Health Policy Series

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Past Reflections

Dear friends:

The development of health technology assessment (HTA) in Latin America and the Caribbean (LAC) has experienced significant growth during the last few years. While countries like Mexico, Colombia, and Brazil have implemented formal institutions for HTA, others have made significant efforts to introduce formal processes to support decisions regarding coverage of health care interventions. As a consequence of this progress, the number of professionals trained to support the HTA process has increased in countries of the LAC region.

“News Across Latin America” was launched in 2012 as an initiative of the ISPOR Latin American Consortium for the regional consortium, chapter, and wider ISPOR membership. It is published in three languages simultaneously: Spanish, Portuguese and English. The main objective is to serve as a communication platform to inform readership of recent advancements in research, training, and policies across the countries of our region.

In the first stage, one of the objectives was to produce a set of articles able to account for and share the recent developments in HTA in the LAC region. This led to inclusion of the health policy section, primarily focused on the HTA processes that various countries were implementing.

After two years, eight articles were published, gathered, and presented in this special edition of “News Across Latin America” along with a special preview of an upcoming policy focused on Brazil.

On behalf of the Editorial Board, I thank all authors who received our invitation and submitted articles to our editorial review process. The contributions they have made, now presented in this single exclusive conference edition, are a priceless source of information on the state of HTA in the LAC region.

Finally, the articles presented in this edition do not only have value in terms of the information produced, but also reflect the achievement of long term collaboration between researchers across the region. The immense work of articulating and coordinating this editorial initiative has been possible thanks to the platform provided by ISPOR. As 2012-2015 Editor-in-Chief, I would also like to take the opportunity to thank all Co-editors and staff of “News Across Latin America” and extend the invitation to our colleagues in LAC to continue their participation in initiatives that serve to broaden and deepen international understandings of applications of HEOR in practice.

Sincerely,

Manuel Espinoza, MD, MSc, PhD
2012-2015 Editor-in-Chief
News Across Latin America
Future Directions

Dear readers:

This is an exciting, momentous time in the history of ISPOR. Our organization is proud to be celebrating a 20-year history that is shaping the future of health economics and outcomes research, and we celebrate ISPOR is the leading global professional society in pharmacoeconomics and outcomes research.

In a few days, we will be holding the 5th ISPOR Latin America Conference in Santiago, Chile. For this occasion, “News Across Latin America”, the ISPOR Latin America Consortium newsletter, offers a Special Edition featuring nine articles of its Health Policy Series on developments in pharmacoeconomics and health technology assessment in Latin America.

I am thrilled to become the new Editor-in-chief of “News Across Latin America” in this exciting moment for ISPOR. My role with the Latin America Consortium newsletter is to help capture this excitement, the opportunities, and the challenges to raise health economics and outcomes research scientific standards. Under my term, a few more articles will be incorporated into this valuable health policy series on developments in pharmacoeconomics and health technology assessment in Latin America; some to cover additional countries in the region and one multinational article that will offer a broad perspective on these developments in Latin America. Then, a new health policy series will be initiated on one of several issues of interest to the global challenge of providing efficient and effective health care for our people.

We are confident that “News Across Latin America” will be expanding its coverage in areas of interest for the membership of the ISPOR Latin America Consortium. Our editorial board is comprised of an outstanding team of experts eager to make a significant contribution to the development of our disciplines in the region. Finally, I would like to invite professionals from across the region interested in pharmacoeconomics and outcomes research to join our editorial work.

We also welcome readers to view the articles presented in other regional languages: Spanish and Portuguese, which are available on the “News Across Latin America” webpage.

Kind regards,

Yajaira Bastardo, PhD
2015-2018 Editor-in-Chief
Current Status of Health Technology Assessment in Argentina

In 1991, health economics became officially institutionalized in Argentina with the founding of the Health Economics Association. The fundamental purpose of this association was to generate a scientific-academic field dedicated to the reflection on, research, and training of human resources in the area of health economics, especially to improve efficiency and equity in the Argentinian health care system.

Throughout the first years of the new millennium during a period of increasing variability in clinical practice, new equipment, and pharmacological therapy developments in the country (especially in the area of biotechnology), it became essential to explore the tools that health technology assessment (HTA) offers to consider the economic, financial, and clinical impact of these new scenarios—particularly given the uncertainty surrounding the effect of certain diagnostic and therapeutic interventions. Political agendas from that moment onward began to acknowledge the need to work with entities that would effectively address studies on therapeutic development through the use of HTA.

The first milestone came with the “Decree 1343/2013”, issued on 4 October 2007, which amended the organizational chart of the Ministry of Health. It also created the Health Economics Directorate and assigned to this entity, among its primary responsibilities, the task of “assessing the national and provincial health care system’s services delivery performance by conducting cost-benefit analysis within the sector that would allow for a reallocation of resources at the political level”. Also during that same year, the ISPOR Argentina chapter was founded.

The first health economics congress for Latin America and the Caribbean was organized by the HTA Directorate in March 2009. Issues associated with HTA were incorporated in the agenda and the participants included representatives of Brazil, Paraguay, Cuba, Chile, Uruguay, Costa Rica, Argentina, and PAHO/WHO.

Along the same line of work, the Ministry of Health authorities declared the “Resolution 458/2009” on 14 October 2009 whereby the Coordinating Unit for Evaluation and Implementation of Health Technology (UCEETS) was created. The objective of this entity is to guarantee access to quality, equitable, and efficient health care services for citizens and advocate for the periodization of these topics within health care policies. HTA as a key tool for guiding rational decision making, based on scientific methods, provides many answers to questions posed by the various health care stakeholders, making it useful for not only health professionals, but also public authorities, insurers, administrators, payers, and the population at large.

UCEETS integrates several actors from the health care sector, such as payers and implementers, including: (1) the National Administration of Drugs, Food and Medical Technology (ANMAT); (2) the National Administration of Laboratories and Health Institutes (ANLIS); (3) the Health Care Services Superintendence; (4) the National Institute of Social Services for Retirees and Pensioners (INSSJP); (5) the National Single Central Institute for the Coordination of Implants and Ablation (INCUCAI); (6) the National Directorate of Health Regulation and Health Services Quality; (7) the Directorate of Health Services Quality; (8) the National Committee of Health, Science, and Technology (SACYT); (9) the National Hospital "Dr. Alejandro Posadas"; and (10) the National Pediatric Hospital SAMIC" Professor Dr. Juan P. Garrahan".

The objectives established for UCEETS are the following: (1) develop a strategic annual plan of inclusion, needs, and prioritization of technologies requiring assessment; (2) identify and evaluate new or previously established technologies that require evaluation; (3) establish and manage an accreditation system for the national implementers of health technology assessment; (4) generate HTA products, particularly Clinical Practice Guides and Technical Reports on technology considered a priority for UCEETS; (5) encourage research and development of HTA for priority areas of health care, especially when using economic evaluation methodology adapted to the local context; and (6) develop projects that promote international cooperation in the elaboration and dissemination of HTA products.
Between 2012 and 2013, UCEETS produced numerous reports related to the regulation of gluten-free foods, the cost-effectiveness of the conjugated pneumococcal vaccine, bosentan for pulmonary fibrosis in children, bevacizumab in metastatic colon cancer, etc.

There is also another institutional body of excellence dedicated to HTA in the country, the Institute of Clinical and Health Care Effectiveness (IECS), which was designated as a Collaborating Centre of Health Technology Assessment by PAHO/WHO in 2013. The IECS is a source of knowledge not only for Argentina, but for many countries in the region as well, such as Bolivia, Mexico, Panama, Peru, etc. Both UCEETS and IECS are members of the International Network of Agencies for Health Technology Assessment (INHATA).

Recently, the ISALUD University, an academic entity that has always been at the forefront of issues related to health economics, opened its Health Technology Assessment Centre (CETSA), composed of highly qualified professionals.

By disposition of the “Decree 4632/2012” dated 8 August 2012, the National Administration of Drugs, Food and Medical Technology (ANMAT) created the “Health Technology Assessment Programme”. The essential competency of this new program is the technological evaluation of products. Its tasks are to: (1) provide requested consultations; (2) generate evaluation reports and/or recommendations on the application of technologies; (3) collect scientific evidence to explore opportunities and convenient usages; and (4) provide accurate and updated data in the subject area of competence. This goal should be achieved through the use of agile and reliable data collection tools, storage and dissemination related to health technology assessment, and applied research and statistical developments.

The Federal Network of Health Technology Assessment (RedARETS) was created in 2012. RedARETS has direct intervention in the cooperation between provinces in order to support the efficient application of consensus generated in health care decision making.

