

A summary of HCTM report in Iran

Title of study : To review the Iranian system for health technology assessment and licensing and design the system for the selection and use of appropriate

Technology in the health system

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Terms of reference

One of the visualizations of health reforms is to encourage the selection and use of appropriate health technologies. Iran has done marvelous in ensuring the use of generic drugs, but given the demographic and epidemiologic transition, new technologies both medicinal and equipment arriving and the rising expectations of people the health cost has been skyrocketing. To study a review of the existing system of selection and use of health technology and design a new model of technology/medical equipment selection and use this study is conducted.

Specifically the APW holder have done these steps :

1. work with the international consultant in designing the study;
2. design detailed protocols for the study, documenting every step;
3. present study design to the stakeholder, seeking their comments;
4. collect data and using appropriate software/method analyze the data;
5. maintain a trail of events/evidence for subsequent validation of the study process and findings; and
6. report the study in a most professional manner;

Drawing up details and designing the system for the selection and use of appropriate health technologies

The Principle investigator and HTA & M team have studied current situation of medical equipment management system to draw details and design the system for the selection and use of appropriate technologies. In this process, this national investigator was assisted by an international consultant who reviewed the study findings and outline the possible modifications in the existing system that it favors selection and use of appropriate technologies.

Executive summary

The issue

A large number of scarce financial resources of Iran's health sector is allocated to medical equipment expenditures which includes 35% of curative expenditures .Increasing interest of health providers to import or buy new costly equipments and debates around effective use of existing equipment and rational selection and use of health equipments is the main cause of this study . Due to health reform program interest to study Iranian system for the selection and use of medical equipments and design a system for the selection and use of appropriate equipment in the health system, the Iranian health technology assessment group analyzed the current situation and designed the improved model of medical equipment management in Iran.

Objectives

To review and analyze current system for the selection and use of medical equipments in terms of policy making & planning ,financing ,selection and use administrative and legal dimensions and methods to design an improved model of medical equipment appropriate selection and use in Iran.

Methods

The study is based on the SSADM structured System Analysis and Design methodology through exploring, confirming and completing interviews with expert group of medical equipment management from all stakeholder organizations in Iran .The report also was enriched with a broad view of international literature and international consultants ideas added to data from internal experts . A structured questionnaire focused on the basic issues of medical equipment management was utilized for data collection and its findings were analyzed after confirming and complementary interviews according to SSADM methodology .To clarify current organizational arrangement and relationships the results of this phase of study were translated to DFDs data flow diagrams Entity Relationship Diagrams .Then we outlined the optimized system of selection and use of medical equipment based on WHO documents ,literature search results on health technology assessment and management issues in the world and international consultants recommendations .After a systemic managerial analysis and comparing the existing system with ideals ,and seeking stakeholder attitudes around outlined system ,we designed improved DFDs with a focusing approach on process -based structuring . In this approach the different less- valued committed duties in the field of medical equipment management like administrative process of licensing will be replaced by high-valued process like need assessment, technology assessment and maintenance by expert's contribution. Also we defined conceptual perspective, organizational structure, infrastructures, prerequisites of model and new relationships in an integrated national model.

Results:

This report details the current situation of medical equipment selection and use system in Iran and presents these aspects that require immediate attention which is considered

in the systemic designed model :

- At present health technology/medical equipment policies of MOH are not an integral part of health policies. The fact that the best decisions of equipment policies and plans can be formed when health managers develop health system priorities ,essential care package and prioritize setting of technologies in the strategic and operational health plans should be more attended .
- The current organizational approach and structure of health technology /equipment management system are confused with variety of non defined duties with less value for increasing efficiency and productivity in a very complex relationships .These should be replaced by important effective process like assessment of population and health program's needs to technologies/equipments and selection of best available alternatives in terms of safety ,effectiveness and economical dimensions and compatibility with Iranian health system.
- A network activities of health technology/health equipment assessment should be established by arranging of elementary activities on technology pre-assessment in limited hospitals and universities and mini HTA in well developed universities and hospitals and medical equipment center of MOH and comprehensive HTA in a national HTA agency . The level of permitted decision making depends on the price of technology and acuteness of care and its impacts on the health system outcomes.
- An integrated ration who met the need to appropriate technologies dealing with strategic plans and priorities of health system ,technology assessment views and effective allocation pattern .
- A model for stratification of health organizations and defining their role in the new system of assessing medical equipment requests and needs is suggested.

Conclusively, the report presents a systematic analysis of current situation on the "medical equipment selection and use system" in three levels of MOH Medical equipment office ,Medical universities and hospitals and so principles of optimized model and finally recommends an improved national model as it is detailed with improved diagrams including DFDs & policy ,organizational ,administrative and legal infrastructures and necessities in the text.

