HTA Forum - Pakistan

Report on :

International Seminar & Workshop on Health Technology Assessment

Islamabad, 12-14 February 2004

Organized by

HTA Forum

HTA Forum - Pakistan

In collaboration with

Ministry of Health, World Health Organization
Pakistan Institute of Medical Sciences &
The Network for Consumer Protection

TheNetwork for Consumer Production

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HTA Workshop participants

Acknowledgments:

On behalf of the HTA Forum I am thankful to the Honorable Federal Minister for Health Mr Muhammad Nasir Khan, Maj. Gen. (R) Muhammad Aslam, Director General Health, Dr Majeed Rajput and Dr Ashfaq Ahmed from the Federal Ministry of Health whose patronage provided us the direction.. This whole effort could not have materialsed with out the strong and persistent support of Dr Khalif Bile Mohamud, WHO Representative Pakistan and his team and Dr Itziar Larizgoatia from WHO Geneva. Dr Fazal e Hadi Executive Director PIMS kindly allowed us to hold the seminar in the premises and Dr Tanvir Khaliq coordinated the event and made it into a success. Dr Zafar Mirza and TheNetwork for Consumer Protection provided wholehearted support to the HTA Forum from it's inception till date. I would like to express my deepest gratitude to Dr Alicia Granados and Dr S Sivalal from Spain and MoH Malaysia respectively and all the members of HTA forum, the speakers and participants for their enormous contribution in making this event a success.

Dr Assad Hafeez, Coordinator, HTA Forum Pakistan
Email; htapak@yahoo.com

Report prepared by: Ayyaz Kiani, HTA Forum, 40-A, Ramzan Plaza, G-9 Markaz, Islamabad, Ph: +51-2261085, E-mail: ayyaz@thenetwork.org.pk

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Message

Muhammad Naseer Khan

Federal Minister of Health

Every health policy maker has to make tough decisions about where to spend money to get maximum outputs. This is a classic struggle they have to go through on day to day basis and particularly so when resources are scarce. This dilemma of choice is similar at every level of health care, may it be the clinicians, hospital administrators, provincial or federal ministries, private providers or others.

Health workers are often confronted with competing choices and one wrong decision about using an expensive and not much needed technology can have serious implications on quality and equity in health care services. The ultimate concern of clinicians, managers and policymakers is value for money. This is where Health Technology Assessment can be a useful tool and has been utilized in developed and progressive countries.

I would like to see HTA as an essential component of health policy formulation in Pakistan at every level of healthcare and am confident that the group of dedicated professionals involved in the effort would be able to take the initiative forward with the help of relevant government departments. I wish this seminar and workshop arranged with the collaboration of WHO every success.

Message

Dr. Khalif Bile Mohamud

WHO Representative in Pakistan

Consistent with the WHO strategy for improving health systems performance, the WHO department of Health Services Provision (OSD) is promoting "Evidence based decision making" in health service provision and generation of health systems resources. Health technology assessment (HTA) is an essential tool to this effect It creates linkages between evidence based practices and policy decisions. The concept of HTA is well established worldwide and is being fostered by WHO in all the regions. It is an essential requirement for decision making at all levels of planning in healthcare, particularly in the third world countries, where resources are scarce and demands on health care systems are enormous. Such a transparent and objective method is an absolute necessity.

The broad objective of the Health Technology Assessment is to introduce general guidelines that would assist health sector in Pakistan to adopt evidence based approach in decision making at all levels.

I would like to congratulate the organizers on holding this event which I'm sure would go a long way in achieving its purpose. The WHO would be supporting this movement of EBM in this country in every possible way.

Message

Maj. Gen. (Retd.) Muhammad Aslam HI(M)

Director General Health

As health care providers, managers or policy makers we are doing some sort of HTA in our day to day work either knowingly or unknowingly. In this sense it is not an entirely new concept. However, the methodology used by HTA practitioners providing a specific and systematic approach makes it a very new science. This new science is about identifying priorities in the fullest societal context, analyzing them objectively, preparing strategies recommendations and then selecting the most appropriate technologies for our health setups. It is also about making decisions which objective, transparent and workable. In my opinion this is the most important cause for introduction of HTA in Pakistan. The newly established National Health Policy unit in the Ministry can definitely make use of HTA while formulating and considering policy issues.

I am confident that this conference will sensitize health care professionals to the concept of HTA and will also provide the valuable opportunity to exchange views and learn from each other. We have a galaxy of individuals attending this conference comprising of a cross section of Pakistani healthcare system both geographically and structurally. These include policy makers, managers, clinicians, pharmacists, paramedics, nurses, public health specialists and others form all parts of the country.

I particularly welcome our experts from Geneva, Spain and Malaysia, who have taken out time from their very busy schedules, despite all odds, to come over and share their expertise with us. I would also like to commit full support form the government of Pakistan for any such initiative which would improve the health care for our people.

'May God give us the serenity to know what we can, the courage to change what we can, and the ability to make a difference'

Foreword

Technological innovation has yielded truly remarkable advances in health care during the last three decades. New breakthroughs in biotechnology, biomaterials, pharmaceuticals, surgical techniques, and computer technology have helped to improve health care delivery and patient outcomes. This proliferation of health care technology is inevitably accompanied by burgeoning health care costs and bewilderment of decision makers and practitioners in health in choosing from the vast array of available treatment modalities.

Health Technology assessment (HTA) arose in the mid-1960s from an appreciation of the critical role of technology in modern society and its potential for unintended, and sometimes harmful, consequences. In Pakistan concept HTA was introduced at a meeting held at Pakistan Institute of Medical Sciences, Islamabad in 2002. The main theme was to assess the feasibility of HTA in our country. A few priority areas were identified and various studies on small scale have been carried out to collect evidence on usefulness of different technologies. While this meeting laid the foundation of the HTA Forum in Pakistan it also highlighted the need to conduct an international seminar and workshop.

Now with the help of WHO, Federal Ministry of Health, Pakistan Institute of Medical Sciences and TheNetwork for Consumer Protection this international event has been materialized. We hope that this first ever international seminar and workshop on HTA in Pakistan proves to be a land mark in development of HTA in this country. The seminar and workshop agenda featured an impressive range of topics anticipated to capture the interests of researchers, clinicians, administrators, and policy makers alike.

This report documents the theoretical and conceptual ground covered in the seminar and the workshop to serve as a reference to those who attended and to provide the necessary background information for those could not but were interested to know more in the area of HTA. This is a humble beginning and first step towards establishing HTA Forum Pakistan which will be able to work in close collaboration with the Ministries of Health and hospitals both in public and private sectors.

Dr Tanwir Khaliq

Workshop Coordinator

"The man who goes alone can start today; but he who travels with another must wait till that other is ready"
Henry David

Introduction to HTA Forum Pakistan

HTA Forum Pakistan consists of a group of professionals who are dedicated to the promotion of culture of "evidence based medicine" in Pakistan. The group started on a very small scale in 2001 by holding brainstorming sessions to evaluate the usefulness and utility of Health Technology Assessment in Pakistan. The idea was to exchange experience, to better understand country needs, priorities, challenges and opportunities, and thus help shaping the opinion for fostering the use of HTA for improving evidence base of health policy- and decision-making and the performance of health systems and services. The group is convinced that this is the most important tool to bring about the desired change in the mindset of health professionals.

The following main activities have been carried out so far:

1. Regular meetings of interested professionals.
2. Publications in various journals regarding HTA.
3. Presentations regarding HTA at different forums and conferences.
4. Research and HTA reports on basic problems.
5. Identification of priority HTA areas.
6. Some HTAs conducted and reports were prepared for dissemination.
7. Visiting consultants from abroad.
8. Establishment of links with Health Technology Assessment International.(HTAi)
9. Establishment of links with WHO Geneva office for HTA Promotion
10. Identification of individuals at national level for HTA activities.
11. Sensitization of Federal Ministry of Health Pakistan and provincial health departments towards HTA
12. Training of group members by attending workshops and lectures.

HTA Forum is establishing networks and closer collaboration with regional and international HTA forums. The Forum will provide a platform and expertise for involvement of health ministries, professionals and consumer of health technology in HTA process in order to design and conduct HTA reports in priority areas and also to provide necessary expertise to adapt HTA reports from international sources.

Abstract

"The tragedy of life is not that it ends so soon, but that we wait so long to begin it"
W.M. Lewis

This report presents the concepts covered, proceedings, presentations and conclusions of a seminar and a training workshop which brought together a number of Health Technology Assessment practitioners from Pakistan and abroad with an array of senior clinicians, academia staff, researchers, health activists and professionals. Participants included an HTA expert from WHO, Geneva, a consultant from Catalan, Spain, a consultant from MoH Malaysia, clinicians and managers from KRL and PIMS Hospitals, Islamabad, clinicians from Rawalpindi Medical College, Rawalpindi, clinician and scientists from Atomic Energy Commission, members of TheNetwork for Consumer Protection, nursing chief of PIMS, policy makers and health managers from MoH, NWFP, regional head of the College of Physicians and Surgeons of Pakistan and public health teacher from Agha Khan University, Karachi.

The seminar took place at Pakistan Institute of Medical Sciences, Islamabad and the workshop at the Pearl Continental Hotel, Bhurban. These meetings were part of a broader collaboration between the HTA Forum, Ministry of Health, World Health Organization, Pakistan Institute of Medical Sciences and TheNetwork for Consumer Protection.

An understanding of the difficulties in appraising health technologies and the need to base all decisions related to them on evidence based appraisals, whether at the level of individual clinician, at health care institution level or at macro policy level, was present throughout these meetings. The point was brought home that health institutions and policy makers must adopt a decision making process which enables them to both identify and reject technologies which represent a poor use of scarce resources and do not ensure optimal health care.

While these meetings provided the participants with the opportunity to exchange conceptual and contextual basis for organizing HTA in Pakistan, there was a sense of urgency amongst the participants to avoid further delay in evidence based decision making for the cause of optimal health outcomes. There also prevailed a sense of timeliness of this HTA initiative in Pakistan in the context of the Ministry of Health's recent setting up of a Health Policy Unit which was expected to be the hub of evidence based health policy decision making.

"My best friend is the one who brings out the best in me" - Henry Ford

1. Synopsis of the Meetings

The following themes, issues, and contextual considerations ran through the intellectual discourse in the meetings. As such, the understanding built by the facilitators and the participants on them through the course work, case studies, dialogue and group exercises during the different sessions, provide the conceptual premises on which the recommendations and conclusions of the two events are built.

