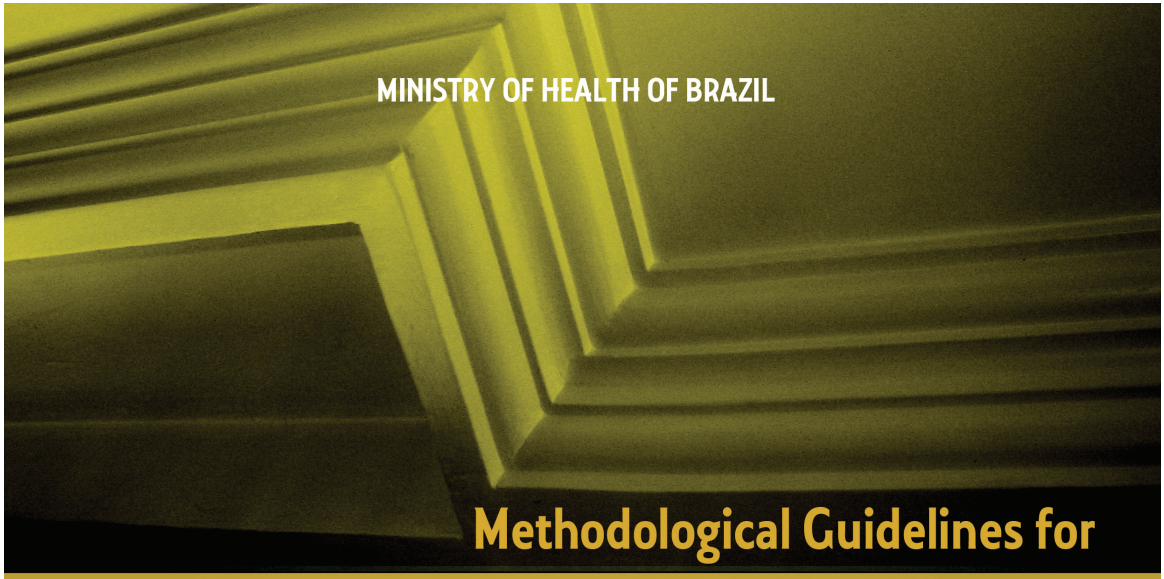

MINISTRY OF HEALTH OF BRAZIL

Methodological Guidelines for Appraisals on Health Technology Assessment for the Ministry of Health of Brazil

BRASÍLIA - DF
2007

MINISTRY OF HEALTH OF BRAZIL
Secretariat of Science, Technology and Strategic Inputs
Department of Science and Technology

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PREFACE

The use of quality evidence in the processes of Health Technologies Assessment (HTA) was one of the main recommendations of the "Workshop on Priorities of Research in Health – Thematic Issues", which took place on March 8-9, 2006. In this workshop, organized by the Department of Science and Technology, the need to elaborate methodological guidelines for appraisals, systematic revisions, and studies on economic evaluation was identified by the Ministry of Health, with the aim of guaranteeing the quality of such studies.

In this way, the project to elaborate the Methodological Guidelines for HTA Studies of the Ministry of Health was instituted. This project was agreed upon in the Permanent Workgroup of Evaluation of Technologies in Health of the Council of Science, Technology, and Innovation. Next, we moved on to the composition of a subgroup with specialists in the field of medicine based on evidence, evaluation of technologies, and health economics aiming at the elaboration of a document base to be widely debated in a consensus workshop.

The Methodological Guidelines for Appraisals on Health Technology Assessment for the Ministry of Health of Brazil have the aim of contributing to the standardization, qualification, and evaluation of opinions elaborated by the Ministry of Health, whose demand is expected to raise to the degree that the HTA are instituted as one of the elements to be considered in the process of incorporation of new technologies in the country.

In this context, it is important to call attention to the National Policy of Management of Technologies in Health (NPMTH) – Administrative Rule No. 2,510/GM of 12/19/05, whose first guideline clearly speaks about the importance of HTA in the process of making decisions in the incorporation of technologies in health: "Using scientific evidence to subsidize management: Evaluation of Technologies in Health". Among the activities foreseen is the elaboration of the methodological guidelines for studies on the evaluation of technologies, considering the specificities of each technology and their stage of development.

Additionally, in 2006, the Commission for the Incorporation of Technologies of the Ministry of Health (Citec) – Administrative Rule No. 3,323 GM of 12/27/06 was instituted, and the Secretariat of Sci-

ence, Technology, and Strategic Inputs participate as member and is responsible for the promotion of studies in HTA necessary to support the decisions. This commission is responsible for managing the process of the incorporation of technologies.

All of this new process of management of technologies in the Brazilian health system, initiated by the NPMTH, should direct its actions to the HTA in Brazil and, as such, contribute to the increase of technical analyses about technology by the Ministry of Health technicians.

As such, the Guidelines have the Ministry of Health technicians as well as managers of the Brazilian Public Health System as a target public interested in the topic. Besides this, managers of Supplementary Health and external researchers can use the document, which will be widely divulged.

In this sense, it is intended that the Guidelines will be added to the various efforts that are being undertaken for the structuring and dissemination of the Health Technology Assessment in Brazil.

Ministry of Health of Brazil

1 INTRODUCTION

As part of the different advances in various fields of knowledge and technology, medicine reached formidable results during this last century, which include, among others, reduction of mortality and morbidity in areas such as with infectious, perinatal, and cardiovascular diseases; increase in life expectancy; transplantation of organs and tissues; therapy with stem cells, and even the cure of some types of cancer.

At the same time, problems with the use of technologies have been increasingly observed, by studies that did not find scientific evidence for widely used procedures as well as by studies that showed a substantial variation in the use of technologies without improvements in health results (OFFICE OF TECHNOLOGY ASSESSMENT, 1994; GARBER, 2001; WENNBERG et al. 1988). In other cases, technologies that have been proven to have no effect, or deleterious effects, are still widely being used, to the point that many that have been proven to be effective are little used. Another common point is the use of technologies outside of the conditions and indications in which they were shown to be effective.

