

## 第七章

1. ランドルト環による基礎実験の追加項目
2. G7 GHAP SP4 最終報告書について

## 第七章 その他

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#### 1. ランドルト環による基礎実験の追加項目

昨年度に引き続き、テレビ会議システムをLANで接続し、ノイズを加えたランドルト環により、テレビ会議システムの画質評価を行った。

今回は必要十分なデータが得られたため、ROC曲線の理論分布に依存しないジャックナイフ法で信頼限界を算出した。ジャックナイフ法は、データの組織的な再サンプリングによって母集団の理論分布を十分に推定する方法である。

その結果、正規分布を仮定する検定と同様の結果を得た。つまり、拡大・縮小を制限すると、ビデオチャネル(H.261)よりもデータチャネル(アプリケーション共有)を利用した方がROC曲線は有意に優れた結果を示した。さらに、拡大・縮小を認めた場合は、両チャネルの差は無くなった。

このことから、一般に、解像度が要求される応用ではデータチャネルによる静止画伝送が優位であり、対話性が要求される応用ではビデオチャネルによる動画伝送で十分であることが考えられた。

本実験はとりまとめの上、米国telemedicine journalに投稿中である。

#### 2. G7 GHAP SP4 最終報告書について

1995年から1999年にかけて、11の国際パイロットプロジェクトがG7（主要7カ国財務省・中央銀行総裁会議）の合意に基づき実施された。その中で、地球規模の健康応用プロジェクト(GHAP: Global Healthcare Appliation Project)は我が国では当時の厚生省が担当した。GHAPは、さらに10の分科会(Sub-project)に分かれていて、その第四部会(SP4)は遠隔医療(telemedicine)に関するものである。G7 GHAP SP4は東海大学が専門家として参加した。5回の世界フォーラム(FORUM)と国際多地点バックボーン回線(IMPACT)の結果はまとめられ、分科会では唯一の報告書を上程したプロジェクトとなった。

英文の報告書はSP4の幹事であるモントリオール大学のラクロワ教授によって2000年秋に発表された。氏によると著作権は放棄している、とのことである。日本語の翻訳は本研究の範囲であり、日本医療情報学会誌に発表する予定である。英文は東海大学のホームページ(<http://mi.med.u-tokai.ac.jp>)で公開している。日本語訳についても翻訳語のチェック後にホームページで公開する予定である。

*G7 GHAP SP4* 最終報告書  
原文(英語)と日本語訳

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Information Society



Global Healthcare Applications Project

## **International Concerted Action on Collaboration in Telemedicine**

### **Final Report and Recommendations of the G-8 Global Healthcare Applications Project-4**

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## **Abstract**

The main objectives of the G-8 Global Healthcare Applications (GHAP) Sub-Project (SP)-4 were to establish an international concerted action on collaboration in telemedicine, telehealth, and health telematics. In order to promote and facilitate the implementation of telemedicine or health telematics networks around the world, it was necessary to resolve certain key issues. Five thematic solution-seeking FORUMS, each addressing a key issue, including interoperability of telemedicine and telehealth systems, impacts of telemedicine on healthcare management, evaluation and cost effectiveness of telemedicine, clinical and technical quality and standards, or medico-legal aspects of national and international applications, were held between May 1998 and December 1999.

The main objective of these FORUMS was to establish best practices and a thorough review of the issues through interactive discussions with experts to determine the best solutions for the facilitation of global international telemedicine networks. More than 650 invited participants from 16 countries attended the five FORUMS, which were 2-3 days in duration. These FORUMS provided a foundation for a very rich discussion and exchange of ideas resulting in the initiation of collaborative activities. Based on the discussions and reflections, which followed plenary review presentations and working group discussions held during these FORUMS, a series of recommendations were prepared by the national representatives of the G-8 GHAP SP-4. These recommendations propose to political leaders and healthcare managers of the G-8 and other countries roadmaps to follow in order to accelerate the achievement of a Global Society in Healthcare via Telemedicine, Telehealth, and Health Telematics.

A significant outcome of this international collaboration has been the initiation of the International Multipoint Project of Advanced Communication in Telemedicine (IMPACT) feasibility study. This activity is conducted through multi-point exchanges between telemedicine units in academic centers of the participating G-8 countries. This initial international network serves as a test-bed to develop and evaluate the recommendations generated from the FORUMS. The fields of telemedicine, telehealth, and health telematics are emerging and complex; their full integration in healthcare delivery will require years of concerted efforts to solve some of the issues identified by this working group. Continued collaboration between members of this working group and other experts in the field should be pursued synergistically with international organizations in healthcare.