Finally, it is important to mention that in 2012, Argentina modified its reimbursement system, specifically as it relates to low-incidence and high-cost treatments for its social insurance agents when the Single Reimbursement System (SUR) was created. In this system, the implementation of a Guardianship System of Emerging Health Care Technologies is under consideration. It would include 46 “guarded pairs”, the pathology with the corresponding therapy. These thematic pairs vary from paroxysmal nocturnal hemoglobinuria to various cancer types. The regulation priorities focus on patient safety and setting maximum fixed values for the reimbursement of pharmaceuticals.

It is clear there has been significant development in the creation of qualified institutional bodies to produce economic evaluations. However, that the country still does not have an "Argentinian Quality Adjusted Life Year" value, which is necessary measure to estimate costs based on robust methodological tools and generating a national QALY should therefore be considered in the near future. Some of these tools could include the construction of a federal epidemiological map to measure the actual disease burden of each region and province, the discussion of thresholds, etc. A national QALY would allow for scientifically informed health care coverage policies, which would help in determining cost-effective innovations, supported by clear rules of coverage, safety, clinical variability, and efficient health care resources management.

Published in Volume 2 Issue 2, August/September 2014 edition of “News Across Latin America”.
A Perspective on Health Technology Assessment Activities in Brazil

The authors would like to thank Carisi A. Polanczyk, MD, ScD and Ricardo Kuchenbecker, MD, ScD, Institute of Health Technology Assessment (IATS/CNPq), Hospital de Clínicas de Porto Alegre and Graduate Studies in Epidemiology, Federal University of Rio Grande do Sul, Porto Alegre, Brazil, for their helpful comments on a previous version of this article.

In Brazil, visible Health Technology Assessment (HTA) processes have been in place since 2000 (1). This was carried out by the Secretariat of Health care provision (SAS, Secretaria de Atenção à Saúde) of the Brazilian Ministry of Health (MS, Ministério da Saúde) and followed by the Department of Science and Technology (DECIT, Departamento de Ciência e Tecnologia) under the auspices of the Secretariat of Science, Technology and Strategic Inputs (SCTIE, Secretaria de Ciência, Tecnologia e Insumos Estratégicos). A decade later, Law 12.401 of December 2011 established an institutional framework for HTA and National Clinical Guidelines via the creation of the National Committee for Incorporation of Technologies (CONITEC, Comissão Nacional de Incorporação de Tecnologias) in the Unified Health System (SUS, Sistema Único de Saúde). As part of SCTIE, CONITEC succeeds the former Commission for Incorporation of Technologies (CITEC, Comissão de Incorporação de Tecnologias) established in 2006 and supports a more rational decision-making process at both clinical and policy levels (1) in line with priorities identified by the Ministry of Health.

Current HTA Framework in Brazil

CONITEC consists of an Executive Secretariat and 13 members. Of the latter, 7 members emanate from different secretariats of the Ministry of Health, representing the same composition as CITEC. However, six other members are now part of CONITEC: the National Council of Municipal Health Secretaries (CONASEMS, Conselho Nacional de Secretarias Municipais de Saúde), the National Council of State Health Secretaries (CONASS, Conselho Nacional de Secretários de Saúde), the National Health Council (CNS, Conselho Nacional de Saúde) the National Agency of Supplementary Health (ANS, Agência Nacional de Saúde Suplementar), the National Health Surveillance Agency (ANVISA, Agência Nacional de Vigilância Sanitária) and the Federal Council of Medicine (CFM, Conselho Federal de Medicina).

This composition reflects the complex multifaceted governance structure of the Brazilian public-funded national health care system which provides universal access to all Brazilian citizens to free health care at primary, secondary, and tertiary levels. Decision-making processes involve social control of public policies by means of the CNS, 27 State Councils, more than 5000 Municipality Councils, in addition to the Tripartite Committee at the federal level and the bipartite committees in each of the states.

The mission of CONITEC is to make recommendations on the incorporation, alteration or exclusion of health technologies in the National Medicines List (RENAME, Relação nacional de medicamentos essenciais) and the National list of Health Actions and Services (RENASES, Relação nacional de ações e serviços de saúde), as well as for the update of Clinical Practice Guidelines and Therapeutic Directives (PCDT, Protocolos Clínicos e Diretrizes Terapêuticas). These recommendations are made in line with social, health, and management needs of the SUS through using an evidence-based approach. (2) With the introduction of CONITEC, all requests for coverage of technologies need to present scientific evidence regarding efficacy and safety, in the form of systematic reviews or technical-scientific advice, as well as health economic evaluation and budget-impact studies.(2) On average, CONITEC convenes during two-day sessions on a monthly basis. The full list of recommendations is regularly updated on the website of CONITEC.
In parallel, DECIT has continued to be involved in health research, HTA studies, training dissemination and management of the Brazilian Network for Health Technology Assessment (REBRATS, Rede Brasileira de Avaliação de Tecnologias em Saúde). The creation and influence of the Institute for Health Technology Assessment (IATS, Instituto de Avaliação de Tecnologia em Saúde), a National Institute of Science and Technology, promoted by the National Council for Scientific and Technological Development (CNPq, Conselho Nacional de Desenvolvimento Científico e Tecnológico), composed of several national institutions and research groups, has been beneficial to a variety of health care facilities and decision makers.

IATS supports the development of health care strategies, by evaluating the incorporation of economic, ethical and public health consequences of new technologies by public and private health care providers in Brazil. Last but not least, the Brazilian Chapter of the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) has claimed to act as an educational resource in Brazil, by translating Health Economics and Outcomes Research (HEOR) concepts into Brazilian Portuguese and by encouraging the adoption of Consolidated Health Economic Evaluation Reporting Standards (CHEERS Checklist) (3) into the recently published pharmacoeconomic guidelines by the Ministry of Health (4).

**Two year assessment of CONITEC’s activity (2012-2013)**

We analyzed publicly available CONITEC recommendations on the incorporation of pharmaceutical drugs and vaccines for 2012 and 2013. Medical devices, diagnostics and procedures were excluded from the study since they only represented a fourth of CONITEC reports for the given period. One third of all requests emanated from a department pertaining to the MS and 56 percent from pharmaceutical manufacturers. For the latter, only one fourth received a positive response for drug incorporation, while this was the case for the large majority of MS claims, as shown in Figure 1.

![Figure 1. Breakdown of CONITEC recommendations per claimant request in percent, between 2012 and 2013](image-url)
Most drugs and vaccines that obtained a positive recommendation were later included in RENAME. This may suggest a clear alignment between CONITEC’s work agenda and evidence-based public health priorities, further illuminating how HTA sustains rational decision making within the Brazilian SUS.

Almost half of drugs and vaccines that obtained a positive recommendation belonged to the class of antineoplastic and immune modulating agents, followed by anti-infective for systemic use and respiratory drugs. This could be linked to the fact that over the same period, the Brazilian government placed strong focus on access to oncology treatments, which is illustrated by a national policy for the prevention and control of cancer in 2013, published by means of an Ordinance in May of 2013.

There were several reasons for rejecting a drug for incorporation. Among them appeared to be the lack of further results related to its safety and efficacy, counter-evidence identified by means of a systematic literature review, and the existence of a therapeutic alternative available in the SUS with lower cost of treatment. CONITEC also frequently cross-referenced HTA conducted by other agencies, such as the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Australian Pharmaceutical Benefits Advisory Committee (PBAC), as a justification for rejecting a drug.

Perspectives on HTA development in Brazil

Kuchenbecker and Polanczyk (2012) highlighted that “the SUS has been incorporating new interventions and technologies in a context of chronic underinvestment” which has led to right-to-health litigations for “high-cost medications that sometimes have unproven and/or even debatable benefits. In this context, “HTA will certainly contribute toward better decision making in Brazil, by enhancing its transparency and accountability.”(5) Indeed, the introduction of CONITEC represents a step towards more transparency and societal participation in the process of HTA. This is proven not only by the consistent online availability of CONITEC reports, but also the existence and effective use of the public consultation procedure, meaning that the civil society’s perspective is considered in CONITEC’s recommendations. However, the role of civil society in other appraisal committees, such as in Germany, Australia, Sweden, Scotland and England, still seem to be stronger.

As of today, CONITEC, as its name indicates, is still a Committee, following priorities identified by the government, and by 7 out of 13 members composed of MS representatives. CONITEC is not yet an independent agency, at the example of the French National Authority for Health (HAS, Haute Autorité de Santé).

Another important issue to take into consideration is that the HTA trend in Brazil should not only be measured at the national level. Indeed, important initiatives have emerged at the state level, such as the HTA Network of the São Paulo state.

Last but not least, HTA processes are embedded in the complex governance structure of the SUS. This raises the question whether political and economic dimensions do not outweigh technical and scientific contributions gained in the HTA process, through networks and initiatives, such as REBRATS or IATS. Their potential benefit would be much more important if the decentralization process of the SUS would had been more effective since its creation 25 years ago.
Conclusion

HTA implementation in Brazil has been a stepwise and concerted process, involving a wide range of actors and continuously building on societal consensus. A strong network between several universities and the Ministry of Health has been established in the creation of national guidelines for high-cost medicines as well as in the IATS initiative. The Brazilian experience shows that a unified HTA commission can be created in a federal State despite various regional contexts and an important number of administrative entities.