1.1 The policy dilemma

There are some very critical question that policymakers in Pakistan, and indeed elsewhere, are faced with today. How can they do more with less: less resources, less authority, less discretion? How can they develop the necessary new models of health system governance with fewer public financial resources and with less direct control over service providers? How can they provide the levels of regulation that a more diffused and diversified health system requires? Put otherwise, what new role for the State in this changing health sector environment?

These questions are contextualized in the experience of more than a decade of healthcare reform (under structural adjustment regime) in Pakistan which has constrained the role of national policy makers. In part, the constraints come from limits on the availability of public funds and growing poverty in the population. But there are also constraints on the ability of national policy makers to act partly because of decentralization to lower public levels of authority and partly to supra-national IFIs.

Constrained as they are, the public policy formulators continue to contend, on the one hand, with issues like: the changes in the epidemiological and demographic patterns, the fast development of bio-technology and communication, the higher demands and expectations of the population and health care professionals, the increasing concern with the growing cost of care and the macro economic changes. And on the other hand, there is a growing tension between the "necessity" to reduce the size of the public services and the demand that health and health care is considered a citizens' right where universal coverage and public funding are the two pillars.

Another, ironic, difficulty for the policy makers arises from the wide spectrum of possibilities and strategies available to them today than ever before. Solutions are available in abundance but, unfortunately, there is no magic formula to lead to the perfect solution. Although more evidence in management is becoming available we are still far away from an "evidence-based management doctrine".

To contain the increasing cost of health services while focusing on equity, accessibility, improved outcomes and efficiency remains an elusive dream today.

1.2 The knowledge divide

There is an asymmetry of knowledge between users (patients and their carers) and providers who are seen as "experts". Because of "ignorance", the patient delegates his demand making role to the 'experts'. If they act neutrally, offering only interventions which are cost effective, resources will be used efficiently.

However, providers, be they doctors, hospital managers or pharmaceutical manufacturers may, because of the knowledge asymmetries, induce demand to enhance their income rather than the health of patients. Traditionally, the Government has been a weak provider and regulator of health care, leaving providers to induce demand and inflate expenditure.

1.3 Evidence based medicine & HTA[1]

At all levels of medical practice there are major variations. These variations may be related to over and under utilization of services and between qualities of care provided across the private-public as well as public-public nexus. These variations in medical practice are, in part, explained by variations in opinion about the appropriateness of many procedures. As most of these interventions have not been evaluated scientifically there is a growing concern about the evidence base in medicine being *poor*.

This problem was emphasized by Cochrane (1972) over a quarter of a century ago and, in the last decade, has been translated into the Cochrane Collaboration - an international network which has begun the enormous task of systematically reviewing the evidence base in medical practices. Much of the work is focused on clinical effectiveness (does the intervention affect health status?) and this facilitates the abandonment of useless procedures.

However, public purchasers need to be concerned about allocating resources on the basis of the patient's ability to benefit (i.e. relative cost effectiveness). This approach would ensure maximization of improvements in population health from available resources and requires that all new health technologies are demonstrably cost effective. Without such evidence they should not be reimbursed. Thus evidence based medicine (EBM) which focuses on clinical effectiveness alone is an insufficient method for the achievement of efficiency. What is required is health technology assessment (HTA), and the adoption of its results, which is focused on cost effectiveness i.e. economics based medicine is the appropriate form of EBM!

[1] Health technology assessment (HTA) is defined as all the methods, used by health professionals, to promote health, prevent & treat disease and to improve rehabilitation and long term care (Dept of health NHS UK 1994). These methods include "hardware" such as syringes, medicines and diagnostic equipment etc, and "software" as health education, diagnostic & therapeutic policies/procedures as well as skill of people involved in the profession.

1.4 The societal context

Health systems in Pakistan, as any where else, are strongly influenced by the underlying norms and values of the broader society. Health care services thus are mirrors that reflect the deeply rooted social and cultural expectations of the citizenry as a whole. These fundamental values while generate outside the formal structure of the health system, are responsible for the system's overall character and capacity.

In the societal construct of heath care system, health providers are the "agents" of society in interventions for patients and there exists a social contract based on trust between the providers and society. In Pakistan this trust is eroded by the general failure of providers to evaluate their practices and practice EBM. As explained above, the causes of these problems are related to the knowledge divide, perverse incentives and the absence of a framework of accountability for the use of patients' and public funds. At the macro policy level, there is a growing reference made in Pakistan to the health care reform debate in the world today which revolves around the moral imperative of maintaining health as a social good. However, addressing these problems at a societal level is not easy as the society at large has had little to do with defining the very *evidence base* in this regard.

In this background it should not be surprising that private and public decision makers operate, and reform, their systems of health care with much emphasis on rhetoric and opinion. Little reference is made to whether the services, and changes in them, facilitate the achievement of policy goals such as cost containment, efficiency and equity. The paternalistic arrogance and ignorance of such decision makers is matched by the same qualities in health providers who emphasize importance of, and demand, total clinical freedom i.e. the freedom to practice inefficiently.

While the evidence base to inform the design of efficient systems of accountability remains poor as it is, perhaps it is high time that the society invests in evidence based decisions making. This will ensure that the policy makers and practitioners keep up-to-date in terms of knowledge about changes in technologies as well as be proficient in manual tasks and counseling/dealing with patients.

1.5 Understanding HTA

The most frequent activity in HTA is assessment of efficacy and cost effectiveness i.e. analyzing the benefits and financial costs of a particular technology or a group of technologies. The main objective of such an exercise is to improve "value for money" in health care without compromising standards of care and is mainly used as an input for policy decisions. However, HTA takes a rather broad view of technology and technological changes - analyzing the situation from a number of perspectives. These include ethical, social, economic, efficacy, effectiveness, equity, acceptability and a variety of other factors which may have an impact on the outcome of technology

under question.

HTAs can be of many kinds and types ranging between a wide variety of technological issues and questions e.g. assessment of a medical device carried out by a regulatory body, an ethical analysis concerning cloning or gene therapy, assessing the usefulness of routine chest X-Ray or Urine RE before administering general anesthesia. In order to illustrate the more comprehensive form of the process of HTA let us consider that policy makers in the government are faced with questions like whether or not there should be a public offer of influenza vaccination of the elderly? An HTA exercise would start by first changing these "policy questions" into specific "HTA questions" and then finding appropriate answers to them. The process to follow would comprise of forming a multidisciplinary team which will further specify the questions and critically review the literature on the topic, looking closely to measure different aspects of the technology, from the patients' and society's health, social and economic aspects.

The HTA result would come out with a verdict of "effective" or "ineffective" keeping in mind all the factors for the technology in question i.e. in this case, vaccination of the elderly against influenza virus. The process of HTA, however, does not complete here. The work is not finished without the diffusion and/or translation of the results into a practice informed by the outcomes of the process. The implementation and impact assessment is, therefore, an integral part of every HTA.

The difference between HTA and pure research must also be kept in mind. Research done solely for the purpose of increasing scientific knowledge is not HTA. Although new studies may be conducted in HTA but in majority of cases existing information is utilized. It may be safe to say that HTA is not simply a discipline in itself but also an interdisciplinary process based on systematic scientific evidence and information. People from various fields like clinicians, public health specialists, social scientists, epidemiologists, statisticians, economists, engineers, consumers and ethicists are a few among the long list of role players.

1.6 Methodological issues in HTA

If the information emanating from the appraisal is to be reliable and comparable with other work, it must be arrived at through a clear and consistently applied methodological framework. Although the term *health technology assessment* (HTA) has come to be used to describe the systematic process of evaluating the impact of new or current practice on the objectives set for this practice, there remain a number of issues to which the practitioners, and users, of the discipline must be fully cognizant.

The HTA discipline can, in principle, be applied to a wide range of healthcare 'interventions', including medical, surgical and other clinical techniques, drugs, equipment and devices, methods of healthcare delivery (for example, homecare, minimally invasive surgery, ambulatory surgery and so on) healthcare policies and reform initiatives. For this reason, the techniques involved in HTA have a clear and

obvious utility in informing capital investment decisions. The initial stages in HTA in all of these areas will be common:

- Definition of the health technology to be appraised, in particular, the definition of its objectives;
- Context analysis;
- Search and review of the available evidence.

A 'technology' can only be assessed in terms of its contribution to meeting pre-specified objectives. These may relate *inter alia* to need, safety, efficacy and/or effectiveness, appropriateness, equity, efficiency and so on. The choice of the objectives for a technology defines, in turn, the data required for assessment and, to some extent, the methodology employed for the assessment. This insight can, of course, be readily generalized to all appraisal contexts. However, it is clear that the objectives of healthcare assessment projects are often *not* adequately specified. One of the principal ways, therefore, in which external scrutinizers can add value to projects is in demanding the clearest possible indication of what projects are designed to achieve (and as a corollary, what data and analysis will be necessary to judge whether the project has been successful in these terms).

It is argued that all HTA projects must be set firmly within the economic, social, cultural and political context, and sometimes also within a moral and ethical context. This 'contextualization' is the process of moving from the assessment of efficacy (impact under experimental conditions) to the assessment of effectiveness (impact under 'every day' conditions). This distinction is, perhaps, most clearly seen in the assessment of the impacts of new drug therapies. A drug may prove to be highly efficacious under controlled experimental conditions (for example, where patient compliance is actively and successfully managed) but highly ineffective in 'every day' patient situations. For example, a given technology might require radical change in patients' daily routines – without proper assessment of this 'context', the potential benefits of innovation may be over-stated.

There are numerous parallels with other types of health technology. The maximization of the use of 'day case' surgical techniques may prove highly effective in some contexts but ineffective in others. For example, economic and/or social poor may not be suitable for this kind of surgery. In this case, investments in day case facilities may fail to deliver the expected benefits because of extended hospital stays which are socially, even if not clinically, indicated.

The general conclusion is that no investment decision can ever be viewed independently from the social and economic system in which it takes place. Overall resource constraints are a consistent feature of the economic context, but the nature of healthcare investment is such that there are inevitably 'knock on' implications. For example: the decision to save system costs of excess bed occupancy by early discharge policies can have a direct negative impact on home care costs for the economic and social poor. Another example is the impact of a policy of running down in-patient psychiatric facilities on relatives and other carers.

Appraisals which purport to take account of the full social impact of investment decisions cannot ignore these important contextual aspects. This is equally important in the case of investments which represent an entire program of expenditure across a country or region.
In the developed world, there has been much progress in HTA where use of economic evaluation techniques has moved from the purely academic to much more regular application amongst health service professionals, managers and administrators. However, notwithstanding the accelerating use of these techniques, the proportion of healthcare interventions which have been subject to high quality appraisal remains small.