Recommendations for capacity building of implementation:

- Build required capacity which is needed for application of new model
 - Define prioritized health care package in each level of health services
 - Detect convenient health technology who meets health care services in each level
 - Develop real strategic and operational plans clarifying required technologies
 - Design inventory and preventive maintenance soft wares
 - Train policymakers, managers & staff to be familiar with new approach and be capable of producing qualified reliable assessment of technology/health equipment or its implementing.
- Support Health technology assessment activities and institutionalize the need to assess health technologies /equipments before their acceptance and acquisition in health system

Overview

The research Framework: Health technology/medical equipment assessment and management in Iran

The Health Sector Reform Project has developed a master plan of investigations and pilot programs leading to these five main objectives:

1. Designing and testing a universal basic minimum health services package and strengthening patient referral system, ensuring a better quality health services that are responsive to the needs of the communities;
2. Assuring the stewardship and good governance in the public sector health system guaranteeing the pro-poor policies;
3. Improving health planning and management including decentralization in the health sector by delegating the administrative and financial authority;
4. Reviewing the existing health financing options for introducing measures to assure fair financing, eliminating inefficiencies and bringing equity; and
5. Making organizational arrangements for conceptualizing, formulating and implementing health sector reforms

Health Technology assessment and management is one of strategic issues which was selected by NHRU as a topic of APW to be reviewed and implemented in Iran's health system. To achieve the main objectives of this research comprising :reviewing current system of health technology/Medical equipment selection and use and design an improved system ,the project team conceived these components to be studied in the current system:

1-Involved divisions in HCTA &M within MOH and other ministries and their role

The components of the health care technology/Medical equipment management are provided by a number of public and private sector institutions and divisions within country inside MOH or out of it. Maybe a single division is responsible for a number of components of the package.

2- Management and Planning of health care technology/Medical equipment

The effective use of imported or selected health care technology/Medical equipment has to be planned as an overall process .Both in the immediate need to establish a functioning technology service and the longer -term goal of increasing national and regional self-sufficiency must be kept in mind.

3- Allocation of financial resources to medical equipment

In most countries, the funds allocated for the purchase of technology ,spare parts and maintenance services are much less than would be required to keep to service functioning .Existing constraints with regard to budgeting for depreciation ,the procurement of imported spares ,and payment for private maintenance services often prevent more effective use of resources. Often training requirements for the maintainers of technology are not included in training budgets.

4-Selection of technology

The assessment of technology requirements for health provision requires a team which includes health workers, technical personnel, health system and economics professionals and planners .In many cases very little accurate information is provided to those who choose technology .There are a number of potential sources of the required information ,and strategies are needed to ensure that it is available.

5-Procurement

Effective procurement of technology and related fittings on the international markets requires expertise .Where mistakes are made ,the cost can be high .One issue requiring study is the functioning of tender system .In many health units ,the only consideration is cost, with no attention being paid to the need to ensure effective after sale support .

6-Preuse activities like site preparation, installation, commissioning ,initial calibration

There is a need for effective installation, commissioning, acceptance testing and user training for technology/Medical equipment in the first instance ,which will require a combination of in-house maintenance unit ,other public sector workshops ,suppliers and other technical support services .

7-Continued operation in terms of consumable , accessories ,spare parts,..

The continuous use of technology must be planned for with and adequate supply of consumables .Many examples exist of ineffective or even dangerous use of technology ,therefore plans of required for on-going safety and performance testing and refresher training courses of users .There needs to be an automatic and effective system in place for the disposal and replacement of equipment when it reaches the end of its life: only in this way will any health service offered to the community continue to be provided.

8-Maintenance and repair

A combination of institutions include in-house units of the MOH ,companies in relation with foreign suppliers ,local private companies ,small enterprises provide after sale services. The establishment of an effective maintenance system is dependent on the level of commitment by the MOH and on its capacity to manage the use of the services offered by the providers.

9-Human resources

It is essential to have health workers with necessary skills and knowledge for all aspects of the use , maintenance and management of technology/Medical equipment .

10-Health Technology Assessment

It is a tool to support decision making process by assessing safety, clinical effectiveness and economical attributions of technologies by research methodologies which recommend one of alternatives for policy makers .

Reviewing these items and demonstration of current activities in the frame of organizational structure and process built a basis for developing a new structured

system with improved concept of HTA & M in health system. Since we utilized the health technology assessment and management approach for both stages of this study, definition of these words are mentioned below.

Health Technology Assessment: A definition

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 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 policymakers 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 answer to them. The process to follow would comprise of forming a multidisciplinary team which 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. ([www.http://:HTAi.com](http://HTAi.com)).

In addition to actual assessment studies, the HTA process comprises also the dissemination of the results and an impact assessment of resulting changes.

Healthcare Technology Management : A solution

No country can provide health services to meet all the needs of its population. The need to set priorities arises from the fact that not all illness can be eradicated nor all needs met. This failure to be able to meet all needs arises, principally, not because of the limitations of currently available technology, but because of the lack of sufficient resources. Planners and decision-makers in the health sector therefore have to manage technologies in ways that maximise health outcomes.

Healthcare technologies are an essential component of healthcare delivery, in all countries. Their appropriate selection, installation, utilisation and maintenance are vital for efficient and cost-effective healthcare delivery at all levels of the health system, from the first level to upper level of health care.

