Special Section

REPORT FROM THE EUR-ASSESS PROJECT

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INTRODUCTION TO THE EUR-ASSESS REPORT

Health technology assessment (HTA) is analysis of the implications of health care technology that is intended to influence decision making. For more than 10 years, member states of the European Union have been engaged in developing the field. Some have also institutionalized it within their health systems. HTA is moving to center stage as an important mechanism to assist in making difficult choices.

The European Union and the European Commission have gradually become more active in health care, especially since the acceptance of the Maastricht Treaty, which includes public health as a task for the European Commission for the first time. European Health Ministers have asked the European Commission for help in dealing with strategic issues in health care that affect all Europeans. One issue identified by the Health Ministers is "value for money in health care." In 1991 the Health Ministers identified HTA as a key tool to improve the management of scarce health care resources.

This report concerns the EUR-ASSESS project, a special project aimed at promoting coordination of HTA among member states of the European Union.

THE EUROPEAN CONTEXT

European health care programs are in a period of rapid change. During the period until the 1960s, the main thrust of policy was to improve access to care. But around 1965, all of the countries in the European Union began to experience rising expenditures for health care. With the rising costs of care in the mid-1960s, governments intervened to try to control costs. One of the implications of such control was that they tried to encourage greater efficiency in the production or use, especially use, of new technologies. HTA was born in this context.

Rising expenditures are fostered not only by new technology, broadly defined, but also by such factors as aging of the population, changing of the patterns of disease, and rising demands from the public. The combination of issues and challenges has stimulated reform movements in most countries of the European Union. Reform movements seek, at the same time, to maintain universal access, to control costs, to promote the use of cost-effective technologies, and to improve efficiency and quality of health care. In addition, many reforms are trying to enhance consumers' choice of provider. These somewhat contradictory goals will not be easy to meet.

HTA is organized and implemented in a somewhat different way in each country. One of the main determinants of such differences is the nature of the health system of the country. Some countries, such as Sweden, Spain (and Catalonia), and France, have an actual public agency for assessment of health technology. Others, such as the Netherlands, implement HTA primarily in relation to payment through sickness funds. The United Kingdom has embedded HTA in the R&D Programme of the Department of Health in an attempt to bring HTA into all administrative and clinical decisions. Likewise, methods differ. Sweden and France use synthesis of existing
knowledge as their most important tool. The United Kingdom and the Netherlands, on the other hand, also commission prospective studies on high priority subjects. In Catalonia, synthesis of existing knowledge and prospective studies are both used in an integrated way.

The heterogeneity and diversity that now exists in HTA in Europe may stimulate an exchange of experiences within Europe. There is no one right way to do HTA or to use it to improve health services. Diversity can be very valuable when those from different regions and countries share methods and results.

While HTA has a growing importance in Europe, it is only one means among others to try to achieve the goals stated above. Furthermore, HTA is fundamentally an exercise in rationality. Human and political behavior is not necessarily rational. HTA does not by itself determine decisions: that is a human and political process. Many factors besides rational analysis go into decision making. No one working in the field of HTA wishes to be responsible for actually making decisions. The goal for those working in the field of HTA is to assist in the difficult task of making those decisions.

**THE EUR-ASSESS PROJECT**

With the development of HTA in Europe, North America, and Australia during the 1970s and 1980s, it was natural to think of international communication and cooperation. Such international work may be said to have begun formally with the first meeting of the International Society for Technology Assessment in Health Care (ISTAHC) in 1985 in Copenhagen. The International Network of Agencies for Health Technology Assessment (INAHTA) was created in 1993. The EUR-ASSESS project was inaugurated on May 1, 1994. This event was preceded by years of preparation and slow development.

More than 20 years after the formal establishment of HTA as a field about 1975, the harsh reality is the very small amount of money available for HTA in relation to the huge expenditures on health care services or the active efforts to develop and diffuse new technology. At the same time, annual meetings of ISTAHC have allowed those working in the field to identify gaps and duplication in coverage of technology assessment. An early example of duplication was the carrying out of similar studies on heart transplant in the United States, the United Kingdom, the Netherlands, and Sweden. More recently, bone density screening for osteoporosis has been formally studied by more than 10 HTA agencies. Myopia treatment by excimer laser has been studied by five or more agencies. This duplication of efforts may have been necessary, but in the future ways of working together need to be found. Cooperative projects may be possible. Coordinated efforts can assure the efficient use of scarce assessment resources.

