

# Overdiagnosis and its implications in Clinical Engineering

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## Abstract

The objective of this study was to analyze the indiscriminate use of medical technologies could cause damage. The methodology involved a literature review of the use of technologies that can precociously detect diseases, generating premature diagnoses, unnecessary actions and burden health systems. Resulting in guidelines that seek the rational use of medical technologies to ensure access to those who really will benefit and protect those who do not need to be exposed to risk. The objective of Clinical Engineering is to help and even intervene in the health sector aiming for wellbeing, safety, cost reduction and quality in health services. Health care costs have been increasing drastically and are a global concern. Financial resources are finite compared to the numerous technological resources. Ethical and bioethical issues that should support the policies and practices of health professionals were considered in the end.

**Keywords:** Biomedical engineering. Health systems. Bioethics and biomedical technology.

## Resumo

### Sobrediagnóstico e suas implicações na engenharia clínica

Pretendeu-se analisar em que medida o uso indiscriminado de tecnologias médicas pode causar prejuízos. A metodologia envolveu a revisão da literatura acerca do emprego de tecnologias capazes de detectar doenças de maneira bastante precoce, gerando diagnósticos prematuros, ações desnecessárias e oneração dos sistemas de saúde, o que resultou em orientações centradas no uso racional das tecnologias médicas, para garantir o acesso aos que realmente terão benefícios, bem como a proteção dos que não precisam ser expostos a risco. A engenharia clínica destina-se a auxiliar, e mesmo interferir, na área da saúde em função de bem-estar, segurança, redução de custos e qualidade nos serviços de saúde. Os custos com a saúde têm aumentado drasticamente, e é uma preocupação mundial. Os aportes financeiros são finitos diante de inúmeros recursos tecnológicos disponíveis. As questões éticas e bioéticas que devem fundamentar as políticas e as práticas dos profissionais de saúde foram consideradas ao final.

**Palavras-chave:** Engenharia biomédica. Sistemas de saúde. Bioética e tecnologia biomédica.

## Resumen

### El sobrediagnóstico y sus implicaciones en la Ingeniería Clínica

El objetivo de este estudio fue analizar que el uso indiscriminado de tecnologías médicas podría ocasionar perjuicios. La metodología incluyó una revisión de la literatura sobre el uso de tecnologías que pueden detectar muy anticipadamente enfermedades, generar diagnósticos prematuros, acciones innecesarias y resultar onerosos para los sistemas de salud. Resultando en directrices que buscan el uso racional de las tecnologías médicas para garantizar el acceso a aquellos que realmente se beneficiarán y protegiendo a aquellos que no deben ser expuestos al riesgo. La Ingeniería Clínica tiene como objetivo ayudar e incluso interferir en el cuidado de la salud buscando el bienestar, la seguridad, la reducción de costos y la calidad de los servicios de salud. Los costos de atención de la salud han aumentado drásticamente y es una preocupación mundial. Los recursos financieros son finitos frente a los inúmeros recursos tecnológicos. Las cuestiones éticas y bioéticas que deben fundamentar las políticas y prácticas de los profesionales de salud fueron consideradas al final.

**Palabras-clave:** Ingeniería biomédica. Sistemas de salud. Bioética y tecnología biomédica.

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Among the precepts of medicine is the *primum non nocere* principle (above all, do no harm). All medical technologies bear some inherent risk and thus should be used when benefits outweigh the potential harm. The use of medical technologies in face of insufficient benefits maximizes the risk and ends up resulting in potential loss.

The indiscriminate use of these technologies may compromise the efficiency of health services, given that the promotion of service quality must pursue the best clinical outcomes, greater benefits and fewer risks to patients, at an appropriate cost.

The so-called hard medical technologies include medical-care equipment, whose life cycle is characterized by the following phases: innovation, dissemination, incorporation and abandonment<sup>1</sup>. High complexity equipment has a high cost of acquisition. To have an idea of such costs, the Management and Information System for Equipment and Materials funded by the National Health System (Sigem)<sup>2</sup> makes available the updated values of some devices used in diagnostics, as shown in Table 1.

**Table 1.** Cost of medical care equipment used in highly complex diagnostics - Brazil, 2015

Equipment	Cost (BRL)
Positron emission tomography (PET-CT)	5,000,000
Nuclear magnetic resonance 1,5 T	3,800,00
Computerized tomography (64 channels)	1,900,000
Scintigraphic camera (Gamma Camera)	1,100,000
X-ray machine with remote-controlled fluoroscopy	650,000
Digital mammography device	600,000
Fixed digital radiology unit (DR)	330,000

Source: FNS/Sigem, 2015<sup>2</sup>.