It is recognised that in many developing countries, available resources permit importation of high-cost interventions for only a small proportion of the population therefore lowering or optimizing cost methods of cost management will need to be

developed from the wide range of technologies and procedures that now exist, or that are coming into being” .The importance of "political” support also cannot be over-emphasised, especially in developing countries, since such support (or lack thereof) determines issues of policy, resource allocation, infrastructural support and organisational efficiency. Without these enabling factors, the chances of successful HTM interventions are diminished, and a vicious cycle of failure following upon failure may result.

Methodology

To carry out the study we used descriptive-analytic method with SSADM (system structured analysis and design) approach .The main objective of this study is designing a model for health technology /medical equipment selection and use in Iran .The special objectives are:

- To identify current structure ,plans, allocation pattern, selection , acquisition and maintenance mechanisms of medical equipment management in MOH
- To modify or improve health technology/medical equipment management system including structure ,plans ,decision making methods, budget allocation mechanisms & selection and use health technologies/medical equipment in MOH and related care.

Research community covers all involving organizations in HCTM and HTA process, including Ministry of Health, Management and planning Organization, Welfare Ministry containing Social health security and Medical services insurance and armed force health insurance Organization, Medical universities, hospitals, Medical equipment suppliers .

To collect data from macro, meso and micro level of HTA&M system ,we adopted a structured and stratified "country situational analysis questionnaire" after its validation for three mentioned levels. The data was gathered through explorative, confirmative and complementary interviews . Interviewees were selected by quota method from policy makers like MOH managers, insurance organization's policy makers ,intermediately level like medical university’s medical equipment experts and hospital medical equipment engineers, and final level such as physicians , laboratories, and medical equipment sailors .

Questions stratified in three level of interviewees to meet range of information due to Their responsibilities and positions, Also introduction to project aims, glossary and abbreviation that precede it, provide preknowledge to answer questions.

Interviewees were selected from a combination of expertise in technical services, suppliers, finance, human resource, clinical services, administration and planning field who are divided in this manner:

A) Ministry of Health and Medical Education	6 interviewees
B) Management and planning Organization	2 interviewees
C) Welfare Ministry	6 interviewees
D) Medical Universities	4 interviewees
E) Hospitals (public ,private ,insurance and armed forced related hospitals	9 interviewees
F) Medical Equipment Companies	3 interviewees

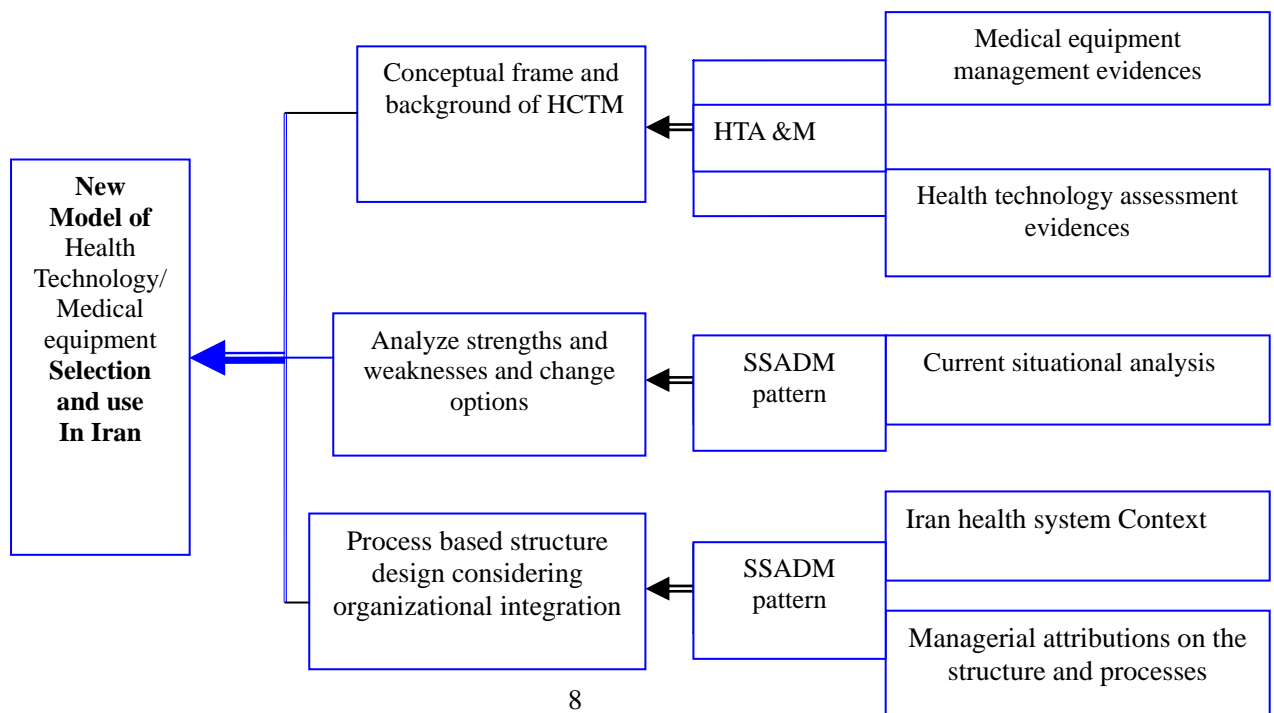
Principle lines of data gathering around health technology selection and use were:

- structure of HCTM & involved units role
- Plans
- Flow of required information
- Resource allocation
- Selection of technology
- Procurement
- Pre use and use activities
- Control mechanisms

SSADM structured system analysis and design as a managerial research approach ,helped us to show the finding of study and new model with a unique tool called DFD or data flow diagram as you can find later .In these diagrams you can seek the following units in deferent levels, main duties and systemic relationships with each other .Also the information linkages between each unit with other units and decision making levels is illustrated in several tables.