With the creation of CONITEC, the relationship or the link between HTA and evidence-based policy has become stronger. A larger question that is valid both for Brazil and for other emerging countries is to know whether the use of HTA has led to improved access to quality medicines for the patients, which is the goal that HTA should ultimately serve. A comprehensive national database would be helpful to better estimate such impact.

References


Health Technology Assessment in Chile: Reflections on a Slow Process

Efforts to formalize a Health Technology Assessment (HTA) process in Chile date back to the year 1997, with the creation of the Health Technology Assessment Unit in the Chilean Ministry of Health. This unit was formed with the aim of aiding the decision-making process by preparing synthesis reports on evidence concerning health intervention effectiveness and safety. Nonetheless, these reports did not always respond to health authority needs and in practice, the reports did not necessarily lead to the proper development of institutional mechanisms for implementing an HTA process as we understand one today. This unit was in operation until 2008, when the unit’s last two reports were published.

In Chile, evidence-based decision-making processes concerning health technology coverage are still in development under the auspices of the latest health reform, which began its implementation in 2005. One element of the reform was the creation of an explicit guarantee system for a set of health issues. This forced not only prioritization of diseases and health problems, but it also forced the definition of a set of health services guaranteed by law, regardless of whether the patient possesses public or private insurance. As a result, clinical practice guidelines were generated based on information concerning the efficacy, effectiveness, and safety of interventions. However, the guaranteed set of services is only defined upon completion of an assessment on the feasibility of financing those services. Although the clinical guidelines generation process benefits from sufficient legitimacy due to the participation of academic experts and scientific societies, the decision on financial coverage still does not comparatively have a systematic, clear, and transparent process.

Along with the Ministry of Health, various sectors of Chilean society have made efforts to advance developments in the decision-making process. In Chile, evidence-based medicine is undoubtedly the fastest growing field in HTA. Its development can be seen in the consolidation of research groups in this area in several universities in Chile, as well as the creation of post-graduate training programs in the field. At present, Chile can now count on qualified local professionals to take on HTA in the field of intervention efficacy and safety evaluations.

Development of certain aspects of HTA economics has been more limited. In 2007, the founding of the ISPOR Chile Chapter has played a significant role in maintaining a flow of activities, which has allowed for the continuous training of professionals in areas such as economic evaluations, HTA, and health economics, in general. However, the ISPOR Chile Chapter is not the only institution actively engaged in this arena. Universities have also made significant efforts. The Catholic University of Chile established an economic evaluation degree program in 2010 and the Universities of Chile and the Andes have also been developing extension courses on this subject. In addition to those previously mentioned, other institutions have integrated the subject area into their post-graduate programs and at the same time have produced relevant research, as is the case of Universidad de La Frontera, Universidad Mayor and Universidad Católica del Norte. Finally, recognition must be given to the efforts of the pharmaceutical industry in promoting continuous training and discussion of these matters by organizing seminars and extension courses with the participation of well-regarded international experts.
One of the most important milestones in recent years for the development of HTA in Chile was the formation of the National Health Technology Assessment Council in the Chilean Ministry of Health. This council is different from the previous national HTA Unit in terms of its structure and objectives. The National HTA Council consists of 16 members representing the various entities that make up the health authority and 2 advisers to carry out technical tasks as required by its members. The Council's main objective is to formulate a proposal for standardizing the implementation of an HTA model in Chile based on the review of normative considerations, international experiences, and an assessment of the country's internal capabilities; the proposal would be strictly adjusted according to scientific and technical considerations. There is hope that the work of the Council will have a positive impact not only on the health authority, but also for the various stakeholders who should feel part of this process.

The implementation of a systematic, transparent, and socially legitimate decision-making process on health technology coverage ought to be a goal for society as a whole, extending to various political sectors and social movements. In other words, the institutionalization of an HTA process is not, nor should it be, considered a policy bound to one sector, but as an area of public policy, where debates should focus on scope and process definition and implementation. We believe this argument resonates beyond the borders of Chile and is applicable to all countries of the region that are still in the incipient stages of HTA development.

Finally, we acknowledge the work of the National HTA Council as a fundamental actor of HTA development in Chile. However, it is far from being the only one. It is necessary for the country to have other social sectors taking part in public dialogue concerning the proposal being drawn up by the Council. Therefore, we consider it essential to invite scientific and health professional societies, leading health authorities, and institutes relating to public health, as well as the private sector, to actively contribute to the discussion in order to obtain a result that, although imperfect, has the societal support a health policy requires.

Published in Volume 1 Issue 4, September/October 2013 edition of “News Across Latin America”.
Health Technology Assessment in Ecuador

Over the past five decades, technological innovation has produced truly remarkable advances in health technology worldwide (1). On the other hand, growth of public expenses and particularly, health technology expenses have made Health Technology Assessments (HTA) play an important role in decision making in health technology in several countries (2).

In Ecuador, HTA is a process that began in late 2012 as a tool to aid health technology related decision-making within the Ministry of Public Health from Ecuador (MPH), which is the governing body of the sector. The Health Intelligence Bureau is responsible for the development of the HTA process; and work under the General Coordination of Strategic Development in Health (GCSDH), which is vested with advisory enabling capacity, according to the Organic Statute of Organizational Management for Processes from the MPH. Together with the Department of Health Economics, the GCSDH generates information based on the best scientific evidence available regarding the use of health technologies.

Since the beginning of HTA applications in the country, reports generated on this subject have been used as input for making informed decisions on the inclusion or exclusion of technologies for the Basic Tables or Set of Benefits, the purchase of technologies outside the Set of Benefits, and any other decision that involves allocating public resources within the scope of work designated to the MPH and National Health System of Ecuador.

The HTA process in the MPH include four components: (1) generation of HTA reports; (2) distribution of information related to HTA; (3) training on issues related to HTA for key players in the process; and (4) monitoring the impact of the reports in decision making.

Most HTA reports developed by the GCSDH are rapid responses, resulting from requests made on demand by authorities from the MPH in issues related mostly to the domains of efficacy, safety and economic considerations. In 2014, 82 rapid response reports were generated; 53% referring to medications; 7% to diagnostic tests; 6% to medical procedures; 5% to health programs; 1% to devices; and 18% to other technologies.

Considering that medication have been the type of technologies most frequently evaluated, at the end of 2014 a prioritization process of health technologies was proposed that would use the multi-criteria decision analysis method (MCDA) (3). This method supports decision makers who face the assessment of health alternatives, for which multiple explicit criteria are taken into account during the selection period. The selected criteria for the development of the prioritization matrix included: the impact of illness; intervention context; the type of technology benefit; and cost and quality of the available scientific evidence related to the relevant technology. From the prioritization process, rapid, short, and complete HTA reports of HTA were developed based on the technologies defined as high priority during 2015.

In regard to the distribution of information related to HTA, the MPH publishes quarterly HTA newsletters aimed towards key players in the process. The connection among actors involved in HTA is important; training and distribution processes in HTA allow decision makers, applicants, patients, and thematic experts to properly connect and gives them the opportunity to create agreements, legitimize, and consolidate the process.

Since late 2014, a mechanism for evaluating the impact of HTA report on decision making in our country was proposed. It aims to collect information on the usefulness of the process in health care decisions.
With the report from the 67th World Health Assembly from the World Health Organization (WHO) (4), governments were urged to use interventions and health technology evaluation in support of universal health coverage. Ecuador acknowledges the importance of HTA to achieve better decisions for universal coverage.

The significance of participating in HTA international networks lies in the opportunity it provides to exchange experiences and improve analytical capabilities in working with HTA issues. Ecuador actively participates in several networks, such as the Health Technology Assessment Network in the Americas (RedETSA) and Andean Network of Health Technology Assessment (RAETS) since 2013; and since 2014 in the HTA component of the International Cooperation project on Information Generation for the Improvement of the Efficiency in the Management of High Financial Impact Medications, financed by the Inter-American Development Bank (IDB), which participates currently with Colombia, Mexico, and Ecuador with the purpose of achieving a regional HTA direction.

Ecuador is in a critical moment vis-a-vis the development of HTA thanks to the institutional support provided by MPH, an entity that see the process as an invaluable tool for decision making.

Given that the country is at an early phase of HTA development, several institutions, particularly in academia, have expressed their interest in generating HTA centers as if the case of the City of Knowledge, Yachay. They could be involved directly in supporting the National Health Authority to respond to HTA requests.