In diagnostics, the use of these technologies may allow the detection of diseases at a very early stage. Numerous technological varieties compete for the establishment of early diagnoses. However, when isolated and with inadequate evaluation, such diagnoses may lead to premature treatment and unnecessary actions, in addition of burdening health systems. Thus, the rational use of these technologies is an indispensable measure to avoid exposure and the unnecessary treatment of healthy individuals.

Technological innovations are constant and accompanied by the proliferation of sophisticated diagnostic tests, which are the result of biomedical

discoveries that heavily pressure the market and the health industrial complex. Such innovations must be assessed so that they can be incorporated into the safest and most effective technologies when it comes to cost.

This study analyzes the impact of overdiagnosis in the clinical area, considering aspects related to the management and financing as well as ethical and bioethical conflicts, which have been constant in that context. The work methodology involves bibliographical and documentary review.

## Overdiagnosis

Diagnosis can be defined as the classification provided by a physician to a disease or physiological state, based on medical history assessment as well as on the observation of symptoms and various tests. Overdiagnosis occurs when symptomless individuals are diagnosed by means of a simple image or laboratory finding, which, at first, would not result in symptoms or damage.

Therefore, the challenge is to best distinguish benign abnormalities from those which will progress and lead to damage. Issues regarding overdiagnosis may be discussed based on two perspectives: the first one relates to the patient on an individual level and refers to the unnecessary exposure of patients to the risks inherent in medical technologies; the second one has a collective dimension and concerns the rationalization of resources used.

The rational use of medical technologies must focus on ensuring access to those who will truly benefit, as well as on protecting those who do not need to be exposed to the risks arising from the use of such technologies. In summary, resources must be offered to those who will truly benefit and the access to such resources must be guaranteed. Avoiding excesses will allow access to potential users. Therefore, access and excess must be balanced.

In a study made for the Institute of Supplementary Health Studies (IESS), Reis and Mansini claim that the US health care system wastes between US \$ 543 billion and \$ 815 billion annually. *The amount represents 20% to 30% of the total invested in the sector or 3.6% to 4.5% of the American Gross Domestic Product (GDP)*<sup>3</sup>. In a statement published on the IESS website in April 2015, the institute's executive superintendent, Luiz Augusto Carneiro, points out: *We are aware that health cost variation above inflation is a global phenomenon. Nevertheless, this causes a lot of concern in Brazil, as the increase in*

costs has remained at a very high level<sup>4</sup>. The burden resulting from overdiagnosis significantly threatens collective health systems.

Complementary tests are important, provided they are made based on the appropriate criteria. The responsibility of overdiagnosis lies in several factors: lack of adequate medical training, resulting in lack of assurance in the diagnosis; marketing issues pressing for the increased number of patients assisted and decreased consultation time; inefficient government policies, such as disease screening in healthy individuals; commercial interests and marketing strategies used by medical technology suppliers; defensive medicine, supported by legal mechanisms which fight underdiagnosis, but do not punish overdiagnosis; the popular culture of “the more, the better”; patient’s preference and insistence when it comes to requesting diagnostic tests, which is driven by the belief that the mere request made by physicians represents a parameter to assess the quality of care provided by them.

A few decades ago, physicians could examine a patient in 50 minutes and ask for a few tests to confirm the diagnosis. Medical history and a physical exam were the basis of clinical diagnosis and guided the request for further tests. When performed under appropriate conditions and by qualified physicians, a medical history assessment can account for up to 90% of correct diagnostic hypotheses, thus having great value in the diagnosis procedure. Nowadays, however, this situation is reversed: tests precede the diagnosis, and the doctor-patient relationship has come to be mediated, if not monopolized, by the use of hard medical technologies.

A series of negative events may result from excessive and uncontrolled use of medical technologies. In addition to unnecessary therapies and to the fact that the financial resources allotted could promote more benefits if used in the treatment and care of real pathologies, other factors must be considered: anxiety, adverse effects and absenteeism on the part of patients; expansion of the limits of pathology characterization and lower thresholds for treatment in medical practice<sup>5</sup>.

Health strategies aimed at preventive care led to increased disease screening of apparently healthy individuals. While screening is conducted broadly, its benefits are neither universally defined nor accepted<sup>5</sup>.

