35th Annual International Conference of the IEEE EMBS
Osaka, Japan, 3 - 7 July, 2013

Model for assessing aesthetic devices based on interdisciplinary work among the government, academy and industry*

Martha L. Zequera, *Member IEEE*, Daissy C. Toloza, Jorge E. Arévalo, Juan P. Balcazar, Lorena A. Hernández, Sergio González, Ana K. Carrascal, Ratko Magjarević, *Senior Member IEEE* and Mauricio Cubides.

Abstract— **In Colombia, just the same as in the whole World, globalization of the market led to a large increase in importating of diverse devices. In case of devices for aesthetic use, importing a large number of different device types without adequate control of products, increases the risk of appearance of adverse events for their users. On the other hand, there are very few studies of adverse events caused by their use, or risk assessment studies. This paper presents the role of academy in defining the conditions for safety of aesthetic devices and evaluation of medical devices "Class 1", for use in aesthetics. With support of the Colombian government, the Pan American Health Organization PAHO, and the regulating entity INVIMA, we proposed a model of control and regulation of use of devices for aesthetics in order to achieve ease of classification and ensure adequate use of devices for aesthetics, and to minimize the risk for users of the technology. As a result of this model, a tool was developed to facilitate to the regulatory entity the classification and evaluation of devices for aesthetic use "Class 1", which will be implemented by the Colombian government with the support of biomedical engineers having the required knowledge and skills.**

I. INTRODUCTION

Globalization is driving the development and implementation of new technologies in the field of aesthetics and it has caused changes in the methodologies of evaluation and control used by regulating entities in Colombia and Latin America, in order to minimize the risk to the patient, the user of the technology and promote environmental conservation [1][2][3]. The use of emerging technologies in this field requires new skills for training professionals in the area of technology evaluation and for the training of experts in cosmetic procedures. This implies relevant changes in the curriculum of different institutions of formal and informal education. Additionally, it requires the harmonization of these changes with the existing national and international standards and regulations [4].

Due to the significant growth in the Colombian market of medical devices for aesthetic use, manufactured nationally and internationally, and with the aim of identifying the risks associated with the use of this type of emerging technology; and considering the lack scientific evidence-based studies to ensure the safety of the patient, The "*Ministerio de Salud y Protección Social*" from Colombia with support from the Pan American Health Organization took the initiative to develop policies for control, evaluation and regulation of technologies for aesthetic use, to facilitate the work of the regulatory entity for the identification, evaluation, classification and proper use of devices for aesthetic use. In this respect, the academy takes a starring role as the body responsible -for training, researching and transferring knowledge to the welfare of society and specifically in this field as a facilitator in creating control policies in coordination with the government of Colombia (*Ministerio de Salud y Protección Social*), international organizations (PAHO), regulating organisms (INVIMA), business sector of devices for use in aesthetics and the network of aesthetic service providers [5][6][7][8].

The Colombian government finds in the academy an ally to generate policies for the control and regulation, grounded in research and knowledge transfer in the development of tools to facilitate the work of the regulating entity with the support of professionals trained in skills such as: multi-disciplinary work skills, knowledge in basic science, engineering, medicine, professional and ethical responsibilities and, knowledge of national and international regulations and standards. This situation is similar in other countries in Latin America. [9] [10] [11] [13].

II. METHODOLOGY

The proposed model is oriented towards medical devices for aesthetic use and it was developed and simulated under the following scheme:

1- Objective: implement a management model for medical devices for aesthetic use, focused in minimizing the patient risk, based on ethics.
2- Workgroup selection: a group of qualified specialist for approaching this project from a multi-disciplinary point of view [13].
3- Actors: A search was made for all entities that are related with the proposed objective.
4- State of the art: international, national and local search of assessment models, current standards, and technical specifications of medical devices for aesthetic use.
5- Checking the state of art: Visits for recollecting of information from manufacturers and institutions serving in aesthetics in Bogotá DC.

This research was supported by "Pontificia Universidad Javeriana".

M. L. Zequera is with the "Pontificia Universidad Javeriana", Bogotá, DC, Colombia (corresponding author to provide phone: +57 -3002777261; e-mail: mzequera@javeriana.edu.co).