The increasing innovation and use of technology in health has also been intimately related to the increase in expenses with health. In a situation in which there is an increase in costs, with cut backs on resources, and the restructuring of health services, which aims at greater effectiveness and better use of public money, managers see themselves as being pressed. They need coherent, well-founded information about the benefits of health technologies and their impact on health services in order to be able to make decision (PANERAI; MOHR, 1989).

All of the elements that were mentioned above have competed for the interest of governments, up holding their regulatory function, by basing themselves on criteria to prioritize the technologies that should be incorporated into the health systems in their countries (NUNES; REGO, 2002). In this context, the importance and the interest in the health technology assessment has increased.

Health Technology Assessment (HTA) is a great process, through which clinical, social, and economic impacts of health technologies are evaluated, considering aspects such as efficiency, effectiveness, safety, cost-effectiveness, among others (GOODMAN, 1998, HUNINK; GLASZIOU, 2001). The main goal of HTA is to aid health managers in making coherent and rational decisions about the incorporation of health technologies (PANERAI; MOHR, 1989, HUNINK; GLASZIOU, 2006). Health technologies are understood to be medications, equipment and technical procedures; organizational, informational, educational, and support systems, and the programs and protocols which aid through the attention and care with health are administered to the population (BRASIL, 2005c).

HTA Appraisals are a support tool for management and decision-making, based on the same rationality that involves HTE, however with more simplified execution and content. Even though they involve, as a rule, a literature review that is less extensive or in-depth than a systematic review, and are executed and elaborated more quickly, the HTAs should represent a systematized and in-depth report of the knowledge that is able to be supplied in this context, helping in the qualification of the decisions to be made (CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT, 2003, NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE, 2004a, DANISH CENTRE FOR EVALUATION, 2005).

The Methodological Guidelines for the Elaboration of HTA Appraisals has a priority audience of technicians from the Ministry and other spheres of government involved in the processes related to the incorporation and evaluation of health technologies. Its aim is to contribute to the standardization of the opinions made, for external consultants as well as for the proper technicians of the Ministry.

2 METHODOLOGY TO BE APPLIED IN THE ELABORATION OF HTA APPRAISALS

2.1 In which cases and how shall a HTA appraisals be elaborated?

As stated before, the HTA appraisals is the first step in the evaluation process of demands for the incorporation of new technologies - or of new applications for existing technologies - in the health system. It is particularly justifiable in cases where considerable political or social pressure exists for a rapid decision of the Ministry of Health concerning the incorporation of a given technology.

In this situation, the HTA appraisals presents the results of a preliminary evaluation so as to enable quick responses to the first questions about the technology: its effectiveness, the population that will benefit from it, and the possible consequences, including cost and financial impact, of its incorporation in the health services. This preliminary evaluation may indicate that the available evidence is sufficient so as to warrant decision making, recommending or not incorporating the technology. On the other hand, the evaluation may indicate that evidence obtained is insufficient or inadequate, requiring a deeper study to better analyze clinical, economic and social effects or impacts of the technology. In this case the HTA appraisals may suggest, among others, that a Systematic Revision or an Economic Evaluation should be carried out, both of which will require more time to be elaborated.

However, the use of HTA appraisals is not restricted to new technologies (those not yet incorporated into the health system, even though available for use in Brazil). On the contrary, it can and should be used for the analysis of health technology in whatever stage of its life-cycle it may be. Thus, HTA appraisals can be a useful element in analyzing established technologies, but for which adaptations or new uses are being proposed, as well as potentially obsolescent technologies through the incorporation of other safer, more effective or cost-effective ones.

The HTA appraisals should be a short document, not to exceed 20 pages or 20,000 characters, excluding attachments, and taking some

basic points into consideration: the question the opinion should reply to; the description of the epidemiological aspects of the health condition the technology is meant for; the description of the technology, of the alternative technologies and the impact of its incorporation on the health system; results found and recommendations of authors.

The complete methodology for the elaboration of the opinion should be presented in attachment, including a complete and detailed description of the search for scientific evidence, the criteria for including or excluding articles, the criteria for classifying articles in accordance with the quality level of evidence and possible biases.

Authors must keep in mind that the HTA appraisals is directed at managers. Consequently, care should be taken as to the language utilized, it being fundamental that the managers be able to understand and evaluate and utilize the results in their daily practice. The terminology should be comprehensible to a non-specialized public. Abbreviations are to be avoided, except those widely known (e.g. Aids, HIV). When essential, abbreviations should be spelled out when first used. Names of medicines and of procedures that are internationally understandable should be used whenever possible.

The document should contain all elements that allow readers to evaluate the validity of the analysis, including information that permits: understanding of methodology adopted, verification of sources of evidence, verification of the relevance of information and putting the recommendations in the context of their implications on clinical practice, on services and on research. Future subjects of research should be pointed out, possibly arising out of analysis results and leading to establish priorities to be researched.

An executive summary of not more than 2,000 characters and written in language accessible to a non-specialized reader should be placed at the beginning of the document. Elements that should be present in this summary, always as concisely as possible: intensity of the recommendations (according to the Level of Scientific Evidence classification used in the HTA appraisals - **Annex E**) context (purpose of elaborating the opinion), question to be answered (including the technology analyzed and its alternatives, the health condition for which it is indicated and the result in the health of interest), methodology, main results, conclusions and recommendations.

2.2 What are the basic stages for the elaboration of a HTA appraisals?

The stages which should be complied within the elaboration of opinions requested by the Ministry of Health are described below. The entire methodology pointed out in the following topics is based on internationally published methodological guidelines (CANADIAN COORDINATING, OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT, 2003, NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE, 2004a,b, DANISH CENTRE FOR EVALUATION, 2005).

