EDITORIAL

CLINICAL PRACTICE GUIDELINES IN COLOMBIA

In this issue we continue with the publication of the Clinical Practice Guidelines (CPG) for the Colombian General Social Security System in Health. The version published in this Journal follows the medical journal format in accordance with the applicable international standards (1). Both the full as well as the abridged versions were published recently by the Ministry of Health and Social Protection (2).

Clinical Practice Guidelines (CPG) are defined as a set of recommendations developed systematically to help professionals and patients in their decision-making regarding a more appropriate healthcare system, and in selecting the more adequate diagnostic and therapeutic options, when it comes to approach a health problem or a specific clinical condition (3).

CPGs were first introduced between the 1950s and the 1970s and gained significant momentum starting in the 1980s, culminating with the mandate from the Agency for Health Care Research and Quality (AHRQ) requiring the development of clinical guidelines in the USA (4). They have become a proposal for health systems in terms of quality improvement, reduction of variations in medical care, and improved organized and efficient management of resources (5, 6). They also come from the medical community, in an attempt to preserve autonomy in an increasingly restrictive environment created by the pressure imposed by the paying and regulatory agencies (7). Over the past few years, many countries have gained considerable experience in the development, assessment and implementation of clinical practice guidelines in professional, institutional, regional and national realms, recognizing that guidelines are a key for improving the quality and relevance of health services (8-10). The consensus required to prepare the guidelines was made possible by the advent of new techniques such as the Delphi methodology (11) the wider use of controlled clinical trials, which gradually became the gold standard for assessing the therapies (12) and methodologies that serve as foundations for evidence-based medicine, such as the definition of answerable questions, systematic searches, and critical approach to the quality of medical literature (13).

Colombia entered the path of developing guidelines in the 1990s, when the Social Security Institute (no longer in existence) published Clinical Practice Guidelines developed jointly with the Universidad Javeriana (14). Later, in 1998, local regulation 117, mandated the compulsory implementation of induced-demand activities, procedures and interventions, and care for diseases of public health interest. It also regulated and mandated the issuance of Standards and Care Guidelines for POS (Mandatory Health Plan) Actions (15). This resulted in a call to develop the Technical Standards for Specific Protection and Early Detection, as well as the guidelines for diseases of interest for public health. The focus would be on high frequency, and severity of the social and economic burden; transmissibility or rapid effects of externalities; and diseases that could be avoided by means of low complexity interventions with rapid positive impact. This gave birth to Resolution 412 of 2000 (16) which was developed on the basis of a combined methodology: most of the standards and guidelines came from expert consensus, but family planning was the only area were an existing World Health Organization (WHO) guideline was adapted. The standards contained in Resolution 412 of 2000 established *mandatory* cost-effective activities,

procedures and interventions that should be developed sequentially and systematically in the population, and stated the minimum annual frequencies as well as the healthcare professionals in charge. The guidelines were not mandatory, and this created confusion because coverage for the diseases was compulsory, but not necessarily by means of the activities contained in the guidelines, except for therapeutic regimens for leprosy, malaria, tuberculosis and skin and visceral Leishmaniasis. In the process of developing Resolution 412 there was an asymmetric participation of the various players in the health system, with primary influence coming from the experts, and no peer reviews or pilot studies, despite the fact that it was formulated at a national level. Moreover, there have been many hurdles to its application because of care level, geographic distribution, lack of resources, technical and administrative difficulties, and insufficient adherence from those in charge. Beside these barriers to implementation, flow charts were unclear, there was no recognition of exceptions in special circumstances, or recognition of local or regional aspects.

In 2005, the Ministry called for an update of certain standards and guidelines contained under Resolution 412 of 2000, and most of the ones related to Sexual and Reproductive Health were entrusted to the Universidad Nacional de Colombia. This time, the developer team at the University used a verifiable and reproducible methodology to gather the evidence available in the international literature in order to conduct a critical assessment and build recommendations. Unfortunately, the work of updating Resolution 412 did not take the additional step of raising the output to the level of a standard. The result of the work saw the light in a publication by the Program for the Support to the Health Reform in May 2007 under the title "Guidelines for health promotion and disease prevention in public health" (17). Again, this created confusion in the country because the Standard is mandatory, and although many standards were updated, the leap from guidelines to standards did not happen, and the guidelines contained in Resolution 412 of 2000 continue to be in force. In 2006, the National Cancer Institute published, with the support of the Universidad Nacional de Colombia Clinical Research Institute, the guidelines for breast cancer, cervical cancer screening, and vaccination in cancer patients (18). In 2008, the Universidad Nacional de Colombia updated the standards for hemorrhagic and hypertensive complications of pregnancy, and Universidad de Antioquia did the same for congenital syphilis in response to the call of the Ministry of Social Protection through the United Nations Population Fund (UNFPA). However, those guidelines were never published.

The work presented in this issue of the Colombian Journal of Obstetrics and Gynecology, the Clinical Practice Guidelines for Pregnancy and Delivery are the result of the joint sustained efforts of some of the most important academic groups in Colombia: Universidad de Antioquia, Pontificia Universidad Javeriana and Universidad Nacional de Colombia, gathered around a common project, the Research Center for the Evaluation of Health Technologies (CINETS) which seeks to provide a thorough, rigorous and academic analysis of the technologies most recently available in health from the point of view of their effectiveness and cost rationale, using cost-effectiveness or cost-utility studies. This has been possible thanks to the joint decision of the academic institutions of including in their research and extended agendas the most pressing health problems affecting the Colombian population, with the idea of approaching them from a critical perspective, free of bias and external pressures, and in order to conduct technical studies that will contribute to enhance the actions of decision-makers.