A study by Welch and Black involving several types of cancers describes the large repertoire of subclinical findings in autopsy analysis of several in-

dividuals who died from causes other than cancer itself<sup>6</sup>. In the same study, the authors emphasize that the main factor responsible for accidental cancer detection is the increased use of diagnostic imaging, not necessarily resulting from a larger number of tests performed, but rather due to the increased sensitivity of the tests.

The practice of medicine based on clinical evidence tends to replace general exams for more cost-effective health actions, such as the selective periodic health exam, targeting specific characteristics of individuals<sup>5</sup>.

When the benefits of screening strategies are analyzed, it is necessary to consider ways to identify those “initial abnormalities” which, although found in the tests, will never progress, and consider their possible impact on budget constraints as well as on morbidity and mortality rates. Harm analysis must consider aspects such as the assessment of the damage caused by exposure to these technologies; the false-positive result rate; overtreatment due to indolent-behavior malignant lesions treated regardless of the certainty about their evolution. In addition to false-negative results, false-positive ones lead to significant clinical, social and psychological impacts: about one-third to one-fifth of the cancers identified in screening are considered to be overdiagnosis; that is, if it were not for screening, the disease would not have been diagnosed and would not have caused harm to patients<sup>7</sup>.

Besides the ability to make the diagnosis, physicians must have capacity to distinguish the findings which will develop into a disease, thus becoming a health problem, from those present in tests of individuals who have the disease but showed no symptoms or health problems related to this diagnosis. Daniel Guimarães Tiezzi, physician and professor of mastology and gynecological oncology at the Ribeirão Preto Medical School (FMRP), University of São Paulo (USP), reports that, *through mammography we can diagnose lesions that may or may not develop into a more aggressive cancer, as well as highly invasive lesions which would never progress, or would progress so slowly they would have no effect on patients’ current or future quality of life*<sup>8</sup>.

A study undertaken by Santiago et. al. to assess the prevalence and factors associated with screening tests for prostate cancer in elderly individuals in the city of Juiz de Fora/MG, concluded that *the benefits and risks of screening for this type of cancer have been widely discussed in medical literature and there is no consensus on the guidelines for its use at population level, in addition, it continues to*

have significant implications for public health, such as overdiagnosis and overtreatment<sup>9</sup>.

According to the National Cancer Institute (Inca), we must carefully weigh a number of factors before requesting additional tests, as conducting multiple tests does not necessarily mean a more accurate diagnosis. There is often an excessive request for tests, which leads to increased health care costs. It should also be noted that, contrary to current opinion, the fact that a service relies on sophisticated equipment does not necessarily mean that the standard of care is superior<sup>10</sup>.

In their study, Marsaro and Lima report the following in regard to hypertension overdiagnosis during medical appointments (HC): *It has been known for a long time that BP (Blood Pressure) may increase in the presence of physicians, however, the advent of ambulatory blood pressure monitoring (Map) allowed the exaggerated increase in BP, related to consultations, to be recognized and referred to as the white-coat effect. This persistent pressure increase in the medical environment may reach levels which are typical of HA (Hypertension) and be associated with normal ambulatory BP on other occasions.* According to the authors, the white-coat effect causes an overestimation of BP and overdiagnosis of hypertension, both qualitatively and quantitatively, and is responsible for the improper use of antihypertensive medication in some patients<sup>11</sup>. To correct this effect, it is recommended that blood pressure be measured after the establishment of a doctor-patient interaction.

### Clinical engineering and overdiagnosis

In the 1960s, in the United States, in response to concerns about patient safety and the intense proliferation of clinical equipment, engineers were encouraged to enter hospital service<sup>12</sup>. Clinical engineering is defined as the branch of engineering dedicated to assist and, even interfere in, health, to achieve well-being, safety, cost reduction and quality of services available to patients and the hospital's multidisciplinary team, which occurs through the application of managerial and engineering knowledge to health care technology. Overdiagnosis significantly impacts clinical engineering, as it is often related to the excessive reliance on hospital equipment used to detect diseases and establish diagnoses.

It can even be said that this impact is felt in all fields of activity in clinical engineering: medical

and hospital technology management; research, development and innovation; evaluation of health care technologies; regulatory agencies; insurers and the commercial area. In addition, overdiagnosis clearly interferes in services and routines, making it difficult to maximize available resources and reduce the risks of exposure to health care technologies.

As new methods and technologies become available in hospitals, the dimensions of actions and the knowledge domain regarding clinical engineering are multiplied. Such actions consist in assessing the needs for improvement when it comes to patient care, as well as in checking their compliance with effectiveness and safety requirements<sup>12</sup>.