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### Acronym List

|         |  |
|---------|--|
| CHUM    | Centre Hospitalier de l'Université de Montréal (Montreal University teaching hospital) |
| FDA     | Food and Drug Administration   |
| GETS    | Global Emergency Telemedicine Service  |
| GHAP    | Global Healthcare Applications Project   |
| IMPACT  | International Multipoint Project of Advanced Communications in Telemedicine            |
| ISDN    | Integrated Services Digital Network  |
| LAN     | Local Area Network   |
| MedITAC | Medical Informatics and Technology Applications Consortium                             |
| NASA    | National Aeronautics and Space Administration  |
| NGI     | Next Generation Internet   |
| PACS    | Picture Archiving Systems  |
| PKI     | Public Key Infrastructure  |
| QOS     | Quality of Service   |
| SP      | Sub Project  |
| TCP/IP  | Transmission Control Protocol/Internet Protocol  |
| VCU     | Virginia Commonwealth University   |
| WAN     | Wide Area Network  |
| WHO     | World Health Organization  |

## **INTRODUCTION**

The ministers responsible for the promotion and development of a global information society in G-7 countries met in Brussels in February 1995 and selected eleven pilot projects for international collaboration. One of these, Global Healthcare Applications Project (GHAP), set the objective to improve quality and cost-efficiency of healthcare delivery through the use of telematics tools. Within the GHAP, six sub-projects were approved initially and were eventually extended to a total of ten sub-projects. Subproject (SP)-4 was focused initially on the use of telemedicine tools in emergency medicine. This first project, Global Emergency Telemedicine Service (GETS), was one of the projects of the European Union's Fourth Framework Program and was led by Professor Louis Lareng from the European Institute of Telemedicine in Toulouse, France. The objective was to establish a trans-national and multilingual emergency system to improve the promptness and effectiveness of interventions and services through telemedicine connections. An expanded form of this project became one of the 6 initial GHAP SP's with the objective of a "24-hour multilingual and multidisciplinary telemedicine surveillance and emergency service around the world". A feasibility study, launched in December 1995, was conducted mainly as a bilateral activity between France and Italy with participation of other G-7 countries. The conclusions were presented at the world conference on emergency telemedicine in Rome, Italy on December 16<sup>th</sup> 1996. It was concluded that, from a technological viewpoint, a worldwide telemedicine network was feasible and could be implemented gradually and stepwise.

The various GHAP projects were reviewed during a G-7 national coordinators meeting held in Bethesda, Maryland on January 27-28 1997; despite the technical feasibility of SP-4, it was felt that there was not a sufficient demand to justify the investment from G-7 governments for establishing a service at that time. However, it was agreed that the growing number of regional and national initiatives in the area of telemedicine required a reinforced cooperation between G-7 countries. Furthermore, the scope of the effort was extended to include telemedicine in general and not to be limited to emergency telemedicine. This extended cooperative work was to include the inter-operability, cost-efficiency of applications, legal aspects, and healthcare management. Canada was designated as the lead country for this activity.

Why should international collaboration in telemedicine and health telematics be promoted? The economic and social benefits of telemedicine and health telematics in healthcare delivery are certainly more of regional and national importance. However, the rapid sharing of knowledge and expertise in areas of the sciences and human needs are no longer constrained by geographical and political barriers. The most industrialized nations bare the responsibility to develop and evaluate new technologies, which have demonstrated a potential to improve the quality of life and of healthcare in less industrialized countries.

Physicians and allied health workers in highly specialized academic centers offer telemedicine services to regional and local colleagues. They also need to be able to discuss their difficult cases or share knowledge and experiences with other world experts. These exchanges will constitute an extraordinary enrichment for the students in healthcare training programs. Traditional international conferences are of great importance for sharing information, but are widely dispersed and are expensive, which often results in limit participation. Today, patients are able to acquire healthcare information through the Internet, resulting in smarter patients with higher expectations and a demand for high-standard quality care. High levels of travel and population migrations require local healthcare providers to be more knowledgeable of diseases from specific geographical distributions.

## **SECOND PHASE OF G-8 GHAP SP-4**

Following the recommendations of the G-7 GHAP national coordinators, a new orientation of SP-4 was planned during a business meeting of the national representatives held during the 3<sup>rd</sup> International Conference on the Medical Aspects of Telemedicine in Kobe, Japan, on June 1<sup>st</sup> 1997. National representatives from each of the SP's were nominated by their respective national GHAP coordinator to be participants. The national representatives for GHAP SP-4 are listed in Table 1. Following the addition of Russia to the group of initial countries in 1998, the project became known as G-8 GHAP SP-4. Australia had indicated its interest to



participate in G-7 GHAP projects from its initiation, and, thus, also delegated representatives to this working group. This project was very fortunate to be able to count on a group of experts, which have accumulated a vast experience in conducting collaborative telemedicine, telehealth, and health telematics activities in their own countries, as well as within several international projects.

In addition to the national representatives, G-8 GHAP SP-4 has largely benefited from the contributions and efforts from many other experts recruited by the national representatives from the G-8 and non G-8 countries in the planning and implementation of its activities.

| Country                  | Representatives                  |
|--------------------------|----------------------------------|
| Canada                   | André Lacroix (Chair)            |
| France                   | Louis Lareng, Guy Rossignol      |
| Germany                  | Dittmar Padeken, Michael Nerlich |
| Italy                    | Marcello Bracale                 |
| Japan                    | Yoshikazu Okada, Yoich Ogushi    |
| Russia                   | Oleg I. Orlov                    |
| United Kingdom           | James McGee, Richard Wootton     |
| United States of America | Jay H. Sanders                   |
| Australia                | Sandra Prerost, Ian McDonald     |

**Table 1: G-8 GHAP SP-4 National Representatives**

Global telecommunications networks could contribute significantly towards the achievement of a healthier world. However, in order to promote and facilitate the implementation of telemedicine and telehealth networks around the world, there are a number of challenges to resolve. In order to understand these challenges, the G-8 GHAP SP-4 representatives agreed to hold a series of international workshops to examine key issues and to propose solutions.