Below ,the method of using study finding to feed new model is showed in summary :

Ration of research on " Iran health technology /medical equipment selection & use system"



To design new model these items in the field of technology/medical equipment were considered:

- System integration between hospital, medical university and MOH level
- Policy integration between health departments and equipment units through strategic and operational plans
- Focusing on valued process instead of scattered duties in structure design
- Predicting assessment activities on under use or new technology/medical equipment before selection and use
- Stratifying decision making levels for technology/medical equipment selection and use and their interactions

Findings

As a result of the first part of the study we found 10 involved departments or units inn MOH and its subsystems and 9 other organizations out of MOH who affect technology/medical equipment management in Iran. Varity and plurality of policies and regulations make a complex condition for integration and professional interventions. The main findings of reviewing current situation are:

-A central responsible office called "Medical equipment office exists in MOH structure with 14 years history who, potentially can direct technology/medical equipment policies in the country.

-There is no clear integration between long-term and short-term development or annual plans of health care in Iran with technology/medical equipment plans and budget or expenditures. However a subjective committee on this issue is established recent years but the consensus or voting is the base of decisions for main buying actions.

-The standard package of services and technologies are designed for some levels of health care, but they are not updated and generalized to all levels of health facilities especially in inpatient services which are most costly.

After starting the project activities in 2003 consultant committees formed by project team members in central office of medical equipment in MOH to set the priorities and plans of technology/medical equipment but they are not institutionalized in the formal structure. Before that the preferred issues of this office were focusing on regulation and acquisition activities and central procurement of devices for MOH .

- Data banks & Information required for technology /medical equipment like inventory and preventive maintenance ,performance level were not provided

to enable forecasting future needs .Several universities have developed innovative softwares for their domain of activities but they are not integrated to provide national information .

-Strategic or annual expenditure plans, clarifying needed technologies ,life cycle costs of existing equipment or prioritized use of new devices coped with health priorities and service package are not developed also the priorities for donation also are not defined.

-The recurrent and capital budget lines of medical equipment including installation, maintenance, depreciation, spare parts, replacement and accessories of devices are not clarified. Also the cost information are not available.

-The routine selection parameters includes :available resource for buying, assured safety &quality by FDA or reliable national or international licenses, recent subjective experiences of same brand use by Iranian providers and after sale services. Of course in some cases due to particular conditions they are extended to detect costs and effectiveness by research projects .Appropriateness of technology with health policies and required services , community needs and health system context are mostly ignored.