Health care costs have increased dramatically, and this is a global concern. Financial resources are finite in face of the countless technological resources available. Therefore, clinical engineers must strive to rationalize resource distribution, seeking to maximize health care benefits, ensuring access to safe and effective technologies.

In addition to substantially fostering the economy and expertise, medical technologies actively contribute to the field of innovations. Clinical engineering professionals are pressed by advances in science and engineering, and are responsible for evaluating technologies in terms of their functionality, efficiency and effectiveness, cost-effectiveness, results and outcomes, safety, actual level of innovation (incremental or radical) and dissemination phase so that the decision on whether such technologies will be adopted can be made. In summary, they must technically assess these innovations so as to distinguish marketing strategies disguised as technological advance.

Gadelha emphasizes the role of the medical equipment industry *permanently encourages the debate on the tension between industrial and sanitary logic<sup>13</sup>, which happens both due to this industry's innovation potential – it strongly incorporates the advances associated with the microelectronic paradigm – and due to the impact it has on services – as it represents a constant source of changes in health care practices.*<sup>13</sup>

The uncontrolled adoption of medical technologies affects health care services, overloads the hospital technological park and contributes to the waste of resources. In general, aggregate new technologies are cumulative and characterized by the complementation of existing methods, rather than by their replacement, *which actually presses the cost of health care services*<sup>14</sup>.

Based on considerations made by Panerai and Peña-Mohr, the Ministry of Health comments on technological innovation and the obsolescence of medical equipment: *the technological innovation rate since World War II was not accompanied by a similar rate of abandonment of older technologies, resulting in a continuous increase in the inventory of health care technologies available. It took some technologies which have proven ineffective or obsolete long to be definitely abandoned*<sup>15</sup>.

For the Ministry of Health, *unlike technologies that resist abandonment, a considerable number of other technologies are forced out of the market due to the so-called "artificial obsolescence". This strategy is used by many industries to increase their sales. Artificial obsolescence often involves small innovations rather than radical ones, adding little value for patients or physicians*<sup>15</sup>.

Gadelha says that the dissemination of technological innovations linked to the medical equipment industry happens extremely fast in health care services. For the author, *more relevant than the effort for productive efficiency is the permanent pressure to add new procedures, such as the use of magnetic resonance imaging, computed tomography, ultrasound and X-rays, often in the same units providing diagnostic imaging services*<sup>14</sup>.

In summary, the contribution made by clinical engineering must focus on the evaluation of health care technologies, so as to ensure the safety and quality of services with cost control, avoiding excessive consumption of hard medical technologies, the use of ineffective equipment and unnecessary exposure to risk.

### Bioethics and overdiagnosis

In the field of bioethics, overdiagnosis has clear implications on the principles of justice, beneficence and nonmaleficence. Health care systems have an ethical obligation to extend benefits as much as possible and reduce damage or loss to the most minimum level. Their actions must be based on justice, equality of opportunity, the rule of efficiency, the provision of quality services as well as on increasing the number of accesses and the degree of service coverage<sup>16</sup>.

The Code of Medical Ethics and other regulations provided by the Federal Council of Medicine establish that, in the relationship with patients, physicians are forbidden to *exaggerate diagnosis or prognosis severity, complicate therapy or exceed in*

*the number of consultations, visits or any other medical procedures*<sup>17</sup>.

Correa and Mejía state that, in the management of the public health care system, distributive justice occurs through the identification of the needs and the establishment of priorities so that resources are properly distributed. However, for the authors, without scientific basis, such resources may be allocated to non-beneficial services, instead of being put to better use in other needs<sup>18</sup>.

In the management of health services, ethics must consider that resources are insufficient to meet all needs and that, therefore, efficiency becomes *sine qua non* for the establishment of fairness as well as of an ethical imperative at the administrative level<sup>19</sup>. Health care professionals and public health managers are ethically obliged to optimize resources to contemplate more access to the system, with the best quality and at the lowest possible cost<sup>19</sup>. At all levels, health technology management must consider the ethical implications of its actions.

According to the National Policy on Health Care Technology Management, provided by Ministry of Health, the evaluation of health care technologies *is the ongoing process of analysis and synthesis of health care benefits, as well as of economic and social consequences related to the use of such technologies, considering the following aspects: safety, accuracy, efficacy, effectiveness, cost, cost-effectiveness and fairness, in addition to ethical, cultural and environmental impacts involved in their use*<sup>20</sup>.