About 1990, a group of agency heads and others, including Egon Jonsson (Sweden), David Banta (the Netherlands), Michael Peckham and Chris Henshall (UK), Yves Matillon (France), Alicia Granados (Catalonia), and Richard Cranovsky (Switzerland) began to talk about the need for coordination of HTA activities in Europe. These discussions culminated in a decision to apply to the BIOMED Programme of Directorate General XII of the European Commission for support to establish a coordinating network. The first application in 1992 was unsuccessful, but the partners decided to persevere, encouraged by informal contacts with Commission staff, who welcomed a proposal of apparent priority to European Ministries of
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Health. A second strengthened proposal was submitted in 1993 and led to the funding of the present project (EUR-ASSESS).

While EUR-ASSESS is aimed at improved coordination, it is seemingly difficult or impossible to gain the European Commission's support for this activity by itself. Thus, the project was developed with four substantive tasks that could contribute to improved coordination. The formal objectives of the project are:

1. To contribute to the effectiveness and cost-effectiveness of health care in Europe by stimulating and coordinating developments in the field of HTA in Europe.
2. To improve methods of priority setting in the HTA programs in Europe.
3. To develop, formulate, and apply a common method for assessing technology in HTA programs in Europe, with a focus on increasing the international applicability of findings.
4. To ensure effective dissemination of results of HTA programs in Europe and evaluation of the effects of such dissemination.
5. To improve decision making by health insurance organizations and other payers by stimulating wider use of technology assessment in such decisions.

The Swiss partner expressed a strong interest in studying the use of HTA in insurance coverage and was able to obtain supplementary funding from the Swiss Federal Office for Science and the Swiss National Research Foundation to examine this area.

The EUR-ASSESS Steering Committee devoted considerable effort to ensure that the partners had a common and consistent picture of HTA. It also coordinated the work of the different subgroups in order to develop a comprehensive final report.

HEALTH TECHNOLOGY ASSESSMENT (HTA)

Health technology assessment—also known as health care technology assessment or medical technology assessment—is a form of policy research that systematically examines short- and long-term consequences of the application of a health technology, a set of related technologies, or an issue related to technology. The goal of HTA is to provide input to decision making in policy and practice. The essential properties of HTA are this orientation to decision making and its multidisciplinary and comprehensive nature.

Health technologies are the drugs, devices, procedures, and the organizational and support systems within which health care is delivered.

HTA takes a broad view of technology and of technological change and carries out analyses of such issues from a number of perspectives. The field includes studies of ethical and social consequences of technology; factors speeding or impeding development and diffusion of health technology; the effects of public policies on diffusion and use of health technology and suggested changes in those policies; and studies of variation in use of technologies. The most prominent part of HTA is to determine, insofar as possible, the benefits and financial costs of a particular technology or group of technologies. The main goal of such studies is to improve "value for money" in health care.

Given this broad context, HTA is not defined by a set of methods but by its intent. A technical assessment of a pharmaceutical or medical device carried out by a program as a part of a regulatory decision can be considered HTA. Likewise, an ethical analysis concerning gene therapy done to clarify its implications before deciding whether to provide it can be considered an HTA. The most frequent activity

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in HTA is a synthesis or systematic review of available information, especially on efficacy and cost-effectiveness, to assist different types of policy decisions. A prospective randomized clinical trial or prospective cost-effectiveness study done for policy reasons, as in the Netherlands or the United Kingdom, is also a technology assessment. On the other hand, clinical research or even clinical trials done solely for the purpose of increasing scientific knowledge are not technology assessments (see Methodology Report).

Given the wide scope of HTA, it is not a discipline or a field. In fact, HTA is a systematic interdisciplinary process based on scientific evidence and other types of information. It involves physicians and other clinicians, economists, social scientists, public health and health services researchers, engineers, and ethicists. Increasingly, the general public and its representatives are involved in HTA.