6- Systematic analysis of the information: All the collected information was organized, digitalized and archived in a database, for the discussion in the workgroup. Obtaining as a result the background of the actual situation and a list of advantages and disadvantages of the current model.
7- New model development: The full quality cycle is applied for the implementation of a new process that conserves the advantages of the current models and compensates the disadvantages.
8- Tests and adjustments: The model generates a tool, which is processed and improved continuously until the optimization of its performance.
9- Final stage: the model and the tool are presented in physical format. Additionally, the tool is presented in digital format.

III. DISCUSSION

A. Approach: Apply a total quality process (the patient as central axis, ethics and environment conservation)

As the result of the search listed in item 4 of the previous section, two models for health technology assessment were considered: WHO model [12] and Colombian government [14]. These two models were analyzed to find their advantages and disadvantages.

TABLE I. WHO MODEL ANALYSIS

Entity	**Health Technology Assessment applied to medical devices**	
	Advantages	***Disadvantages***
WHO	It is the summary of the problem of medical devices worldwide. The study brings together government agencies and particular from countries such as European countries, USA, Australia, Brazil, Canada, Colombia, among others. The Analysis of medical devices, research and development, regulation, regulation, evaluation and management, are studied each as an independent cycle and interrelated. It is a multi-disciplinary study with professionals from various disciplines.	Not materialize interlocking cycles to those described in: medical devices, research and development, regulation, regulation, evaluation and management. There is no sequential control of the devices to minimize the risk to the patient. There is no integration among standards such as: manufacture, sale, use and application, with the academy, regarding the skills required of people who use these technologies, there is a vacuum that increases the risk to the patient being out of control.

TABLE II. COLOMBIAN GOVERNMENT MODEL ANALYSIS

Entity	**Teaching guide for management models in biomedical equipment of IPS**	
	Advantages	***Disadvantages***
Colombian Government	Multi-disciplinary team in its preparation It develops in cycles. While some considered closed. It has a solid support from the economic standpoint.	No cycles intertwine Missing concepts and technical analysis, as the total scheduled maintenance. The aim of the process is not the patient. No continuous monitoring throughout the process Not taken into account the protection of the environment The patient is not considered in any of the cycles

According to the items 7-8 from the previous section, a new model was generated which should compensate the disadvantages of models we studied while preparing the assessment methodology. The supervision and control of this assessment process ensures total quality, minimizing the risk of devices used in cosmetology to the patient, the user and the environment. The diagrams of this cycle and actors are shown in Figs. 1-2.

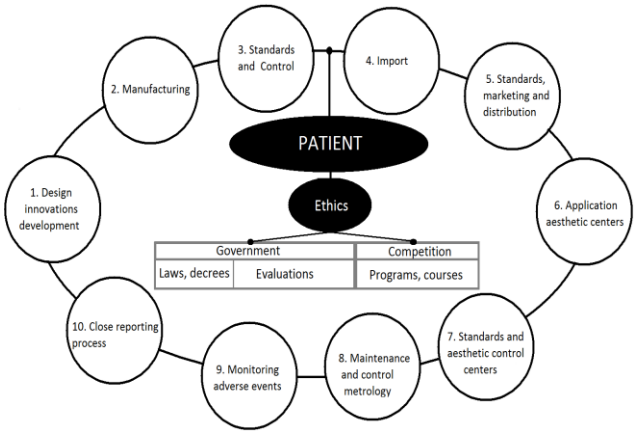

Figure 1. Cycle- Model of assessment and monitoring devices lifecycle

1. *Design and development of devices:* innovation with new products, their development, control and settings already produced according to reports from users.
2. *Manufacturing:* designs and device settings that become projects reality.
3. *Standards and control*: The design and manufacture must be consistent with all existing standards for this purpose, such as: Electrical, Security, Ergonomic,

Facilities, Environment, Renewable Energy use and others that are issued by the control entities.

