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> SECOND DAY / SECOND SESSION

PRESENTER- Now, Dr. Stephan SCHUG from the European Health Telematics Association will inform us on “E-Prescribing and Electronic Health Records in Europe”. I would like to invite him to the desk.

Dr. STEPHAN SCHUG (European Health Telematics Association⁸)

Thank you very much. Welcome and thank you for inviting me. It has really been an interesting visit for me to come here. Especially, the last presentation made by the Ministry impressed me very much. I am going to make a presentation that will more or less complete it. I was very impressed also by the presentations made in the morning and of course the other ones were very important as well, but because of its being an issue concerning the network we gained more knowledge on interoperability and similar topics. We heard a presentation that gave answers to all questions in our minds such as what is going on in Turkey.

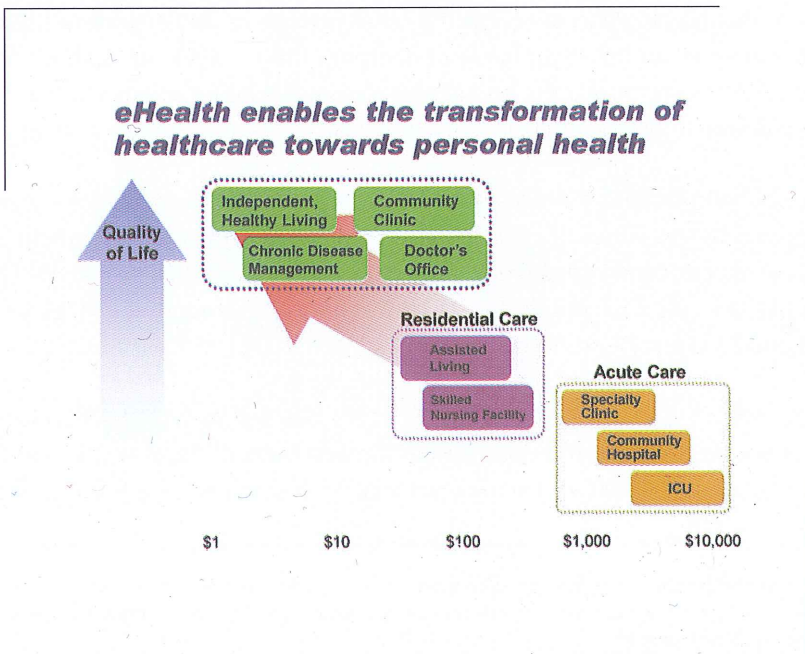
As it was said before, I would like to draw a basic framework on electronic prescribing and electronic health records. Besides this, I will try to mention and show the e-health and interoperability trends in Europe. Because, I am a physician and I had education on public health. I have been working for the EHTEL since 2000 and as a part of administration team of the EHTEL since 2002.

I would like to tell shortly what the EHTEL is. It looks like an old-fashioned name. This is because we started this work in the first days of the e-health. EHTEL was established in 1999 as a kind of association. It emerged as a Pan-European

⁸ European Health Telematics Association (EHTEL): A communication network for the stakeholders in health care that was established in 1999 for the betterment of healthcare delivery through e-Health. For a detailed information see: <http://www.ehtel.org/about-ehel>.

Telematic: Combination of the words telecommunication and informatic. It is the Information and Communication Technologies known generally as ICT. It is a branch of science that deals with the precesses of data sending, receiving and storing through telecommunication tools.

multi-stakeholder forum providing a leadership and networking platform. Its members have been mostly European corporate, institutional and individual actors. Particularly the institutions responsible for the application of e-health are part of the EHTEL. Of course we are dedicated to the betterment of healthcare delivery through e-Health. For us, e-health can be defined as follows. Many things concerning this subjects were explained by Ivana and other colleagues. There are several high level developments in this area. On the other hand, we know that e-health is just a technology but also a cooperative process and aims at intensifying and changing the interactions of all stakeholders in health and social care. We need to improve the continuity of the development in health care and patient safety. At the same time, e-Health aims to be a tool to ensure information, choice and empowerment for European consumers and patients. E-Health primarily aims a transformation of healthcare towards personal health.