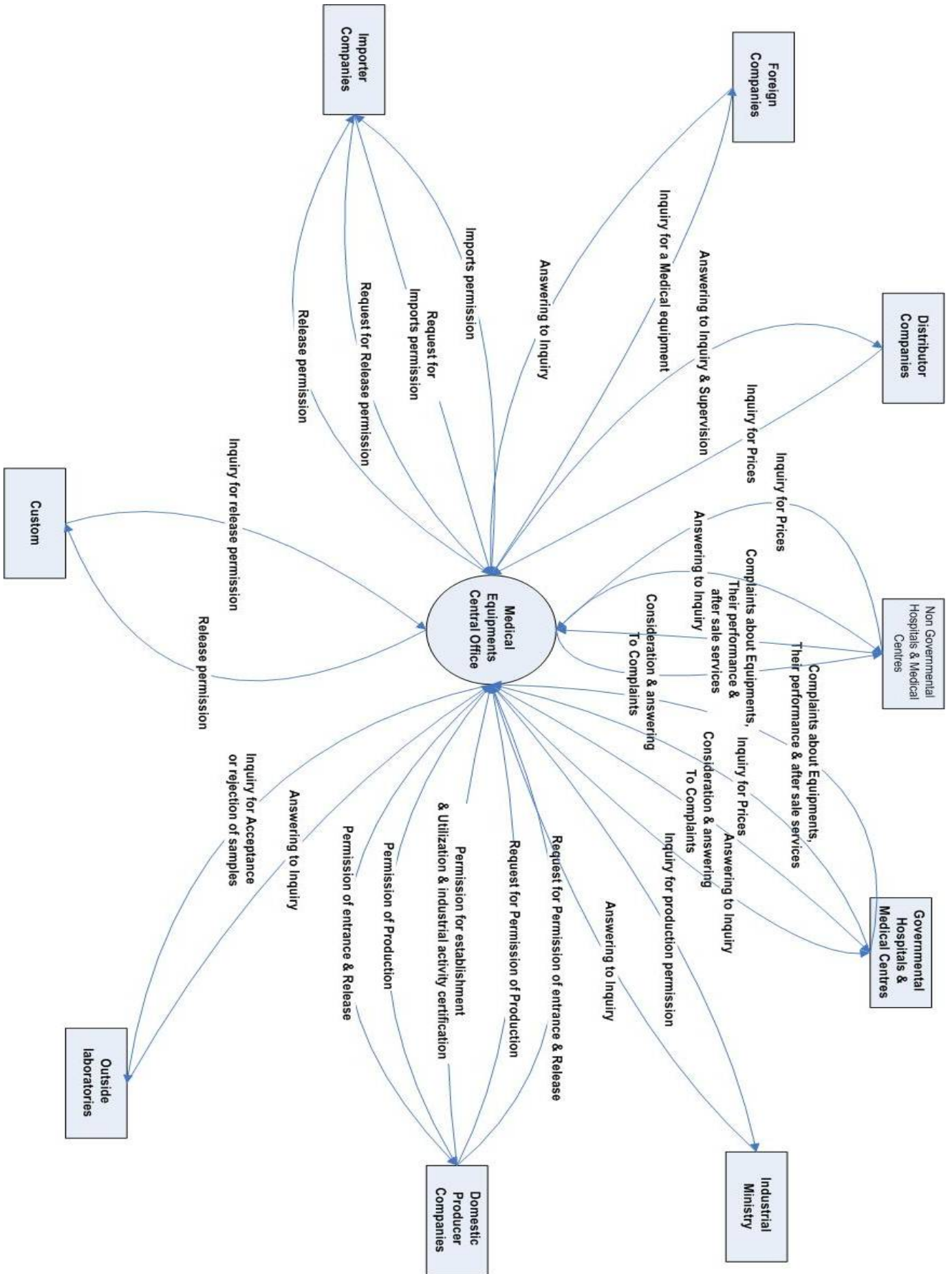
-Public providers contract themselves by vendor and supplier companies while there is no guide or notification to meet all rights of care-users and providers in this contracts.

- Various duties of medical equipment (dental, laboratory, medical)administration like importation , clearance, following sale services and prices lead to a duty based structure in this field.

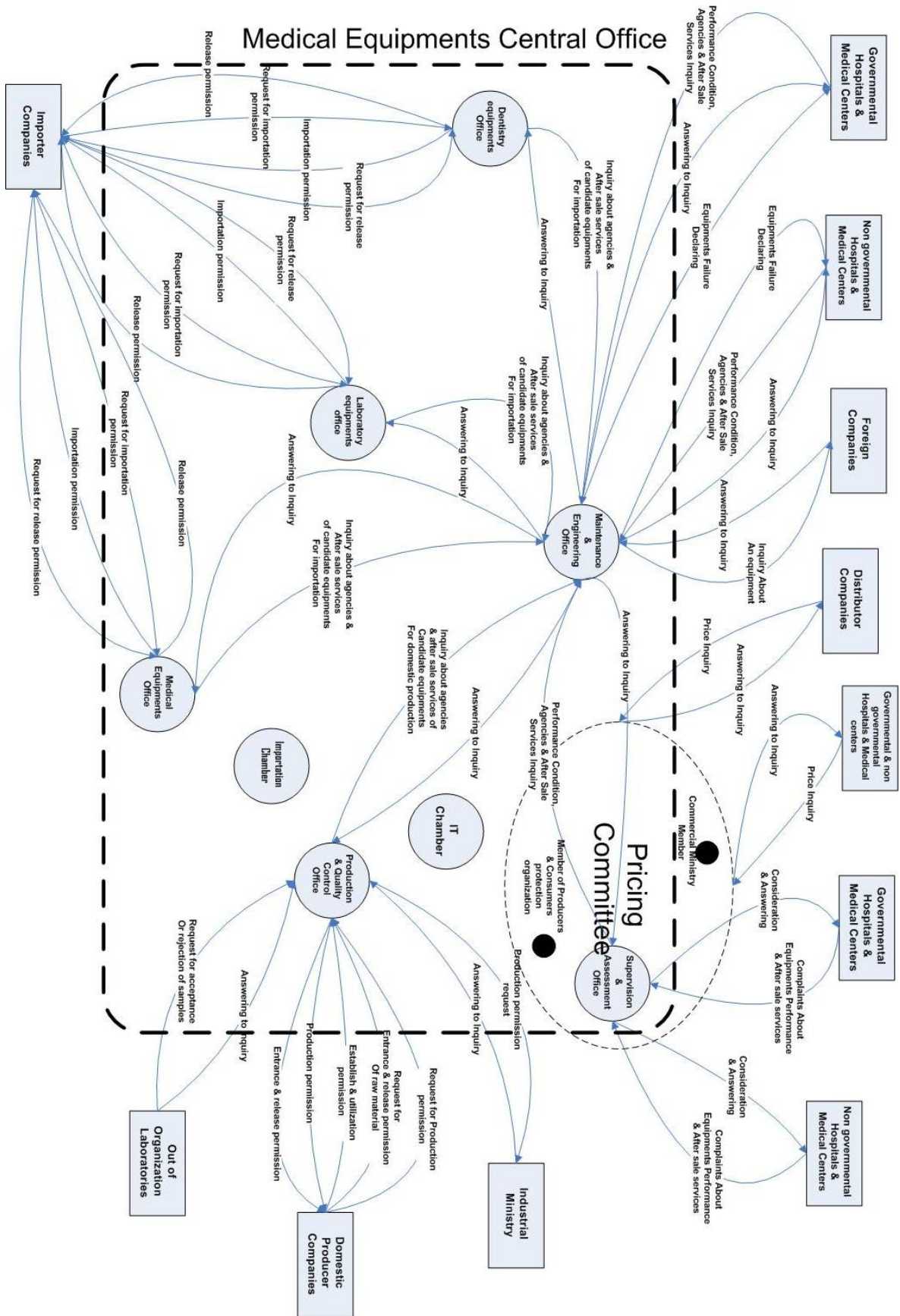
We explained in details the findings of review phase in any mentioned dimensions of technology/medical equipment management specially its selection and use in the report.