1.7 HTA in Pakistan

Systematic HTA is new to Pakistan. Some effort has been done in this connection under the HTA Forum during the last couple of years but it as been inconsequential so far as it has not had an effect on either the policy or the practice. Need less to say that there is a lot of scope though. However, the problems related with availability of information, financial and professional resources are important considerations.

Whilst the 'information revolution' brought about by the information and communication technology may have transformed the customer and the provider experience in service industries (e.g. travel and banking), access to timely, reliable and meaningful data in the healthcare sector continues to be problematic. Even the most cursory scan of health system data in Pakistan demonstrates the nature of the problem. Virtually all of the indicators undergo significant variations between sources.

In Pakistani context, therefore, it could be argued that instead of undertaking large HTA projects it would be prudent to adopt and adapt evaluations done elsewhere with a full analysis of the context. It is quite clear from above discussions, however, that any mechanistic transfer of findings from another context to here will only mislead.

Perhaps the best scope of HTA in Pakistan lies in the area of medicines' assessment. We can take heart from the fact that the best HTAs so far have been in the area of medicines starting as early as 1930s and 1940s involving drugs such as penicillin, sulfonamides, antimalarial drugs, and antituberculosis drugs. New medicines come on the market on daily basis – medicines which have the ability to transform side effects from the traditional individual physical level to a societal level in the form of economic, political and ethical consequences.

HTA's success in medicines is perhaps due to the fact that medicines are by far the most regulated medical technology today and that more information is available on their efficacy and safety than of any other technology. But, we have to be fully cognizant of the need for development and improvisation because of the ever burgeoning body of knowledge about hitherto undocumented side effects experience with today's and, perhaps more so, with tomorrow's drugs.

For their contribution to health care costs and as a technology whose risks, benefits, and cost-effectiveness must be considered carefully, the fact can not be overemphasized that medicinal drugs must be accorded much more attention in Pakistan than they presently get. It can only be done through an organized system for HTA carried out under the supervision of drug

registration and regulatory agencies.

1.8 Clinical Practice Guidelines[2] and HTA

HTA also has a role in providing the evidence base for the drawing up of clinical practice guidelines (CPG). There have been instances where CPG have been derived from HTA, effectively translating policy to practice. The current trend is to have CPG based on evidence taking into account local practices and constraints. Here too, CPGs for Pakistan can be drawn up based on CPGs done elsewhere, adapting them to suit the local needs.

CPGs are advocated to decrease practice variation, slow down the rate of rise of healthcare costs and monitor inappropriate practices for reasons of transparency and accountability. CPGs are also promoted in the context of the fact that doctors have a proven difficulty in staying ahead of knowledge advances in the art and science of caring for the sick. According to studies the estimated average reading time per week is as follows: medical students: 1½ hrs; house officers and medical officers: almost nil; average clinician <30 min.

The It is interesting to also have a look at the theoretical basis CPGs and the political and cultural issues and debates surrounding them.

Doctors accumulate an *idiosyncratic* knowledge of medicine through a deductive reasoning process of distilling experiences into values that guide their future treatment of patients. This knowledge is passed on to their colleagues in ways both informal (e.g., lunchroom conversations) and formal (e.g., teaching in the medical colleges, ward rounds, conference presentations, journal articles, etc.). There is a body of evidence to prove that doctors generally are strongly inclined to hold to their idiosyncratic views, even in the face of strong contrary research evidence.

Then there is this growing breed of *technocratic* doctors who collect data from entire populations, crunch the numbers, and express their conclusions as to what works best in terms of population-wide statistics. Their “evidence based” methodology is more quantitative and, on the surface, at least, more objective than medicine's traditional way of assessing the effectiveness of health care, that is, by cumulating the qualitative observations of individual physicians based upon their experiences with individual patients.

Unfortunately, the two kinds of doctors are pitched against each other some times in a contest – the contest between the subjective judgment of individual professionals derived from and applied to case-by-case experiences and across-the-board rules distilled by health services researchers from "large *n*" studies. It is also a contest between professional discretion and "cookbook medicine," between the "art" of medicine and cold, hard science.

[2] Systematically developed statements based on best evidence that assist practitioners & patients in making decisions about appropriate health care for specific clinical circumstances (Institute of Medicine, 1990)

"To know the road ahead, ask those coming back" - Chinese proverb

2. Conclusions & recommendations

The main consensus reached at the end of the workshop in Bhurban was quite clear, as follows:

> *"HTA must be started in Pakistan urgently and earnestly with a stronger, wider and sustainable institutional arrangement ensuring participation of the governmental (federal, provincial and perhaps also local) and professional bodies and agencies, as well as national and international non-governmental resource agencies*."

Some of the salient recommendations were:

- The future HTA institution in Pakistan should work closely with the government as the main beneficiary and user of HTA. However, it must remain independent to maintain the spirit and initiative.

- While donor funding should be sought for the future institutional needs, the existing sources of financial and institutional supports should be secured to continue.

- Efforts should be made for capacity building of potential assessors and HTA resource persons in Pakistan. Activities (seminars, workshops, lectures etc) should be planned on regular basis to promote HTA in Pakistan.

- Linking HTA with the newly formed Health Policy Unit at the MoH will be a preferred strategy and HTA Forum should explore the ways means to do that.

- Linkages with the international HTA bodies (e.g. HTAi, Cochrane Collaboration, INHATA, NICE etc) should be actively sought.

- In the absence of strong public systems, committed and resourceful individuals' support within the public sector institutions becomes important. HTA Forum should actively work for identifying such individuals and link up with them.

- Efforts should be made to have provincial cells of HTA where appropriate persons should be actively identified and involved.

- College of Physicians & Surgeon can be a very important strategic ally and should be asked to be involved as an important player.

Recommendations

- HTA pushers (i.e. HTA Forum) need to include key people as ambassadors of this cause to market the need and potential benefits to the stakeholders i.e. Government, civil society, academia, professionals, private sector.

- HTA practice in Pakistan should be aimed in the beginning at answering the "hot" issues which would help getting noticed and gather recognition. Also this should be kept in mind that if there is no implementation of the HTA reports then it defeats the purpose and therefore choice of issues and priorities must be driven by this consideration.

- The most important contribution of HTA in Pakistan is considered to be in the area of drug control i.e. registration, procurement and regulations of the drugs sold in the country.

- Procurement of new equipment in the government sector is also an important area where the HTA report should be used to make the decision about the need as well as the choice of technology. There is also a definite role of HTA in evaluating the registered drugs and installed equipment in health facilities.

- CPSP should be asked to undertake the work of preparing clinical practice guidelines in Pakistan with help and support from the HTA Forum.

- CPSP may also be approached for the adoption of HTA in its courses like hospital administration. PMDC and teaching institutions like AHU and HSA should be approached for inclusion of HTA in their curricula.

- HTA Forum should have its own publication. Besides, possibilities should be explored to dedicate some pages of journals like PIMS Journal of Surgery and others to HTA related work.

- Email based communication network of HTA in Pakistan should be started. HTA Forum should also actively participate in the regional (developing countries) ad international forums.

- The focus of HTA must remain on the ultimate consumer, the patient, and his/her welfare must be central to all the discussions.

Seminar – 12th February

MCH Center auditorium, PIMS, Islamabad

Inaugural Session – Chaired by Dr. S. Fazle Hadi, Executive Director, PIMS

Welcome address……..	*Dr. Assad Hafeez, HTA Forum Coordinator*
Need & Use of HTA……	*Dr. Itziar Larizgoitia, WHO, Geneva*
Key note address……..	*Dr. Fazle Hadi, Chairman*
Vote of thanks……...	*Dr. Tanwir Khaliq, PIMS*

Technical Session # 1 – Chaired by Dr. Abdul Majeed Rajput, Chief, NHPU

Introduction to HTA……	*Dr. Alicia Granados, CAHTAR, Spain*
Global perspective on HTA…….	*Dr. Itziar Larizgoitia, WHO, Geneva*
HTA in Pakistan……...	*Dr. Assad Hafeez, HTA Forum Coordinator*
HTA in hospital practice……	*Dr. Tanwir Khaliq, PIMS*
HTA in diagnostics……..	*Ayyaz Kiani, TheNetwork*
HTA in mental health……..	*Dr. Waquas Waheed, UK*
Telesurgery – a new technology……..	*Dr. Asif Zafar, Rawalpindi Medical College*

Discussion……...

Remarks by Chair…….

Lunch

Technical Session # 2 – Chaired by Dr. Abdul Majeed Rajput, Chief, NHPU

National Health Policy in Pakistan……	*Dr. Talib Lashari, TheNetwork*
Linking HTA with National Health Policy…….	*Dr. Zafar Mirza, TheNetwork*
Challenges in setting up national HTA program……..	*Dr. Alicia Granados, CAHTAR, Spain*
Where to start – how to set priorities…	*Prof. Ghazala Mehmood, PIMS*

Discussion……...

Remarks by Chair…….

Programme

Workshop – 13th -14th Feb.

Pearl Continental Hotel, Bhurban

Day One

HTA Concept……..	*Dr. Alicia Granados, CAHTAR, Spain*
Techniques for retrieval of evidence and critical appraisal……...	*Dr. S. Sivalal, Malaysia*
Critical appraisal…….	*Group exercise – Dr. S. Sivalal*
Literature search…….	*Group exercise – Dr. S. Sivalal*

Day Two

Recap of day one……..	*Dr. S. Sivalal*
Synthesis……	*Dr. S. Sivalal*
Clinical practice guidelines…….	*Group exercise – Dr. S. Sivalal*
HTA in Malaysia……..	*Dr. S. Sivalal*
HTA critique…….	*Dr. S. Sivalal*
Conclusion and recommendations……..	*Dr. Aslam Shah, Dr. Itziar Larizgoitia, Dr. Assad Hafeez, Ayyaz Kiani*

- ***Introduction to HTA ……..(Dr. Alicia Granandos)***
- ***HTA in Pakistan……. (Dr. Assad Hafeez)***
- ***HTA in Hospital Practice……. (Dr. Tanwir Khaliq)***
- ***HTA in Diagnostics…….. (Ayyaz Kiani)***
- ***Critical Appraisal of Literature... (Dr. S. Sivalal)***
- ***Participants' Lists***

Introduction to HTA: Dr. Alicia Granados

HTA : a tool for better decision making

Islamabad February 2004

Dr. Alicia Granados
CAHTAR and Associate Professor
University of Barcelona

OUTLINE

Health Technology Assessment:
- WHY?
- WHAT?
- WHO?
- HOW?
- AND THEN WHAT?