#### **G-8 GHAP SP-4 FORUMS IN TELEMEDICINE, TELEHEALTH AND HEALTH TELEMATICS**

Five themes were established as the foundation of these international workshops or FORUMS. The objectives of these FORUMS were to assemble national healthcare authorities, key decision-makers, and users of telemedicine, telehealth, and health telematics applications, to share their views and experiences on requirements, necessary information and planning for the establishment of international collaboration in telemedicine, telehealth, and health telematics networks. The FORUMS reviewed the various national positions on telemedicine, telehealth and health telematics in not only the G-8 countries but also in other interested countries including Australia.

Five separate meetings of 2-3 days duration were held between May 1998 and December 1999. The following themes were the principle focus of each meeting:

- Interoperability in Telemedicine and Telehealth;
- The Impact of Telemedicine on Healthcare Management;
- Evaluation and Cost Effectiveness of Telemedicine;

- Clinical and Technical Quality and Standards of Telemedicine; and
- Medico-Legal Aspects of National and International Telemedicine.

Each FORUM was organized and chaired by the national representatives of the host country with the help of the steering committee composed of the representatives of each G-8 country and of Australia. There was no central source of funding provided for the G-8 GHAP SP's. The organizers in the host countries assumed responsibility for obtaining financial support from public or private sources in order to provide the facilities for the FORUMS. Each national representative recruited up to 8-10 experts from each G-8 country and Australia to participate in the FORUMS. Experts from other non G-8 countries were also invited to participate by the organizing committee. Participation expenses of the delegates were provided either from their own institutions or from support from their country.

Each FORUM included plenary presentations by participants from each country to review their past experiences and lessons learned on the topic under discussion. Working group sessions were also conducted with the objective to agree on the main conclusions and to propose recommendations to promote the international collaboration in telemedicine and telehealth. A report summarizing the main issues discussed and each working group's recommendations were prepared and are included herein. The locations, dates, hosts and participation in the five FORUMS are presented in Table 2.

| FORUM | Theme   | Date            | Location             | Program Chairs  | Participants | Countries Represented |
|-------|---|-----------------|----------------------|-----------------|--------------|-----------------------|
| 1     | Interoperability in Telemedicine and Telehealth                 | May 28-30, 1998 | Montréal, Canada     | André Lacroix   | 124          | 11                    |
| 2     | The Impact of Telemedicine on Healthcare Management             | Nov 21-23, 1998 | Regensburg, Germany  | Michael Nerlich | 280          | 17                    |
| 3     | Evaluation and Cost Effectiveness of Telemedicine               | Feb 19-20, 1999 | Melbourne, Australia | Ian Heath       | 54           | 11                    |
| 4     | Clinical and Technical Quality and Standards of Telemedicine    | Apr 29-30, 1999 | Washington, USA      | Jay H. Sanders  | 120          | 9                     |
| 5     | Medico-legal aspects of national and international Telemedicine | Nov 28-29, 1999 | London, UK           | James McGee     | 102          | 11                    |

**Table 2.** Summary of G-8 GHAP SP-4 FORUMS

**FIRST FORUM: INTEROPERABILITY IN TELEMEDICINE AND TELEHEALTH**

The first FORUM, held in Montreal, Canada focused on the interoperability of telemedicine and telehealth. Interoperability was defined as “measures that enable secure, accurate and reliable sharing of health information and services between healthcare providers and citizens at any distance”. Ostensibly such issues appear to be technical in nature but in reality the effectiveness of a technical regime is a product of organizational structures. Furthermore, both the technical solutions and the organizational responses are highly

influenced by a multitude of human factors. In fact, many of the issues in strengthening international coordination and cooperation in telemedicine, telehealth, and health telematics are tied to resolving legal and professional matters. In addition, economical aspects, international competition and globalization provide a background which limits and stimulate cooperation at all levels.

### ***Technical Interoperability***

It is clear that a truly integrated global telemedicine/telehealth infrastructure is possible. It is predicated on developments in many fields, most notably those derived from the convergence of computing and telecommunications. From a technical perspective, the infrastructure for interoperability in networks can be seen as evolving within a hierarchical structure. The base of this structure is various healthcare centers and metropolitan and regional networks. To date, most of these networks have been implemented using conventional telephone infrastructure. This approach is typically characterized by relatively narrow bandwidth applications. However, the local and regional environment around many urban centers in G-8 countries are experiencing rapid development of an array of digital broadband networks. Moreover, these new services are being offered by an increasing number of suppliers, including traditional communications carriers, cable operators, and utilities.

The next layer up is the national telecommunications infrastructure. It is predominantly telephone based and as a result retains the narrow bandwidth typical of this medium. However, national communications infrastructures in G-8 countries, among others, are experiencing both rapid technological change and increased competition as various alternative broadband approaches become commercially viable. These include both wire and wireless solutions. G-8 governments are actively sponsoring national broadband research and development networks such as CA\*net 3 in Canada and Internet2 and the Next Generation Internet (NGI) in the U.S. Similar efforts are underway in Europe and Japan as well as elsewhere.

The top layer in this hierarchy is the international interconnections provided by linking national communications infrastructure between countries. This is a combination of wire and wireless systems ranging from direct terrestrial links through underwater cables to satellites. Here again, the traditional network model has been based on the telephone. However, trends in deregulation and increased competition are being stimulated by a range of competing technologies, including alternative ways of adapting and using the existing infrastructure.