Coming diagrams demonstrates current medical equipment management structure of MOH (Medical Equipment Office), Medical Universities and Hospitals.

Medical Equipment Current National Situation Data Flow Diagram Zero level



Medical Equipment central Office Current situation Data flow diagram (first level)



Results

After reviewing and analyzing current system and study HTA & M background in other countries we designed a new model which meets these principles:

- Simplify existent complexity and disintegrity of structure for multi-center decisions of this field
- Changing duty based structure to HCTM process based structure predicting managerial process in management structure
- Focusing on the selection part of this chain with HTA approach
- Coping with stratified levels of health system in Iran and clarifying role of each level in the new system
- Setting decision making method and relationships in subsystems of health

To design a comprehensive management structure of medical equipment ,we should notify to the cycle of managerial roles of MOH ,Medical universities and hospitals in this area .All these levels should be represented as subsystems of this model and the process of HCTM and their authority related decision making being clarified.

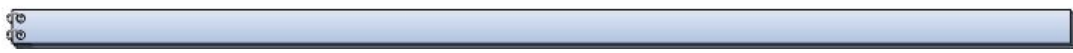
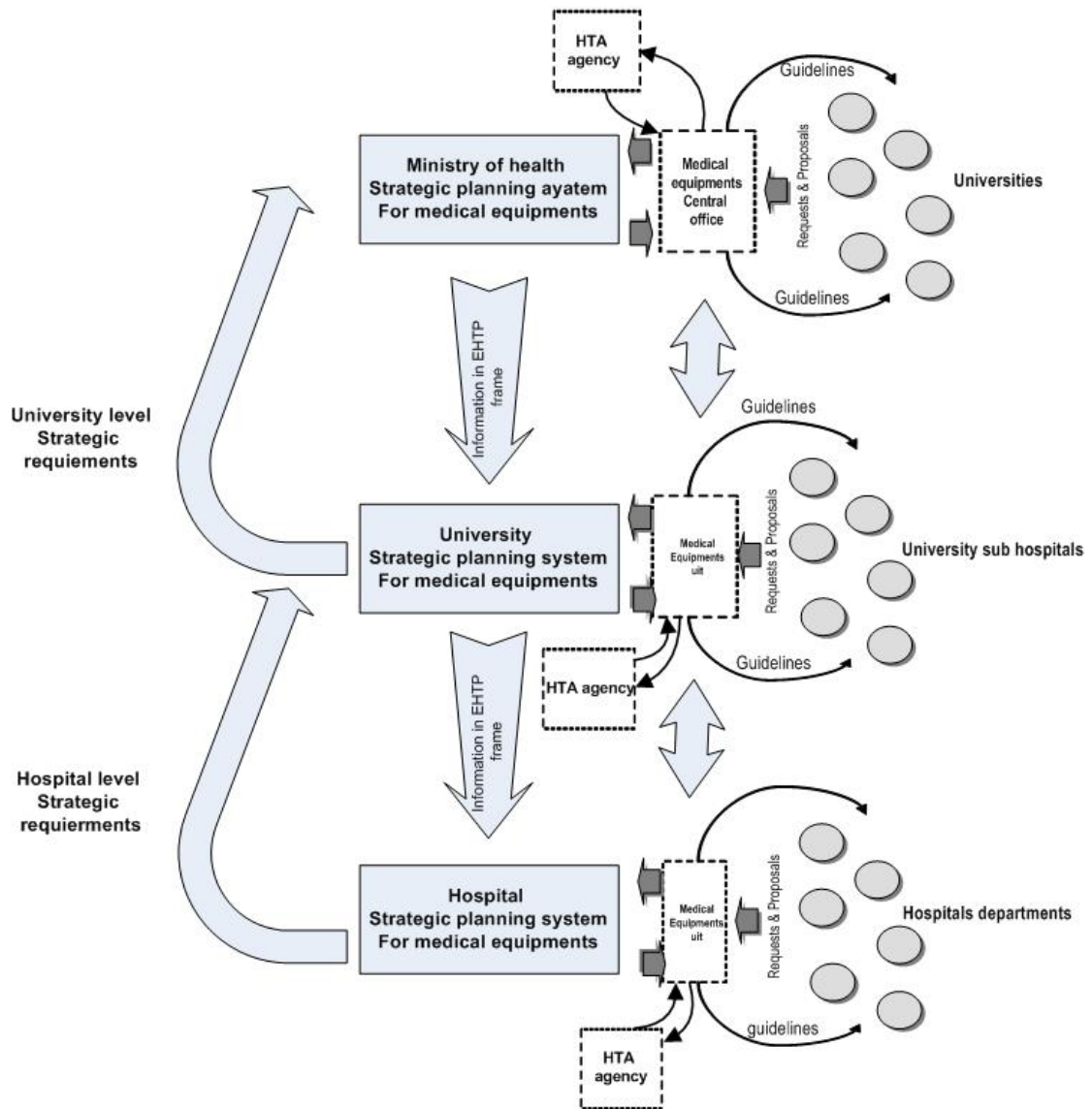
In this manner the general master diagram shows integrity of health policies and strategic plans with technology policies and decisions ,on the other hand the expected process and responsible units were drawn in three levels.