Health Technology

- Instruments, equipment, procedures, and drugs used in prevention, diagnostic, treatment and rehabilitation of health conditions.
- Modes of interventions including delivery facilities, financing systems and infrastructure characteristics affecting health services and health technology use.

WHY?
Factors influencing the introduction and diffusion of HTs.

- The characteristics of HTs themselves.
- The country context.
- The role of HTA.

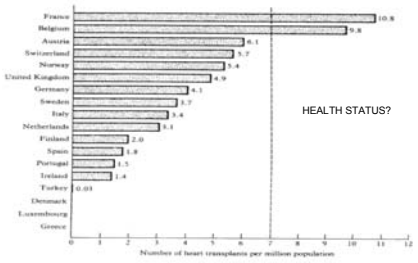
Factors influencing the diffusion of HTs.

The characteristics of HTs themselves:
- the relative advantage (assumed or proved) over its comparators.
- complexity.
- observability.
- triability

Factors influencing the introduction and diffusion of HTs.

The country context:
- country's health status?
- country wealth?
- social values?
- regulation?
- clinicians?
- health care providers (hospitals, others)
- commercial interests?, market protection?
- mass media?
- financial incentives?

Heart transplantation rate in European countries 1988



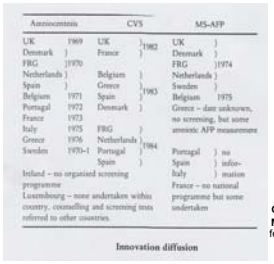
HEALTH STATUS?

Age- & sex-standardized surgical rates per 100,000 population in the US, Norway, and UK

	US	Norway	UK
Hernia repair	276	186	137
Appendectomy	128	150	177
Cholecystectomy	238	86	89
Prostatectomy	264	236	132
Hysterectomy	540	118	220
Hemorrhoidectomy	76	45	28
Tonsillectomy	289	64	172

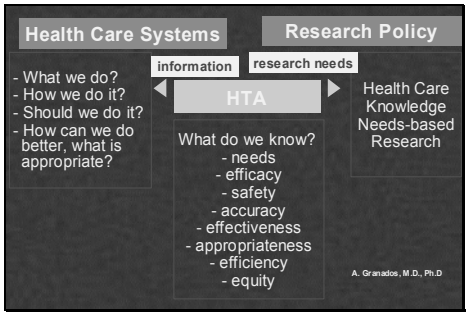
McPherson K, Wennberg JE, Hovind OB, Clifford P. Small-area variations in the use of common surgical procedures: an international comparison of New England, England, and Norway. N Engl J Med 1982; 307:1310-1314.

Introduction of prenatal screening technologies in European countries



CLINICIANS?
REGULATION?
SOCIAL VALUES?
COMERCIAL INTEREST?

CVS: chorionic villus sampling
MS-AFP: maternal serum alpha-fetoprotein screening



Why do we need HTA?

- To inform choices in health care
- To enhance quality of health services
- To contain rising health care costs
- To create travelling opportunities for assessors?

Health System (WHO 2000)

- All the activities whose primary purpose is to promote, restore or maintain health

www.who.int/en/

Goals of Health Systems

- Respond to people's health needs and expectations by providing high quality essential services on the basis of efficacy, effectiveness, cost and social acceptability.
- Provide financial protection against the cost of ill-health
- Improve the health of the population it serves

Ultimate Aim of HTA…..

- Potentiate the capacity of a health system to reach its goals.

"Technical information needed by policy makers is frequently not available, or not in the right form. HTA identifies policy issues, assess the impact of alternative sources of action and presents findings"

U.S. Congress, 1967

Some Pioneers

- United States: OTA (Office of Technology Assessment)1972
- Creation of ISTAHC 1985.
- Europe:
  - SBU (Swedish) 1986
  - CAHTA (Catalonia, Spain) 1987

The 90's Consolidation, expansion and international collaboration

- America 3
- Europe 8
- Australia1
- Middle East 1
- Asia 2
- INAHTA (International Networking of Agencies for Health Technology Assessment)

HTA in 2000+

- HTAi (ww.HTAi.org)
- HEN (www.who.dk/HEN)
- EU : Public Health Priorities

INAHTA

1993……6 Agencies

2004……42 Agencies

>30 Years of Health Technology and Medical Practices Evaluation All Over the World:

From Expert Opinion to a Global Movement for Scientific Evidence....

HTA

Is part of an intellectual, scientific and professional movement promoting the utilisation of the results from scientific research for decision making in health care (from the practice of clinical medicine to health care policy).

Approaches to HTA

- Health Technology Assessment (HTA), Health Services Research (HSR), Outcomes Research (OR), Evidence Based medicine, (EBM), clinical management and disease management (DM), among others, are some of the names given to similar approaches

- "The approaches are determined by the different emphasis given to the use of the existing sources of scientific evidence, as well as by the choice of the best evidence available to inform **decisions in health care"**.

A. Granados. International J. of Technol. Assess. in Health Care 1999

Dimensions evaluated

Health effects
Relative Cost
Values

Specific parameters

- Technical properties (technical efficacy) and safety.
- Clinical efficacy/ effectiveness.
- Efficiency (Cost-consequence)
- Impact on health system: health-related, organizational and economic
- Social acceptability (ethical and social aspects)

WHO?

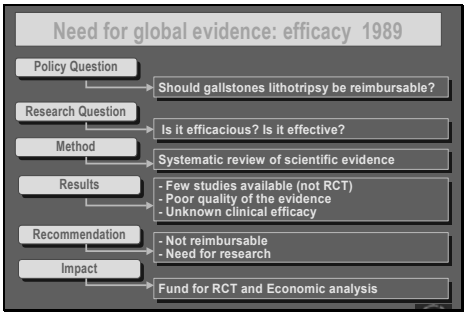
- Who does HTA and who uses it?

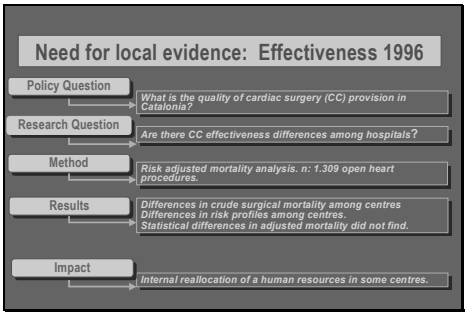
Doers:
Universities
Consultancies
Government and Governmental agencies

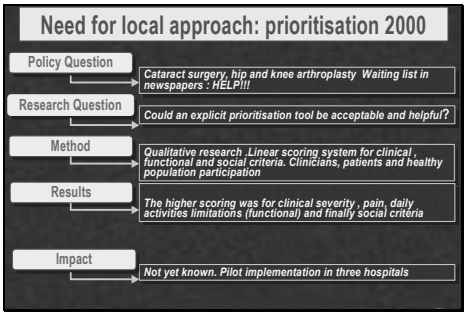
Users:
Clinicians
Managers
Policy makers

Health Technology Assessment (HTA) Process

- **Identification & prioritisation** of HTs or health problems in need of assessment.
- Translation into **adequate research questions** *(Needs? Efficacy? Safety? Effectiveness? Appropriateness? Equity? Efficiency?*
- Search, review, synthesis or production of **scientific evidence**
- Analysis of **context**
- **Recommendations** for public or professional decision-making (*public health strategies, clinical practice guidelines….)*
- **Dissemination** of the findings of assessments
- Promote the **implementation of findings** in policy and practice
- Analysis of **impact**





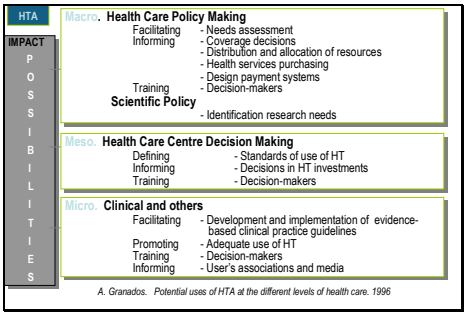


HOW?

- Scientific capacity
- Rigour and quality
- Dissemination and training
- Resources
- Networks

AND THEN WHAT?

- Knowledge translation
- Receptor capacity
- Incentive mechanisms
- Culture of assessment
- Public debate



A. Granados. Potential uses of HTA at the different levels of health care. 1996

HTA has a great potential for:

- **Assess the effectiveness of care.**
- **Improve the quality of health care provided.**
- **Reduce variability of clinical practice.**
- **Improve the efficiency of health care.**
- **Introduce scientific evidence into practice.**
- **Foster medical education and patient education.**
- **Improve the diffusion and adoption of effective technologies.**
- **Enhance equity.**
- **Enhance transparency and accountability of decisions.**

"Bringing about effective change in health care practices is not straightforward and there are no panaceas or "magic bullets"
Oxman et al. 1995

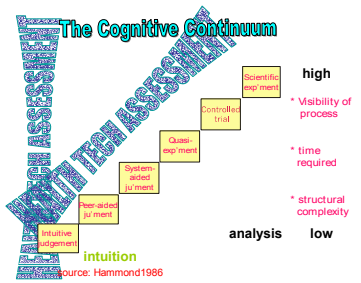
Technology Assessment might not be the "magic bullet" to solve all health care problems, but it might be the best possible solution if appropriately used

HTA in Pakistan: Dr. Assad Hafeez

DR ASSAD HAFEEZ

FCPS, MRCP, FRCPCH, MSc Epidemiology
Coordinator HTA Forum Pakistan

- 60-90% of all therapeutic injections are not necessary
- Are tonsillectomies really helping the patients
- Diagnostic aids like ultrasounds and x-rays are being misused, at various levels.
- Introduction of a new vaccine in EPI. Who decides & how ?
- Which particular equipment/technology should be bought by a new hospital, for it,s I.C.U.



Health Technology Assessment (HTA)

All the methods used by health professionals to promote health, to prevent & treat disease, and to improve rehabilitation & long term care.

These include **"HARDWARE** such as syringes, drugs, diagnostic equipment e.t.c. and **"SOFTWARE"** as health education, diagnostic & therapeutic procedures, as well as skills of people involved in the profession.

Purpose of HTA

- **Health care provider institute**- to decide which technologies to acquire or adopt.
- **Health care payers** - to determine what technologies to cover & to what extent.
- **Health care product manufacturers** - to decide what products to develop.
- **Physicians** - to decide the appropriate interventions for particular health problem.