The adoption high-cost complex technologies – often prematurely abandoned due to lack of inputs and spare parts – contributes to the formation of actual equipment graveyards in hospitals<sup>21</sup>. It is estimated that up to 40% of medical equipment in the public sector is underutilized or inoperative, resulting from misuse, improper acquisition, maintenance and infrastructure issues<sup>22</sup>.

Underutilized, or even inoperative, medical technologies lead to losses to health care services, compromising access to the system and the offer of health care actions. The indiscriminate use of complex technology, with high added value and broad commercial appeal - marketed as indispensable and which are often prematurely abandoned – not only negatively impacts the rationalization of resources, but also generates issues related to the disposal of such equipment, because, apart from the housing, many of these pieces of equipment contain elements whose recycling or disposal processes are costly and laborious, such as pipes and

X-ray generators, electronic elements, chemicals, among others.

When it comes to the use of these medical technologies, excess must consider the entire life cycle of the equipment, from the innovation phase to abandonment. In addition to creating opportunities of access and quality services, both the risk-benefit and cost-effectiveness ratios must be taken into account.

### Final Considerations

Rationalizing the use of technology and promoting its proper assessment are extremely important measures to support the decision-making process within health care systems. Therefore, it is necessary to ensure that health care professionals would be willing to give up the unjustified use, without clinical evidence, of the most sophisticated technological innovations in favor of more effective technologies which are accessible to most of the population. To that effect, the focus of health care must be reconsidered taking promotion and prevention into account, with no unnecessary resource imbalances and risks, so as to protect healthy individuals and assist those who truly need health care services.

The idea, which is widespread among the general population, that to maintain health it is essential to carry out numerous tests must be reconsidered. It is the culture of the more, the better. Such perspective is based on the concept that modern technologies are necessarily superior to conventional ones. However, we must think of health care as a set of factors that include health,

quality of life, healthy habits, rather than as the unnecessary conduction of numerous tests to identify alleged infirmities which are unlikely to bring any harm to patients.

We must verify whether the increased number of tests has actually contributed to reduce morbidity and mortality, whereas considering the impact of false-positive results in the early detection of pathologies which are unlikely to cause harm. Medical technologies must be adopted based on scientific evidence, rather than on the basis of market logic. Adherence to technologies must be based on benefits which outweigh potential risks and justify related costs.

Advances and technological innovations, along with the importance of prevention, increasingly drive the demand for additional tests. Thus, it is necessary not only to balance and optimize resources based on the sustainability of health care systems, but also to avoid the excessive use of these technologies, which, in addition to burdening the system, may lead to damage to the health of individuals. Such initiatives are made possible by strengthening the sustainable management of hospital technology parks, encouraging moderate consumption as well as actions to avoid underutilization and early abandonment of hard medical technologies.

Rationalization and effectiveness of resources in diagnostic services not only represent a challenge for clinical engineering, but require the commitment of the medical profession, society and decision makers in the scope of health systems. When contemplating the bioethical debate, such instances must start from the central question, which is that these actions must prioritize the welfare and safety of human beings as well as of the community.


### References

1. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. Diretrizes metodológicas: elaboração de estudos para avaliação de equipamentos médicos assistenciais. Brasília: Ministério da Saúde; 2013.
2. Brasil. Fundo Nacional de Saúde. Sistema de Informação e Gerenciamento de Equipamentos e Materiais. [Internet]. 2015 [acesso 17 ago 2015]. Disponível: <http://www.fns.saude.gov.br/visao/pesquisarEquipamentos.jsf>
3. Reis A, Mansini G. Fontes de desperdício de recursos no sistema de saúde americano. [Internet]. São Paulo: IESS; 2013 [acesso 17 ago 2015]. p. 3. Disponível: <http://www.iess.org.br/html/TD0049Derperdicio.pdf#sthash.ussc7Esq.dpuf>
4. Instituto de Estudos de Saúde Suplementar. Custos das operadoras de planos de saúde sobem 17,7% e superam 2,5 vezes inflação medida pelo IPCA. [Internet]. 29 abr 2015 [acesso 17 ago 2015]. Disponível: <http://www.iess.org.br/?p=imprensa&categoria=noticia&id=96>
5. Moreira AC, Santos J, Moreira M, Silva MF. Os exames gerais de saúde salvam vidas?. Rev Port Med Geral Fam. [Internet]. 2013 [acesso 17 ago 2015];29(2):131-4. p. 132. Disponível: <http://www.scielo.mec.pt/pdf/rpmgf/v29n2/v29n2a10.pdf>
6. Welch G, Black W. Overdiagnosis in cancer. J Natl Cancer Inst. 2010;102(9):605-13. p. 605-7.