The goal of HTA is change. It is not research for knowledge sake. HTA should help to demonstrate problems and potentials in disease control. This means that topics chosen for assessment must be important to society. Information should be timely and should be presented in a form useful to the intended audience, whether these are national policy makers and politicians, hospital administrators, clinicians, or the general public. Because it is well known that the results of information dissemination are limited, the issue of implementation of HTA results is becoming an important part of the tasks at hand. Implementation involves not only dissemination of information, but attention to factors that promote change, such as physician preferences, patient preferences, regulation, and financial incentives. A recent preoccupation in a number of countries concerns how to affect technological change through health insurance coverage decisions.

Technology assessments are useful to a wide range of decision makers in health care, including government policy makers, insurance companies and other payers, industry, planners, administrators, clinicians, and patients.

Despite its policy goal, HTA must always be firmly rooted in science and the scientific method. The process of technology assessment must be carried out with integrity, and the results must be valid.

HEALTH TECHNOLOGY ASSESSMENT AND POLICY

Every country (or autonomous region) has a structure of health policies that influences—and is influenced by—health technology. While these policies have mostly not been developed with the idea of channeling health technology development and diffusion, they affect technology. From its beginnings, HTA has focused on these policies, especially policies related to regulation, quality, and payment for care, as a target for its work. The primary philosophy has been to try to develop assessments useful for policy makers and policy making.

Health policies that may be related to HTA fall into the following categories:

- Research and development
- Regulation of pharmaceuticals and equipment
- Regulation of numbers and location of services
- Payment for services
- Quality assurance
- Education and training of providers
- Consumer education
Health care technology is certainly influenced by research and development. For example, applied research can be targeted to specific health problems or to specific technological areas. Insofar as applied research comprises new technical devices or drugs and is funded by industry, early results may be kept confidential, and the new technologies may appear on the market rather suddenly. On the other hand, projects of clinical research in universities may be known long before any results are anticipated. It is thus necessary for those working in HTA to be well acquainted with ongoing research both in industry and universities in order to judge the cost-effectiveness of emerging technologies as early as possible.

Most countries regulate pharmaceuticals, biological products, and equipment for safety and, to an extent, efficacy. In Europe such regulations have been partially harmonized by laws of the European Union. Heath technology assessment is an integral part of these regulations. In general, a company applies for a license to test a new product in patients, carries out the testing, and submits the results of the testing to a regulatory program. The regulatory program then assesses the results and decides whether the product can be marketed. In these programs, cost-effectiveness is not assessed. While such programs assure a degree of assessment of products, they have little influence on diffusion and use after product approval.

A related type of regulation seen in some countries develops direct controls over some technologies, especially those in public health. For example, in the Netherlands, any proposed population screening program must have a thorough assessment before it can be implemented on a routine basis.

A number of countries regulate the numbers and placement of services. For example, in the Netherlands about 15 capital-intensive services involving high technology are regulated, including radiotherapy, transplants, renal dialysis, intensive care, and cardiac and neurosurgery. During the last 10 years, HTA has become part of the decision-making process in such programs. Generally, the government decides to regulate a technological area and requests an assessment from a special HTA body before making a decision. The government can also ask for an assessment of an existing regulation with the purpose of modifying it. In the Netherlands, the assessment role is played by the Dutch Health Council.

Payment for services, whatever its form, obviously has a great influence on the shape and nature of services. In countries with some form of system-level budgeting, including Sweden, the United Kingdom, France, and the Netherlands, expenditures can be directly controlled. Tight control over expenditures puts pressure on providers and makes choice necessary. Up to the present, however, there is little evidence that HTA has played much of a role in these choices. Furthermore, while fixed budgets can control costs, they are not selective with regard to technology. Cost-effective technologies may be restricted just as much as technologies that are less cost-effective. It may be that health systems are becoming less open to innovation and new technologies as a result of such budgets.

There are many other options for using payment to control technology, but these generally have been little explored. For example, levels of payment can be used to stimulate or discourage the use of particular technologies. One option that has received much attention during the last few years is to determine coverage decisions based on HTA. Under this option, technology would not be covered by insurance until it had been shown to be cost-effective. This option is the subject of a full analysis in this report.