Methodology

Factors

- Equity or Access
- Acceptability
- Ethical issues
- Safety
- Efficacy
- Others (Legal, political, social)

Ineffective technologies after wide diffusion

- Thalidomide for sedation in pregnant women
- Gastric freezing for peptic ulcer disease
- Bottle-feeding instead of breast-feeding for infants
- Silicone breast implants

ACUTE LOW BACK PAIN

(Case Study)

Technology	Effectiveness
• Bed rest	Ineffective
• Massage	Ineffective
• Short-wave Diathermy	Ineffective
• Ultrasound	Ineffective
• Acupuncture	Ineffective
• NSAIDS	Effective
• Continued activity	Effective

Reference: Back Pain Neckpain, An evidence based review Systematic review by SBU 2000

Scenario in Pakistan

- No concept of HTA
- Shrinking resources with rising costs in healthcare
- Push & Pull of manufacturers
- Vested interests
- Ambiguous policies
- Rapidly emerging technologies
- Existing obsolete technologies
- Interests of private sector in healthcare
- Others

- **HTA Forum Pakistan**
  - **2001**
  - **Group of concerned professionals**
  - **Managers, clinicians, public health spts, allied fields**

1. Create awareness
2. Sensitize providers & users
3. Informed users
4. Develop a methodology according to our requirements

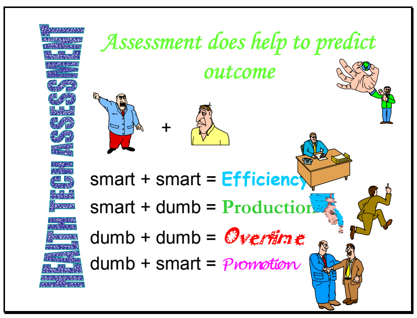
- **Meetings**
- **Guest speakers**
- **Priority settings exercises**
- **HTAs**
- **Cost analysis**
- **National and international workshops**
- **Publications and papers**
- **Liaison with international agencies**

HEALTH TECH ASSESSMENT

- Misuse of diagnostics
- Equipment procurement
- Misuse of therapeutic techniques
- Unnecessary injections
- Others

HEALTH TECH ASSESSMENT

- Routine pre op CXR
- Routine pre op Investigations
- Circumcision
- Ultrasound & Diagnostics
- CT scan for abdo malignancies



HTA in Hospital Practice: Dr. Tanwir Khaliq

Health Technology Assessment (HTA)
in hospital practice

Tanwir Khaliq
FCPS FRCS
ASSOCIATE PROFESSOR OF SURGERY PIMS ISLAMABAD

HEALTH TECHNOLGY ASSESSMENT (HTA)

- HTA is a policy research approach that examines the short and long term consequences of the application or use of technology

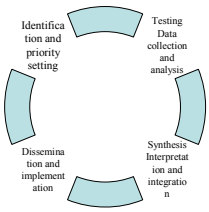
A BETTER HEALTHCARE SYSTEM

- Aetiology and pathogenesis of disease, conditions for the maintenance of good health
  Basic science and epidemiology
- Organisational optimisation of healthcare services
  Health Services Research
- Evaluation of health technologies
  Health Technology Assessment
- Translation of basic sciences and technologies into applications for healthcare

Focus areas of HTA in hospital practice

- 1. TECHNOLGY (CILINICAL EVIDENCE)
- 2. ECONOMY
- 3. PATIENTS
- 4. ORGANISATION

HTA Cycle



Objective.

- Appropriate use of existing and new technologies in terms of

safety,efficiency,effectiveness,accessbility, and equity providing input to decision making in policy and practice

Goals in hospital practice

- To improve the quality and cost effectiveness of health care
- Discouraging the use of health technologies of little or no additional value
- Encouraging the technologies that improve value for money

Population below poverty line:
35% (2001 est.)
GDP - per capita:
US$ 492
Health Budget 0.7 % OF TOTAL BUDGET

Areas.

- There are tens of thousands of health technologies but to date only a fraction of these have been evaluated
- Specialties medical ,surgical
- Diagnostics radiology, pathology
- Operating theatres
- Outpatients
- Medical treatments
- Drugs
- Procedures

AREAS (con'td)

- Surgical procedures
- Endoscopies
- Follow up
- And preoperative routines
- antibiotics
- TPN
- VENTILATORY SUPPORT IN ICU

NEW TECHNOLGY

- LAPAROSCOPIC SURGERY
- ENDOSCOPIC PROCEDURES
- MRI ,CT SCAN, MRCP
- Interventional cardiology
- Telesurgery
- Robotic surgery

PREOP ROUTINES

- Hb
- ECG
- X-RAY CHEST
- ELECTROLYTES
- UREA / CREATININE

Preoperative chest x-rays in elective surgerical patients below the age 40 years

- Time consumed during routine x-rays **1 to 3 hours (mean 75 minutes) FOR INDOOR PATIENTS ONLY**
- Cost : (direct cost of x-rays film) **90 Pak Rupee = 1.5 US Dollars**
- **MANPOWER,HOSPITAL EXPENSES NOT INCLUDED**
- K Tanwir et al 2003

Results

Group 1

- Asymptomatic cases 373
- Normal x-rays 371
- Abnormal x-rays 02
- DIAGNOSIS- *TB (Healed) 2

Conclusion

- *A routine chest x- rays in patients below the age of 40 undergoing elective surgical procedures is unnecessary and does not alter the surgical plan.*
- *It causes an extra burden not only on the patient's finances and health but it also abuses health technology and overloads the radiology department.*

CT SCAN IN ADVANCED ABDIMINAL TUMOURS

- CT scan done in advanced abdominal tumours where ultrasound has confirmed the extent of the disease is an ineffective technology as laparotomy or laparoscopy is necessary to confirm the diagnosis or do some palliative procedure.

LAPAROSCOPIC SURGERY

- Cholecystectomy an effective technology
- cost effective, patient satisfaction, short hospital stay
- Hernia repair ineffective technology for the primary unilateral hernias
- cost, hospital stay, patient satisfaction
- (NHS,NICE UK report

ANTIBIOTIC PROPHYLAXIS

- Cost very high but when compared with the treatment of an established infection it is an effective technology
- Streamline and develop hospital based antibiotic policy both for prophylaxis and long term treatment for established infections. It should involve clincians,pathologist and administrators.

RESEARCH

- Research to look at conditions for the establishment and maintenance of good health.
- Research on the wider causes of poor health; poverty, diet, inequalities of access to services etc.

HTA ??

- GENETICS
- CONGEITAL ANOMALIES
- SPINA BIFIDA AND MENINGOMYELOCOELE
- GENE THERAPY
- ONCOGENES

Whom to address

- ETHICAL ISSUES BASED ON
- *COMPARATIVE AND EMPIRICAL APPROACH*
- Should be addressed to

1. Decision makers in health policy
2. Policy makers
3. General public

SUMMARY

- HTA is new in the healthcare system of Pakistan.
- Needs careful and slow implementation in hospital practice
- Training HTA experts in hospital practice
- Integration of clinicians in assessing and choosing technology.

HTA in Diagnostics: Ayyaz Kiani

HTA in Diagnostics

"Diagnostics Effectiveness Study at Metropolitan Corporation Lahore" *

Health Technology Assessment Seminar
Islamabad, 12 February 2004

Ayyaz Kiani
Deputy Executive Coordinator
TheNetwork for Consumer Protection

* Garner P, Kiani A, *Diagnostics in Developing Countries – time for an essential diagnostics program*, BMJ 1997, 315:760-761

Diagnostics Effectiveness Study

- Study commissioned by MCL's donor to review impact of diagnostic equipment at 12 primary health facilities of MCL to decide whether further such investment was justified
- 9 of them designed for general practice and conduct X-rays and lab tests ("diagnostic clinics")
- 3 were provided additionally to conduct U/S and specialist visits ("filter clinics")
- Qualitative and quantitative data collected (fact sheets) on pre-specified criteria at four levels: system, center, equipment, patient
- Findings/recommendations discussed with key MCL stakeholders before submission of report
- Report resulted in influencing the policy decision
- BMJ's editorial strongly supported broader implications and recommendation made in the study

Findings

- All 13 centers had labs, microscopes, and technicians. Only 2 carrying out any tests
- All centers had X-rays. No evidence of impact on patient outcomes
- Most X-ray scans referred from private GPs
- Safety for staff and patients not observed
- Average cost (Rs. 515) of X-ray scan >4 times the market rate
- Cost of X-ray provision (Rs 2.26 M) across centers >2 times that for drugs
- U/S used where unlikely to diagnose or alter treatment
- Cost (Rs160) >3 times the market rate
- Fetal sex determination with at least one case of abortion recorded

Findings (contd.)

- No system of equipment management and quality assurance.
- Drug supply at half of the centers was poor, doctors did not follow nationally accepted standards of Rx for two common child conditions
- Doctor absence and general staff demotivation rampant
- Patient through put low
- Low specialist visit, no referral system or integration with provincial health dept facilities
- There is no significant "consumer lead" demand for investigations. Emphasis on tests is "doctor lead".
- Medical equipment companies' promotion is likely to have a strong influence on decision makers

Results

- Study provided a useful opportunity to make informed decision
- The audit showed that the equipment is:
  - Inappropriately placed at this level
  - Ineffectively used
  - Highly costly at the level of utilization
  - Having no +ve impact on health of the users
  - Potential existed for improving outcomes in some cases (eg fractures, TB) but no matching clinical services were provided

Recommendations

- Further up gradation of services should not be supported
- Provision of drugs at the centers is likely to improve utilization levels
- Health managers at municipal level should:
  - Urgently review safe practices of X-rays
  - Introduce a policy of effective clinical practice
  - Establish equipment maintenance system
  - Improve human resource management (which would require substantial institutional reform)
  - Establish a system of referral with provincial centers

Conclusions

- This audit highlights an important planning issue concerning the limited potential effectiveness of diagnostic equipment supplied in PHC in Pakistan.
- Given the level of government investment in equipment purchase, the findings of this work have wider relevance, and could form the basis of further HTA work.
- This should be in collaboration with health policy personnel to help form policy guidelines for a "Rational Diagnostics Program"

HTA in Diagnostics: Some Suggestions

- Besides systematic review methodologies, HTA discourse should also actively include development of "audit" protocols for installed technologies
- Standardized "Audit-Feedback" mechanisms developed on the lines of Essential Drugs Program will greatly help micro level policy and management decisions
- HTA methodologies need to be simplified and standardized to be more accessible especially in the developing countries

Critical Appraisal of Literature: Dr. S. Sivalal

CRITICAL APPRAISAL OF LITERATURE

2004-03-26

INTRODUCTION

- Critical appraisal – important component in evidence based medicine
- Studies vary widely in quality

2004-03-26

INTRODUCTION

"Some (perhaps most) published articles belong in the bin, and should certainly not be used to inform practice"

Alkman DG

(The scandal of poor medical research. BMJ 1994; 308:283-284)

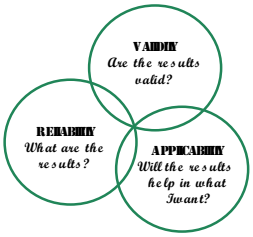
2004-03-26

WHAT IS CRITICAL APPRAISAL?