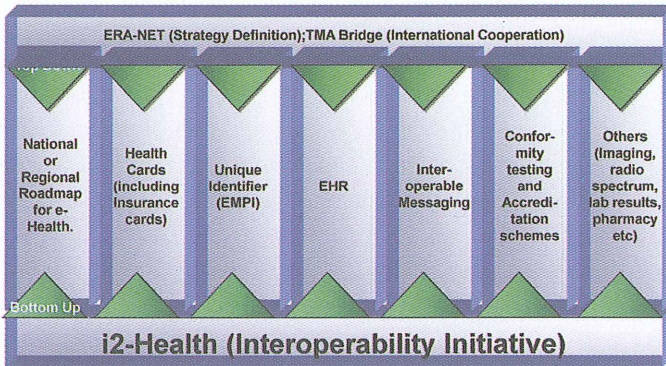
Here you see a clear picture prepared by us. As you see here, there is acute care at the bottom. E-health applications do not only improve the quality of life and health care but also decrease the costs for the society. We are working on it actually for bringing people an independent and healthy living. We are trying to develop it from acute care to the upper points through home based methods such as tele-medicine and tele-monitoring. In the former presentations, a picture of the image of orchestra was shown to explain the interoperability. That orchestra should really work harmoniously. The starting point of this project is the input that I am going to use in the next 20-25 minutes. This is a project which aimed particularly to improve interoperability and our motivation was as follows: Emerging e-health applications might stop at country borders and other barriers. In other words, this is not just an issue of blocking cross-border communication but at the same time fragmentation of health ICT market. In fact, there are so many policy drivers for the interoperability of the e-health applications. European Court of Justice has many decisions particularly on the citizens mobility and border regions. European Court of Justice emphasizes the people's transnational right to health care. In addition, information and communication technologies have been already mentioned. There is pressure from stakeholder groups that shapes our policies.

This is a process going on for 4,5 years in the area of the European Union. In the beginning it targeted a charter of the Commission on the e-health: COM (2004)356.

By the end of 2006, Member States together with the European Commission had to identify a common approach to patient identifiers. I hope to talk about the issues related to the European Union would not make you tired. I know Turkey is a candidate country thus the same legal conditions for several points might not be valid for Turkey. It is different in Germany and France of course but all the European elements focus on the problem of interoperability. As you see, the second element is the development of interoperability standards for health data messages and electronic health records by the Member States together with European Commission.

This especially aims to standardize health data messages and electronic health data, electronic prescriptions.

Actions on COM(2004) 356



Therefore, one of the actions that the notification number COM(2004)356 put was as follows:
i2 - Interoperability Initiative that the European Commission should follow.

I will not explain all of them now but there is such a thing as: This is a project developed to bind different elements together. The training health plans and the outcomes that would be provided are really consistent with today's subject. This would provide a conceptual framework for the generic elements. On the other hand, there is the analysis of infrastructure concepts and building blocks, services and applications. The second one is in-depth analysis of e-Health issues that includes definition of actors and identification of interoperability in the workflow. In the conceptual space for interoperability, there are self care and public health institutions, and it has an approach of going towards long-term care. We see a full picture of health care services here and when we say interoperability of health systems we actually mean assuring the continuous abilities to exchange, understand and act on patient and other health information and knowledge, and cooperability among linguistically and culturally disparate clinicians, patients and other actors. In addition, decision making cases should be included in the cooperation dimension. On the other side, when we look from the technical point of view, when a health message is produced at a point of the system it should be understandable at the other point of the system. It means that it should also be understandable for the computer system besides the physician and the patient.