From a technical perspective, there is a clear sense that standards are a valuable aid to advancing interoperability at all levels from medical devices linked to Local Area Networks (LAN) to common applications and data formats operating across global Wide Area Networks (WAN).

Security is also a major issue in telehealth and telemedicine networks. The deployment of public key infrastructure (PKI) will further the overall development of reliable network security. G-8 governments have already launched such undertakings. In the future, all telemedicine and telehealth projects will incorporate PKI solutions. In the meantime, it will be necessary to gather more information about the development of PKI throughout the world.

In general, application interoperability correlates with the application area. Health telematics is a complex interdisciplinary system comprising emerging new developments in informatics (such as language independent terminology/ontology, knowledge based systems development), medical informatics (enabling systems using virtual reality modeling of real organs for e.g. surgical navigation and intervention), communication technologies (such as new developments in wireless communication (WAP) and medicine. Describing the overall process model of healthcare delivered through telemedicine requires dynamic modeling, i.e. the model to take into account the interactions that occur by combining technology with organizational resources and rules. These interactions will change the classical way healthcare is delivered to patients without using telematics tools; probably more, as telematics will foster cross-organizational collaboration. The technical systems designed to support such collaboration must be designed in a way that will allow to adapt the functionality of the system to evolving processes.

Clinical needs obtained from these process models should be developed by purpose per application and include technical needs such as Quality of Service (QOS), applications interoperability and security.

### ***Organizational Interoperability***

From an organizational perspective, attention to standards in technical infrastructures is an important element in ensuring that a common platform can be applied, while the organization evolves its institutional systems. One of the key means to enhance organizational change has been observed through the application of best practices. The application of best practices is expected to aid in advancing interoperability at all levels. Consequently, attention to standards and the application of best practices leads to enhanced efficiency and effectiveness that broadens the use of telemedicine and telehealth applications among the many players in the healthcare sector.

Organization is critical to many facets of the healthcare system. For example, achieving better organization, particularly with respect to process, can lead to significant improvements, including: better information; better access and increased choice; enhanced efficiency; and greatly increased patient focus. However, achieving these still require overcoming a number of barriers. The most notable of which is achieving integrated telehealth services, from a number of perspectives, related to the following:

- Tension in the overall healthcare system resulting from the uncertainty created by change;
- Credentialing of healthcare workers in a telehealth environment;
- Pressure of cost containment in a period of restructuring;
- Finding appropriate and equitable formulae for reimbursement for services rendered;
- Political will to make hard decisions and to see them through;
- Lack of concerted and coordinated efforts to embrace all stakeholders to effect change within both a national and intra-regional context; and
- Technology induced pressures on ways and means to ensure privacy, confidentiality and security of the systems and their information.

Organizational issues encompass a mandate to consider telemedicine and telehealth in the context of the real world. This is a bold challenge. Moreover, many areas are diffuse with respect to how best to approach the issues and what to prescribe as a means to resolve them. As a result, the challenge could be defined in the context of an integrated model linking the environmental externalities that the system must accommodate, the patient and the internal elements needed to create, operate and evaluate telemedicine and telehealth systems. Furthermore, such a model captures the delivery mechanism for telemedicine and telehealth systems in the form of the organizational strategy as well as the technological regime necessary to create and operate telehealth systems.

### ***Human Factors Interoperability in Telemedicine and Telehealth***

Improved decision making and higher productivity are in many ways dependent on a variety of human factors. A major human factors issue that requires serious attention before these kinds of benefits can materialize on any significant scale is to ensure that telemedicine and telehealth sites have compatible equipment with adequately trained personnel familiar with the operation of each element of the local telehealth application and underlying system components.

Since human communication is at the core of telemedicine, there is a need for more 'standardized' forms of communication, particularly considering the international multi-cultural and multi-lingual uses of telemedicine.

>From a human factors perspective, the number one issue is information overload. It was argued that this situation has arisen as a result of the ultimate goal in applying telehealth that is being to make better decisions with better information. Unfortunately, there are few filters on the information at hand. Consequently, there is a need to map the decision making process in accordance with the emergence of essential data sets.

Given a choice, healthcare providers still prefer to use traditional delivery mechanisms resulting in the under utilization of telemedicine and telehealth solutions, even when they are in place. Consequently, there is a need to have telemedicine and telehealth planners take more time to understand practice patterns and needs of providers and tie solutions to troubling clinical situations they encounter on a regular basis. Healthcare providers do not articulate their needs or understand the effects that telehealth could have on their practice. Therefore, better needs assessment methods are required.

It is widely recognized that the full benefits of telemedicine and telehealth will not accrue to either providers or patients until telemedicine and telehealth is widely deployed. In order to facilitate deployment, it is proposed that a two-step process be followed. Specifically, there is a need to ensure that the current 'islands' of automation will merge in both organizational and technical terms. Second, telemedicine and telehealth should be made a fundamental component of professional education programs.

There are a number of 'soft' issues with respect to human factors in telemedicine and telehealth. An example is how to deal with the confidence in professional ability of those rendering and receiving telemedicine and telehealth services. The traditional human interaction associated with establishing trust and confidence must remain.

To facilitate the acceptance of this approach requires basic training and familiarity with the computer and associated communication systems. This approach, which is one of many, will help many healthcare providers gain a sense of confidence with basic tools that eventually will lead to a willingness to work with telemedicine and telehealth applications and systems.