As with most countries where the application of HTA arose for decision making, in Ecuador there are some clearly identified barriers that limit the development process—among them, limited technical capacity for the development of HTA reports, increased need for a prioritization of technologies and the existence of insufficient data on local health problems.

Finally, several recommendations were proposed to further develop HTA in Ecuador—among them, consolidating a work team with analytical capabilities related to the field of HTA, achieving an adequate interaction with all players involved in the HTA process, and working with a regional HTA vision. All of this would help to better enable decision making in the field of health in the country to be based on the best available scientific evidence.

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(5) 67.ª Asamblea Mundial de la Salud, Evaluación de las intervenciones y las tecnologías sanitarias en apoyo de la cobertura sanitaria universal, WHA67.23. 2014 [67th World Assembly of Health, Evaluation of health interventions and technologies in support of the universal health coverage]
Ten Years of Pharmacoeconomics in Mexico

Over the course of these last 10 years, the General Health Council has positioned itself as the main health technology assessor given that it is this collegiate body’s sole responsibility to constantly maintain and update the Basic Formulary Medications List and Healthcare Supplies Catalog (Cuadro Básico y Catálogo de Insumos del Sector Salud - CBbyCISS). This document groups, characterizes, and encodes the drugs, medical supplies, instruments, medical equipment, and diagnostics used by National Health System’s public institutions to provide health services to the population. The Basic Formulary Medications List applies to the first level of care and the Healthcare Supplies Catalog applies to the second and third levels.

The fundamental aim of this list is to assist in optimizing public resources directed at addressing health problems in the country, by means of using technologies tested for safety, therapeutic effectiveness, and efficiency. Additionally, the supplies list is a reference tool that serves to notify and assist, which aims to achieve updating health professionals.

All of the foregoing is based on the Internal Regulations of the CBbyCISS Inter-Institutional Commission, whose legislation aims to regulate the manner in which the CBbyCISS is drawn up, updated, and published, in order to assist in improving the quality, safety, and efficiency of health care offered by public institutions of the National Health System. It establishes the ethical principles and commitments of the CBbyCISS Inter-Institutional Commission aimed to achieve efficient, transparent processes based on scientific evidence.

This year marks precisely the 10th anniversary of the General Health Council’s update to its regulations, requiring the inclusion of a pharmacoeconomics study. This factor triggered the development and strengthening of health technology assessment, as a national priority.

The first signs of the importance of this new requirement were, among others, the creation of pharmacoeconomics management departments by several pharmaceutical companies, the establishment of the ISPOR Mexico Chapter (August 2006) with no less than 15 members, and 4 new consultancy firms in the country.

Following the modification of the regulation, the General Health Council published its Guidelines for Conducting Economic Evaluation Studies in the year 2008 and its Guidelines for Evaluating Healthcare Supplies in the year 2011, as well as a new regulation which further strengthened the specific requirements pharmacoeconomics studies should contain.

In principle, this new regulation and the Guidelines for Evaluating Healthcare Supplies meant a structural change to evaluating supplies, as specific criteria were established such as defining a 1PIB per capita threshold. This change clearly meant a growth in employment creation given the opening of new positions within the industry, consultancy firms and government and a clear need for training human resources.

Companies that started off with a single pharmacoeconomics manager, now have a department with at least 4 positions. Likewise, the ISPOR Mexico Chapter currently has grown more than 70 active members and has organized and carried out two training seminars during this time period. The growth of the number of people who are dedicated to this matter is more than obvious, although it is still insufficient given the large number of submissions presented to the General Health Council.
A total of 118 requests were received during the period between September 2011 and May 2013, which solely concerned medication. Of these, only 89 were evaluated since the remaining did not meet basic requirements. Of the total requests evaluated, 47% were approved to be included in the CByCISS. It is important to mention that 29 of these were requests for modifications, in other words, the inclusion of new indications, new dosage forms or the submission of drugs already listed, and 13 were requests for new inclusions (Figure 1).

Figure 1. Number of approved requests

It should be noted that 7 of the 13 requests for the inclusion of drugs correspond to the endocrinology and metabolism and oncology therapeutic groups (Table 1). The foregoing reflects the positive correlation between public health problems that affect our population and the current list of health care priorities made by health authorities.

Table 1. New Inclusions of Drugs by Therapeutic Group

<table>
<thead>
<tr>
<th>Therapeutic Group Name</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrinology &amp; Metabolism</td>
<td>3</td>
</tr>
<tr>
<td>Communicable &amp; Parasitic Diseases</td>
<td>1</td>
</tr>
<tr>
<td>Hematology</td>
<td>2</td>
</tr>
<tr>
<td>Pneumology</td>
<td>1</td>
</tr>
<tr>
<td>Oncology</td>
<td>4</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>13</td>
</tr>
</tbody>
</table>

Thus, in recent years, pharmacoeconomics has been the most important factor, although not the only one, in the decision-making process to include the CByCISS. However, although the General Health Council has been the leader of the entire technology assessment movement by giving economic evaluation studies a leading role, it has not neglected the importance of clinical information. Alternative oncology or orphan drugs may not have been cost-effective alternatives, per se; however, they are alternatives, which cover latent health needs. Therefore, in this way the Council is currently starting to evaluate new methodologies, which consider each variable (clinical, social, and environmental) to keep promoting and strengthening the decision-making process for innovative drugs with the ultimate objective of patient access.

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Health Financing and Expenditure

Health financing refers to the movement of resources from their funding sources to the financial agents in health. In Paraguay, the financial bodies are clustered into three subsectors that composing the health care system. Each subsector has its own mechanisms and sources of funding.

The General Budget of the Nation finances the public sector via: (a) resources from the public treasury generated by fiscal income/taxes; (b) foreign loans; and (c) institutional resources collected from the payment of certain fees, donations, and other resources. In 2011, the budget of the Ministry of Public Health and Social Welfare (MSPBS) depended on financing from treasury resources (88%), from foreign loans (2%), and from institutional resources (10%). In 2002, the percentages were 77.7%, 6.5% and 15.9%, respectively. The numbers indicate that the MSPBS financing dependent on the public treasury resources has increased over the last decade. This has decreased the relative weight of foreign loans and institutional resources, which is auspicious because it represents a decrease in out-of-pocket spending for the average families. National universities (Health Departments) and Military and Police Health care, which are also part the public health subsector, are financed primarily by tax revenues.

The Social Security Institute (IPS) is financed by: employer contribution (14%); by the workers monthly salaries (9%); and state contribution (1.5%) of the salaries reported by employers. The 14% employer contribution includes a 1.5% that the IPS collects and transfers to the MSPBS to fund prevention programs and cover the expenditures of the National Programme of Vector Borne Diseases (SENEPA). Some groups, such as teachers working in public and private sectors, are organized into different categories with special contribution schemes. Financing for the IPS health expenses via the Sickness and Maternity Fund stems primarily from taxes collected from the total amount of wages (9%). There are indicators that demonstrate a high evasion of the social insurance by employers, and the state’s failure to enforce compliance to the mandatory contribution is partly responsible for the significant state debt to the IPS.

The private sector is financed by the users’ payment and contributions of prepaid health schemes members.

Figure 1 illustrates the finance flow and health care system expenditure.
When observing the aggregate expenditure on health care, the importance of the diverse financing sources as a whole becomes clear.

The health expenditure numbers as a percentage of the last years’ GDP (2000 to 2009) show that it has been steadily dropping since 2000 (8.4%) to 2008 (6%), the year the lowest numbers of the considered period were recorded. From 2009 on, spending increased to 7.1% of GDP; 57% of which were private expenses. The national aggregated expenditure was an estimated US$ 159 per capita that year (current values). The amount almost doubled that of Bolivia; however it was much lower than that of Argentina, Brazil, and Uruguay, whose per capita expenditure levels are four times higher than that of Paraguay.

The out-of-pocket expenditure in Paraguay represents an 85% of the private health expenditure. It includes direct payments made by families for health care and medicines. A total of 58.6% of the out-of-pocket spending for families was allocated toward purchasing medicines. That amount of out-of-pocket expenditure reveals a highly segmented health care system due to the fact that families have lower effective protection from the state regarding health care; thus, this contributes to increased inequities since, proportionally, the poorest apply a higher portion of their incomes for their health care needs.