For example these four main areas are designed for central medical Equipment Office of MOH :

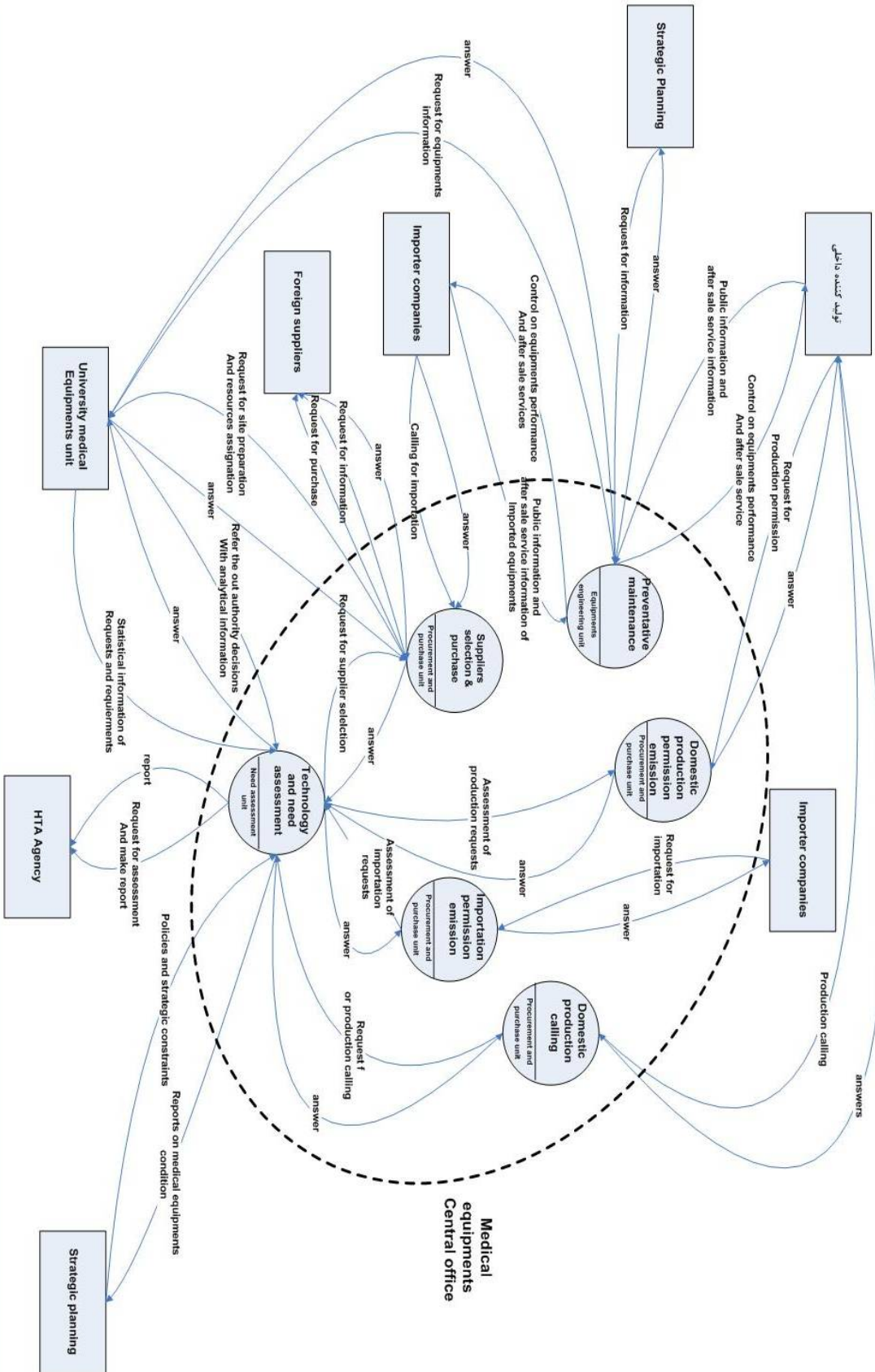
- Technology and need assessment
- Suppliers selection and purchase
- Importation permission emission
- Domestic production calling
- Domestic production permission emission
- Preventive maintenance

This kind of approach to HCTM would provide a process based structure to integrate managerial role of structure boxes and lead to value added outcomes of the system because all affecting dimensions equipment management specially the selection and use seen to be accounted.