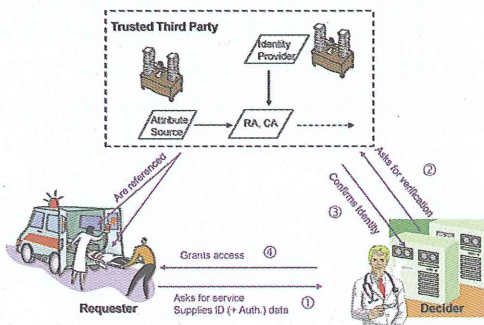
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When we look from the point of framework, there are four action levels that gather different layers together. These are important layers that get down from political and legal levels through organisational levels. Afterwards, semantic and technical levels come which are also very important. The technical level includes IP protocols and other related things. The decisions made by the organs can belong to a country or a hospital. We can see in these levels how interoperability can be assured.

If we give several examples, let us look at what we expect in several levels. It is a matter of cooperation in the political level. For example, we can list what should be done as follows: determining the political-legal framework, vision and strategies. Ensuring the collaboration between service providers, share of organisational structures and culture, exchange of decisions inter and inter-jurisdictional service processes, ensuring change management, behavioural change and re-engineering system thinking and business process are included in the organisational level. There exist terminologies, classifications and translation in the semantic level. Technical level includes the determination of the technical standards, connectivity of hardware and software and formation of interfaces. These of course constitute a rather simple part of the work. In order to implement this system, patient summaries and information should be suitable for interoperability. The exchange of patient information as a kind of data set is a part of this system. Both the patient, the physician and the service provider should be able to access those data, for example in an emergency case. There are different institutions, different cases and different documents. All these should be gathered in patient information summary. Data protection, confidentiality and similar points should also be ensured. As it was mentioned in the morning presentation, the health actors should be defined clearly. The picture shows them in a picture on the data level.

Here, the architecture is one of the most important elements. There are different interactional systems and constituents here. Patient -maybe the professional's as well- identity numbers in this interoperability system. We have focused more on identification management and identity management within this health project. This is a picture submitted by the Government of Netherlands in Amsterdam. If someone would access your health data, the role models should be defined clearly and the person who is trying to access should be identified.

i2-Health WP3: Using an Health eID



At the same time, the person has to prove her competence. Who is that person? What is she allowed to do? The correct answers of these questions should be known. The person gets the right to enter the system in a specific way and can access several data. Of course, this process normally develops upon the permission of the patient but in some cases there is the possibility of automatic permission. There should be the dimension of audition for safety. The conducted works should be subjected to the audition.

We are trying to establish a common approach in Europe. Electronic ID cards or in other words smart cards having chips should be used for safety. In order to process the electronic cards, we need a public infrastructure in such a system. Several institutions were showed at the top as the third trusted part. Then the system can be used to access concrete data. Here you see an emergency case at the left hand side and a normal comprehensive case at the right hand side as complicated health cases.

A similar understanding should be developed in Europe in the establishment of the accounts of health professionals in the implementation level. It is used even in the countries that do not want to bring the patient account system in Europe.

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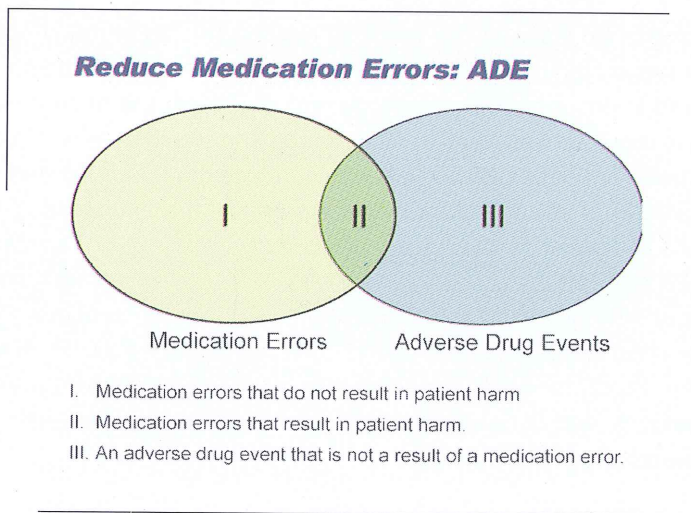
That is actually an old fashioned approach but still can be said right. Such health cards were brought in countries as Austria, France, Lombardy region of Italy, Germany, Slovenia and Belgium. For example, Germany renewed just its existing health system. On the other side, there are also other countries which did not want to discuss these issues. However, the fact that health professionals need cards in European level is emphasized. It is necessary for health professionals to verify their professional roles. In other words, if they want to apply something to someone they need to introduce themselves to the system in a right way. But we will most probably not see that all the patients do not apply everything.

