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Editorial comment on Health Technology Assessment (HTA): Good Practices & Principles. FIFARMA's Position on HTA Processes in Latin America: The Devil Is in the Details

Although inequality in Latin America remains high relative to many other regions globally, it has declined from its peak around the year 2000 to its lowest levels in 3 decades [1]. Reductions in the number of persons living in poverty and increases in the numbers of middle-class persons mean that, auspiciously, emerging markets in Latin America have growing numbers of people with access to modern health care products and services. The need to identify appropriate use of medical technologies in Latin America is thus increasing. Health technology assessment (HTA) is an established set of principles and methods used to synthesize evidence and to develop policy recommendations on the distribution, reimbursement, and coverage of health care products and services.

On their website, FIFARMA, the Latin-American Federation of Pharmaceutical Industry, sets forth the Federation's views on developing health technology assessment in much of modern day Latin America—10 South American countries, the Dominican Republic, and "Central America"—an area larger than the erstwhile Aztec, Mayan, and Incan Empires combined [2]. The authors state: "This document contains the position of FIFARMA and its associated members in Latin America (pharmaceutical companies and local associations of pharmaceutical industry) on the key general and specific principles to which governments and payers should adhere as they evaluate the substance of assessments or consider designing an HTA system."

The FIFARMA authors are to be credited for taking the initiative to call for a structured plan for establishing linked HTA processes in these Latin American countries. They identify five aspects of HTA that require standardization: 1) selection and prioritization of technologies; 2) objective and scope of assessment; 3) methodology; 4) the HTA process; and 5) quality assurance. Identification of these issues sets the stage for a timely discussion on the structure and processes for judging "appropriate" use of health technologies in Latin America.

Regrettably, however, the FIFARMA authors provide only a superficial discussion of the conceptual and practical issues in establishing a common HTA process. For example, the FIFARMA authors state: "The primary goal of an HTA should be to optimize and accelerate patient access to important therapies, not minimize cost at the expense of patient health." The basis for that statement is unclear: What do they mean by "optimize" and "accelerate" patient access, and how do they define "important"? They are correct that cost containment is considered one of three reasons—although not particularly effective—to implement HTA. The other two reasons are increasing the efficiency and improvement in equity of access [3].

Underlying resource allocation decisions in health care are ethical perspectives [4], yet ethics are mentioned only in passing in FIFARMA's position paper: "Social, ethical and legal aspects have to be also considered (eg EUnetHTA core model [3])." The ethical perspective, in turn, drives many of the necessary structures and processes for HTA. As such, this issue requires far greater consideration.

The FIFARMA authors recommend a framework based on a quality-adjusted life year (QALY) approach. Although QALY maximization may be what the FIFARMA authors are contemplating —"the greatest good for the greatest number"—there are other ways that QALYs can be aggregated to reflect different ethical perspectives [5]. Countries with established HTA processes using a QALY framework include the British Commonwealth countries, such as Australia, Canada, and the United Kingdom (England, Wales, and Scotland). Even in those countries, the QALY framework reflects combinations of ethical perspectives. For example, the QALY maximization perspective at the United Kingdom's National Institute for Clinical Health and Excellence makes allowances for medications that prolong survival at the end of life [6]. Although choosing an existing and well-established framework as a potential model for adaptation is a logical and necessary step—and may well end up being a predominantly QALY maximization approach—the FIFARMA authors' recommendation requires considerably more justification.

The authors appear to take for granted that an established approach, such as that used in the British Commonwealth countries, would be applicable in FIFARMA countries, yet there are important differences between these two groups of countries that would almost certainly lead to different levels of success. National indicators of productivity and health care spending in the FIFARMA countries and in the British Commonwealth countries are shown in Table 1. Gross domestic product per capita in the FIFARMA countries range in an order of magnitude from roughly one-third to one-20th of the British Commonwealth countries. Much of Latin America uses a combination of out-of-pocket and Bismarck financing models in contrast to the Beveridge model in the United Kingdom or a national health insurance model in Canada. The GINI index of income inequality centers around 50 in the FIFARMA countries and in the 30s in the British Commonwealth countries. The level of corruption is higher and that of education is lower in FIFARMA countries. In addition to data shown in Table 1, governments in Australia, Canada, and the United Kingdom are parliamentary democracies, in contrast to the presidential republics in the FIFARMA countries.