Quality assurance, including a variety of activities, such as utilization review, certification and accreditation, and evaluation of outcomes, has become increasingly
prominent in recent years. The relation of quality assurance to HTA is not always clear, however, because the term "quality assurance" has a broad meaning that extends well beyond improving cost-effectiveness of services in many people's minds. The obvious relation between quality assurance and HTA is to demonstrate that improved outcomes result from certain processes of care. Such work has begun but has not advanced very far.

Education and training of providers, including dissemination of information to providers, is gaining increasing attention. In a broad sense, the education of providers is obviously of crucial importance in determining their mode of functioning, including their use of evidence in making clinical decisions. In a narrower sense, methods of influencing behavior through information and other means is an active area of research specifically dealt with by EUR-ASSESS (see Dissemination Report).

Finally, provision of information to consumers may influence the use of technology. Certainly, many support the "empowerment" of consumers through providing them with reliable and valid information on such aspects of technology as efficacy and appropriate use. Research on this area is much more limited, but it is also considered in the EUR-ASSESS project (see Dissemination Report).

Overall, HTA has had no more than a moderate impact on the adoption and use of new technologies in the health services. Perhaps the main reason for this is that the preoccupation of policy makers has been with costs and not with technology management. As indicated, costs can be controlled at the national level, but this does not guarantee the appropriateness of provided services. It is seldom realized that already established, "small-ticket" technologies contribute more to high costs in the health services than dramatic technologies such as organ transplants or radiotherapy for solid tumors. To arrive at the optimal cost-effectiveness of clinical services, it may be necessary to involve clinicians in the process of HTA, or at least have them specially informed.

THE STRUCTURE AND PROCESS OF THE EUR-ASSESS PROJECT

The partners involved in the first discussions were able to recruit others from countries that did not (yet) have HTA agencies. The proposal as sent to the European Commission included 12 individuals from 10 countries (in addition to those mentioned above, these included Germany, Denmark, Spain, Italy, and Greece). Switzerland was included from the beginning on a self-pay basis. After acceptance of the proposal, there was an opportunity to add additional partners to the project before the contract was signed, and two additional institutions, one Danish and the other Dutch, were formally added to the project. During the course of the project, new contacts were made and new agencies were established. Therefore, additional members joined the EUR-ASSESS Steering Committee. By the third year of the project, as can be seen on the list of participants, almost every country of the European Union participated in the Steering Committee. The Steering Committee has made all policy decisions in the project, while implementation has been by the coordinator.

Four subgroups were established to carry out the substantive tasks of the project: a) a subgroup on priority setting; b) a subgroup on methods; c) a subgroup on dissemination and evaluation of impact; and d) a subgroup on coverage. It was decided that each subgroup should have a partner from the "north" and a partner from the "south" as co-chairs. Further, it was decided that each of the national and regional agencies participating in the original proposal should be represented on all subgroups to ensure full input and ready acceptance of the results. Thus, the Swedish
Council on Health Care Technology Assessment (SBU), the U.K. Research and Development Programme, the French Agency for Development of Medical Evaluation (ANDEM), and the Catalan Agency for Health Technology Assessment (CAHTA) are represented on each subgroup and the directors or deputy directors of these programs have served as co-chairs of the subgroups. The Swiss partner was the co-chair of the coverage subgroup based on the strong interest on this subject in Switzerland. Other members of the subgroups were defined by interest and expertise, so that each subgroup included experts in that subject. The coordinator of the project acted as secretary to all subgroups (and to the Steering Committee and Executive Committee). The membership of all subgroups is shown at the beginning of the following reports. All of those who have contributed to one or more meetings of the Steering Committee or subgroups are also shown.

Each subgroup followed a similar method: a) to review the literature and other available documentation as a background to its discussions; b) to collect information on activities in Europe, especially those of HTA agencies, primarily by written surveys and interviews; and c) to analyze and synthesize the documentation and existing experience (including that of the members of the subgroups) to arrive at principles, conclusions, and recommendations. Each subgroup wrote its own report. This draft report was then scrutinized by the Steering Committee and revised before being accepted for the final report. These reports from the subgroups form the bulk of this publication.

The subgroups typically met five to seven times during the course of the 3-year project. A work plan that was part of the contract with the European Commission defined the budget for each subgroup and a schedule for its “deliverables.” Budgets for the subgroups were under their own control, although the coordinator held the funds and paid the bills. In addition to subgroup reports, annual reports were submitted to Brussels. The Steering Committee met five times during the course of the project. Because the Steering Committee was too large to fully discuss project policy and because of the expense of large meetings, an Executive Committee was appointed to oversee the project between Steering Committee meetings. The Executive Committee met three times during the course of the project.