2.2.1 How should the question of a HTA appraisals be formulated?

The HTA appraisals should give an answer to a clear and precise question, in which the following is clearly spelled out: the health condicion for which it is applicable (population of interest), the technology to be evaluated, the alternative (comparison) technologies, the parameters observed in evaluation (efficacy, effectiveness, safety, economic impact, organizational aspects, etc.) and the results or consequences on health of interest (mortality, morbidity, adverse effects, incidence of complications, etc.) (Table 1).

Table 1. Example of how to formulate a structured question.

Question of HTA appraisals *

Items that should be contained in the formulation of a structured question:

Population	Women with pos-menopausal osteoporosis
Intervention (technology)	Risedronate
Comparison	Alendronate
Parameter	Efficacy
Outcomes	Fracture of the femur

- Question:

Is Residronate in comparison to Alendronate in the prevention of fractures of the femur in women with post-menopausal osteoporosis?

* Adapted from Kahn and collaborators, 2003

2.2.2 What should be contained in the Introduction?

a) Epidemiological, demographic and social aspects

In this section, the country's scenario should be described in relation to the health condition or the clinical problem for which the technology is indicated (considering the indication contained in the question that the HTA appraisals should answer), including prevalence, incidence, mortality and the seriousness of the health condition, the disease's hardship (if information about this parameter is available) and the economic impact of the disease. Also to be mentioned are characteristics of the population that may carry weight in the evaluation, such as gender, race, age, severity of the health condition, co-morbidities and factors that may describe inequalities and unfairness in health provisions.

To obtain this information, authors should consult available data bases, such as the Rede Interagencial de Informações para a Saúde - RIPSA (Inter-agency Health Information Network), the Sistema de Informação Ambulatorial - SIA (Ambulatory Information System), the Sistema de Informação Hospitalar - SIH (Hospital Information System), the Caderno de Informações de Saúde (Health Information Notebook) and the Indicadores Básicos de Saúde (Basic Health Indicators) among others, all accessible through the electronic portal of the Sistema Único de Saúde (Unified Health System). Such electronic addresses are available in Appendix A.

Further, authors may avail themselves of other data banks or sources of information, such as estimates, investigations and other studies.

b) Description of technology to be evaluated

The technology to be evaluated should be described, mentioning in the first place whether it is registered or not with the Brazilian regulatory agency (Agência Nacional de Vigilância Sanitária - Anvisa) or with regulatory agencies in other countries, and in which conditions it can be used according to such registrations.

If the question to be answered by the HTA appraisals refers to a new indication of the technology, for which it does not have a registration, this should be clearly specified. To know whether or not a given technology is registered with Anvisa, the author needs to visit the mentioned agency's

electronic site (Anvisa, 2006), as per instructions in **Table 2.**

Table 2. Instructions for consulting medicines and products registered with the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária)

Medicines
www.anvisa.gov.br > Areas of Performance> Medications> Registered Products > Consult the registered medications
Health Products
www.anvisa.gov.br > Areas of performance> Health Products> Registered Products> Consult the registered health products> Search for registered health products

The following should be mentioned: the type of technology being evaluated (diagnostic, preventive, therapeutic according to its function in the health care process; medicine, vaccine, equipment, clinical or surgical procedures according to the nature of the technology), its basic characteristics, foreseen uses, different indications, counter-indications and known and published risks.

If a medicine is concerned, if necessary, the pharmacokinetic and pharmacodynamic aspects of its structure and application must be mentioned, as well as its forms of presentation and other aspects pertaining to such substances. In the case of equipment, the technical characteristics and the infra-structure required for its proper usage must be described. In the case of clinical or surgical procedures it is important that the requirements as to education, skills and qualification of the operators be mentioned.

The physical space where the technology is or will be utilized must be mentioned, as well as the existence of other conditions related to the use of the technology which should be considered (need of other associated technologies, need of special environment, etc.).

When available, estimated or actual prices should be described, as well as unit costs and added costs resulting from utilization demand, as well as other data concerning the technology's cost analysis and its financial impact on the health system.

Should no information regarding costs be available, the price paid by SUS (the Unified Health System), the amounts charged by health plan operators and insurance companies or the maximum market price set by Anvisa (specifically in the case of medicines) may be used as parameter. This information may be obtained in the Banco de Preços em Saúde (Health Related Prices Kank) of the Ministry of Health, in the Classificação Brasileira Hierarquizada de Procedimentos Médicos (CBHPM/AMB) (Brazilian Hierarchical Classification of Medical Procedures) and in the listing of the Câmara de Regulação do Mercado de Medicamentos (CMED/Anvisa) (Medicine Market Regulatory Chamber), whose electronic addresses can be found in **Appendix B**.

c) Description of alternative technologies

Existing alternative technologies should be described, as well as those considered as a gold standard for comparison for the health condition in case, and those already well accepted by the scientific community or in clinical practice.

One should compare the range of indications, the unit and added costs and set parameters for comparison between the technologies, if it be the case, such as efficacy and effectiveness.

2.2.3 Methodology

As mentioned before, a clear and detailed description of the methodology used in the elaboration of the HTA appraisals is to be contained in the attachment(s) of the document. Though the research of literature and the evaluation of evidence are typically more limited in a HTA appraisals than in a systematic review, they should nevertheless be systematized, so as to ensure a general overview of the more qualified literature and prioritizing evidence, as far as possible, according to the scientific quality of the works.

a) Search for evidence

The first step for the elaboration of a HTA appraisals is to describe the strategy for the search for evidence, considering the electronic bases utilized, the compilation or not of all literature on the subject, the carrying out of manual search, the description of the algorithm utilized, including the describers, key-words and the utilization of MeSH terms in the electronic research. At each phase of the search for evidence,

the number of studies obtained should be mentioned.