This also raises human factors issues related to communication in general and ethical, legal and social issues in particular. Therefore, there remains a need to invest in research in this area, including learning from the practices of multinational enterprises and from their extended managerial experiences.

## **SECOND FORUM: IMPACTS OF TELEMEDICINE ON HEALTHCARE MANAGEMENT**

The second FORUM, held in Regensburg, Germany, was focused on how telemedicine impacts healthcare management. Over 200 telemedicine experts, representing 14 countries attended this FORUM. More than 70 presentations on a broad variety of current telemedicine activities in the G-8 countries, Norway, Australia, Ireland, and Switzerland were given. Although these presentations were to be focused on projects that have actually changed the delivery of healthcare on a daily basis, many of them have not yet demonstrated the transition from research to practice, and therefore, are limited in their impact on healthcare management.

Many presentations illustrated the potential benefit of telemedicine and telehealth on healthcare management. In an attempt to identify the best examples of effective and efficient telemedicine and health telematics projects, a robust and spirited discussion about the relative merits of telemedicine and telehealth took place. The following key issues were presented:

- Few evaluations of telemedicine have been conclusive because of difficulties in measuring outcomes. It was suggested that standard protocols by which outcomes measurements can be accomplished be developed.
- It has not been possible to compare telemedicine against alternative or traditional forms of delivering and managing healthcare because often there are no comparative processes or outcomes against which to measure telemedicine. It was suggested that emphasis be placed on *access to care*. The assembled group was not aware of anyone measuring the implications of increasing access to care, which would require a focus on effective use of resources. This of course raises the question "How much access is optimal?"

- Presentations, given on tele-dermatology and tele-radiology, were cited as two areas showing promise, though there was little proven evidence of cost-savings.
- In Norway, Dr. Steinar Pedersen demonstrated that tele-consultation changed the way primary care physicians do referrals. Using telemedicine they requested consults less often for routine conditions and more often for complex cases.
- In the U.S., Dr. Ronald Merrell from Yale University demonstrated substantial potential for quality improvement by using real-time telementoring to assist surgeons in remote areas with laparoscopic procedures.
- In British Columbia and in Québec, Canada, the relative merits of on-line prescriptions were shown in two studies with a large number of participants.
- A pediatric cardiology telemedicine study in Québec, Canada was cited as having proven effective for tele-diagnosis as well as avoiding patient transfers.
- Experience in France of networking hospitals for rapid diagnosis of severe trauma cases has proved to be effective from the point of view of patient management, but has not been cost-effective. On the other hand, the Regensburg experience demonstrated clear cost-savings in trauma care using emergency video-conferencing. This variance indicates that perhaps there should be new definitions of cost-effectiveness or perhaps the phenomenon observed between different countries is related to different reimbursement systems in each of those countries. This entails an understanding of what the incentives are in the differing national healthcare systems.
- One example, highlighted during the poster session, demonstrated a film-less hospital in Germany that is having a positive impact on cost containment, as well as illustrating important changes in workflow - with more rapid access to results.
- In view of these difficulties, and since only 5-10% of the pilot projects become long-term projects, the following question was posed to the FORUM, "Should the focus be shifted to *best practices*, as cited in one of the presentations made at this conference?"
- It was noted that, historically, preconditions in medicine have changed and that it is necessary to redefine the preconditions, as well as what is meant by healthcare management. Evaluating telemedicine will lead to a closer look at the existing systems of healthcare management, and this system is always changing.
- There is a reluctance to make a blanket statement about cost effectiveness and cost benefits of telemedicine applications because the studies have been based on small sample size.
- Some of the presentations illustrated that certain studies depend on the use of telemedicine and cannot be done in any other way – the example provided was that of the sleep apnea studies in which the patient needs to be tele-monitored at home for such monitoring to be effective.
- When first introduced, almost every technological advance costs more money. This trend is likely to continue (e.g., MRI, CT). Therefore, one must seriously consider cost-benefit ratios. For example, picture archiving systems (PACS) were not cost-effective when they were first introduced. Today, PACS and film-less radiology have had a major impact on hospital workflow.
- A lot of telemedicine technology can be found to be clinically effective, equal to non-telemedicine intervention, and cost-effective, but implementation into routine use may not be possible because of regional differences, barriers such as lack of infrastructure, and medico-legal or reimbursement issues.
- Sustainability is often stated as a requirement for technological innovation studies. Yet, conditions do not exist for these studies to be sustainable. For example, funding is usually short-term, long-term reimbursement schemes are rare and cover only a few applications, and health policy does not encourage telemedicine. Long-term studies are needed to study the impact on healthcare management and provide evidence-based results for telemedicine.

This FORUM clearly illustrated that it is not the lack of suitable communication technology that limits the impact on systems of healthcare delivery. In fact, there was a wide range of applications showing the huge potential of telemedicine to change the delivery of healthcare tremendously if integrated in the routine clinical processes. The use of the telephone and facsimile machine have had a huge impact on healthcare management, but a sound evaluation of the introduction of these new communication technologies in healthcare has never been done on a broad scale. The impact of information technologies like telephone or facsimile on healthcare management has never been evaluated on a broad scale, probably because it seemed so natural to use these new technical items. In comparison to telephone or facsimile, the impact of multimedia information technology is predicted to be even greater.

