), a pressão do seio coronário (cardioplegia retrógrada) e os intervalos de isquemia devem ser continuamente monitorados durante a CEC.

Standard 7.5: A temperatura do paciente e dos dispositivos deve ser continuamente monitorada durante a CEC.

- Paciente: nasofaríngea, retal, vesical, esofágica.
- Máquina de CEC: arterial, venosa e cardioplegia.
- Trocador de calor (*heater-cooler*): temperatura da água.

Standard 7.6: A análise de gases sanguíneos (gasometria) deve ser monitorada continuamente ou em intervalos regulares durante a CEC (Appendix D).

Standard 7.7: O hematócrito (ou hemoglobina) deve ser monitorado continuamente durante a CEC.

Standard 7.8: A fração de oxigênio (FiO_2) e o fluxo de gás (*sweep flow*) devem ser monitorados continuamente durante a CEC (Appendix D).

Standard 7.9: A porcentagem de oclusão da linha venosa do oclusor venoso (*clamp* venoso automatizado), quando disponível, deve ser monitorada continuamente durante a CEC.

Standard 7.10: Saturação venosa de oxigênio deve ser monitorada continuamente ou em intervalos regulares durante a CEC.

Guideline 7.1: A remoção de CO_2 ($etCO_2$ ou pCO_2) deve ser continuamente monitorada durante a CEC.

Guideline 7.2: A saturação arterial de oxigênio (SaO_2) deve ser continuamente monitorada durante a CEC.

Guideline 7.3: As seguintes pressões do paciente devem ser monitoradas durante a CEC:

- Pressão venosa central (PVC); e/ou
- Pressão da artéria pulmonar.

Guideline 7.4: Os gases sanguíneos devem ser continuamente monitorados (in-line) durante a CEC.

Guideline 7.5: A oximetria cerebral (NIRS) deve ser utilizada durante a CEC sempre que dísponível.

Guideline 7.6: O fluxo sanguíneo arterial deve ser monitorado continuamente em um ponto no circuito no qual reflete com precisão o fluxo entregue ao paciente durante a CEC (p. ex., distal à "*purge line*").

Standard 8: Anticoagulação

Standard 8.1: O perfusionista, em colaboração com o cirurgião responsável, deve definir o algoritmo pretendido para o manejo da anticoagulação (heparina) e um algoritmo alternativo para a heparinização não adequada, incluindo intervalos aceitáveis para o tempo de coagulação ativada (TCA).

Standard 8.2: O perfusionista deve trabalhar em estreita colaboração com a equipe de cuidados cirúrgicos na monitoração e no tratamento do estado de coagulação do paciente antes, durante e após a CEC.

Guideline 8.1: A equipe cirúrgica deve determinar o alvo do TCA considerando fatores relevantes, incluindo variabilidade em sua medida atribuída às características de desempenho do dispositivo.

Guideline 8.2: A dose inicial de heparina específica para o paciente deve ser determinada por um dos seguintes métodos:

- Peso;
- Curva de dose-resposta (automatizada ou manual);
- Volume sanguíneo; ou
- Superfície corpórea.

Guideline 8.3: O monitoramento da anticoagulação deve incluir o TCA, devendo-se realizar um TCA inicial, outro após a protamina e, durante a CEC, pelo menos um a cada 30 minutos. Testes de monitoramento adicionais podem incluir:

- Nível de heparina (p. ex., titulação de heparina/protamina ou nível de heparina não fracionado);
- Tempo de tromboplastina parcial ativada (TTPa);
- Tromboelastograma;
- Tempo de trombina (TP); e/ou
- Anti-Xa.

A execução dos testes laboratoriais remotos – TLR (*point- of-care*) deve estar vinculada a um laboratório clínico do hospital. O responsável técnico pelo laboratório clínico é responsável por todos os TLR realizados dentro da instituição. O laboratório clínico deve disponibilizar, nos locais de realização de TLR, procedimentos documentados com orientações sobre suas fases pré-analítica, analítica e pós- analítica, incluindo:

a. Sistemática de registro e liberação de resultados provisórios.
b. Procedimento para resultados potencialmente críticos.
c. Sistemática de revisão de resultados e liberação de laudos por profissional habilitado.