The allocation of the national budget to the health sector, as measured by the MSPBS' budget allocation has significantly increased in the last years, growing 4 times. In the last 11 years, even though in relation to the GDP, the public sector represents only the 3%. The budget execution capacity measured by the PE/PA ratio was an average of 81% for the 2000 -2001 period. The lowest execution level was observed in the year 2000 reaching 72% and the highest in the year 2010 when it reached 90% as is shown in the following table:

Table 1: Health care and Public Health Aggregated Expenditure, Paraguay, 2009

<table>
<thead>
<tr>
<th>Subsectors and its main source of financing</th>
<th>Participation Percentage</th>
<th>GDP %</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Public (mainly taxes)</td>
<td>25.4%</td>
<td>1.8%</td>
</tr>
<tr>
<td>b. Social Security (IPS) (contribution from wages)</td>
<td>17.5%</td>
<td>1.25%</td>
</tr>
<tr>
<td>c. Private Sector (user payment)</td>
<td>57.1%</td>
<td>4.05%</td>
</tr>
<tr>
<td>Total expenses in health</td>
<td>100.0%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

Source: Gaete, R. elaboration with data from the Global Health Observatory, WHO, and Satellite health accounts from Paraguay, MSPBS.
Table 4

Classification of Expenditures of the MSPBS and the IPS according to the Type of Services: 2005 - 2008 in %

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MSPBS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governing body</td>
<td>9%</td>
<td>9%</td>
<td>13%</td>
<td>5%</td>
</tr>
<tr>
<td>Public Health</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>Individual Health</td>
<td>77%</td>
<td>77%</td>
<td>74%</td>
<td>81%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>IPS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governing body</td>
<td>9%</td>
<td>9%</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Public Health</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>Individual Health</td>
<td>77%</td>
<td>77%</td>
<td>77%</td>
<td>77%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>MSPBS + IPS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governing body</td>
<td>9%</td>
<td>9%</td>
<td>11%</td>
<td>7%</td>
</tr>
<tr>
<td>Public Health</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>Individual Health</td>
<td>77%</td>
<td>77%</td>
<td>75%</td>
<td>79%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

The relative value available in Table 4 provides information on the expenditures of Paraguay’s two principal health care provider institutions established by the MSPBS and the IPS. The table reveals values related to the governing body activities, which entails leading, coordinating and regulating the sector; public health activities constituted by the set of actions and services designed to protect the population’s health as a collective unit (promotion and prevention); and individual health care, which consists of health care provision (inpatient and outpatient health services, diagnosis and other services).

In the 2005 - 2008 period, the public health sector channeled most of its expenditure (77.3 %) towards individual health activities, 13.8% to public health activities and, 8.9% to the governing body activities, respectively, on average. This expenditure composition remained constant in the years 2005 and 2006, varying significantly in the years 2007 and 2008 in respect to the governing body and individual health activities, while spending on public health remained constant.

In a strict sense, public health is considered a public good: the fact that resources to fund these activities increased to only the 13.8% of the public budget reveals that the preventive and promotional expenditure orientation is still insufficient. There exists an important opportunity to influence the order of the sectorial resource allocation priority to improve allocative efficiency.

Alloca
tive efficiency implies assigning resources following the declared health policy priorities or the main goals that society would like achieve collectively. International evidence suggests that health care systems based on primary assistance have better health outcomes are more efficient, and achieve higher user satisfaction when compared to systems with weak orientation to primary care assistance.

It is in that sense that improving the allocative efficiency in a country, such as Paraguay involves increasing the proportion of resources destined to primary care assistance, which implies the reorientation of health care services to promotion and prevention.

Furthermore, in the context of resources allocation via the public budget to improve allocative efficiency, the short-term perspective must be exceeded. Whereas the annual budgets do not consider the medium-term implications of current decisions, e.g., the recurring future expenses associated to current investments. Another alternative is to reduce the imbalance of resources allocation, e.g., health care establishments where there are 4 dentists but only one dental chair and no anesthesia; x-ray equipment but no radiologists; or for example existing therapy equipment but no professional to use it.

Process of Decision Making for Health Technology Incorporation

Health technology plays an essential role in the pursuit of equity, quality, and efficiency of health care systems and entails an increasing budgetary impact that could jeopardize its sustainability.

The establishment of an institutional framework for decision making on the incorporation health technologies in the health care system aids in overcoming one of the principal obstacles identified in the World Health Report 2010 to accomplish universal coverage: the inefficient use of resources.
A key tool to guide decision making in a rational and efficient manner, based on scientific methods, is health technology assessment, as it is the nexus between scientific knowledge and the decision making process. In a broader approach that addresses the distinct functions related to the health technologies regarding regulation, incorporation, and rational use, HTA should be applied.

In Paraguay, the current institutional mechanisms to control the inclusion of health technologies in the health care system do not guarantee the incorporation and use of those that achieve improved health status. Even those technologies whose effectiveness are doubtful or unknown find a place within the system. This is observable in the diverse scope of existing technologies -from the simplest to the most complex- in both the private and public sectors.

While providing a broad approach to HTA in Paraguay is not issue of this article, the process of establishing the Essential Medicines List (LME) in 2008 and the Essential Medical Supplies List (LIME) in 2012 may be mentioned as positive milestones in the use of HTA for decision making in the medicines and supplies area. Both instruments constitute a reference framework for the acquisition, distribution and use of the medicines and supplies in all the management and attention levels of the public sector, as well as a tool for prioritized inputs manufacturing and for the health registry that regulates marketing and usage.

The methodology utilized for developing the LME consisted of 3 stages: (1) formation of a National Technical Committee integrated by MSPBS technical division officials, national universities, and national institutes directly related to the medicines selection activities; (2) dissemination of the proposed LME through the strategy of focus groups of prescriber clinicians of representative health care regions and specialist clinicians by pharmacological groups; and (3) technical review of the medicines proposed to be included or excluded from the development of the LME (a stage in which the national technical committee evaluated the suggested recommendations in the dissemination process and made the necessary adjustments by identifying and applying the reference information from the best available evidence). This is important for reviewing efficacy and safety aspects of the medicine given that the selection is based on primary election indications for each health issue. The specialized information sources were consulted on aspects related to the pharmacological characteristics of the medicines, to check the content of each selected medicine.

The criteria considered by the national technical committee for the selection of the medicines included in the LME are promoted and applied by the WHO in the elaboration of the Model List of Essential Medicines and are presented below: (a) relevance to the pattern of prevalent diseases; (b) demonstrated efficacy and safety; (c) evidence that the expected results are produced in diverse environments; (d) adequate quality, including bioavailability, and stability; (e) favorable cost-benefit relation in terms of the treatment total cost; (f) desirable pharmacokinetic properties and local production possibility; and (g) marketing as individual compounds. The development of the LIME followed a similar process of the LME.

In a health care system like that of Paraguay, one where it is clear that the country has still large social inequities in health (inequality), the process of health technology assessment must necessarily incorporate the equity dimension in order to assess all impacts of a particular technology (including the impact on equity) for the HTA to contribute to a more efficient and fair system.

Therefore, developing a regulatory and operational institutional framework that comprehensively addresses the varied functions related to the health technology regulation, incorporation and rational use, is a challenge for Paraguay. It is especially necessary to strengthen the link between HTA and the decision making process of health technology incorporation in order to contribute more effectively to achieve more efficient, equitable and quality health system.

1 The MSPBS has implemented free healthcare since 2008, which implies the removal of all healthcare provision charges (copayments) in all the healthcare facilities that depend of this institution. The MSPBS still receives fees, however, these come from the registration of drugs in the National Direction of Healthcare Surveillance, the registration of food in the National Institute of Food and Nutrition (INAN) or control of professions, instead of healthcare services.
2 The IPS covers short-term (health care) and long-term (retirement and pension) benefits.
3 For the MSPBS budget, this contribution constitutes the funding through institutional resources.
4 Data from the Global Health Observatory, WHO
6 PE: Executed Budget; PA: Allocated Budget
7 Calculus based on Satellite Health Accounts of Paraguay, Public Sector – 2007 (Exploratory Exercise). MSPBS. PAHO/WHO

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Implementing Health Technology Assessment in Peru: A Gradual Process

Even though it is true that in Peru efforts are being made to introduce health technology assessment (HTA) as an essential tool for health care decision making, the fact is that after many years the results are not very encouraging.

The Ministry of Health is the entity that has made the most progress in the implementation of HTA. In 2010, the Ministry of Health established the Health Technology Assessment Unit and supported investing in staff training programs in health economic evaluations such as the one provided by the Institute for Clinical Effectiveness and Health (IECS). In addition, the Sectorial Committee on Health Technology Assessment in Health and High Cost Diseases was founded in 2011 to "promote and conduct health care technology assessments to technically support decisions related to the selection, integration and dissemination of technologies in the Ministry of Health and gradually, in the Health Care System". This committee includes representatives of the General Directorate of Medicines, Supplies, and Drugs (DIGEMID) and the National Institute of Health (INS). The Health Technology Assessment Center is part of this committee and it is expected to become the head of a network of HTA centers throughout the nation.

Among its various functions, a primary role of this Sectoral Committee is "to plan, organize, and develop HTA activities to support coverage decisions and other health care-related decisions", but it does not have the power to directly determine or recommend which technologies should be covered by the Ministry of Health, much less for the general health care system. Ideally, their recommendations should have a binding effect in order to enable the adoption and implementation of its conclusions without further administrative burden.