Perhaps the most important result of the project was that about 100 or so technology assessors, academic experts, and others of many nationalities worked enthusiastically and creatively on each subject, often involving others in their respective organizations. The exchange of knowledge and ideas during this work substantially added to the quality of the reports. The experience gained during this cooperation demonstrates the possibilities of future, more permanent collaboration within Europe in the field of HTA.

ANALYTICAL RESULTS FROM THE EUR-ASSESS PROJECT

HTA is a highly complex process. One representation of this process is shown in Figure 1. However, the process is much more complex than can be indicated in this figure. For example, technologies must be selected for evaluation partially by consideration of the extent of available information and the predicted impact of an assessment. Therefore, the different stages of an assessment are linked together in many ways.

In the EUR-ASSESS project, a relatively simple version of these stages was used:
1. The Process of Developing and Disseminating Information on Efficacy and Safety.


Figure 1: The Process of Developing and Disseminating Information on Efficacy and Safety.
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- Identification and priority setting
- Assessment
- Dissemination and implementation (including coverage)

This representation is a convenient way to separate the HTA process into more specific building blocks, each considered by itself. However, there are many explicit and implicit links between the different areas.

ACHIEVEMENTS OF THE EUR-ASSESS PROJECT

The obvious achievement of the EUR-ASSESS project has been to form an informal network for HTA in Europe. Not only have existing programs become part of a network, but new programs and activities have been identified or stimulated. Before EUR-ASSESS, those working in HTA had had little contact with their counterparts in HTA in such countries as Austria, Portugal, Germany, and Greece. All countries in the European Union are now part of the network.

Related to this achievement is the fact that professionals from different countries and cultures, from different disciplines, and speaking different languages, were able to come together to work on common problems (in English). The high level of the critical discussions was often commented on. Participants became aware of the different rules and regulations that govern activities in different countries. A mutual respect and understanding was created as the participants came to know each other more thoroughly as the project developed. The different perspectives and experiences were found to be both useful and interesting.

The four subgroup reports, each addressing a specific part of HTA, sum up the best available knowledge regarding those dimensions. They have been written in order to address problems in the real world of practice, administration, and policy-making. They are aimed more at answering practical questions than being academic exercises, and should thus be helpful to those actually working with HTA programs.

SOME CONSIDERATIONS IN DEVELOPING AN AGENCY OR PROGRAM FOR HTA

The EUR-ASSESS project has given partners the chance to discuss their programs and those of others. During these discussions, considerable informal advice has been given, especially to those whose activities are not so mature. This section is an attempt to capture some of the lessons that have been passed on.

A new HTA program generally is proposed and developed because of policy concern about a special health care technology used or about to be introduced in the health service. The ministry or department of health has then usually been concerned about the cost of the new technology, and the hope or expectation is that HTA can help in controlling cost.

In many areas, there is also growing clinical concern for health care technology that supports the policy concern. However, clinical concern typically focuses on quality, broadly conceived, and cost is not a priority problem. Clinicians are often responsive to evidence that they are not providing optimal care, or that health status is not as good as might be expected in certain groups.

The combination of these two groups of concerns have led to establishment of formal programs for HTA in a number of countries and regions, and this development seems to be accelerating. Typically, the first development is a committee or council...
located within the ministry or department of health, but with limited resources and staff support.

First assessments are almost always driven by political concerns. The first HTA done in Sweden, for example, examined the computed tomography scanner, because it was a highly visible, expensive new technology. In these early years, assessments almost always dealt with such new technologies. With time, concerns for quality and improving health status have brought new priorities, such as improved care for people with diabetes or mental problems.

HTA programs have universally observed the importance of attention to the quality of their reports, especially because of the political motivation behind their work. The medical profession has initially been skeptical about the possibility of changing practice through HTA, as this has been regarded as part of a political process. Without ongoing concern about reliability and validity of results and active efforts to assure quality, HTA programs cannot succeed.

At the same time, HTA programs have discovered the value of consulting stakeholders early and often to ensure that important concerns are addressed and that results will be addressed to real and important problems.