O laboratório clínico deve manter registros dos controles da qualidade, bem como procedimentos para sua realização.O laboratório clínico deve promover e manter registros de seu processo de educação permanente para os usuários dos equipamentos de TLR[12].

Guideline 8.4: As doses adicionais de heparina durante a CEC devem ser determinadas usando a titulação pelo TCA e/ ou heparina/protamina. Nota: em pacientes que requerem tempos de CEC mais longos (> 2 a 3 horas), pode-se considerer a manutenção de concentrações de heparina mais altas e/ou específicas para o paciente durante a CEC, para reduzir a ativação do sistema de coagulação e o consumo de plaquetas e proteínas de coagulação, assim como evitar ou reduzir a transfusão de hemoderivados (Classe IIb, Nível de evidência B)[13].

Guideline 8.5: A reversão da heparina deve ser confirmada por TCA, tromboelastrograma e/ou titulação da heparina/ protamina.

Standard 9: Manuseio transfusional

Standard 9.1: O perfusionista deve aderir às práticas recomendadas para minimizar a hemodiluição e evitar transfusões de sangue desnecessárias[13].

Standard 9.2: O perfusionista deve minimizar o tamanho do circuito de CEC no intuito de reduzir o volume do *prime*[13].

Standard 9.3: O perfusionista deve calcular e comunicar à equipe cirúrgica o hematócrito/hemoglobina pós-dilucional previsto para o paciente antes de iniciar a CEC.

Guideline 9.1: As definições dos protocolos de transfusão de hemoderivados (*patient blood management* – PBM) devem incluir[13]:

- Participação do perfusionista nas discussões (*briefings*) pré-operatórias com toda a equipe cirúrgica (Standard 5.1) em relação às estratégias de transfusão e valores "alvos" de hematócrito.
- Participação do perfusionista no grupo multidisciplinar de PBM.

Minimizar a hemodiliução por meio de:

- Seleção do tamanho do circuito de CEC compatível com o tamanho do paciente.
- Preenchimento do circuito com sangue autólogo, incluindo enchimento retrógrado do circuito com sangue (*retrograde autologous priming* – RAP).
- Utilização de tubos com revestimento biocompatível/bioativos em todos os componentes de CEC.
- Recuperação perioperatória de células sanguíneas (*cell savage*) e reinfusão após processamento adequado.
- Recuperação do sangue do circuito de CEC ao final do procedimento ("*blood cell savage*" do "*prime*" do circuito).

Guideline 9.2: Monitoração da hemostasia por meio de "*point-of-care*" deve ser utilizada na minimização da perda sanguínea.

Essa monitoração deve incluir:

- *International normalized ratio* (INR ou RNI);
- Tempo de tromboplastina parcial ativada (TTPa);
- Tempo de protrombina (TP);
- Tempo de trombina (TT);
- Tromboelastograma;
- Contagem de plaquetas; e/ou
- Agregação plaquetária.

Standard 10: Troca Gasosa

Standard 10.1: A troca de gás deve ser mantida durante a CEC de acordo com o protocolo, considerando:

- Características individuais do paciente e perfil de risco;
- Tipo de oxigenador, *design* e instruções de uso; e
  Fluxo sanguíneo, temperatura e demanda metabólica.

Standard 10.2: Os dispositivos utilizados para medir a troca gasosa devem ser calibrados de acordo com as instruções de uso do fabricante.

Standard 10.3: A análise sanguínea dos gases (gasometria) deve ser realizada e anotada de acordo com o protocolo.

Guideline 10.1: Exames realizados com dispositivos "*point- of--care*" devem ser considerados para propiciar informações precisas e instantâneas para análise de gases no sangue[14].