However, there are still significant, well-known barriers that hamper the routine use of telemedicine. These include:

- Lack of win-win situations for telemedicine users, especially lack of reliable, long-term reimbursement mechanisms, i.e., incentives for clinicians to change their behaviours and routines are very limited;
- Lack of needs assessment of the potential users (physicians, other clinical staff, patients);
- Legal issues are not clearly and sufficiently addressed;
- Psychological drawback of distance technologies; and
- Lack of sound evaluations that would allow an evidence-based purchase decision.

Telemedicine and telehealth in many countries still is perceived as a method to support interaction of two or more health professionals in diagnostic, care planning, counselling, and treatment processes. However, a trend from the U.S. strongly suggests that the predominant telemedicine and telehealth encounter in the near future will have the patient at one end and the health professional on the other. That means telemedicine and telehealth is transitioning from academic research centres into the patients' home. At this point, it is widely believed that both patients and practitioners still need to find out how their professional relationship and the patient - provider relationship respectively is affected by the use of new means of interaction.

Although the FORUM illustrated that a widespread, significant impact of telemedicine at this point is only reported from very few countries, the meeting was extremely helpful in getting an understanding what the impact might be once the environment is ready for the routine use of telemedicine. The FORUM provided a strong signal towards politicians and health policy decision-makers. Increasingly, expanded knowledge about the real life impact of telemedicine applications replaces the early scepticism ("toys-for-boys") and promotes the use of high technology and the tools of information technology in innovative quality healthcare systems of the future.

### **THIRD FORUM ON THE EVALUATION OF THE COST EFFECTIVENESS OF TELEMEDICINE**

The third FORUM, held in Melbourne, Australia was focused on the evaluation of cost effectiveness of telemedicine, specifically the lack of a coherent methodology for telemedicine evaluation and a lack of critical mass of analyses. Methodologies for the evaluation of telemedicine applications are extremely important issues in the healthcare sector both from the programs and policy perspective. It has been argued that evaluation has lagged behind the diffusion of telemedicine. However, it is also a critical building block to the wide integration and diffusion of telemedicine into the health sector.

Evaluation then is a key tool to assist resource allocation. Governments are interested in the allocation of public resources and the extent to which telemedicine might assist them to achieve their broader healthcare delivery objectives. Cost reduction of the overall health costs bill is a major preoccupation. Provision of healthcare services for a large and aging population is another focus. For many governments, the potential benefits

of developing a telemedicine industry is also a priority. Government also affects some of the enablers for the development and diffusion of telemedicine such as the influence of government policy on issues such as reimbursement and communications infrastructure as well as any direct research and development funding.

The G-7 GHAP Information Society project theme has a strong interest in such an outcome seeing it as both an essential and evolving evaluative tool as well as forming the basis for implementation of good practices in hospitals and health services and as well as individual practitioners. A critical mass of case studies for evaluation and “good practice” guidance and protocols as well as capabilities will become increasingly important as telemedicine is fully integrated into healthcare delivery systems in developed countries throughout the world.

A review of the current literature reveals the lack of a coherent methodology for telemedicine evaluation and a lack of critical mass of analyses. Methods for the evaluation of a clinical consultation or diagnostic tests remain immature. Cost efficiency assessments are also not sufficiently developed because they are limited to static comparisons, which ignore clinical outcomes. It also reflects the mixed set of objectives for the application of telemedicine. In most cases, telemedicine has rarely progressed beyond a specific research and development project or demonstration, and consequently evaluation often reflects assessments for achievement of particular technical outcomes. On the other hand, a telemedicine application operating within a healthcare system necessarily involves a broader assessment, measuring cost variables, technical variables, clinical effectiveness and quality or satisfaction and access variables. There are different evaluation requirements for an initial start up, in service telemedicine application as opposed to a longer term in service operation. For a broader based healthcare service both regional and national variables regarding the achievement of policy and program objectives for the health sector as a whole need to be included. Conventional techniques of economic evaluation are not always relevant in the health sector and similarly, clinical outcomes are not always easy to identify.

This was regarded as one of five significant impediments to the diffusion of telemedicine by the G-8 GHAP SP-4 and constituted the focus of this third FORUM. The following questions were discussed in great detail at this FORUM. (1) Why evaluate telemedicine and what is special about it? (2) Where are we now in terms of telemedicine evaluation and in particular assess what projects appear to be cost effective, focusing on what is transferable and replicable to other telemedicine applications evaluation? (3) What kinds of evaluation should be done? (4) What are the underlying principles for telemedicine evaluation as a first step toward the development of a good practice framework for the evaluation of telemedicine?

#### ***Why evaluate telemedicine and what is special about it?***

Evaluation and assessment of the applications of information and telecommunications technologies as they apply to healthcare are not new, however, the inclusion of the assessment of clinical outcomes as well as professional and consumer and patient acceptance is new. In addition, the diffusion of telemedicine has elements of both product and process innovation. Telemedicine may enable the same service to be done more inexpensively or effectively (the ambit of cost efficiency and cost effectiveness analysis) but may also (and perhaps always in the mid to longer term) enable completely new things to be done in radically different ways. The blend of those two possible outcomes poses particular challenges for evaluation.

Conventional techniques of economic evaluation are not always relevant in the health sector. Qualitative improvements in patient care through enhancing access to services, better education and support to remote and rural health workers, and higher quality referrals to specialists are some of the valued, but not readily quantified benefits of telemedicine. There may also be broader economic and social benefits in providing telecommunications infrastructure more generally to rural and remote communities, where this may have been installed initially to support a telemedicine application. However, it was stressed that increasing access to health services may also result in increased cost through greater use of services; many technological advances have led to increased costs for the health service in question or healthcare in general.