In EsSALUD (the public social security agency where workers who contribute 9% of their salary through their employers have the right to access services), the implementation of health technology assessment processes has not yet been formally and effectively established. There have been projects emanating from some of its authorities, but unfortunately, they have not been successful. For example, in August 2013, there was a project to create a management body for technological innovation in healthcare upon which a sub-management committee for health technology assessment should have depended. However, no specific unit responsible for performing HTA has been established in EsSALUD thus far. Currently, the Pharmacological Committee has added to its duties the task of evaluating cost-effectiveness related issues. EsSALUD urgently needs to have an HTA unit in place, given that the various health care technologies that require assessment go well beyond the scope of drug evaluation alone; and extend to the rational use of health care resources. According to 2012 data, the drugs requested by EsSalud exceeded 25% of those available in the National List of Essential Drugs, which is defined by the Ministry of Health to be applied in all health care facilities throughout the nation (Ministry of Health, regional governments, local governments, social security, health care services of the police and armed forces of Peru, clinics, and others from the private sub-sector).

The ongoing work being carried out by institutions like the Pan American Health Care Organization (PAHO- PERU) has made notable contributions to raising awareness and providing training on the need to promote the development of HTA. From the Technical Meeting on Health Technology Assessment and Management that was developed jointly with the Ministry of Health and EsSalud, which culminated in a panel discussion entitled: "Implementing Proposals for Health Technology Assessment and Economic Evaluations for Decision Making in Peru" last year in October, it can be inferred that we are still currently in the early stage of the process in Peru.

The private sector has become increasingly more interested in health technology assessment and economic evaluations, especially in the pharmaceutical industry and with private insurance companies (health care providers), but there are still few institutions that have established some form of management or positions dedicated exclusively to economic evaluations and HTA in general.
Interest in developing economic evaluations in Peru has existed for several years. The first International Seminar on Health Economics took place in Lima as early as 1995. The seminar was organized by the Peruvian Association for the Development of Health Care Economics and sponsored by, among others, the Inter-American Network on Health Economics and Financing (REDEFS) and the Economics Department of the National University of San Marcos (UNMSM).

The University of San Marcos, through its Economics Department, has been and remains one of the greatest academic driving forces of health economics in Peru and is developing a Master’s degree program in Health Economics since 2000. In addition, other universities have sporadically developed seminars or certificate courses on health economics, pharmacoconomics, or health technology assessment. There is a labor market demand that is gradually growing at the public level and that has grown even more greatly within the private sphere, as is the case for the pharmaceutical industry and health care insurance companies.

The strong interest of many professionals involved in this field has led to the formation of several associations, such as the Peruvian Society of Health Economics, founded in 2007. Moreover, in January 2011 the regional chapter of ISPOR (International Society for Pharmacoconomics and Outcomes Research), ISPOR Peru, was established. It should be noted that the demand for research on economic evaluations and health technology assessments has increased, but it is primarily sought by the private sector. This demand is mainly seen in high-cost products, which are generally those that face greater obstacles to inclusion on the National List of Essential drugs from public institutions and private health care insurance companies. Usually, the public sector does not directly require cost-effectiveness studies, but it is beginning to use them as evaluation criteria for decision making. For example, although at the Police and Armed Forces institutions there is no coherent and serious policy on the routine use of health technology assessment, the truth is that other institutions have expressed interest; last year the National Police Hospital invited ISPOR Peru to give a presentation on health technology assessment and its usefulness in decision making.

In our country, as elsewhere in Latin America, efforts are being made to improve access to health services, however these efforts are not enough; we must ensure that everyone is able to access quality services. When we affirm that access must be accompanied by equal quality for all, we are talking about an essential issue, that of equity.

At this point, it is important to highlight that health technology assessment is not solely about evaluating the economics of an intervention; rather it is a broader tool that primarily seeks to identify interventions that are not effective or may be inefficient in order to avoid costs that could be employed to serve more people with better technologies. Often, health care decisions are not simple, much less so when a patient’s health depends on how much we can spend; but if we are a country with scarce resources, it is all the more reason, for us to learn to use tools that allow us to make better decisions. The most important step to advance the implementation of HTA in Peru is to sensitize the current governing authorities to regularly enact these policies that may withstand the changes of government.
Current Status of Health Development Challenges and Strategies in the Decision-Making Process for Health Technology Incorporation in Trinidad & Tobago

Introduction
Trinidad & Tobago is a twin-island democratic republic located off the north coast of Venezuela in the Caribbean Sea. The country achieved independence from Britain in 1962, followed by Republican status in 1976; however, it remains a member of the British Commonwealth. Its Constitution provides for the separation of powers of the three branches of government – the Executive, Legislative, and Judicial – and the country is organized into thirteen administrative areas. Tobago is administered separately by the Tobago House of Assembly (THA).

The total population of the two islands is 1.33 million, with 4% living in Tobago. There is a male: female ratio of 1:1, and an ethnic mix of East Indian 41%, African 40%, and other groups 19% (Chinese, European, and Middle Eastern). The annual growth rate is estimated to decline from 0.5% in 1995-2000 to -0.11% for 2014; fertility rates have been declining since the 1970s. Life expectancy at birth was estimated at 69.42 years for males, and 75.24 for females in 2014, which compares favourably with the figures for more developed countries.

Health systems and services
The Government of Trinidad & Tobago has made a policy decision to achieve developed nation status for the country by the year 2020 and has developed a strategic framework to bring this vision to fruition. A health sub-committee was established to develop a strategic framework for the sector. The mission statement articulated by this sub-committee was “To create a nation of individuals, families and communities empowered to achieve and sustain the highest standards of health and well-being through the provision of efficient, effective, equitable and collaborative services that support good health.”

The following seven goals for health have been identified:

- Improve the general health status of the population
- Enhance the management of communicable and non-communicable diseases
- Improve the performance of health care delivery systems
- Improve the quality of health care services
- Unify the delivery of health care services
- Develop/strengthen the health research system to facilitate evidence-based decision making, policy formulation, new learning, and development
- Create a patient-centred health care environment

The goals were developed to harmonize with the Health Sector Reform Programme (HSRP), and the success of this harmonized approach will depend on a high degree of intersectoral collaboration and commitment to continuity by successive governments. While the Vision 2020 strategic framework for the health sector has been developed, the MoH has yet to make it operational, through the development of a strategic health plan.

In July 1996, the Government of Trinidad and Tobago signed a loan agreement with the Inter-American Development Bank (IADB) for the implementation of HSRP. The health reform programme was intended to bring about fundamental changes through the strengthening of the leadership role of the Ministry of Health, development of health systems, and implementation of the Regional Health Authorities Act of 1994. The Act defined the Ministry’s role as being a ‘purchaser’ of health care services with Regional Health Authorities (RHAs) being the providers. However, implementation has been slow and challenging, and the loan was extended to the end of 2006. At this time, the MoH has not yet been able to effectively assume the leadership role and transform itself into an effective policy, planning, and regulatory organisation.

Major challenges are present in the current health system, which does not have a health workforce that corresponds in quantity, competencies, and quality to the current and projected health needs of the population, due to inadequate strategic human resource planning.
There are vacancies in key management positions and a shortage of staff even for acting positions. Transfer of staff from the MoH to the RHAs and resolution of industrial relations issues have been problematic. Pre-service and continuing education training programmes have not been effectively adapted to meet training needs for the health workforce due to inadequate dialogue among critical stakeholders in the health and education/academic sectors and professional bodies.

Professional bodies operate within the framework of regulations; however, enforcement of these regulations is a concern. Dual work practices, which allow many senior public service doctors to work in private as well as public practice, have resulted in the limitation of their public sector work hours, to the detriment of those who cannot afford to pay to see doctors in private practice.

In Trinidad and Tobago, the health budget has declined from 12% of the total budget in the early 1970s, to about 7% in 2003.

The public health system in Trinidad & Tobago comprises hospitals – tertiary level, district, and specialist (long-stay) – and a mix of primary health care (PHC) facilities, with district health facilities at the hub of health and outreach centres. The private sector involves practitioners, hospitals, maternity centres, pharmacies, biomedical laboratories and radiological diagnostic services. Though the private sector remains highly unregulated, some publicly-funded health institutions are outsourcing some of their health and ancillary services to private providers. Trinidad and Tobago also serves as a tertiary care referral centre for persons from other CARICOM (Caribbean Community) countries. Nearly all health centres continue to offer traditional services.

**Current health sector development challenges in decision making**

There is insufficient evidence-based planning and decision making for health technology incorporation in the health sector due to the lack of an integrated health management information system. The system for drug utilisation is inadequate, the national drug policy and formulary are outdated, and there is a lack of drug utilisation reviews. The laboratory system has been unable to adequately meet service needs due to many factors, including limited financial resources, inadequate physical plant, insufficient professional and technical leadership, outdated regulations, and poor dialogue with clinical services.