Also critical to efficient HTA processes are the legal and regulatory contexts for each HTA process, which differ between FIFARMA countries. The biggest issues here surround licensing and pricing of medications and are associated with use,

Table 1 – National indicators of productivity and health care spending in FIFARMA countries and Australia, Canada, and the United Kingdom.

	GDP* (billion $US)	GDP per capita ($US)	Health expenditures				GINI index‡	Corruption perceptions index§	Population with at least some secondary education (%)‖
			Per capita ($US)	Total (% of GDP)†	Public (% of health expenditure)	Out-of-pocket (% of health expenditure)			
Argentina	583	13,432	605	5	55	31	43	32	57
Bolivia	33	3,095	209	6	72	23	48	34	53
"Central America"									
Belize	2	4,907	279	6	67	23	53¶	NA	76
Costa Rica	51	10,630	970	9	73	25	48	55	51
Guatemala	64	3,903	233	6	38	52	49	28	23
Honduras	20	2,496	212	9	51	44	51	31	27
Mexico	1,144	9,009	677	6	52	44	48	35	58
Nicaragua	13	2,087	177	9	56	38	47	27	39
Panama	52	13,268	959	8	73	22	51	39	52
Colombia	292	6,056	569	7	75	15	53	37	56
Chile	240	13,384	1,137	8	50	32	50#	70	75
Ecuador	101	6,248	579	9	49	48	45	32	40
Peru	192	6,122	359	6	61	29	44	36	61
Dominican Republic	67	6,374	269	4	67	21	47[7]	33	54
Uruguay	53	15,574	1,442	9	71	16	42	74	53
Australia	1,340	56,328	6,031	9	67	19	35**	79	94
Canada	1,551	43,248	5,292	10	71	14	34**	83	100
United Kingdom	2,849	43,734	3,935	9	83	10	33††	81	100

NA, not available.

* GDP and GDP per capita as of 2015; statistics obtained from the World Bank DataBank: http://data.worldbank.org/.

† Health expenditure statistics as of 2014; statistics obtained from the World Bank DataBank: http://data.worldbank.org/.

‡ World Bank estimate of GINI index statistics as of 2014 unless otherwise indicated; GINI index shows distribution of income on a scale of 0 (perfect equality) to 100 (perfect inequality); statistics obtained from the World Bank DataBank: http://data.worldbank.org/.

§ Corruption Perceptions Index as of 2015; CPI shows perceived level of public sector corruption on scale of 0 (highly corrupt) to 100 (very clean); statistics obtained from Transparency International: http://www.transparency.org/cpi2015.

‖ Population with at least some secondary education (% aged 25 years and older), as of 2014; statistics obtained from United Nations Development Programme Human Development Indicators: http://hdr.undp.org/en/countries.

¶ As of 1999.

As of 2013.

** As of 2010.

†† As of 2012.

reimbursement, and coverage. The need for harmonization of regulatory and HTA processes between and among countries is a topical issue and was recently discussed at a plenary presentation at the 2016 International Society for Phamacoeconomics and Outcomes Research European meeting in Vienna [7]. Although the central issues are now well characterized, there is seemingly little progress in harmonizing the regulatory and HTA processes. An important issue with respect to access as articulated by the FIFARMA authors is the timing of an HTA process relative to regulatory and pricing reviews.