The availability of clinical practice guidelines for prevention, early detection and treatment of pregnancy, partum and post-partum disorders means, among other things, the ability to standardize prenatal care in Colombia, emphasizing prevention, early detection and timely treatment of disorders affecting

gestation. The goal is to reduce associated maternal morbidity and mortality in order to improve maternal health and the quality of medical care at all levels of obstetric care. The clinical guidelines of the Ministry of Health and Social Protection are expected to become the reference for the application of healthcare processes in primary, secondary and tertiary centers. The statements for each process reflect the scientific evidence available at the time they were prepared.

The dizzying pace at which science is moving, the technological explosion, the globalization of knowledge, and the new trends created by the free trade agreements must become mechanisms for development, social progress and continuous improvement of the wellbeing conditions of the communities, supported by the principles of equity, respect, fairness and quality. In the health sector, these advances and the huge opportunities they create run in parallel with significant threats to the stated principles, i.e., the economic interests of monopolies, and the imposition of technologies that do not meet the requirements of utility and economic rationality, on the sole basis of opportunity cost considerations.

This work is a wonderful opportunity to highlight the role of the academia, of professional groups, scientific societies gathered around the universities as managers of knowledge, social change, and wellbeing, respecting the right of patients in all modern societies of accessing timely, effective, top quality services designed to promote, sustain or recover health in conditions of equality.

Clinical practice guidelines are only a tool in the quality assurance system, but if developed adequately, they serve as the means to provide patients, regardless of their social standing, geographic location, economic status, or other variables, with prompt and efficient care, in accordance with the highest quality standards, and based on the best knowledge derived from leading edge research as well as from the medical experience implementing good practices.

At this point, the country faces a very big challenge beyond raising these guidelines to the level of standards and making them mandatory, and this challenge is one of implementation. This is a more protracted and complex process requiring the transfer of knowledge to decision-makers, and which translates in the use of the best scientific evidence available for each clinical scenario. Foreign experience has shown that implementation and adherence to the recommendations is low, and that CPGs are underused. We hope that the strategies proposed by the developers of the Ministry of Health and Social Protection will be put into practice, and that implementation will become a reality in Colombia.

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REFERENCES

1. International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. 2013. [Visited 2013 Sep 24]. Available at: http://www.icmje.org/index.html
2. Ministerio de Salud y Protección Social República de Colombia. Guías de Práctica Clínica. [Visited 2013 Sep 24]. Available at: http://gpc.minsalud.gov.co/Pages/Default.aspx
3. Field MJ, Lohr KN, editors. Clinical Practice Guidelines: Directions for a New Program, Institute of Medicine, Washington, DC: National Academy Press; 1990.
4. Weisz G, Cambrosio A, Keating P, Knaapen L, Schlich T, Tournay VJ. The emergence of clinical practice guidelines. Milbank Q. 2007;85:691-72.
5. Open Clinical. Clinical Practice Guidelines. [Visited 2013 Sep 24]. Available at: http://www.openclinical.org/guidelines.html

6. Fowkes FG, Roberts CJ. Introducing Guidelines into Clinical Practice. Eff Health Care. 1984;1:313-23.
7. Timmermans S, Kolker ES. Evidence-Based Medicine and the Reconfiguration of Medical Knowledge. Journal of Health and Social Behavior. 2004;45:177-93.
8. Guía Salud. Guías de Práctica Clínica. [Visited 2013 Sep 24]. Available at: http://www.guiasalud.es/web/guest/guias-practica-clinica
9. National Institute for Clinical Excellence. NICE Guidance. [Visited 2013 Sep 24]. Available at: http://www.nice.org.uk/guidance/
10. National Health and Medical Research Council. Clinical Practice Guidelines Portal. [Visited 2013 Sep 24]. Available at: http://www.clinicalguidelines.gov.au/
11. Linstone HA, Turoff M. The Delphi Method: Techniques and Applications, Reading, Mass: Addison-Wesley; 1975.
12. Sackett DL, Haynes RB, Guyatt GH, Tugwell P. Clinical epidemiology: a Basic Science for Clinical Medicine. 2nd ed. Boston: Little Brown; 1991.
13. Davidoff F, Haynes B, Sackett D, Smith R. Evidence based medicine. BMJ. 1995;310:1085-6.
14. Instituto de Seguros Sociales Colombia. Guías de Práctica Clínica. Bogotá: ISS. [Visited 2103 Sep 24]. Available at: http://www.iss.gov.co/portal/index.jsp?cargaHome=50&id_categoria=103&id_subcategoria=113&id_seccion=831
15. Ministerio de Salud Colombia. Acuerdo 117. [Visited 2013 Sep 24]. Available at: http://www.minsalud.gov.co/Normatividad/ACUERDO%20117%20DE%201998.pdf
16. Ministerio de Salud República de Colombia. Resolución Número 412 de 2000.
17. Ministerio de la Protección Social. Programa de Apoyo a la Reforma de Salud. Guías de promoción de la salud y prevención de enfermedades en la salud pública. Bogotá, Colombia; 2007.
18. Instituto Nacional de Cancerología. Recomendaciones y Guías. [Visited 2013 Sep 24]. Available at: http://www.cancer.gov.co/contenido/contenido.aspx?catID=-1&conID=766