Authors should consider some reference bases in the search for quality scientific evidence, such as: the Cochrane Collaboration; the organizations, public entities and international networks of HTA (**Appendix C**); besides the electronic bases of Medline, EMBASE and Lilacs (**Appendix D**).

b) Criteria for the selection or exclusion of articles

The criteria for inclusion of studies in the HTA appraisals, stemming from the above described search for evidence, must be clearly mentioned. Some criteria that may be used are:

- Outline of the study: random and non-random controlled clinical tests, cohort studies, case control studies, prospective studies, systematic reviews, case studies, etc.;
- Population or sub-groups of interest: health problem, seriousness of the problem, age, gender and race;
- Evaluated intervention or technology;
- Outcome (results in terms of health): mortality, morbidity, incidence of complications, life quality, etc.

Similarly to the selection criteria, the criteria for exclusion of studies should also be described, mentioning the number of studies excluded in each phase of the search, in accordance with described criteria for exclusion.

c) Evaluation of the quality of evidence

According to the characteristics of the type of the document itself and of mentioned indications, the methodological rigor to elaborate a HTA appraisals may be less than that required for a Systematic Review, therefore allowing the inclusion of the analysis of subjects that are of interest to decision-makers, even those subjects for which evidence is less than optimal (particularly in the initial stage of a new technology's life-cycle).

It is generally accepted that a hierarchy of evidence is utilized for the evaluation of the quality of studies, where the highest value is attributed to systematic reviews of high-quality random controlled clinical studies and to adequately designed randomized control trials (RCT), whereas the lower levels contemplate non-randomized studies, co-

hort studies, case control and series of cases. In the context of this document it is suggested that the Evidence Level Classification of the Oxford Centre for Evidence Based Medicine be used (**Appendix E**).

Although a strong preference exists for decision making to be based on RCTs, it is important to acknowledge that several technologies or interventions (such as e.g. surgical procedures or health programs) seldom are researched based on this type of study usual for medicines. Consequently, other types of studies have to be considered when they are the only option, and the highest quality one available for the intervention in case is to be chosen.

Moreover, the level of evidence is not the only factor to be considered when evaluating the studies. A low quality random clinical study may supply less information than another non-random but well designed study. It is therefore important that the quality of evidence be always evaluated and mentioned - (**Anexo G**). One should describe the method utilized to evaluate the quality of evidence found, including the quality criteria considered for each type of study utilized in the HTA appraisals, as well as source used, as criteria may vary according to author or institution in question (GUYATT; RENNIE, 2006, SACKETT et al., 2003, OXMAN et al., 1994).

Biases present in selected studies should be pointed out and commented upon and, considering that they interfere in the quality of evidence, they should be analyzed as limiting factors to the studies included in the HTA appraisals.

A synthesis of the evaluation of the studies should be presented in a table clearly showing the quality level of the evidence of the studies considered, placing them in a hierarchical order of quality, according to the type of technology being researched (surgical procedures, diagnoses, equipment, medicines, other therapies, etc.) and based on criteria as per **Appendix E**.

2.2.4 How should results be presented?

a) Presentation of study results

The studies considered in analysis should be presented in the form of a table, containing identification of the study, country where made, number of participants, type of study, intervention performed and alternative

technologies, description of outcome and results obtained. An example of a table containing such information is shown in **Appendix F.**

One should furthermore present the results of the quality evaluation of evidence of the studies used in the HTA appraisals, make a critical analysis of literature found and justify the use of lesser quality evidence.

Mention must be made of the results of economic evaluation studies existing in researched data bases, emphasizing indication of the technology being researched, alternative technologies, the standards of effectiveness utilized and the ratio of incremental cost-effectiveness obtained. When no economic evaluation studies exist or when they are inconclusive in relation to the technology's cost-effectiveness, vis-à-vis their technological alternatives, this should also be mentioned.

It is important that upon analyzing economical information, especially that originating from so-called complete economic evaluations (i.e. cost- effectiveness, cost-utility and cost-benefit studies), a consistent approach be used, both regarding costs and results, allowing comparison of intra and inter-evaluations.

b) Interpretation of results

After presentation of studies utilized in HTA appraisals and of their results, one should proceed to interpretation of these results, always basing oneself on the question that oriented the carrying out of the HTA appraisals and its importance for decision-making regarding the technology being evaluated. The statistical and clinical significance of the results should be considered, comments being pertinent regarding the statistical and association standards utilized (ratio of risks, ratio of chances, and necessary number for treatment).

Moreover, as the majority of random and non-random clinical tests are carried out outside of Brazil, one should take into account that some health technologies may present a reduced benefit in the Brazilian reality. In this context one should take into account population and epidemiological differences and the conditions necessary to introduce the technology, possibly not existing in Brazil, such as qualification of human resources, infrastructure, maintenance capabilities, among others.

In this section, authors should comment on and discuss the conditions for the introduction of the technology, as well as factors that

may lead to bad utilization of such technology in the Brazilian reality or factors contributing to results and performance that are different from those found in external evaluations of it.

2.2.5 Recommendations

The authors of the HTA appraisals may, as the case may be, digress about the incorporation or the utilization of the technology in the Brazilian reality, its foreseen impact on health services, its relation to specific care policies related to the health condition in case, the relevant factors that may contribute to identify inequalities that can be changed and to promote fairness in access to the technology.

The opinion should end with the presentation of recommendations concerning the implications of the results of the evaluation for clinical practice, for the services and for research. In connection with the latter, we would like to emphasize the importance of suggesting study subjects that may fill information gaps detected.

In this context, particularly in those cases where cost and utilization estimates indicate that the use of the evaluated technology is probably extensive and/or very costly, it is desirable that information stemming from the HTA appraisals may later be better examined with a formal economic evaluation, and the need for this should be contained in the authors' recommendations.