7. Takimi LM. Programa de formação para as redes de atenção às doenças crônicas não transmissíveis: enfrentamento do câncer de colo de útero e câncer de mama. [Internet]. [S.l.]: Edição Montenegro; 2014 [acesso 14 out 2015]. (Apresentação em *slides*). Disponível: <http://www.slideshare.net/lutakimi/montenegro-ca-mama>
8. Dentillo DB. Excesso de exames para detecção de doenças pode gerar diagnósticos prematuros e ações desnecessárias. Cienc. Cult. [Internet]. 2012 [acesso 17 ago 2015];64(3):10-3. p. 10-1. Disponível: <http://cienciaecultura.bvs.br/pdf/cic/v64n3/a05v64n3.pdf>
9. Santiago LM, Luz LL, Silva JFS, Mattos IE. Prevalência e fatores associados à realização de exames de rastreamento para câncer de próstata em idosos de Juiz de Fora, MG, Brasil. Ciênc Saúde Coletiva. 2013;18(12):3535-42. p. 3536.
10. Instituto Nacional de Câncer. Exames complementares no diagnóstico do câncer. [Internet]. [S.d.] [acesso 17 ago 2015]. Disponível: [http://www.inca.gov.br/conteudo\\_view.asp?ID=50](http://www.inca.gov.br/conteudo_view.asp?ID=50)
11. Marsaro EA, Lima EG. Hipertensão de consultório. Arq Bras Cardiol. 1998;70(5):361-4. p. 361.
12. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Manual de tecnovigilância: abordagens de vigilância sanitária de produtos para a saúde comercializados no Brasil. Brasília: Ministério da Saúde; 2010. p. 251. (Série A. Normas e Manuais Técnicos).
13. Gadelha CAG. A dinâmica do sistema produtivo da saúde: inovação e complexo econômico-industrial. Rio de Janeiro: Editora Fiocruz; 2012. p. 105.
14. Gadelha CAG. Op. cit. p. 107.
15. Brasil. Ministério da Saúde. Secretaria-Executiva. Área de Economia da Saúde e Desenvolvimento. Avaliação de tecnologias em saúde: ferramentas para a gestão do SUS. Brasília: Ministério da Saúde; 2009. p. 24. (Série A. Normas e Manuais Técnicos).
16. Correa LAV, Mejía JMM. Ética y salud pública. [Internet]. [acesso 17 ago 2015]. Disponível: [http://www.sld.cu/galerias/pdf/sitios/infodir/etica\\_y\\_salud\\_publica.pdf](http://www.sld.cu/galerias/pdf/sitios/infodir/etica_y_salud_publica.pdf)
17. Conselho Federal de Medicina. Código de Ética Médica. [Internet]. 2010 [acesso 17 ago 2015]. Disponível: [http://portal.cfm.org.br/index.php?option=com\\_content&view=article&id=36:capitulo-v-relacao-com-pacientes-e-seus-familiares&catid=10:codigo-de-etica-medica-versao-de-1988&Itemid=123](http://portal.cfm.org.br/index.php?option=com_content&view=article&id=36:capitulo-v-relacao-com-pacientes-e-seus-familiares&catid=10:codigo-de-etica-medica-versao-de-1988&Itemid=123)
18. Correa LAV, Mejía JMM. Op. cit. p. 168-9.
19. Correa LAV, Mejía JMM. Op. cit. p. 172.
20. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. Política Nacional de Gestão de Tecnologias em Saúde. Brasília: Ministério da Saúde; 2010. p. 17. (Série B. Textos Básicos em Saúde).
21. Brasil. Ministério da Saúde. Avaliação de tecnologias em saúde: ferramentas para a gestão do SUS. Op. cit. p. 76.
22. Agência Nacional de Vigilância Sanitária. Confiabilidade metrológica no setor da saúde no Brasil. [Internet]. 2001 [acesso 17 ago 2015]. p. 15. Disponível: [http://portal.anvisa.gov.br/wps/wcm/connect/372d3700474576338445d43fbc4c6735/confiabilidade\\_saude.pdf?MOD=AJPERES](http://portal.anvisa.gov.br/wps/wcm/connect/372d3700474576338445d43fbc4c6735/confiabilidade_saude.pdf?MOD=AJPERES)

#### Participation of the authors

Fotini Santos Toscas conceived and wrote the paper. Fernanda Toscas made the critical review.



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