To be successful, each FIFARMA country would require clarity as to the main purpose of its HTA process. Given the three possible purposes for HTA [3] outlined above—containing costs, increasing efficiency, or improving equity—each FIFARMA country may emphasize a different purpose and approach. It would be challenging, possibly intractably so, to align processes among countries that have processes designed to maximize different purposes. Even assuming that this hurdle could be overcome, it would still be necessary to clarify the goals of a common process: developing economies of scale, reducing inequity, or some other reason. Although addressing this issue is not FIFARMA's responsibility, lack of recognition of this fundamental challenge to developing a unified approach among countries that are sometimes at odds politically and that span a huge geographical area is a notable omission. Nevertheless, there are precedents for cooperation and collaboration in Latin American and Caribbean countries represented by the FIFARMA, including the political organization Community of Latin American and Caribbean States (CELAC) and its Latin American Parliament (Parlatino); Latin American Integration Association (LAIA), which promotes integrated economic development in the region; and the Latin American and the Caribbean Economic System (SELA), which promotes economic cooperation and social development. Understanding the structures and functions of such existing regional organizations would strengthen the likelihood of success of the FIFARMA proposal.

Along with the conceptual issues list above, a host of other practical issues needs to be addressed at the hospital, national,

and regional levels. Some of these are listed in the World Health Organization report cited by the FIFARMA authors [8]. Many other authors have addressed key elements in developing HTA [9–16] The interested reader can use that very limited listing as a starting point for studying the issue; however, the FIFARMA's position paper would benefit from a more systematic and thorough review of this body of knowledge and practice. Drawing from the existing literature, below is a partial list of issues, in no particular order, recognized as being important to consider in developing HTA processes:

- Differences in HTA and decision making between public and private payers
- Willingness to pay thresholds differing across the FIFARMA countries
- Role, governance, scope, processes, and stakeholder engagement
- Financial resources
- Link between HTA and the rest of the health care system
- Legal framework for HTA
- Transferability of the results of the HTA tools among the FIFARMA countries [17]
- Dealing fairly with special interests

Many more issues would need to be added to this list. A systematic approach for developing HTA would increase the likelihood of cooperation among the FIFARMA countries and lessen the burden on each. The best existing model for international cooperation in developing HTA, mentioned only in passing by the FIFARMA authors, is European network for Health Technology Assessment (EUnetHTA; www.eunethta.eu/). The academic and gray literatures are replete with information about EUnetHTA. The EUnetHTA Core Model Domains and project phases form useful starting points for planning HTA in the FIFARMA countries:

The nine EUnetHTA Core Model Domains are as follows:

1. Health problem and current use of technology
2. Description and technical characteristics of technology
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organizational aspects
8. Social aspects
9. Legal aspects

The seven EUnetHTA Core Model Phases are as follows:

1. Definition of the technology to be assessed
2. Definition of project type
3. Relevance of assessment elements
4. Translation of relevant issues into research questions
5. Compiling of a core HTA protocol
6. Research
7. Entering the results

In terms of expertise required to develop and review the dossiers competently, the FIFARMA authors suggest "accreditation of vendors." This is not a trivial undertaking and does not exist in other jurisdictions performing HTA. Many more details are required: Who does the accreditation? How often is it done? In terms of finding qualified personnel to develop and review dossiers, a starting point could be Argentina's IECS—the Institute for Clinical Effectiveness Health Policy—which has a data base of almost 12,000 HTA researchers and HTA users in Latin America [18].

By transparently and systematically laying out relevant issues, HTA can quantify and inform discussions about resource allocation. This can lead to more coherent and standardized decisions for allocating scarce health resources. As such, HTA is an important step forward for the health care system. However, HTA is not a panacea that solves all problems of resource allocation. Even in countries with established HTA processes, many issues remain: lack of discussion and consensus about how to address conflicting ethical principles, perverse incentives, political interference, and many others. At the end of the day, resources allocation needs to reflect the values of the population.

The FIFARMA position paper represents a potentially important step in jump-starting a much-needed discussion about the development of HTA processes in Latin America. Such processes would be an important tool in reducing inequity and improving efficiency of health care delivery in the region. As such, it represents an important step in the right direction. However, achieving a common HTA process in these Latin American countries would require a great deal more planning of both the conceptual and practical elements than those laid out by the FIFARMA authors.

In short, the devil is in the details.

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