Guideline 10.2: O cálculo da oferta e consumo de oxigênio deve ser utilizado para avaliar e otimizar a troca gasosa[15]:

Oferta de oxigênio: $DO_2 = 10 \times IC \times CaO_2$

Consumo de oxigênio: $VO_2 = 10 \times IC \times (CaO_2 - CvO_2)$ Em que:

CaO_2 (conteúdo de oxigênio arterial) = $(Hb \times 1{,}36 \times SaO_2) + (0{,}0031 \times PaO_2)$

e

CvO_2 (conteúdo de oxigênio venoso misto) = $(Hb \times 1{,}36 \times SvO_2) + (0{,}0031 \times PvO_2)$

HB = hemoglobina IC = índice cardíaco

PaO_2 = pressão parcial de oxigênio no sangue arterial PvO_2 = pressão parcial de oxigênio no sangue venoso SaO_2 = saturação arterial de oxigênio

SvO_2 = saturação venosa de oxigênio

Standard 11: Fluxo de perfusão

Standard 11.1: O fluxo de perfusão alvo deve ser determinado antes de iniciar a CEC de acordo com o protocolo institucional. Obs.: superfície corpórea x índice cardíaco = fluxo sanguíneo calculado, no qual a superfície corpórea em metros quadrados é igual à raiz quadrada da altura vezes o peso dividido por 3.600 (√altura × peso/3.600), utilizando altura em centímetros (cm) e peso em kilogramas (kg).

Standard 11.2: O perfusionista deve trabalhar em estreita colaboração com a equipe cirúrgica na manutenção da taxa de fluxo sanguíneo definido/calculado durante a CEC.

Guideline 11.1: As variações do fluxo sanguíneo definido/ calculado devem ser comunicadas ao médico/cirurgião responsável.

Guideline 11.2: O fluxo de perfusão adequado deve ser definido pela avaliação de:

- Balanço ácido-base;
- Excesso de bases (BE);
- Nível anestésico;
- Pressão sanguinea arterial;
- Oximetria cerebral (NIRS);
- Nível de lactato;
- Entrega e consumo de oxigênio (observar a fórmula no Guideline 10.2);
- pO_2 venosa;
- pO_2 arterial;
- Concentração de hemoglobina;
- Saturação arterial de oxigênio;
- Resistência vascular sistêmica;
- Temperatura; e Saturação venosa de oxigênio ($SaVO_2$).

Standard 12: Pressão arterial

Standard 12.1: O perfusionista, em conjunto com o médico/cirurgião responsável, deve definir e comunicar o algoritmo de tratamento pretendido para o gerenciamento da pressão arterial antes da CEC, incluindo seus níveis aceitáveis. Obs.: em muitas circunstâncias, o médico responsável pode direcionar o perfusionista para modificar a administração da pressão arterial pretendida para atender às circunstâncias que ocorrem durante o procedimento de CEC.

Standard 12.2: O perfusionista deve trabalhar em conjunto com a equipe cirúrgica para manter a pressão arterial de acordo com os protocolos da CEC.

Guideline 12.1: A variação entre a pressão arterial definida/calculada e a atingida deve ser documentada e comunicada ao médico responsável para permitir alterações no plano de manejo da pressão arterial.

Standard 13: Avaliação e Melhorias na Qualidade

Standard 13.1: O perfusionista deve participar ativamente dos programas institucionais e departamentais de controle e melhoria da qualidade.

Guideline 13.1: O perfusionista deve coletar dados relativos à condução da perfusão por meio de um registro clínico ou banco de dados.

Guideline 13.2: O perfusionista deve usar esses dados para projetos de controle e melhoria de qualidade[16] [17].

Guideline13.3: O perfusionista deve avaliar em ficha padrão (Appendix E) o pós-operatório do paciente, armazendo dados para avaliações periódicas da perfusão no serviço[18].

Guideline 13.4: Reuniões específicas e periódicas devem ser realizadas para a revisao de erros evitáveis que ocorram no serviço.