4. *Import*: the device manufactured outside the country, should at least comply with manufacturing standards of the United States of America and the European Union standards.
5. *Marketing and distribution:* The government bodies must do physical tests to devices that will be placed on the market and monitor compliance with security in storage, transportation and delivery.
6. *Application in aesthetic center:* the buyer of the device must have the appropriate structural environment and meet the standards for the use of the device. Likewise, have staff with the skills to do so.
7. *Standards and control in aesthetic center*: the control entity must monitor compliance with the Standards for Empowering Beauty salons and civil works must comply with all requirements for the proper use of the devices for patient safety.
8. *Maintenance and metrology*: Aesthetic Center already running must meet established standards for the maintenance and control of parameters (metrology) to ensure minimal risk to the patient.
9. *Adverse events control*: the standards also provide guidelines if any alteration or modification is detected in medical devices, it is reported to: Control Government Institution and Manufacturer. These adverse events reports have their format and protocol.
10. *Reports to close general process*: the closing process takes place when the manufacturer receives information of adverse events and activates again the whole process, so that these changes will not allow repetition of these events and ensure the protection of the patient.

In Fig. 2, the actors that involved in the model of the Fig. 1. are shown

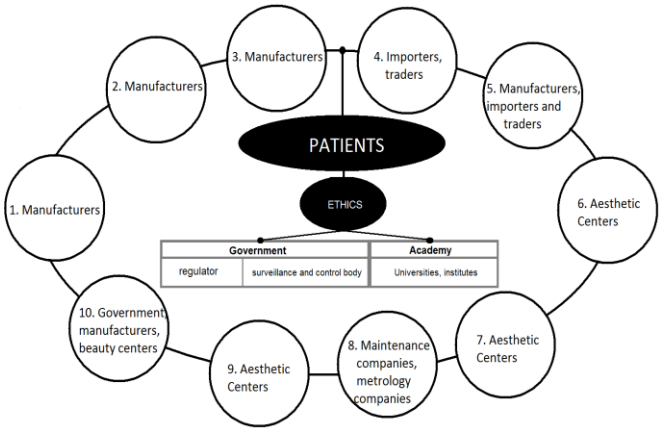

Figure 2. Actors-Model of assessment and monitoring devices lifecycle

B. Total quality: the overall quality of the structure and form of the project ensuring risk control on the patient.

C. Government agencies: the agencies should create and maintain control standards for medical devices for use in aesthetics, according to new technology and product innovation, both technically as in the academy. There must be an organization dedicated to the technical surveillance of these devices, it controls: electrical, safety and ergonomics, power and signal measurement (metrology). There should be a government agency to monitor standards in academy.

D. Academy: institution that transfer knowledge about new technologies, form the professionals who design, produce and operate new products, and train the personal of the control entities.

E. Ethics: the development of the whole process should be supported on the bases of ethics. [15] [16].

F. Patient: the central subject of the processes and cycles for safety and quality ensurance.

As a result of this model, a software tool was developed and simulated for the classification and evaluation of devices for aesthetic use "Class 1", with the support of regulatory entity INVIMA making a feedback to improve the tool. The proposed model involves all the actors in the system, government, academy, manufacturers, importers, traders, users and patients in Colombia. This process is focused in minimizing the risk to the patient and it is based on ethical principles. Moreover, the model establishes that the government entities evaluate and control the process continuously. This implies the constant update of regulations and standards and the creation of an entity to control the new medical devices for aesthetic use.

IV. Conclusion

In this paper, the principle of a model of technology assessment for class 1 medical devices, used exclusively for aesthetics in Colombia, is described. The model takes into account patient safety as the center of the process and it is based on ethical principles. This model links actions of the government, the academy and the manufacturers. The cycle includes control stages during the whole process and ensures keeping continuous monitoring of the devices once they are put to the market. The control entities must have professionals capable of performing assessment along the development of the cycle. The proposed model may be adapted and implemented to other countries in Latin America.

Acknowledgment

We would like to thank Jeaneth Solano and Gustavo Solano from the "*Ministerio de Salud y Protección Social*". We would like to acknowledge Claudia Quiroz and Luis Vilcahuman for advices and support during the development of the model presented.

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