In earlier years, dissemination of products of HTA had been largely passive, mostly limited to publication and distribution of published reports. This strategy has failed to affect more than formal policies. Efforts are now developing to expand dissemination activities. For example, in Sweden, the Minister of Health observed the great potential impact of technology assessment on practice and therefore allocated special resources for the purpose of increased dissemination of results of technology assessment projects. To an extent the same phenomenon has been seen in other countries, such as the United Kingdom and Catalonia. An integral part of dissemination and implementation of results is to evaluate impact.

As indicated, an HTA program typically begins with a committee. Soon, however, it becomes apparent that such a committee needs resources, including staff support, and some sort of institution begins to form. The actual form of such institutions varies widely, as already noted. It could be an agency, a defined program in a ministry, a coordinating body, or some other type of institution. Staff are not only physicians and economists. In fact, the type of training, as long as it is based in science, has not seemed to be the most important determinant of good staff. Personal attributes such as integrity, commitment, and intelligence are perhaps more important. Staff of an HTA program must be both committed to scientific analysis and comfortable at working in a political environment. Clear and critical thinking is a must and can, of course, be fostered by formal training.

Because HTA is a multidisciplinary activity by its nature, different disciplines must be involved in its activities. Expertise in medical, economic, and social aspects of technology is necessary. However, these disciplines do not necessarily have to be available on the staff. HTA agencies typically have a network of consultants and, in addition, may have a specially appointed expert group to oversee their work. Among other tasks, both staff and consultants assure a rigorous HTA process. Such expert advice is critical for the success of HTA.

As assessment begins, concerns about political pressures on assessment begin to surface actively. In some countries, at least, assessors realize that they cannot be completely effective as part of the ministry of health, and policy makers see that independence of the process is necessary if the results are to be trusted by the outside world. Therefore, a natural evolution is to see the establishment of an independent, free-standing agency, as has occurred in Sweden, France, Catalonia, and other places.
FUTURE NEEDS

The foundation for an effective activity in HTA has been developed in Europe. A number of successful assessments have been carried out, HTA is respected throughout Europe, and impact of assessments is growing. The two key needs at the moment are for more national and regional resources in assessment and for expanded European cooperation and communication. A strong network can deal with European priorities and carry out coordinated assessments. It can also disseminate available assessments to meet national, regional, and local needs for information.

At the moment, a system for exchange of information between assessment programs is partially developed under the auspices of the International Network of Agencies in Health Technology Assessment (INAHTA), with the secretariat located in Sweden. In the near future, the exchange of information will be improved, especially through the use of the Internet. In addition, the U.S. National Library of Medicine has invested large and increasing resources in developing high quality databases for HTA.

Wider international collaboration is needed. For example, the Cochrane Collaboration, an international network of institutions and people, has pioneered the development and testing of improved methods for identifying and synthesizing information, mainly from randomized trials. In time, the Cochrane Collaboration will produce more and more information of value to practice and policy. At the same time, other efforts are needed to examine other types of evidence and broader perspectives. HTA agencies can collaborate with the Cochrane Collaboration and other similar efforts to assure that its results are appropriately used to improve the health of the population of Europe.

GENERAL CONCLUSIONS AND RECOMMENDATIONS

For the European Union:

- There is value in bringing those involved in HTA in different countries together. They can compare methods and results and learn from each other. Diversity then becomes a strength. Waste and duplication are avoided, while high priority issues are more likely to be tackled. Resources should be allocated, supporting activities aimed at fostering such community, including conferences and meetings. Such subjects as methods of assessment, priority setting, dissemination, and coverage decisions could be considered in such meetings and conferences.

- The countries of Europe need more efficient methods for sharing information. Such means as the Internet have not been effectively exploited for such sharing. There is a need for support to explore the possibilities of developing robust and reliable systems for sharing information in Europe.

- While there is certainly value in diversity, the existing diversity is not understood or documented. The relationship between HTA and the health system in different countries has hardly been examined. Resources should be devoted to studying the relationships between HTA and health systems in the member states of the European Union.

For individual countries:

- Each country should have at least one organization (or a coordinating body) that can serve as a contact point for technology assessment activities, including priority setting, dissemination, and implementation.