Guideline 13.5: Todo e qualquer evento adverso deve ser notificado por escrito ao setor responsável, o qual dará encaminhamento às agências regulatórias e demais orgãos competentes após apuração. O serviço deve incentivar a realização constante das notifica-

ções, estabelecendo uma linha de comunicação direta entre a equipe e a gerência de risco, garantindo seu sigilo[19].

Standard 14: Manutenção

Standard 14.1: O perfusionista deve assegurar que o equipamento utilizado na condução da CEC tenha sua manutenção corretamente realizada e em perfeito estado de funcionamento, incluindo (mas não limitado a):

- Máquina de CEC
- Bombas
- Timers
- Monitores de pressão
- Monitores de temperature
- Alarme de nível
- Detector de ar/bolhas
- Sensores de fluxo sanguíneo
- Trocador de calor (*heater-cooler*)
- Vaporizador de anestésico
- Misturador de gases e fluxômetro
- Analisador de oxigênio
- Equipamentos auxiliaries
- Pressão intra-arterial
- Dispositivos de assistência circulatória
- Dispositivos de recuperação sanguínea (*cell salvage device*)

Standard 14.2: A manutenção preventiva do equipamento de perfusão deve ser realizada e documentada de forma regular pela equipe de perfusão e/ou equipe de engenharia biomédica apropriadamente treinada e qualificada.

Qualquer um ou todos os seguintes itens pode determinar o intervalo dessa manutenção:

- Recomendações do fabricante;
- Recomendaçõnoes das agências de acreditação; e/ou
- Protocolos institucionais.

Obs.: em equipamentos consignados, o proprietário da máquina de CEC é responsável pela manutenção no equipamento de perfusão, e todas as responsabilidades e questões legais serão imputadas a ele. Em caso de evento adverso decorrente do uso deste equipamento, quando comprovada falha, mesmo com provas de manutenção adequada e não relacionada ao uso indevido por parte do perfusionista, o dono do equipamento, e não a instituição, deverá ser responsabilizado.

Portanto, deve existir um documento atualizado para cada um dos equipamentos utilizados, com as datas e os detalhes de manutenção preventiva e corretivas e que deve ser arquivado na unidade de perfusão ou de engenharia clínica da instituição[20].

Standard 14.3: A instituição deve ter o procedimento padrão por escrito documentando as falhas potenciais e ocorridas no equipamento de perfusão, bem como as condutas a serem adotadas ou correções implementadas[21].

Standard 14.4: Os suprimentos necessários de perfusão de "*backup*" devem estar prontamente disponíveis.

Obs.: quando a máquina de CEC não é propriedade da instituição (em caso de equipamento consignado), o proprietário do equipamento será responsável pela substituição e terá responsabilidade legal em caso de evento adverso decorrente do uso deste equipamento, quando comprovada falha não relacionada ao uso indevido por parte do perfusionista.

Standard 15: Horas de Serviço

Standard 15.1: O perfusionista pode ser contratado pelo hospital ou por empresa de serviços médicos, respeitando as leis trabalhistas de acordo com o vínculo firmado.

Standard 15.2: É sumariamente proibido que o perfusionista seja contratado para realizar perfusão e exerça outra função no serviço com o mesmo contrato trabalhista.

Guideline 15.1: O perfusionista deve ter um mínimo de 8 horas de período de descanso para cada período de trabalho consecutivo de 16 horas[22-24].

Appendix A (Portuguese version)

Informação do paciente

1. Número do registro médico
2. Nome e sobrenome do paciente
3. Dados demográficos:
   a. Idade (data de nascimento)
   b. Sexo
   c. Altura
   d. Peso
   e. Superfície corpórea (SC)
4. Tipo sanguíneo
5. Dados laboratoriais:
   a. Hemoglobina/hematócrito
   b. Hematócrito predito em CEC
   c. Leucócitos
   d. Contagem de plaquetas
   e. Tempo de protrombina parcial ativada (TTPa)
   f. Sódio
   g. Potássio
   h. Ureia/creatinina
   i. Glicemia
   j. Outros valores laboratoriais relevantes
6. Alergias do paciente
7. Procedimento cirúrgico planejado
8. História médica e fatores de risco (recomendado):
   a. Cardiovascular
   b. Pulmonar
   c. Renal
   d. Neurológico
   e. Gastrointestinal/endócrino