In the same way, when the conclusions of the opinion point to the existence of a lot of available evidence or, on the contrary, when insufficient evidence exists for decision-making, the elaboration of further studies must be recommended, such as a systematic review, a clinical study, respectively.

2.2.6 References

References utilized in the elaboration of the HTA appraisals should be presented according to instructions and rules of ABNT (the Brazilian Association of Technical Standards), at the end of the document.

3 General Structure of the HTA Appraisals

The table below synthesizes the suggested way of elaborating and writing the HTA appraisals:

Format
Structured summary with 2000 characters - Intensity of evidence of the recommendations - Description of the technology evaluated and its alternatives - Information about the technology's target population (epidemiological indicators) - Methodology (data base where the search was done, quality of the evidence found, number of studies analyzed) - Summary of the recommendations
Content
- Context (justification of the importance of the HTA appraisals question) - Question (aim of the study, questions to be answered by the documents) - Introduction (epidemiological information, description of the technology, its indications, costs, expenditures, risks and description of the alternative technologies) - Methods (sources of data, selection of studies, quality evaluation) - Recommendations (implications for clinical practice, service, and research) - Results (main findings, table of study results)
Annex containing details on the Methodology

FINAL CONSIDERATIONS

Those who would wish to express an opinion on this document will find in (Appendix H) an evaluation form of the Methodological Guidelines for HTA appraisals of the Ministry of Health.

All users (managers, health professionals, consultants of the Ministry of Health and its agencies) are invited to fill out this form and send it to us, enabling us to periodically review this document, if necessary, thus guaranteeing its quality.

The Work Group for Elaboration of Methodological Guidelines for Health Technologies Assessment of the Ministry of Health thanks everyone's participation and trusts that these Guidelines may be useful in each one's practice.

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GLOSSARY

Added cost: amount paid for the technology in relation to utilization demand (considers the total population which will effectively benefit from the technology) (MINISTRY OF HEALTH, 2005).

Biases: any process, in any stage of inference, that tends to produce results and conclusions that differ systematically from the truth. Their effect is to distort the estimate of a variable, e.g. increasing the average of a variable or reducing the prevalence of a characteristic (FLETCHER et al., 1982).

Cohort study (follow-up study): a linear study in which the researcher, after separating individuals as exposed or not exposed to a given factor being studied, follows them during a certain period of time to verify the incidence of an illness or clinical situation among the exposed and the non-exposed (HULLEY et al., 2006).

Confidence interval: margin of error around a statistic (CALLEGARI-JACQUES, 2003).

Cost-benefit: a type of economic evaluation which puts a price on costs and outcomes in monetary terms (MINISTRY OF HEALTH, 2005).

Cost-effectiveness: a type of economic evaluation in which consequences (results) of the health technologies are measured in natural health units, such as years of life gained or clinical events avoided; this term is sometimes also used to refer to all types of economic evaluation (MINISTRY OF HEALTH, 2005).

Cost-utility: a type of economic evaluation in which consequences (results) of the health technologies are measured as health related preferences, often expressed as years of life adjusted by quality (Economic Evalution in Health, 2005).

Economic Evaluation in Health Matters: comparison of different technologies in the health sphere, relative to their costs and effects on the health condition (MINISTRY OF HEALTH, 2005)

Effectiveness: probability of individuals of a given population benefiting from a health technology directed at a given problem in actual

conditions of use (OFFICE OF TECHNOLOGY ASSESSMENT, 1978).

Efficacy: probability of individuals of a given population benefiting from a health technology directed at a given problem under controlled conditions of use (OFFICE OF TECHNOLOGY ASSESSMENT, 1978).

Eqüity: The absence of unfair, avoidable or correctible differences in health of populations or groups defined by social, economic, demographic or geographic criteria (WHO, 2005).

Health cost: amount of resources applied to a therapeutic alternative, to a program or to a health service, over a given period of time (MINISTRY OF HEALTH, 2005).

Health technology: medicines, equipment and technical procedures, organization, information, education and support systems, assistance programs and protocols by means of which assistance and health care are provided to the population (BRASIL, 2005a).

Health Technology Assessment (HTA): a comprehensive process by means of which clinical, social and economic impacts of health technologies are evaluated, considering aspects such as efficacy, effectiveness, safety, costs, cost-effectiveness, among others (GOODMAN, 1998, HUNINK; GLASZIOU, 2001). Its main objective is to help health managers in coherent and rational decision-making concerning incorporation of health technology (PANERAI; MOHR, 1989).

HTA appraisals: a tool to support management and decision, based on the same rationale involved in an EHT, though with simplified execution and content.

Meta-analyses: techniques that apply protocols and utilize statistical methods to revise and interpret critically the combined results of relevant primary investigations that were held, in order to obtain quantitative syntheses about the effects of health technologies, so as to guide decisions (KHAN et al., 2005).

Morbidity: Proportion of patients with a particular illness during a given year in a given population unit (FLETCHER et al., 1982).

Mortality: All deaths reported in a population (FLETCHER et al., 1982).

Non-randomized controlled trial: clinical studies without random selection of patients (HULLEY et al., 2006).

Quality of Life: the combination of an individual's physical, mental and social well-being and not just the absence of illness.

Randomized controlled trial: clinical studies with random selection of patients (HULLEY et al., 2006).

Standard Error: standard deviation of a statistic (CALLEGARI-JACQUES, 2003).

Systematic review: review of a subject starting from a clearly formulated question, which uses systematic and explicit methods to identify, select and evaluate critically relevant research and collect and analyze data of the studies included in the review (COCHRANE, 2001).

Unit cost: amount paid per unit of the technology (MINISTRY OF HEALTH, 2005).