- Determination of validity & applicability of
  - *clinical data, epidemiological data & other published data*
  - *by application of rules of evidence*
- Focus on quality of evidence
- Critical appraisal can only be done with full articles

2004-03-26

WHAT ARE THE ASPECTS ADDRESSED?



2004-03-26

VALIDITY

- "truthfulness" of the information
- criteria must be looked at before an extensive analysis
- study not valid – data may not be useful
- evidence that supports validity -study methodology (internal validity)
- examine the results
- applicability to patients

2004-03-26

DIFFERENCE BETWEEN READING & APPRAISAL

- Appraisal increases the effectiveness of reading
- Critical appraisal enables
  - *exclusion of poor quality papers*
  - *systematic evaluation of good papers to extract salient points*

2004-03-26

WHY CRITICAL APPRAISAL?

- results of published literature are not necessarily valid
- even studies published in peer reviewed journals prone to errors
- one study estimated the possibility of 40% errors.

2004-03-26

OBJECTIVES OF CRITICAL APPRAISAL

- to identify strengths & weaknesses in published papers
- develop better understanding of research methodology
- understand the meaning of relevant technical terms
- foster confidence in analyzing literature

2004-03-26

WHAT COULD GO WRONG

- Bias – conscious or unconscious
- Misinterpretation of information
- Unintentional errors
  - *influence of experience, background, personal beliefs*
- Chance - *random error: eliminated by statistical analysis – p value, confidence interval*

2004-03-26

BIAS

- systematic deviation from the truth – distorts the results of the research
- "to err (be biased) is human……."
- check always – sensitivity analysis
- avoid if possible
- correct if unavoidable

2004-03-26

TYPES OF BIASES

2004-03-26

SELECTION BIAS

- Systematic differences between comparison groups in prognosis or responsiveness to treatment
- *Randomization of large number of patients with concealment of their allocation to different groups*

2004-03-26

MEASUREMENT BIAS

- Systematic differences between comparison groups in how outcomes are ascertained.
- *Blinding of study participants & outcome assessors*

2004-03-26

CONFOUNDING BIAS

- Systematic difference between comparison groups in terms of other factors – age, sex, smoking rates
- Case control studies
- *Ensuring approximately equal number of confounding variables in each group*
- *Individual matching*

2004-03-26

PERFORMANCE BIAS

- Systematic differences in care provided apart from the intervention being evaluated
- *Standardization of care protocol*
- *Blinding of clinician & participants.*

2004-03-26

ATTRITION BIAS

- Systematic differences between comparison groups in terms of withdrawals or exclusion of participants from the study sample
- E.g. side effects of the intervention
- *Inclusion of such participants in the analysis*
- *Combined with sensitivity analysis*

2004-03-26

PUBLICATION BIAS

- tendency for studies with positive results only to be published
- other biases - country, author etc.
- relevance of gray literature
- importance of hand-searching non-peer-reviewed journals

2004-03-26

STEPS IN CRITICAL APPRAISAL

- skim reading to get flavour
- analyze more slowly by screening before closer scrutiny:
  - *is a clearly focused issue addressed?*
  - *randomization in assignment of patients?*
  - *proper accounting of all patients at end of trial?*

2004-03-26

...steps in critical appraisal
ABSTRACT

- review
  - *objectives*
  - *study design*
  - *important results*
  - *Conclusion*
- Serious flaws can be detected at this stage

2004-03-26

...steps in critical appraisal
OBJECTIVES

- are they clear & precise?
- have the objectives been met – conclusions match objectives?
- do the objectives & study design match?

2004-03-26

...steps in critical appraisal
OVERALL STUDY DESIGN

Are the study designs appropriate?

- therapy - *efficacy of drug treatments, surgical procedures, service delivery, other interventions* RCT
- diagnosis - *test valid, reliable* – **cross - sectional**
- prognosis - *follow-up* - **cohort study**
- causation - **case control or cohort** *(depending on rarity of condition)*

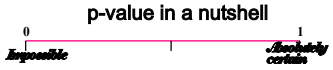
2004-03-26

...steps in critical appraisal
SAMPLING

- source of sample
- sampling method e.g. SRS, cluster
- sampling size - statistical power
- inclusion/exclusion criteria - age, sex, social class
- non-respondents - affect sample size
- control group - source, matching, randomization

2004-03-26

p-value in a nutshell



$p = 0.001$	Very unlikely	1 in 1000
$p = 0.05$	Fairly unlikely	1 in 20
$p = 0.5$	Fairly likely	1 in 2
$p = 0.75$	Very likely	3 in 4

2004-03-26

- *p*-values describes the probability that a particular results has happened by chance
- *p*-value <0.05 – statistically significant

2004-03-26

...steps in critical appraisal
QUALITY

- validity – does it measure what it intends to measure
  - internal validity (sample)
  - external validity (population),
  - degree of differentiation & discrimination (refers to questionnaire)
- reproducibility
  - value of any test and on its ability to yield the same results (diagnosis)

2004-03-26

- reliability – validity of study results / unbiased assessment of treatment effect
- replicability –method for performing tests has been described in detail to permit replication within another appropriate setting (diagnosis)
  - *dosage levels*
  - *pt preparation*
  - *timing*

2004-03-26

- blinding – e.g . Patients aware of possible risk factors & disease may make greater effort to report risk factors
- quality control – examination of subjects /collection of data / repeatability of observers / instrument calibration etc

2004-03-26

...steps in critical appraisal
COMPLETENESS

- compliance - to intervention
- drop-outs
- deaths
- missing data
- non-respondents

2004-03-26

...steps in critical appraisal
DISTORTING INFLUENCES

- outside influences e.g. patients on RCT with extraneous treatments
- contamination - one group affected by another
- confounding factors -spurious association due to risk factors
- changes over time e.g differences in data due to collection at differing time periods

2004-03-26

...steps in critical appraisal
APPLICABILITY

- applicability of results to local population
- whether all clinically important outcomes were considered - did those neglected affect interpretation
- are benefits worth harm (side-effects etc.)
- comparison of benefits & costs

2004-03-26

..an example
CRITICAL APPRAISAL

SCENARIO

- HTA Expert committee on Home Visiting looking at aspect of *care of elderly.*
- Literature search: Randomized controlled trial of a general practice programme of home-based exercise to prevent falls in elderly women.
  Campbell, AJ et al, BMJ,1997, 315: 1065-69.

2004-03-26

..an example
CRITICAL APPRAISAL

FIRST SCREENING

- objectives clearly focused?
  Yes, there was a definite research question.
- assignment of patients to treatments randomized?
  Yes, done by random number tables
- all people who entered trial properly accounted for ?
  Yes, 117 subjects in control, at end - 109; 116 in intervention, at end - 103

2004-03-26

..an example
CRITICAL APPRAISAL

- blinding to treatment
  severity of falls assessed by researcher blinded to assignment to groups
- sampling
  similar size, matched subjects
- were both control & intervention treated equally?
  all were visited by research nurse initially & at end of study

2004-03-26

..an example
CRITICAL APPRAISAL

RESULTS

- how large was treatment effect?
  32% reduction in risk of 1 - 4 falls,
  39% reduction in falls with injury
- degree of precision
  reduction in first four falls confidence interval (CI) : 0.52-0.90 [wide due to small sample]
  reduction in falls with injury CI: 0.39-0.97

2004-03-26

.....an example
CRITICAL APPRAISAL

- local applicability
  not clear, since details of population not given, physiotherapy support needed
- outcomes
  mention of graded exercise programmes increasing risk of falls in some studies,
  addressed in data collection
- benefits worth harm & costs?
  no adverse clinical effects,
  but no costing given

2004-03-26

.....an example
CRITICAL APPRAISAL

CONCLUSION

- applicability for HTA on Home Visiting
  risk of falls & injuries in elderly women can be reduced by supervised exercise programme

2004-03-26

QUALITY OF EVIDENCE

If literature found to be acceptable after critical appraisal,

- efforts made to rate quality of evidence
- no objective scoring system
- subjective rating - good, fair, poor
  ~ can be clarified by comments in evidence table

2004-03-26

GRADING OF EVIDENCE

- grading carried out after critical appraisal
- quality looks at how well study was carried out - methodology , data analysis, conclusions etc.
- grading refers to classification based on type of literature into different levels

2004-03-26

LEVELS OF EVIDENCE

I	evidence from at least properly randomized controlled trial
II -1	evidence obtained from well-designed controlled trials without randomisation
II-2	evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or group
II-3	evidence from multiple time series with or without intervention
III	opinions of respected authorities based on clinical experience; descriptive studies & case reports; or reports of expert committees

2004-03-26 (US/CANADIAN PREVENTIVE SERVICES TASK FORCE)

LEVELS OF EVIDENCE (CAHTA)

Level	Strength of Evidence	Study Design
1	Good	Meta-analysis of RCT & systematic reviews
2	Good	Large sample RCT
3	Good to	Small sample RCT
4	Fair	Non-randomised controlled prospective trial
5	Fair	Non-randomised controlled prospective trial with historical control
6	Fair	Cohort studies
7	Poor	Case-control studies
8	Poor	Non-controlled clinical series, descriptive studies – multi-centre
9	Poor	Expert committees, consensus, case reports, anecdotes

2004-03-26

CONCLUSION

- "If you are deciding whether a paper is worth reading, you should do so on the design of the methods section and not on the interest of the hypothesis, the nature or potential impact of the results, or the speculation in the discussion"
  Greenhalg, T