**Areas identified and strategies involved for the process of decision making for health technology incorporation**

The health sector development challenges identified are diverse, but the priority challenges are categorized by critical areas that include: planning and policy development – the regulatory framework; health information systems, epidemiological surveillance, data analysis, and the use of information for decision-making; human resources in the public and appropriate competencies; the development of the health system and services; and the coordination, follow-up and networking at the local level for regional and global commitments.

**Planning and policy development - the regulatory framework**

There is need to:

- Strengthen planning, policy, and regulatory capacities and to create a “planning culture.”
- Strengthen leadership and managerial capacities of the Ministry of Health and the Regional Health Authorities.
- Ensure evidence-based planning and decision-making in the health system.
- Strengthen national emergency preparedness and response legislation which would mandate actions.
- Strengthen the leadership role in providing policy direction on the issue of decentralization of environmental health services and to promote collaboration and rationalization of responsibilities between health and the ministries of local government, agriculture, labour, and public utilities, to better utilize resources to ensure a better provision of these services.
- Address the lack of cohesive national policies for waste management (solid and hazardous wastes cover several sectors), with regulations and systems for implementation.

**Health information systems and epidemiological surveillance**

There is need to:

- Develop and strengthen health information systems at the national and RHA levels.
- Develop standardized surveillance methods for public and private health facilities and adequate competencies in surveillance and analysis to heighten surveillance required for both communicable and non-communicable diseases.
Human resources in health

There is need to:

- Develop a policy and plan for human resource development and management, which will address the widening human resource gap in the public health sector.
- Ensure that the vertical services which remain the core responsibility of the Ministry of Health have enhanced human resources and facilities.

Health systems and services development

There is need to:

- Develop and implement a strategy to define and operationalize the Primary Health Care and Health Promotion model, ensuring implementation of prevention interventions, including prevention of violence and substance abuse at all levels and in all sectors.
- Strengthen norms and standards, evidence-based practices, rules, and protocols relating to patient care and safety, and overall clinical management at all levels of care.
- Develop and implement a strategic plan for the strengthening of medical laboratory services and ensure effective maintenance and health technology assessment of the engineering functions of health facilities (plant, buildings, and equipment).
- Appropriately address and improve the quality of health care for pregnant women, including issues of low birth weight (LBW) babies, reduction of exclusive breastfeeding, and iron deficiency anaemia.
- Address overweight and obesity among pre-schoolers, adolescents, and adults, as major public health problems, especially given the profound implications of these conditions for the development of chronic, non-communicable, nutrition-related diseases.
- Promote universal access to prevention, care, treatment and support for HIV/AIDS and ensure accessible and comprehensive sexual and reproductive health (SRH).
- Develop a social health insurance model that is equitable and sustainable.
- Address environmental health issues, including strengthening environmental risk management, including vector control, and ensuring equitable and reliable access to potable water for the population.

Coordination and networking

There is need to:

- Improve and/or establish adequate communication and coordination and operational relationships and mechanisms between the Ministry of Health and agencies/institutions, such as UWI, the RHAs, development agencies, and other health development partners.
- Promote and strengthen involvement and partnership on HIV/AIDS between the public and private sectors, including observation of the human rights of Persons Living With HIV/AIDS (PLWHA).

References and further reading

(1) http://www.indexmundi.com/trinidad_and_tobago/population_growth_rate.html
(3) PAHO/WHO Country cooperation strategy, Trinidad and Tobago, November 2006.

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Value in Health Regional Issues accepts manuscripts on a rolling basis. In order to be considered for the next (2016) Latin America issue, manuscripts must be submitted by 1 July 2016!*

*Articles accepted for publication in the 2015 Latin America issue will also be published online early and will be available for citation.

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The Use of Health Technology Assessment in Military Health Care: Experiences in Uruguay

“In a world with unlimited resources, it would be unnecessary to have methods to determine the best way to allocate those resources among alternative uses. But resources are limited.......”  Frank Sloan

Background
Since January 2008, the Integrated National Health System (SNIS) covers both the public and private subsectors in Uruguay. Under the same law, the National Health Insurance (SNS) was created and financed by FONASA, the National Health Fund, which collects contributions of SNIS users in the form of a salary percentage deduction (between 4.5 and 6.0%) for this purpose. The National Board of Health (JUNASA) manages this fund, and FONASA covers a set of benefits that Institutions must offer to their members, including pharmaceuticals.

The National Therapeutic Formulary (FTN) Commission of the Ministry of Public Health generates and reviews the FTN periodically. This is the essential list of medicines that each therapeutic formulary of every public hospital or private health institution should include. According to the epidemiological profile of the user population, FONASA provides funding to each health care institution; they also include the per capita for this coverage.

The National Resources Fund (FNR) authorizes and funds high-cost medicines (e.g. biologics). The FNR is a non-state based national institution with public institutional characteristics that provides financial coverage for highly specialized medical procedures and high-cost pharmaceuticals for all residents in the country and SNIS users. FNR is financed with the contribution of diverse institutions: FONASA finances its members, the Ministry of Economy and Finances pays the public hospital users and private health care institutions for their beneficiaries that do not contribute to FONASA or other alike.

The National Health Directorate of the Armed Forces of the Oriental Republic of Uruguay (D.N.S.FF.AA.) is not part of the SNIS or the FNR. Therefore, to offer them benefits consistent with international standards of quality and efficiency, the Health Technology Assessment Committee of the National Health Directorate of the Armed Forces (CETM-D.N.S.FF.AA.) was created in August 2008. Its mission is to study all the problems associated with health technologies in the broadest sense: the incorporation of new technologies and the study of existing ones. Health technology is viewed as the set of medicines, devices and medical or surgical procedures used in health care, as well as the organizational and supportive systems within which such care is provided.

In this presentation, we will refer exclusively to high-cost pharmaceutical technology, which is a regular concern for the work of this Committee. The objective of the CETM - D.N.S.FF.AA. is to ensure that patients are cared for with optimal incremental cost-effectiveness treatment. This pharmacoeconomic tool determines which medication will be available and how they should be used to guarantee user satisfaction, the rational use of resources, institutional sustainability and equity for the member population of the health care system.

Organization
The CETM - D.N.S.FF.AA depends directly on the National Director of the D.N.S.FF.AA. and its members should be free from any conflicts of interest. It is structured according to World Health Organization (WHO) recommendations, with permanent, alternate and consultant members. The President must be a referring physician in the institution; the Vice-President, a medical pharmacologist; and the Secretary, a pharmaceutical chemist. The first member must be an economist, the second member an engineer specialized in hospital equipment, and all should demonstrate expertise in health technology assessment. The Commission is supported by two administrative staff members that have neither voice, nor vote.

The alternate members who have voice and vote are specialists appointed by the CETM – D.N.S.FF.AA. that belong to the Armed Forces Central Hospital and are designated when knowledge in specific health areas is required.
Operation
The permanent members of the CETM - D.N.S.FF.AA meet regularly to evaluate the applications received. They are sent via application forms and there are two types of request forms: (a) a request to a specific treatment for a determined patient and (b) a request for the addition of a medication to the D.N.S.FF.AA Therapeutic Formulary.

The applicant doctor must complete these forms with their own information, patient data, the requested medication, indication, dosage, the patient’s clinical condition, and other received treatments along with the scientific basis and pharmacoeconomic studies leading to the request of the particular treatment.

In response to the requests, the Commission undertakes an objective and thorough analysis, based on the reviews of international health technology assessment of incremental cost-effectiveness agencies. Besides the bibliographical evidence, the Commission performs their own incremental cost-effectiveness evaluation for each high-cost pharmaceutical technology acquisition. The evaluation is based on clinical evidence from studies designed according to GCP-ICH publications in peer-reviewed journals taking into consideration local market conditions and the local health system.

Furthermore, the Commission additionally analyzes the economic feasibility and sustainability of pharmaceutical technologies over time. In all required or appropriate cases, alternate or consultant members are consulted before making any decisions. These analyses are performed for medicines that are not included in the institution’s therapeutic formulary or covered by the National Resources Fund (FNR). Criterion proposed by the WHO\(^3\) was applied to set the favorable and unfavorable incremental cost-effectiveness limits. The adopted approach is: 1 GDP per capita is cost-effective; between 1 and 3 GDP per capita are discussed case by case depending on prognostic factors; budget impact; etc., more than 3 GDP per capita is not cost-effective. This approach attempts to adapt the acceptance or rejection thresholds of new technology to the prevailing economic situation in the country at the particular time in which the economic analysis is conducted (the GDP per capita of Uruguay was around US$ 16,000 in 2013).

Economic Impact of Expenses in Medication That Was Not Included in the Therapeutic Form.