ANNEX A

Epidemiological Information Bases in Sites

Ambulatory Information System and Hospital Information System:
http://w3.datasus.gov.br/siasih/siasih.php

Health Information Notebook:
http://tabnet.datasus.gov.br/tabdata/cadernos/BR/Brasil_GeralBR.xls

Interagency Health Information Network:
http://portal.saude.gov.br/portal/saude/ripsa/default.cfm

Basic Data Indicators:
http://tabnet.datasus.gov.br/cgi/idb2004/matriz.htm?saude=http%3A%2F%2Ftabnet.datasus.gov.br%2Fcgi%2Fidb2004%2Fmatriz.htm&obj=%24VObj&botaook=OK

HEALTH INFORMATION – Epidemiology and Morbidity:
http://w3.datasus.gov.br/datasus/datasus.php?area=359A1B624C4D0E0F359G9H0I1Jd4L24M0N&VInclude=../site/infsaude.php

Mortality and Live Birth Information:
http://w3.datasus.gov.br/site/visualiza_texto.php?noticia=4770

ANNEX B

Sites for Research for Prices in Health

Data bank for prices in health - Health Ministry BPS:
www.saude.gov.br/banco

Hierarchical Classification of Medical Procedures from the Brazilian Medical Association:
www.amb.org.br

Regulatory Chamber of the Medications Market (CMED/ANVISA):
http://www.anvisa.gov.br/monitora/cmed/legis/comunicados/06_04_anexo1.pdf

ANNEX C

Sites for Research Institutions and International Cooperation Network for Health Technology Assessment

Societies, Associations, and Academic Centers in the Area of Health Economics

ISPOR — International Society for Pharmacoeconomics and Outcomes Research
http://www.ispor.org/

iHEA — International Health Economics Association
http://healtheconomics.org/

CAHSPR — Canadian Association for Health Services and Policy Research
http://www.cahspr.ca/

CHERE — Centre for Health Economics Research and Evaluation (Sidney/Australia)
http://www.chere.uts.edu.au/index.html

SIHE — Swedish Institute for Health Economics
http://www.ihe.se/english/index.htm

IHE — Institute of Health Economics
http://www.ihe.ab.ca/

CHE — Centre for Health Economics (York/England)
http://www.york.ac.uk/inst/che/

CHEP — Centre for Health Economics and Policy Analysis (Canada)
http://www.chepa.org/home/index.asp?ID={E847C231-6F74-484E-BAF8-8371A7767EFB}

CRES — Economics and Health Research Center – University of Pompeu Fabra
http://www.upf.edu/cms/cres/en/

HERC — Health Economics Research Centre – Oxford, UK
http://www.herc.ox.ac.uk/

HERU — Health Economics Research Unit - Aberdeen, UK
http://www.abdn.ac.uk/heru/

CHE — Centre for Health Economics (Inglaterra)h
http://www.york.ac.uk/inst/che/

AHES — Australian Health Economics Society
http://www.ahes.org.au/

ENEPRI — European Network of Economic Policy Research Institutes
http://www.enepri.org/

AES Argentina — Asociación de Economía de la Salud
http://www.aes.org.ar/

ASHE — American Society of Health Economists
http://www.healtheconomics.us/

APES — Associação Portuguesa de Economía da Saúde
http://www.apes.pt/

AES — Asociación de Economía de la Salud
http://www.aes.es/

CES — Collège des Économistes de la Santé
http://www.ces-asso.org/

CRD — Centre for Reviews and Dissemination (York/England)
http://www.york.ac.uk/inst/crd/index.htm

HERO — Health Economics Research Programme at the University of Oslo
http://www.hero.uio.en el/eng.html

Health Economics and Decision Science – University of Sheffield
http://www.shef.ac.uk/heds/

Office of Health Economics
http://www.ohe.org/

SMDM — Society for Medical Decision Making
http://www.smdm.org/

EURONHEED — EUROpean Network of Health Economic Evaluation Database
http://www.ces-asso.org/PagesGB/EURONHEEDgb.html

CEE — Centre for Economic Evaluation (England)
http://www.ifs.org.uk/cee/index.shtml

ISPE — International Society for Pharmacoepidemiology
http://www.pharmacoepi.org/

Bureau of Primary Health Care – Health Resources and Services Administration. U. S. Department of Health and Human Services
http://bphc.hrsa.gov/bphc/

NICHSR — National Information Centre on Health Services Research & Health Care Technology — Health Services and Sciences Research Resources
http://www.nlm.nih.gov/nichsr/hsrr_search/

Community Health Status Indicators Project Health Resources Services Administration, U. S. Department of Health and Human Services
http://www.phf.org/data-infra.htm

HTA Organizations and Agencies

HTAi — Health Technology Assessment International
http://www.htai.org/

Health Technology Assessment on the Net
http://www.hta.uvic.ca/

INAHTA — International Network of Agencies for Health Technology Assessment
http://www.inahta.org/

PAHO/HSP — Technology Assessment in Health Care / Pan American Health Organization /Division of Health Systems and Services and Development
http://www.paho.org/english/hsp.hsptec.html

German Institute for Medical Documentation and Information (Germany)
http://www.dimdi.de

Australian Institute of Health and Welfare (Australia)
http://www.aihw.gov.au/

ITA - Institute for Technology Assessment of the Austrian Academy of Sciences (Austria)
http://www.oeaw.ac.at/ita/welcome.htm

BCOHTA — British Columbia Office of Health Technology Assessment (Canada)
http://www.chspr.ubc.ca/bcohta

CCOHTA — Canadian Coordinating Office for Health Technology Assessment (Canada)
http://www.ccohta.ca/

CETS — Conseil d'Evaluation des technologies de la santé (Canada)
http://www.mess.gouv.qc.ca/index.html

CCHSR — Coordinating Committee for Health Services Research (Canada)
http://www.chsrf.ca/

Manitoba Centre for Health Policy and Evaluation (Canada)
http://www.unanitoba.ca/centres/mchp/1mchpe.htm

ETESA — Unidad de Evaluación de Tecnologías de Salud (Chile)
http://www.minsal.cl