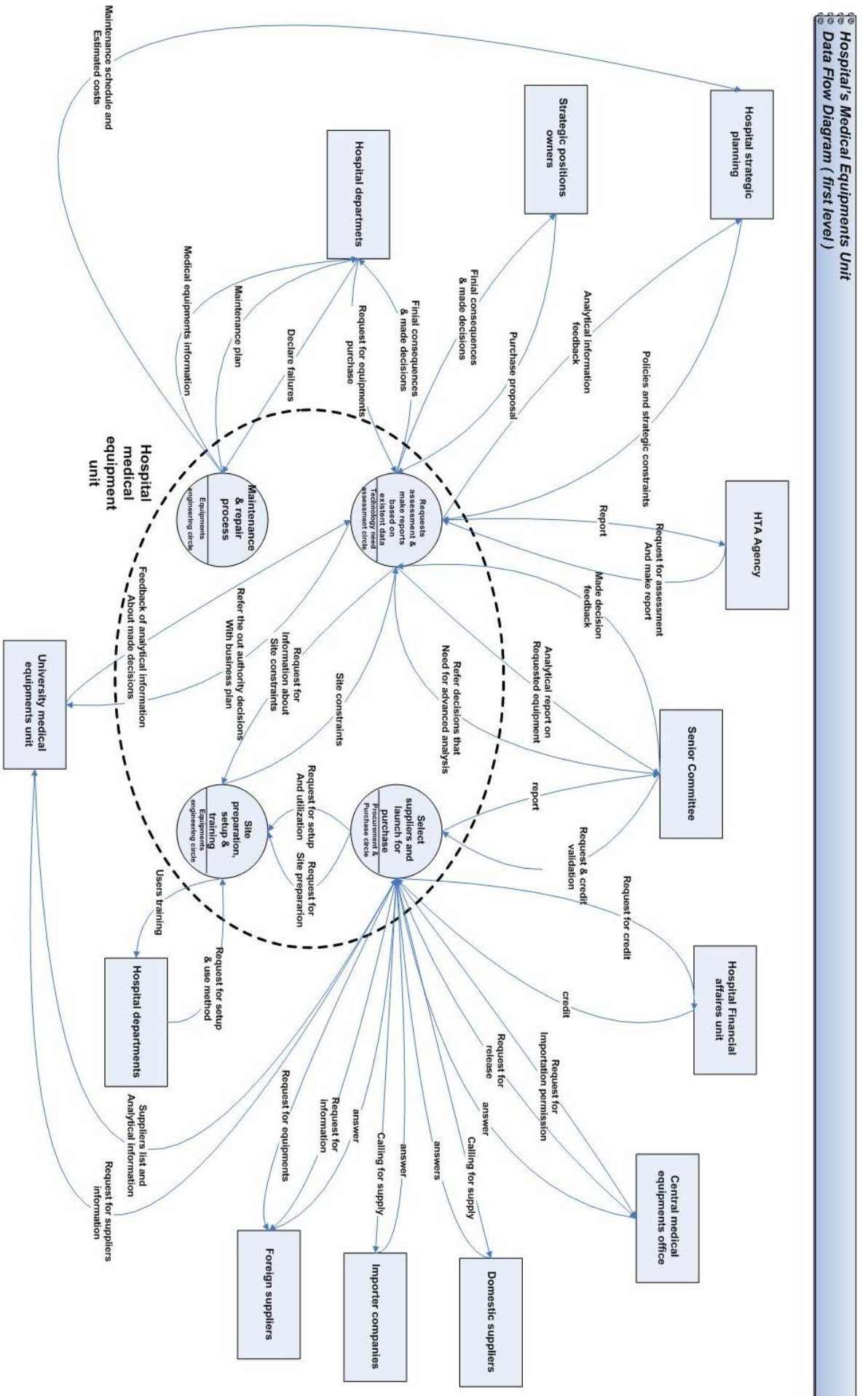
Medical Equipments Strategic Planning procedure



**New arrangement of Medical Equipment management structure in Medical Equipment Office MOH
Data Flow Diagram (first level)**



New arrangement of Medical Equipment Management in Hospitals Data Flow Diagram (first level)



Future researches:

To develop inventory data bank clarifying existent equipment , performance level of medical equipments and invested resources to this field .

To define human resources and required educational programs needed including workshops, degrees and training packages.

Developing guide draft of HCTM for policy makers and managers and experts

To study effectiveness or efficiency of broad use of costly medical equipments in Iran .

Setting prioritized medical equipment for all health care levels.

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