2004-03-26

Participants of HTA Seminar – PIMS, 12 February 2004

Name	Organization	Address	Phone No
1. Maj.Gen.Akbar Prof.Community Medicine	Shifa Hospital	Shifa International Hospital H-8 Islamabad	2254090
2. Prof.Dr.Sakina jafer	PIMS	PIMS Islamabad	9260996
3. Dr.M.Rafiq	Chief HSRRU	Khyber road HRD block Peshawar	091-9210878
4. Haroon A Khan	Pathology Deptt.	PIMS Islamabad	0300-8568112
5. Mahmood Jamal	PIMS		9260782
6. Ayyaz kiani	The Network	40-a Ramzan Plaza G-9 Markaz Islamabad	2261085
7. Umar Bilal	MC	PIMS	0333-5218962
8. Dr.Farrukh Qureshi	HTA Forum	40-A Ramzan Plaza G-9 Markaz Islamabad	2261085
9. Dr.Azam Yosuf	Rawalpindi Medical College	Department of surgery DHQ Hospital Rawalpindi	0303-7752131
10. Dr.Ejaz	Training Centre	MCH PIMS	9260597
11. Prof.Khalida Waheed	CPSP Islamabad	H. No: 36 St:13 F-7/2 Islamabad	03009548139
12. Dr.Shahab Fatim	NORI	Nori Hospital Islamabad	9260611
13. Dr.Zafar Iqbal Toor	NIH	NIH Park Road Islamabad	9255125,03009503819
14. Dr.Ghazala Mahmood	MCH	PIMS Islamabad	9260273
15. Prof.Zaheer Abbassi	CH	PIMS Islamabad	9260750
16. Dr.Tanvir Khaliq	HTA Forum	PIMS Islamabad	9261165
17. Dr.Farhana Zareef	PIMS	PIMS Islamabad	9260597
18. Anwar Ali	Hamdard University	Hamdard University Islamabad	0320 5335007
19. Samina Iqbal	Hamdard University	Hamdard University Islamabad	03005154410
20. Ayesha Hayat	Hamdard University	Hamdard University Islamabad	03005150897
21. Dr.Yasmin Hadi	WHO	NIH Islamabad	9255175
22. Dr.Waqas Waheed	University of Manchester		
23. Dr.M Iqbal	CH	PIMS Islamabad	03204904579
24. Tayyab Janjua	Hamdard University	F-8 Markaz Islamabad	0300 5179673
25. Sajeed Zaib	Hamdard University	F-8 Markaz Islamabad	2282061
26. Kiran Yosuf	Hamdard University	F-8 Markaz Islamabad	03005255914

27. Dr.Saima Qamar	MCH PIMS	E-8 Naval Complex	03005189157
28. Dr.Ghazala	NIH	NIH Islamabad	9255110 ext3060
29. Dr.Talib Lashari	The Network	Islamabad	2261085
30. Dr.Ashfaq Ahmed	Ministry Of Health Islamabad	DDG MOH Islamabad	
31. Latif Ullah	CMT College	PIMS Islamabad	
32. Badar Rasheed	Hamdard University		03005277531
33. Nighat Fareed	Hamdard University		5956064
34. Sadiya Malik	Hamdard University		2290537
35. Prof. Noor Khan	PIMS		9261170
36. Dr. Nabeela Ali	Save The Children	F-7/1 Islamabad	111107108
37. Sadia Yosuf	PAEC,LSG NORI	NORi G-8/3 Islamabad	9260611-266
38. Dr.Maqbool	CH PIMS		
39. Prof. Asif Zafar	PMC	Surgery unit Holy Family Hospital Rawalpindi	4411066
40. Syed Faiz Mahdi	Hamdard University	F-8 Markaz Islamabad	0300-5316694
41. Shazia Chaudhry	Hamdard university	F-8 Markaz	2292347
42. Tabindah Zafar	Hamdard university	F-8 Markaz	4438197
43. Khuram Shahzad	Hamdard university	F-8 Markaz	03335153209
44. Ghulam Dastgeer	Hamdard university	F-8 Markaz	03335218310
45. Tanveer Ahmed	Hamdard university	F-8 Markaz	2252117
46. Raja Rizwan Khalid	Hamdard university	F-8 Markaz	0571-513745
47. Ahmed Sadiq Shaikh	Hamdard university	F-8 Markaz	03005122797
48. Dr. Humaira Aslam	TheNetwork	G-9 Markaz	0512261085
49. Mohamad Ahsan	Hamdard university	F-8 Markaz	5516364
50. Imran khan	CMT	Islamabad	
51. Dr.Ghazala Mumtaz	Capital hospital	G-6/2 Islamabad	9221334/240
52. Zaheer Ahmed	PPI news agency	Super market Islamabad	2872646

53. Dr.Saima Qamar	MCH PIMS	E-8 Naval Complex	03005189157
54. Dr.Ghazala	NIH	NIH Islamabad	9255110 ext3060
55. Dr.Talib Lashari	The Network	Islamabad	2261085
56. Dr.Ashfaq Ahmed	Ministry Of Health Islamabad	DDG MOH Islamabad	
57. Latif Ullah	CMT College	PIMS Islamabad	
58. Badar Rasheed	Hamdard University		03005277531
59. Nighat Fareed	Hamdard University		5956064
60. Sadiya Malik	Hamdard University		2290537
61. Prof. Noor Khan	PIMS		9261170
62. Dr. Nabeela Ali	Save The Children	F-7/1 Islamabad	111107108
63. Sadia Yosuf	PAEC,LSG NORI	NORi G-8/3 Islamabad	9260611-266
64. Dr.Maqbool	CH PIMS		
65. Prof. Asif Zafar	PMC	Surgery unit Holy Family Hospital Rawalpindi	4411066
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73. Ahmed Sadiq Shaikh	Hamdard university	F-8 Markaz	03005122797
74. Dr. Humaira Aslam	TheNetwork	G-9 Markaz	0512261085
75. Mohamad Ahsan	Hamdard university	F-8 Markaz	5516364
76. Imran khan	CMT	Islamabad	
77. Dr.Ghazala Mumtaz	Capital hospital	G-6/2 Islamabad	9221334/240
78. Zaheer Ahmed	PPI	Super market Islamabad	2872646

	newsgency		
79. Dr.Naqeeb Ullah	KRL Hospital	G-9 Markaz Islamabad	9261150
80. Ayesha Yameen	PINSTECH	Life science group PINSTECH Nilore Islamabad	9290231/3436
81. Dr. Nilofer Sami	Aga khan University	Deptt. of CHS AKU Karachi	48594828
82. Dr.Shamsa Rizwan	IIMCT	Railway hospital	
83. Prof. S. Aslam Shah	PIMS	Islamabad	9260115
84. Prof. khalida Akhter	Hamdard university	F-8 Markaz Islamabad	
85. Ahmed Waqas	Hamdard university	F-8 Markaz Islamabad	2856433
86. Tayyaba Ahmed	Hamdard university	F-8 Markaz Islamabad	0333 5201646
87. Safia Shahid	Hamdard university	F-8 Markaz Islamabad	0300 5311585
88. Shazia Hafeez	Hamdard university	F-8 Markaz Islamabad	5513630
89. Amna khan	Hamdard university	F-8 Markaz Islamabad	0300 5384875
90. Haleema Masood	Hamdard university	F-8 Markaz Islamabad	0320 5112212
91. Sidra Shahid	Hamdard university	F-8 Markaz Islamabad	0333 5146178
92. Sharmeen Owais	Hamdard university	F-8 Markaz Islamabad	0300 5348846
93. Mahmood Ahmed	Hamdard university	F-8 Markaz Islamabad	4448515
94. Fahad Nazir	Hamdard university	F-8 Markaz Islamabad	03005176645
95. Dr.Yasmeen khan	IIMCT	Railway hospital Rawalpindi	
96. Dr. Ambreen	IIMCT	Railway hospital Rawalpindi	
97. Ammara khatak	Hamdard University	St.11 H; 2 F-8/3 Islamabad	2852468
98. Saima Islam	Hamdard University	St.11 H; 2 F-8/3 Islamabad	03006107494
99. Huma Shirafat	Hamdard University	St.11 H; 2 F-8/3 Islamabad	0596-534563
100. Sadaf Arshad	Hamdard University	St.11 H; 2 F-8/3 Islamabad	2260081
101. Lubna Chuadri	Hamdard University	St.11 H; 2 F-8/3 Islamabad	4491772,03005 220353

Participants of the HTA Workshop – Bhurban, 14-15 February 2004

Name	Organization	Address	Phone No
1. Dr. Rakhshanda Bilal	PAEC	LSG-RIAD Pinstech PO Nilore Islamabad	9290231 -3414
2. Dr. M. Iqbal Afridi	MoH NWFP	DGHS Office NWFP Peshawar	9210187
3. Dr. Idrees Anwar	Holy Family Hospital	H. No. 34 St. No:37 F-7/1 Islamabad	0303-6526158
4. Kalsoom Akhter CNS	PIMS	H.No;20 St.No;22 c G-10/2, Islamabad	9260492
5. Dr. Kamran Majeed	KRL Hospital	KRL Hospital G-9 Islamabad	9261150
6. Prof. Syed Aslam Shah	PIMS	PIMS Islamabad	9260115
7. Dr. Shahab Fatmi	Nori	NORI Islamabad	9260611
8. Dr. M. Iqbal	PIMS	PIMS Islamabad	9261232
9. Dr. Minhaj us Siraj	PIMS	DED PIMS Islamabad	9261170
10. Prof. Ghazala Mehmood	PIMS	Head Ob. Gyne MCH Centre PIMS	9261273
11. Dr. Shamsa Rizwan	IIMC	Ob & Gyne Department Railway Hospital RWP	2876714
12. Dr. Farrukh Qureshi	The Network	40-A Ramzan Plaza G-9 Markaz Islamabad	2261085
13. Dr. Azam Yusuf	Rawalpindi Medical College	Dept. of surgery DHQ Hospital Rawalpindi	0303-7752131
14. Dr. M. Rafiq	Chief HSSRU Health Dept.	Khyber Road HRD Peshawar	091-9210876
15. Prof. Khalida Waheed	Director College of Physician and Surgeon	CPSP G-8 Islamabad	
16. Azhar Hussain	Hamdard University	Hamdard University Islamabad	0300-8543215
17. Dr. Nuzhat Salamat	AFIT Rawalpindi	AFIT Rawalpindi	0320-49204 44,56132905
18. Dr. Talib Lashari	The Network Islamabad	40-A Ramzan Plaza G-9 Markaz Islamabad	2261085
19. Dr. Nilofer sami	Agha Khan Univ. Karachi	Deptt. of CHS Agha Khan Univ. Karachi	021-48594828
20. Dr. Naqeeb Ullah	KRL Hospital	KRL Hosp Islamabad	9261150
21. Dr. Zafar Mirza	TheNetwork Islamabad	Islamabad	2261085
22. Mr. Ayyaz Kiani	TheNetwork Islamabad.	Islamabad	2261085

A HTA Guide to Internet Sources of Information

(Courtesy: Health Technology Assessment Unit, Medical Development Division, Ministry of Health, Malaysia)

INTERNATIONAL HTA ORGANISATIONS

Agencia de Evaluacion de Technologias Sanitarias (AETS) *http://www.anaes.fr/ANAES* (HTA agency, France)