Appendix B (Portuguese version)
Informações básicas para descrição detalhada do procedimento, pessoal (equipe) e equipamento utilizado

1. Data do procedimento
2. Tipo de procedimento
3. Nome do perfusionista(s)
4. Nome do cirurgião(ões)
5. Nome do anestesista(s)
6. Nome da enfermeira(s)
7. Número da sala de cirurgia
8. Comentários/eventos (recomendado)
9. Equipamento:
    a. Máquina de CEC
    b. Cell saver (autotransfusão)
    c. Trocador de calor (*heater-cooler*)

Nota: os itens a-c são geralmente identificados (p. ex., Máquina (Bomba) 1, 2, 3 etc.). Os números de série de cada um dos componentes (bomba de rolete, vaporizadores, *blender* etc.) devem estar documentados e arquivados em local apropriado.

10. Descartáveis:
    a. Oxigenador
    b. Reservatório de cardiotomia
    c. Circuito de tubos e filtro arterial
    d. Bomba centrífuga
    e. Sistema de cardioplegia
    f. Circuito de autotransfusão (*cell saver*)
    g. Hemofiltro
    h. Cânulas arteriais
    i. Cânulas venosas
    j. Cânulas de cardioplegia
    k. Aspiradores e vent(s)

Nota: o fabricante, modelo, número de série e/ou número do lote devem ser documentados em cada um dos itens (a- k) utilizados.

Appendix C (Portuguese version)
Parâmetros fisiológicos do paciente e ações do perfusionista documentadas com frequência definida pelo protocolo Institucional

1. Fluxo sanguíneo de perfusão (RPM)
2. Pressão arterial
3. Pressão da linha arterial
4. Pressão venosa central ou pressão da artéria pulmonar
5. Retorno venoso assistido com vácuo (VAVR):
    a. Pressão do reservatório venoso/da linha venosa
    b. Pressão negativa do dispositivo de vácuo
6. Gasometria arterial e venosa
7. Saturação venosa de oxigênio
8. Temperaturas do paciente, incluindo:
    a. Temperatura central (ao menos)
        I. Nasofaríngea
        II. Vesical
        III. Esofágica
        IV. Retal e/ou
        V. Timpânica
        VI. Temperatura do miocárdio (opcional)
9. Temperaturas da CEC:
    I. Linha de retorno venoso
    II. Linha arterial
    III. Da água do trocador de calor (opcional)
10. Gases do oxigenador, incluindo fluxo de gases e concentração
11. Entrada de líquidos (volume infundido), incluindo:
    a. Prime
    b. Hemoderivados
    c. Cristaloides
    d. Solução cardioplégica
    e. Componentes autólogos
12. Cardioplegia:
    I. Solução (proporção se diferentes)
    II. Via de administração (anterógrada, retrógrada etc.)

III. Fluxo
IV. Pressão
V. Temperatura
VI. Volume

13. Volume das perdas, incluindo:
    a. Débito uninário
    b. Ultrafiltrado
14. Medicações e/ou anestésicos inalatórios administrados através do circuito extracorpóreo

Appendix D (Portuguese version)
Resultados dos gases sanguíneos, eletrólitos e monitoração da anticogulação

1. Gasometria:
    a. pO_2
    b. pCO_2
    c. pH
    d. Excesso de bases (BE)
    e. Bicarbonato
    f. Saturação
    g. Concentração de potássio
    h. Concentração de cálcio ionizado
    i. Concentração de sódio
    j. Lactato
    k. Glicemia
    l. Hemoglobina/hematócrito

2. Tempo de coagulação ativado (TCA) e/ou resultados da concentração plasmática de heparina/protamina e/ou resultado do tromboelastograma.