Chart 1 shows the relative variation in costs for medication not included in the D.N.S.FF.AA Formulary throughout 2005-2012, which considers 100% of the expenses in 2008, the year of the creation of CETM. In the same chart, it is possible to note that since 2005 there has been a significant growth in annual expenses, which increased between 2006 and 2007, mainly due to the increment of high-cost biotechnology derived medication in the local market.

Chart 1. Relative Variation of Expenses in Medication That Was Not Included in the Therapeutic Form.

In 2008, the growth came to a halt. Given the trend change, the CETM-D.N.S.FF.AA began operating in August of that year to establish a scientific methodology for authorizing high-cost treatments.

From 2008 to 2010, the expenditure dropped and reached, in constant dollars, 30.4% of the accrued expenses in 2008. From 2010, the expenses of medication not included in the therapeutic formulary began to increase gradually. This may be due to the development of new treatments, particularly biologics, in different therapeutic groups, to restore the typical clinical efficacy loss from these products.
Below, Chart 2 shows the percentage of the expenditure on medication not included in the therapeutic formulary by specialty according to the total expense medication in the D.N.S.FF.AA for 2011 (a) and 2012 (b).

Five specialties (oncology, endocrinology, rheumatology, hemato-oncology and hepatology) claim almost 80% of the total budget items intended for medication not included in the therapeutic formulary for both years.

Chart 2 - Percentage of Expenses in Medication not Included in the Therapeutic Form by Specialty. (a) Year 2011 and (b) Year 2012.
Unsurprisingly, specialties such as oncology, rheumatology and hepatology have the greatest weight in the expenses of recent years. For the first two aforementioned, a wide range of high-cost drugs that are marketed for terminal cancer or chronic rheumatic diseases, such as novel monoclonal antibodies and the tyrosine kinase inhibitors was developed. The D.N.S.FF.AA. has the unique referral hospital for liver transplant in the country, therefore the expenses for hepatology are also predictable.

Regarding the expense distribution for medication not included in the therapeutic formulary, of the patients treated with this medication in 2011, 53% required 85% of the total intended budget items, while in 2012, 49% of the patients required 86% of the total budget items.

When comparing medication expenses not included in the Therapeutic Formulary to the total medicine expenses of the D.N.S.FF.AA., the results show that in 2011, the expenses reached 10.5% of total medication expenses and in 2012, it accounted for 13.3% of the total. These expenditures were accrued by 0.20% and 0.24% of the total number of users in those years, respectively.

**Conclusions**

The public budget is overburdened by health expenditures throughout the developed world. Every dollar invested in health will no longer be available to assign to other important state benefits. In addition, a significant amount of our spending is allocated to the buying of medical technologies whose effectiveness and safety are far from justifying the opportunity cost for the health care system.

The Health Technology Assessment Committee of the D.N.S.FF.AA optimized their medication expenditure since the beginning of its management by basing their decisions on objective and scientifically supported criteria, thus becoming an essential tool within the institution to streamline health care and make it sustainable over time.

As far as the demand for high-cost treatments not included in the national benefit plan is concerned, the D.N.S.FF.AA. faces typical challenges with low incidence and high cost medication. They generate high economic impact that is gradually growing. This is a global phenomenon and our country is not exempt due to its small market. On the contrary this phenomenon may only intensify for us.

We must continue to improve communication with specialists working at CETM-D.N.S.FF.AA. in order to obtain a growing support base for decision-making among physicians whose prescriptions have a high budget impact.

This approach is imperative due to the prosecution of medical acts, and the pressure from suppliers and patients exerted on our colleagues is difficult to handle. The determined and scientifically based support of the institution through the CETM-D.N.S.FF.AA., is the only defense that our physicians have to stop prescribing products of questionable or decisively unfavorable cost-effectiveness.

**References**


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ISPOR Health Technology Assessment (HTA) Training Program—COMING TO LATIN AMERICA IN 2016!

The ISPOR Health Technology Assessment (HTA) Training was developed by the ISPOR HTA Council, which consists of the Chairs of the ISPOR HTA Roundtables in Europe and North America, the Chair of ISPOR’s HTAnetAsia, and the Chair of HTAnetLatAm. The ISPOR HTA Training became a priority for the Council based on input from ISPOR members and regional groups for support in knowledge building.

The ISPOR HTA Training Program is a 1–3½ day modular course intended for “users and doers” in HTA, such as Ministries of Health and health insurance funds, evolving and established HTA agencies or other government departments responsible for health care decision making. It is also designed for public and private payers, industry, health plans, academia, and patient group representatives interested in learning how to conduct various aspects of HTA with an emphasis on clinical and economic evaluation. The program is also intended to aid decision makers in understanding how to interpret data presented to them, as well as what a good HTA process requires and how this can be tailored to different settings.

OBJECTIVES

By the end of the course, participants will be able to:

- Describe what a 'good' HTA process looks like and why this is important for health policy decisions
- Understand what evidence is, how evidence needs of patients, providers, payers and regulators may differ; and how to identify and combine clinical research (i.e., meta-analysis and modeling)
- Recognize best practices in conduct and reporting of economic evaluation and be able to conduct a trial- and modeling-based economic evaluation
- Be aware of other important factors in policy decision making, including societal value, patient perspectives, ethical, legal, social and cultural implications of technology use and how these can be incorporated into an HTA process
- Appreciate different issues related to the use and conduct of HTA as well as the importance of different perspectives.

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El Análisis del Impacto Presupuestario: Nuevas Normas

Para los tomadores de decisión es muy importante conocer en que magnitud la cobertura de un nuevo producto puede impactar el presupuesto para atención sanitaria. Si el impacto puede llegar a ser elevado—bien sea porque hay muchos pacientes afectados, o por el costo de la intervención—la decisión puede ir en contra de cubrir el producto, así este sea muy costo-efectivo. Simplemente, el presupuesto no alcanza. Por lo tanto, este tipo de evaluación económica aumenta en frecuencia e importancia y es necesario que existan normas aceptadas para su aplicación.

En 2014, un grupo de trabajo constituido por ISPOR examinó este tema y emitió nuevas recomendaciones que se reparten en tres secciones: el marco analítico, los parámetros y sus fuentes de datos, y la presentación de los resultados. Aunque las recomendaciones están orientadas a los que conducen estos análisis, el tema es de interés para todos aquellos que tienen que ver con los presupuestos de la salud.

Cómo cada jurisdicción tiene aspectos muy específicos, el objetivo principal es crear el marco analítico de forma que pueda ser ajustado localmente, con datos particulares al lugar y resultados que, por lo tanto, son muy relevantes. Este marco debe de considerar como la intervención puede afectar la población a tratar y la utilización de recursos. La población puede cambiar porque la intervención facilita el tratamiento, por ejemplo, o cambia los criterios del mismo. El uso de recursos varía según las características del sistema de salud, como los esquemas de pago, las prácticas clínicas, la captación de la intervención y sus efectos clínicos que modifican el empleo de otros recursos (ej. días hospitalarios). También es esencial tener en cuenta a quien pertenece el presupuesto (perspectiva) y sobre cuánto tiempo le importa la proyección (rara vez más de cinco años). En la gran mayoría de casos, el marco analítico se puede implementar en una hoja de cálculo. Si los cambios efectuados por la nueva intervención son muy complicados porque, por ejemplo, varían bastante con el tiempo, entonces se puede necesitar un modelo más sofisticado que permita incorporar este nivel de efectos. En algunos casos, el análisis de impacto presupuestario acompaña a un análisis de costo-efectividad (es decir, de eficiencia) para el cual puede ya existir un modelo sofisticado. Si es así, el análisis presupuestario puede apoyarse en ese modelo siempre y cuando esto no altere su respeto a las normas.

Una vez existe el marco analítico, el analista debe obtener datos relevantes a su escenario local. Esto puede presentar serios problemas pero se debe hacer un esfuerzo por encontrar estudios locales (ej. registros, estudios de mercado) o bases de datos administrativas que puedan suplir la necesidad. En últimas se puede recurrir a datos extranjeros y/o a la opinión de expertos; pero desde luego que esto debilita considerablemente el análisis. Es importante validar en lo posible tanto las entradas como las predicciones del análisis.

El informe de los resultados debe cubrir de forma muy clara y explícita la metodología, las fuentes de datos, las entradas y su incertidumbre y los supuestos que se hayan hecho. Las proyecciones presupuestarias se presentan según cuando debe ocurrir el impacto (sin descuento temporal) y para varios escenarios que representen las variaciones plausibles. Aunque el resultado global es fundamental, también son de interés sus componentes. Idealmente, se incluye la hoja de cálculo o se comunica cómo se puede obtener acceso.

Siguendo estas normas básicas, se espera que todos los actores del sistema de salud obtengan información esencial que apoye las importantes decisiones que determinan la disponibilidad de nuevas intervenciones para millones de habitantes.
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