INHEM — Instituto Nacional de Higiene y Epidemiologia (Cuba)
http://www.infomed.sld.cu

Danish Centre for Evaluation and Health Technology Assessment (Denmark)
http://www.sst.dk/planlaegning_og_behandling/medicinsk_teknologivurdering.aspx?lang=en

DSI — Danish Institute for Health Services Research and Development (Denmark)
http://www.dsi.dk/

DIHTA —Danish Institute for Health Technology Assessment (Denmark)
http://www.dihta.dk

AETS — Agencia de Evaluación de Tecnologías Sanitarias (Spain)
http://www.iscii.es.aets/

AETSA — Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (Espain)
http://www.csalud.junta-andalucia.es/orgdep/AETSA

CAHTA — Catalan Agency for Health Technology Assessment (Spain)
http://www.aatrm.net/

OSTEBA — Basque Office for Health Technology Assessment (Spain)
http://www.euskadi.net/sanidad/

AHRQ — Agency for Healthcare Research and Quality (USA)
http://www.ahcpr.gov/

ECRI (USA)
http://www.ecri.org

Institute of Medicine U.S. (USA)
http://www4.en las.edu/iom/IOM.html

MTPPI — Medical Technology and Practice Patterns Institute (USA)
http://www.mtppi.org

NICHSR — National Information Center on Health Services Research and Health Care Technology (USA)
http://www.nlm.nih.gov/nichsr/nichsr.html

HRC — Oregon Health Resources Commission – Medical Technology Assessment Program (USA)
http://www.ohppr.state.or.us/hrc/index_hrc.htm

RAND (USA)
http://www.rand.org

VA — VA Research and Development Service - Technology Assessment Programme (USA)
http://www.va.gov/resdev/ps/pshsrd/mdrc_tap.htm

EMEA — The European Agency for the Evaluation of Medicinal Products
http://www.emea.eu.int

FinOHTA — Finnish Office for Health Care Technology Assessment (Finland)
http://www/stakes.fi/finohta

ANAES — L'Agence Nationale d'Accréditation et d'Evaluation en Santé (France)
http://www.anaes.fr

Department of Medical Technology Assessment University of Nijmegen & University Hospital Nijmegen St. Radboud Nijmegen, the Netherlands (Holand)
http://www.umcn.nl/mta

TNO'S HTA GROUP - The Netherlands Organization for Applied Scientific Research (Holand)
http://www.health.tno.nl/en/about_tno/organisation/divisions/publichealth/health_technology_assessment.html

NCCHTA — National Coordinating Centre for Health Technology Assessment (England)
http://www.ncchta.org/

NHS Centre for Review and Dissemination
http://www.york.ac.uk/inst/crd/

SMM — Norwegian Centre for Health Technology Assessment (Noruega)
http://www.oslo.sintef.en el/smm

NICE — National Institute for Clinical Excellence and Health
http://www.nice.org.uk/page.aspx?el=home

NZHTA — New Zealand Health Technology Assessment (New Zealand)
http://nzhta.chmeds.ac.nz/

CMT — Centre for Medical Technology Assessment (Suecia)
http://www.imt.liu.se/CMT

SBU — Swedish Council on Technology Assessment in Health Care (Suecia)
http://www.sbu.se

SWISS/TA — Swiss Science Council/Technology Assessment (Suiza)
http://www.ta-swiss.ch

Data Bases and Bibliographic Archives

NBER — National Bureau of Economic Research
http://www.nber.org/

ECONLIT (base electrónica de literatura económica
http://www.econlit.org/

Health Economics.con — Medical and Pharmacy Resources on the Net
http://www.healtheconomics.con/

EconPapers
http://econpapers.repec.org/

PEDE — Pediatric Economic Database Evaluation
http://pede.bioinfo.sickkids.on.ca/pede

Etext on Health Technology Assessment (HTA) Information Resources. Chapter 11: Health Economics Information
http://www.nlm.nih.gov/nichsr/ehta/chapter11.html

Registers of Clinical Trials

Trials Clinical
http://clinicaltrials.gov/
Current Controlled Trials (UK)
http://www.controlled-trials.con/

CENTRAL — Cochrane Central Register of Controlled Trials
http://www3.interscience.wiley.con/cgi-bin/mrwhome/106568753/HOME

ClinicalTrialResults.Org
http://www.clinicaltrialresults.org

Centerwatch (USA)
http://www.centerwatch.con/

NRR — National Research Register (UK)
http://www.nrr.nhs.uk/search.htm

Trials Central (USA)
http://www.trialscentral.org/ClinicalTrials.aspx

Annex D

Sites for Bibliographic Research

BIREME
http://www.bireme.br/

Cinahl (Cumulative Index to Nursing and Allied Health Literature)
http://www.cinahl.com/index.html

DARE (Database of Abstracts of Reviews of Effects)
http://www.york.ac.uk/inst/crd/crddatabases.htm

EconLit (electronic base for economic literature)
http://www.econlit.org/

EconPapers
http://econpapers.repec.org/

EMBASE
http://www.embase.com/

MEDLINE (via OVID)
http://www.ovid.com/site/catalog/Catalog_DataBase.jsp?top=2&mid=3&bottom=7&subsection=10