Appendix E (Portuguese version)
Avaliação pós-operatória dos pacientes submetidos à circulação extracorpórea

1. Nome do paciente
2. Número hospitalar do paciente

3. Data da cirurgia
4. Hora de entrada na UTI
5. Valores de CK, CKMB e troponina de 6, 12 e 24h
6. Fração de ejeção no pós-operatório
7. Valores das drogas vasoativas utilizadas com 6, 12 e 24h
8. Balanço hídrico a cada 6h, até completar 48h de UTI
9. Pressão venosa central a cada 6h, até completar 48h de UTI
10. Uso de hemoderivados
11. Tempo de extubação
12. Data de alta da UTI

Appendix F (Portuguese version)
Checklist

O *checklist* deve conferir (ao menos):

- Integridade e funcionamento da máquina de CEC e trocador de calor.
- Funcionamento dos sistemas de gases e as conexões com o oxigenador.
- Identificação correta do paciente.
- Disponibilidade de hemoderivados.
- Composição do perfusato.
- Composição e preparo da cardioplegia.
- Cânulas que serão utilizadas.
- Todas as conexões do circuito.
- Calibração e direção dos roletes.
- Calibração dos sensores e alarmes de pressão, fluxo e bolhas.
- Calibração dos sensores de pressão de cardioplegia.
- Calibração e conexão do monitor de gases.
- Disponibilidade de materiais descartáveis e equipamentos
- de emergência (hand crank, luz de emergência etc.)
- Dose e administração de heparina.
- Resultado de TCA antes de iniciar a CEC.
- Disponibilidade de fármacos, agulhas, seringas e equipos
- de soro e sangue para utilização durante a CEC.

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I would like to congratulate the Brazilian Society for Cardiovascular Surgery (SBCCV) and the Brazilian Society for Extracorporeal Circulation (SBCEC) for their joint publication recommending a phased approach to adopting standards and guidelines for perfusion practice in their country. I am certain this effort will be looked back on as a homegrown landmark collaboration and publication which improved outcomes in cardiac surgery patients. Furthermore, it may be viewed as a landmark effort on the world stage with its collaboration with the American Society of Extracorporeal Technology (Am SECT). Healthcare societies should not, and cannot, exist in isolation. As cardiac surgery clinicians, we serve patients. We serve their families. We serve their communities. We serve their countries. We serve humanity. Cardiac surgery professionals from numerous professions advanced their education and training to help others and that should be through all possible means, including collaborating with societies domestically and abroad.

The publication of recommendations for achievable standards and guidelines for Brazilian perfusion teams will set the stage for practice as well as allow for teams to identify future goals in their own programs. There is no disillusion here that programs will simply adopt the Am SECT standards as recommended in the United

States. That may very well not be possible for many programs for years to come. Many changes require cultural shifts in the operating room and that takes effort, time and buy-in administratively and clinically. Albert Einstein has been quoted as stating, "***If you always do what you always did, you will always get what you always got.***" That can be considered current state at many programs. While that may be tough for some to hear, it is the very concept which needs to be bought into you. Perhaps Einstein's additional quote that, "Insanity is doing the same thing over and over again and expecting a different result" is even more apropos. Understanding that one's practice is not precisely where it ***should*** and ***can*** be is the absolute starting point.

The joint SBCCV and CBCEC publication highlights the outstanding history of cardiac surgery in Brazil as well as the challenges within the perfusion profession and the cultural challenges in the operating room. Seven standards are identified as the minimum recommendation for perfusion practice in Appendix 1. These standards vary from the Am SECT standards in thoughtful ways. These are achievable changes which all programs in Brazil should adopt. Additional standards and guidelines can be reviewed, discussed, and worked towards as a perfusion team and cardiac surgery program evolves as listed in Appendix 2. This framework will no doubt be utilized for decades to come. Ultimately, the patients, families and communities served will benefit. Brazil will benefit. The torch will have been passed illuminating excellence in cardiac surgery in a country utilizing all available resources to improve outcomes. It is my hope that Brazil will shine as an example for other countries also looking to improve outcomes in cardiac surgery.

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