Agencia de Evaluacion de Technologias Sanitarias de Andalucia (AETSA) *http://www.isciii.es/aets* (HTA, Andalusia, Spain)

Agence d'Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS) *http://www.aetmis.gouv.qc.ca* (HTA, Quebec, Canada)

Agency for Healthcare Research and Quality (AHRQ) *http://www.ahrq.gov* (HTA. USA)

Alberta Heritage Foundation for Medical Research (AHFMR) *http://www.ahfmr.ab.ca/hta* (HTA, Alberta, Canada)

Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) *http://www.racs.edu.au/open/asernip-s.htm*

Catalan Agency for Health Technology Assessment (CAHTA) *http://www.aatm.es* (HTA, Catalonia, Spain)

CVZ- College voor Zorgverzekeringen/Health Care Insurance *http://www.cvz.nl* (HTA, the Netherlands)

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

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

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

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

Health Services Utilization and Research Commission (HSURC) *http://www.hsurc.sk.ca* (HTA, Canada)

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

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

Medicare Services Advisory Committee (MSAC) *http://www.healh.gov.au/msac* (HTA, Australia)

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

National Coordinating Centre for Health Technology Assessment - *http://www.hta.nhseweb.nhs.uk* (HTA, UK)

New Zealand Health Technology Assessment *http://www.nzhta.chmeds.ac.nz*

Norwegian Centre for Health Technology Assessment *http://www.oslo.sintef.no/smm*

OSTEBA- Basque Office for Health Technology Assessment *http://www.euskadi.net/sanidad* (HTA, Basque Province, Spain)

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

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

TNO- The Netherlands Organization for Applied Scientific Research *http://www.health.tno.nl/en*

University HealthSystem Consortium (UHC) *http://www.uhc.edu* (USA)

E-TEXT OF HTA INFORMATION SOURCES
An electronic textbook providing in-depth coverage of various aspects of HTA information resources: http://www.nlm.nih.gov/nichsr/ehta

CLINICAL PRACTICE GUIDELINES

National Guidelines Clearinghouse *http://www.guidelines.gov* (USA)

New Zealand Guidelines Group *http://www.nzgg.org.nz*

Scottish Intercollegiate Guidelines Network *http://www.show.scot.nhs.uk/sign/index.html*

German Guidelines clearinghouse *http://www.Leitlinien.de*

Canadian Medical Association Clinical Practice Guidelines *http://www.mdm.ca/cpgsnew/cpgs/index.asp*

American Academy of Pediatrics - Clinical Practice Guidelines *http://www.aap.org/policy/paramtoc.html*

National Health and Medical Research Council (NHMRC) http://www.gov.au/nhmrc (Australia)

Alberta Medical Association Clinical Practice Guidelines Program http://www.amda.ab.ca/cpg/index.html (Canada)

HEALTH ECONOMICS

Canadian Health Economics Research Association http://www.chera.ca

Centre for Health Economics, University of York http://ww.york.ac.uk/ins/che (UK)

Centre for Health Economics and Policy Analysis (CHEPA, McMaster University http://hiru.mamaster.ca/chepa (Canada)

Health Economics.com http://www.healtheconomics.com

Health Economics Resource Centre, University of York http://www.york.ac.uk/res/herc/hercwelcome.htm (UK)

Institute of Health Economics http://www.ihe.ab.ca (Canada)

International Health Economics Association http://www.healtheconomics.org/cgi-bin/WebObjects/ihea

OTHER LINKS

CancerNet http://www.cancernet.ncbi.nih.gov

CCT (Current Controlled Trials) http://www.controlled-trials.com

CDC National Center for Health Statitics (CDC NCHS) US http://www.ced.gov/nchs

Centers for Disease Control and Prevention, US http://www.cdc.gov

CenterWatch http://www.centerwatch.com/main.htm

ClinicalTrials.gov http://clinicaltrials.gov

COCHRANE Library http://www.update-software.com/abstracts/Default2.html

Danish Centre for Evaluation & Health Technology Assessment (DACEHTA's) Http://www.mtv-instituttet.dk

Department of Health UK http://www.doh.gov.uk

ECRI http://www.ecri.og

Emedicine *http://www.emedicine.com*

Food & Drug Administration (FDA) *http://www.fda.gov*

Golden Hour medical information *http://www.goldenhour.co.il*

International Obesity Task Force http://www.iotf.org

Journal listings *http://www.nthames-health.tpmde.ac.uk/connect/journal.htm; http://www.pslgroup.com/dg/medjournals.htm*

Medical Devices Agency *http://www.medical-devices.gov.uk*

Medical Matrix *http://www.medmatrix.org/index.asp*

National Cancer Institute (US) *http://www.cancer.gov/clinical_trials*
National Cancer Institute of Canadian Clinical Trials Group *http://www.ctg.queensu.ca*

National Center for Health Statistics (NCHS) *http://www.cdc.gov/nchs/about.htm*

National Heart, Lung, and Blood Institute (NHLBI) *http://www.nhlbi.nih.gov/index.htm*

NHS Centre for Reviews & Dissemination *http://www.york.ac.uk/inst/crd/welcome.htm*

NHS UK Direct Online *http://www.nhsdirect.nhs.uk/main.jhtm*

NHS UK *http://www.nhs.uk*

PUBMED *http://www.ncbi.nlm.nih.gov/pubmed*

ScHARR Netting the evidence *http://www.shef.ac.uk/~scharr/ir/netting*

U.S. Blue Cross/ Shield Association *htpp://www.bluecares.com/consumertec/index.html*

UK - National Horizon Scanning Centre (NHSC)
http://*www.publichealth.bham.ac.uk/horizon*

UK - Succinct & Timely Evaluated Evidence Reviews (STEER)
htpp://www.wihrd.soton.ac.uk/projx/signpost/welcome.htm

UK Cancer Coordinating Centre *http://www.ctu.mrc.uk/ukccr/home.html*

United Nations Statistics Division (UNSD) *http://www.un.org/Depts/unsd/mbserg.htm*

University Health System Consortium (UHC) - *htpp://www.uhc.edu*

WHO *http://www.WHO.int/en*

WHO Statistical Information System (WHOSIS) *http://www.who.int/whosis*

FREE JOURNALS ONLINE

American Journal of Epidemiology *http://www.aje.oupjournals.org*

American Journal of Public Health *http://www.ajph.org*

BMJ (British Medical Journal) *http://www.bmj.ca*

CMAJ (Canadian Medical Journal) *http://www.cmaj.ca*

Free Medical Journals.Com *http://www.freemedicaljournals.com*

Journal of Medical Internet Research *http://www.jmir.org/index.htm*

Lancet *http://www.thelancet.com*

Medical Research Council *http://www.mrc.ac.uk*

New England Journal of Medicine *http://content.nejm.org*

The Journal of the American Medical Association *http://www.jama.ama-assn.org*

Telehealth Ministry of Health *http://www.telehealth.com.my*

Introduction of the facilitators

Dr Itziar Larizgoitia

Dr Itziar is a Scientist at WHO's Department of Health Services Organization in Geneva. A medical doctor, a Fulbright scholar to John Hopkins for PhD in health policy and management, she has vast experience in health services research and policy analysis. Her special interest lies in studying and evaluating primary health care arrangements, as well as in the comparative analysis of international health systems and institutions. She has more than 20 publications to her credit.

Dr Alicia Granados

A leading international figure in HTA research and publication she has over 17 years of experience in Health Technology Assessment (HTA), strategy development, assessment methods, practices and implementation. A MD and PhD, she has to her credit the creation in 1991 of an independent multidisciplinary team on HTA named Catalan Agency for Health Technology Assessment and Research (CAHTAR). She acted as General Director and CEO of CAHTAR until December 1999. She has been the President and CEO for three years at the Catalan Institute of Health, a major health care provider in Catalonia, Spain. Since 1992 she has been temporary advisor of WHO, PAHO, United Nations and World Bank.

Dr S Sivalal

Dr. Sivalal is Head of the Health Technology Assessment Unit at the Ministry of Health, Malaysia. A medical doctor with experience as medical director of a hospital he has a Post-graduate Diploma in Hospital & Health Services Administration (London). He is president of the Malaysian Society for Health Technology Assessment, and currently manages the Health Technology Assessment (HTA) program in Malaysia. Dr Sivalal has been awarded WHO and World Bank Fellowships in Health Technology Management and HTA to Australia, Canada, USA, Spain, and Sweden. He has undergone training at the Canadian Coordinating Office for HTA at ECRI, Philadelphia, USA and at CAHTA, Barcelona, Spain, as well as training on clinical pathways in Australia. He organizes training on health technology assessment for local participants as well as for the region. In addition, he is an honorary lecturer at 2 local universities, teaching Health Technology Management and HTA in Masters in Public Health programs. In addition, he has presented innumerous papers at national and international conferences both locally and abroad like in Sweden, Thailand, and Indonesia.

HTA Forum - Pakistan

The *Health Technology Assessment* (HTA) discipline can be applied to a wide range of healthcare 'interventions', including medical, surgical and other clinical techniques, drugs, equipment and devices, methods of healthcare delivery (for example, homecare, minimally invasive surgery, ambulatory surgery and so on) healthcare policies and reform initiatives. For this reason, the techniques involved in HTA have a clear and obvious utility in informing capital investment decisions.

In Pakistan HTA Forum has initiated the assessment and dissemination work. The Forum consists of a group of professionals who are dedicated to the promotion of a culture of "evidence based medicine" in Pakistan. The group started in 2001 to evaluate the usefulness and utility of Health Technology Assessment in Pakistan. The idea was to exchange experience, to better understand country needs, priorities, challenges and opportunities, and thus help shaping the opinion for fostering the use of HTA for improving evidence base of health policy and decision making as well as the performance of health systems and services. The group believes that this is an important tool to bring about the desired change in the professional and the societal mindset.

The Forum members are committed to the promotion of HTA at national level in Pakistan and they hold regular sensitization seminars and training workshops at various forums and cities. HTA Forum is establishing network and closer collaboration with regional and international HTA forums. The Forum provides a platform for involvement of professionals, practitioners, academia, and officials of the Federal and Provincial Government and health ministries, NGOs and health activists in HTA process in order to design and conduct HTA reports in priority areas and also to provide necessary expertise to adapt selected HTA reports from international sources.

HTA Forum welcomes new members. For further information and joining the Forum, please contact: Dr Assad Hafeez, htapak@yahoo.com

HTA ForuM

HTA Forum - Pakistan

40-A, Ramzan Plaza, G-9 Markaz, Islamabad, Ph: +92-51-2261085, Fax : +92-51-2262495
E-mail: htapak@yahoo.com