MEDLINE (via Pubmed)
http://www.ncbi.nlm.nih.gov/

Periódicos CAPES
http://www.periodicos.capes.gov.br/portugues/index.jsp

PsycINFO (Psychological Abstracts)
http://www.apa.org/psycinfo/about/

SciELO
http://www.scielo.org/

Annex E

Level of Scientific Evidence by Type of Study

Degree of recommendation	Level of evidence	Treatment – Prevention – Etiology	Prognostic	Diagnostic	Diagnostic Differential/ Prevalence of Symptoms
A	1A	Systematic review of controlled randomized clinical trials	Systematic review of cohorts from the onset of the disease. Prognostic criteria valid in different populations.	Systematic review of Level 1 diagnostic studies. Diagnostic criteria of Level 1B studies in different clinical centers.	Systematic review of cohort studies (contemporaneous or prospective)
	1B	Controlled randomized clinical trials with a strict confidence interval	Cohort from the onset of the disease, with a loss of < 20%. Prognostic criteria valid in only one population.	Cohort valid, with a good standard of reference. Diagnostic criteria tested in a single clinical center.	Cohort study with few losses
	1C	"All or nothing" therapeutic results	"All or nothing" case series	Sensitivity and specificity near 100%	"All or nothing" case series

[1]Based on the level of evidence table from the Oxford Centre for Evidence Based Medicine: http://www.projetodiretrizes.org.br/projeto_diretrizes/texto_introdutorio.pdf

B	2A	Systematic review of cohort studies	Systematic review of historical cohorts (retrospective) or of case follow-ups that were not treated as the control group in randomized clinical trials	Systematic review of > level 2 diagnostic studies	Systematic review of > level 2 differential diagnostic studies
	2B	Cohort studies (including lesser quality randomized clinical trials)	Historical cohort study, follow-up of patients that were not treated as the control group in a randomized clinical trial. Prognostic criteria derived from or valid only in fragmented samples.	Exploratory cohort with a good reference standard. Diagnostic criteria derived from or valid in fragmented samples or data banks.	Historical cohort study or with a follow-up of a segment of impaired cases (a large number of losses)
	2C	Observation of therapeutic results (outcomes research).	Observation of clinical evolutions (outcomes research) Ecologic Study	--------	Ecologic Study.

B	3A	Systematic review of case-control studies	----------	Systematic review of > level 3B diagnostic studies	Systematic review of > level 3B studies
	3B	Case-control study	----------	Non-consecutive selection of cases, or reference standard applied in an inconsistent way	Cohort with a non-consecutive selection of cases, or the population of a very limited study
C	4	Case report (including cohort or case-control of poor quality)	Case series (and prognostic cohort of poor quality)	Case-control study or poor reference standard or not independent	Series of cases, or overcome reference standard
D	5	Specialists' opinions lacking critical evaluation or based on basic matters (physiological study or study with animals)			

ANNEX F

Example of how to present study result tables

Table 1. Study results on the effectiveness of inhaled insulin.

Studies	Type of study Population	Parameters	Outcomes
Jendle and Karlberg, 1996	Double-blind RCT Healthy individuals (N=8) Glucose	Serum insulin concentrations Peptide C serum FEV1 Peak flow TPC Diffusion Capacity	4.3 to 2,8mmol/L (p<0.001) 9.5 to 26.1 mU/L (p<0.001) 0.48 to 0.12 nmol/L (p<0.001) There were no significant changes in the ventilator parameters
Himmel-mann et al., 2003	RCT Non-diabetics smokers (N=27) x non-smokers (N=16)	Concentrations of serum insulin Insulin concentration peak Absorption time	63.2 x 40.0 mU/L (p=0.0017) 42.0 x 13.9 (p<0.0001) 31.5 x 53.9 min (p=0.0003)
Henry et al., 2003	NRCT Non-diabetics healthy (N=28) x asthmatic (N=17)	Serum insulin Glycemic reduction FEV1 TPC	1.45x106 x 1.07x106 (p=0.013) 4.880 x 3.419 mg/dl/min (p=0.007) There were no significant changes in the ventilator parameters.
Gerber et al., 2001	RCT Diabetics with inhaled insulin x injectable insulin (N total=69)	Average of satisfaction Convenience and ease of use Social Comfort	35.% x 10.6% (p<0.01) 41.3% x 11.2% (p<0.01) 28.0% x 18.0% (p=0.42)

Key: RCT: randomized clinical trial; FEV1: forced expiratory volume in the first second; Peak flow: in pneumology that measures the peak of expiratory flow; TPC: total pulmonary capacity; NRCT: non-randomized clinical trial.

ANNEX G

Table of the criteria for how to evaluate the quality of the evidence in scientific articles [1]

Criteria	Study 1	Study 2	Study 3
Is the study randomized?			
Was the patients' placement in the groups confidential?			
Were the patients analyzed in the groups in which they were randomly placed?			
Were the patients in the two groups similar in relation to previously known prognostic factors?			
Was it a blind study?			
Were the groups treated equally except for the experimental intervention?			
Was there a thorough follow-up?			
How significant was the treatment effect?			
How precise were the effects of the treatment?			
Were the study group patients similar to the patients of interest?			
Were all of the important outcomes considered?			
Do the observed benefits outweigh the costs and/or damages?			

[1]GUYATT, G., RENNIE, D. Diretrizes para Utilização de Literatura Médica – Fundamentos para a Prática Clínica da Medicina Baseada em Evidências. Ed. Artmed, 1ª edição, Porto Alegre, 2006.

ANNEX H

Evaluation Form for the Guidelines for Technical-Scientific Opinions [1]

Identification		
Client:		
Area (Agency/Institution) with which you are affiliated:		
City, State:	E-mail:	Telephone: ( )
Address:		

Criteria to be evaluated	Inadequate*	Partially adequate*	Adequate
Can the researcher advise the reader well to elaborate a TSO?			
Does the researcher present the concepts in an easy and adequate way?			
Are the methods described and proposed for the elaboration of a TSO adequate?			
Was the document written clearly?			
If inadequate or partially adequate, please, justify, indicating the points that need to be changed:			

Open questions
General comments
Positive points
Negative points
What is the number of copies the institution needs (triage)?

[1] Send to: Brazil, Ministério da Saúde, Edifício Sede, 8º andar, sala 845, Esplanda dos Ministérios, Brasília-DF, CEP: 70058-900 **ats.decit@saude.gov.br**

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