

# The Importance of an Accurate Cost-Effectiveness Analysis for the Introduction of New Technologies in the Brazilian Public Health System

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**M**uch has changed in recent years regarding the availability of new devices for use in Interventional Cardiology in Brazil.

In the 1990s, it was common to joke with our American colleagues that, despite the enormous economic potential of that country, and contrary to what happened in Brazil, interventionists had to wait years to use – and gain experience with – extremely useful devices for the treatment of children with congenital heart disease.

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That has dramatically changed. With the greater autonomy and control of National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) for approving and regulating the use in humans of new devices not manufactured in Brazil,<sup>1,2</sup> the gap between the development of increasingly better materials and their clinical employment has greatly increased. Currently, it is no longer enough to demonstrate proof of efficacy and safety, or consequently obtain the respected seals of approval, such as CE Mark, to allow access to these new materials.

The delay in release has been of such magnitude that some devices, such as the Melody® valve for the pulmonary position, with over 14 years of continuous use in Europe and already approved by the Food and Drug Administration for use in the United States,<sup>3</sup> has only recently had its use approved in Brazil.

Readers should not think that my position is contrary to the regulation of new devices by ANVISA. Certainly not! The control of medical device is extremely important for the population's health, as well as the financial health of the health system, and as such it

should be treated. The thoroughness of state agency in controlling these matters must be supported by all of us. This is the only way that we can treat our patients with devices that have been shown to be safe and efficient in the long term.

However, the bureaucratic obstacles and the small number of technical experts to perform this vital activity lead to a long wait of several years until we can treat our patients with the best that modern technology can offer in terms of health care.

This is the current scenario for patients who can use the supplementary health care network, which, sooner or later, will have access to new technologies for repairing congenital heart defects.

But what about patients who do not have access to the supplementary health care network and are part of the 70% of the population that depends on Brazilian Unified Health System (Sistema Único de Saúde – SUS)? These are patients who we also want to treat, i.e. patients for whom we can make a difference when using percutaneous techniques with minimal clinical and social impact. Thus, it should be possible to reduce the extended stay in the increasingly scarce hospital beds, reducing recovery time and possibly the financial and occupational impact on parents who, rightly so, should stay with their children during the recovery period.<sup>4</sup>

Should this multitude of children wait even longer to have access to materials used since long in other countries and already available in Brazil for those who have access to supplementary/private health care? Moreover, should we mention the risk that other materials, more advanced and better, will be developed – would it be theory that “we should let the technology get older, to make it cheaper?”

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I cannot believe this is the current position because, recently, National Commission on Technology Incorporation (Comissão Nacional de Incorporação de Tecnologias – CONITEC) was restructured and has apparently assessed these themes with great care and impartiality.

I believe that the demands of pediatric cardiologists in Brazil, responsible for the treatment of these children, should be evaluated with care and respect.

For this purpose, we must do our part, which is to provide Brazilian Ministry of Health, responsible for the assessment and possible introduction of new technologies, with scientific support for proper decision-making. This assessment should be based on the actual needs of our patients, which we, as cardiologists know well, and also on the careful analysis of the impact of these new technologies on Brazil budget. The patients' needs and our capacity to treat them are known by everyone interested in the topic and are published in national and international literature, either in original publications or in dissertations or doctoral theses.

However, there are very few studies on the cost-effectiveness of using (not so) new technologies. The article by Costa et al.,<sup>5</sup> published in this issue, is an example of how to seriously evaluate this theme. This group, in addition to their many contributions to interventional cardiology in Brazil, has also focused on cost analysis procedures.

Although most of the paying agencies of medical services see cost-effectiveness from the perspective of the cost, and not the benefit for patients, the analysis of incremental cost-effectiveness of treatment of patent ductus arteriosus performed by Costa et al.<sup>5</sup> allows for

the projection of the long-term impact of the use of this new technology. And the result, after a stringent review of the literature, demonstrated that a small reduction in the current cost of the material used will allow for the use of this technique in patients who need it most.

I hope this publication will be followed by many others, creating a scientifically sound theoretical basis, on which Brazilian Ministry of Health, urged by our society and with the support of the civil society, can rely on to make decisions about the incorporation of new devices that bring real benefits to our population.

## CONFLICTS OF INTEREST

The author declares no conflicts of interest.

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