Once these broader effects have been quantified, then evaluation, especially in terms of criteria employed and data required, becomes more complex. Evaluation of the effectiveness alters depending on whether one is evaluating a pilot project, an initial in service application or a longer term in service project. If the integration of telemedicine into healthcare service is the key issue, then it is precisely these kinds of more complex evaluation that will be required. Perhaps this will involve an approach of observation, description, understanding, assessment and feedback. It highlights the importance of the task of disseminating such results and the methodologies used, to build up a critical mass of information, analytical rigor and ability.

Similarly, clinical outcomes are not always easy to identify. To date, such evaluation of telemedicine projects that been conducted have largely focused on patient and practitioner acceptance, and validating the performance and efficacy of the technologies. Evaluating clinical outcomes, and in particular, benchmarking telemedicine applications against current clinical practice, is likely to prove more difficult. Telemedicine projects inevitably involve some degree of process redesign, even if only at the most basic level of adapting existing processes to the technologies. In some cases telemedicine technologies have made it possible to invent completely new processes and services, such as “telemedicine in the home”. The blending of both forms of assessment is difficult but necessary.

***Where are we now in terms of telemedicine evaluation and in particular assess what projects appear to be cost effective, focusing on what is transferable and replicable to other telemedicine applications evaluation?***

The first observation made was that a critical mass of absolute or normative proof does not exist. Clear evidence is lacking, especially in policy and population well being level. Evidence was largely presented in controlled and limited pilot applications. Potential integration and demonstrable application based on data is no existent or is lacking. The perception is that telemedicine is transitioning to more diffuse applications.

Case studies and discussion demonstrate that there are enormous differences of methodologies and outcomes depending on whether one is doing prospective evaluation, evaluating a pilot study (e.g., often largely a set of technical and or clinical outcomes) or an initial application (e.g., looking at start-up costs, both capital and variable and pay back periods) or a longer term assessment (with an assessment of impacts on broader more systemic variables).

The FORUM’s plenary session did not result in a definitive list of evaluation criteria. These are still developing and evolving, for reasons developed above, and vary by level of application and its objectives. A key issue considered has been to move toward the *development of an integrated, accepted and standardized evaluation framework*. This is contrasted against considerations of experience of other initiatives, policy context and implications, possible barriers and receptors as well as the criteria against which programs are assessed. Implementation of evaluation needs to assure consistent and orderly data collection, similar to clinical trials and a process of reassessment with regular reporting of outcomes and review of past studies.

***What kinds of evaluation should be done?***

Notwithstanding the need to evaluate, there was agreement about the difficulty, the complexity and the challenges of conducting evaluation in telemedicine. The following issues were addressed.

- Evaluation necessarily takes place in a highly dynamic and complex context. It means that traditional cost- efficiency and effectiveness analysis for evaluation is not always useful or workable.
- In addition, rapid advances of information and telecommunications technologies make evaluations vulnerable to obsolescence as key hardware and software components move from being state-of-the-art to being out of date.
- Telehealth or telemedicine is made up of a single, homogenous technology but a group of diverse and often generic technologies. It may be possible to aggregate some applications together such as health information management; patient care or access to appropriate healthcare for remote populations but the complexity of the application of a range of technologies must be recognized.

- Evaluators in a particular site may have difficulty designing evaluation methodologies and then finding appropriate comparison groups to generate a sufficient number of cases from both experimental and comparison sites for reliable comparisons.
- The many consumers and stakeholders of technology including private, public and community sectors as well as clinicians and patients have different viewpoints, priorities and objectives which create difficulties in getting agreement on data definitions, standard data collections and meaningful outcomes. Perhaps there needs to be a stronger consumerist focus as health services “de medicalize”
- Telemedicine strategies will provide for the integration of services that cut across traditional organizational boundaries and may generate indirect costs and benefits. For example, the wider impact of developing communications infrastructure to support telehealth strategies in rural and remote communities should be evaluated in addition to the direct costs and benefits of those strategies. A number of interventions mentioned labor force impacts.
- Economic ramifications of high levels of infrastructure investment are essential to the support of telemedicine initiatives.
- There is a broader impact on the utilization of health services.
- Measurement of cost-benefit and cost-effectiveness particularly in terms of investment over time and in terms of in service applications and mainstreaming has been considered to be highly complex and variable. It depends on identified objectives and needs for the application and the evaluation, specifically whether the application was a pilot project, a start-up in service project or a longer-term application.

The relevance of evaluation criteria was considered important, such that they were able to:

- Demonstrate that a telemedicine application was superior (or not) to other instruments to achieve the same goal;
- Demonstrate appropriateness of the application to the objective and the health service context or environment;
- Describe systemic aspects, in the sense of the applications interaction with other instruments, programs, policies and effects of conditions e.g. government frameworks;
- Enable measurement of efficacy that is a cost effective way to achieve objectives; and
- Assess “adaptive efficiency” of the evaluation and the criteria, that is, whether the results of the evaluation get applied and whether they are sufficiently flexible to incorporate unpredictable effects or change.

Evaluation criteria revealed in case studies presented to the FORUM involved a mixture of technical validation, clinical outcomes and cost effectiveness.

**The following criteria are appropriate for telemedicine evaluation:**

- Quality of care - the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge;
- Improved competence of health personnel for diagnostics and treatment;
- Reliability of telemedicine service;
- Access to services - including the timely receipt of appropriate care, especially in emergency uses;
- Simplification of routines for information processing;
- Improved information exchange and processing;
- Promotion and stimulation of better information to patients;
- Cost and the cost-effectiveness of telemedicine with measures of efficacy and efficiency typically reduced transport costs, reduced variable costs;
- Patient and clinician perceptions – reduced stress, moral were cited criteria; these were considered important for the acceptance and adoption of telemedicine;
- Maintenance of information security to ensure secure and effective treatment;
- Appropriateness of usage of telemedicine within the health system;
- Economic benefits of telemedicine service development - including the impact on other sectors of economic activity resulting from telecommunications infrastructure improvement;

- Broader social costs and benefits of telemedicine -workforce issues and the indirect benefits of provision of care closer to home like reduced disruption to work and family life; and
- One approach presented focused evaluation of the communication process implicit in telemedicine, the “instrument” rather than the (economic) “aim”. Their approach is evaluates changes in communicative behavior by health professionals, the (implied) changes in the healthcare process and the communications costs and outputs (on the basis that these express the economic impact of changes in communication and healthcare process).

***What are the underlying principles for evaluation as a first step toward the development of a good practice framework for the evaluation of telemedicine?***

The plenary session considered that *a clear statement of need or objective* for the telemedicine application and a measure of the outcome was a necessary starting point, against which achievement of objectives and success could be measured at a user level, at the level of the organization, and at the level of the system (nationally and regionally).

There was some support for *a standardized internationally accepted framework for telemedicine evaluation*, to enable comparisons of practice and outcomes and to enable advice on what to do, how best to do it, as well as, what not to do. However it was generally agreed that this was *an iterative process rather than one of setting normative or absolute frameworks*. It was thought that a good outcome would be that descriptions of demonstrably cost effective projects should be diffused widely, to build critical mass and as a guide to future applications. It was considered important to diffuse, not only the elements of success, but also the barriers, the lessons and accountability. Such diffusion would build up experience and knowledge of how to evaluate and how to implement.

***Key principles might include then:***

- Clear identification of needs and some broad criteria for assessment and testing against them;
- Avoidance of “Enthusiasm-Driven” projects and a consciousness of barriers (associated with attitudes, lack of training, sustainability and the re engineering involved);
- Have a feedback mechanism so that issues and problems emerge; and
- Aim for a progressive best practice approach and develop “case effectiveness approach to telemedicine evaluation”

The development of an evidence-based approach to telemedicine was a common theme of a number of the presentations. To take the conclusions of the Teleplans (conclusions echoed in the plenary discussions and case studies), three dimensions are needed to achieve a pragmatic framework for the development of decision tools for the implementation of telemedicine services:

- Development of evidence-based telemedicine through good practice documentation and dissemination;
- Impacting the evolution of telemedicine by feedback of results of telemedicine evaluation and international comparisons and thereby
- Address and help resolve the key management issues for telemedicine application

**FOURTH FORUM: CLINICAL AND TECHNICAL QUALITY AND STANDARDS FOR TELEMEDICINE AND TELEMATICS**

The fourth FORUM was held in Washington, DC. Many organizations participated in this meeting and presented their efforts in defining the status of standards in Telemedicine and Telehealth. Participating organizations included:

- World Health Organization (WHO)
- U.S. National Library of Medicine
- U.S. Department of Defense
- American College of Radiology
- Canadian Institute of Health Information
- National Aeronautics and Space Administration (NASA)
- U.S. Food and Drug Administration (FDA)
- Institute of Medicine, U.S. National Academy Science
- International Medical Informatics Association
- U.S. Department of Health and Human Services
- Medical Records Institute
- G-8 countries academic centers

### ***Technical Standards for Telemedicine and Telematics***

It was apparent from this FORUM that standards have not yet been established for telemedicine and telehealth. Different specialties and fields have different needs and that many “defacto” standards will arise as telemedicine systems are implemented. Technical standards to unite technologies are necessary. Standardized image formats and compression, interoperable software and hardware as well as capture device technology and transmission technology will permit commonality on a global scale in telemedicine.

Health practitioners must determine what is needed to perform clinical services and provide an accurate diagnosis for patients, and/or provide adequate home and remote monitoring of patients. Standards are nonetheless only applicable if they are used in practice.

Joint work between industry and medical specialties is the way of the future in insuring interoperability and interconnectivity standards

### ***Clinical Standards for Telemedicine and Health Telematics***

Clinical standards for telemedicine do not currently exist, and there is no obvious path to develop them. Professional bodies and academic medical centers play a lead role in establishing clinical requirements but it is not clear how to merge the technology standards with the clinical standards.

All standards or guidelines that evolve must be evidence-based and must be supported through rigorous evaluation programs for existing telemedicine services.

### ***Integration of Telemedicine and Healthcare Informatics***

There are a number of organizations, governments and other, who are making progress on the broader issues related to standard for the application of information technology in health. This effort, and those of others developing more specific telemedicine standards, must be considered and coordinated to create a global approach to standards.

## **FIFTH FORUM: MEDICO-LEGAL ASPECTS OF NATIONAL AND INTERNATIONAL APPLICATIONS**