When we say e-prescribing, we are actually talking about a process. In other words, it is not only e-prescription but also e-prescribing. It is not only a document but the whole process. I would like to explain in the next slide what this process includes.

E-prescribing is an issue at the focus of health projects in many countries. Because it has a high potential for improving patient safety. In addition, it has a purpose to improve health and the patient. Because, the patient would be able to have more accessibility in other words she would access more to the decisions taken about her. Besides, it would reduce the fraud and lead savings in cost thanks to a better process. Sometimes there are more than 5 billion transactions in a year. It should be known that savings is not only result of electronic transactions. It might be thought it is only due to electronic transactions. In fact, more savings would arise as a result of quality improvement. We will save more when we improve the quality. 100 million Euros will be saved from logistics part but at the same time 500 million Euros will be saved from labour costs and so on. And of course, improvement in the quality of life, life savings make us earn more.

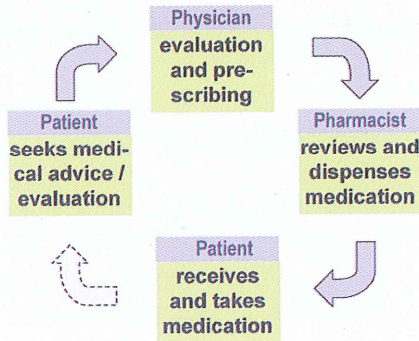
Let's describe the process now. Normally, a physician fills the prescription form which is quite a well-arranged one. The patient directly goes to the pharmacy with this form and buys her drugs while at the same time, the data of the pharmacy is sent to the computer centers related to e-prescribing and e-statistics. Besides, the data is sent to the health insurance institutions as well. There is such a system. Actually, all these processes are carried out in digital

way and operating even when there is no electronic prescription. That is why the logistic part of the process does not bring huge cost savings. The most important thing here would be about the errors in prescribing drugs. Marie-Laure Micoud (Pharmacists Association of France) explained the role of the European Commission in this issue and showed several different errors. We can escape from all the errors such as prescribing errors, diagnosis errors, ignoring allergies in this system. On the other hand, there are also errors in obtaining drugs. This is not only related with the electronic prescribing but of course it would be easier to conduct certain researches and surveillances in this system. As you see on the right hand side, it will serve for the drug safety in the long run. We need to be aware of the following fact: We want to decrease the medication errors. It does not mean that it can take away everything. There are the medication errors that do not result in patient harm in number 1.

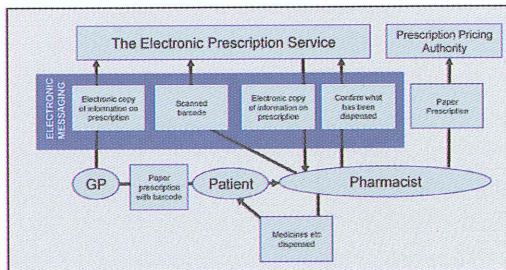


In fact, those are inefficient errors. At the very right, there is adverse drug event that is not a result of a medication error. There are the medication errors that result in patient harm at the intersection of these two.

The eMedication process



National Implementations UK: Connecting for Health



Therefore, in e-medication process, the patient goes to a health professional, receives prescription and then receives medication from the pharmacy where the pharmacist also talks to the patient. Drug interactions are taken into consideration and the patient goes to the physician again for a new examination.

There are so many entries in this system. This picture is belonged to England. It can be highly complicated, as you see.

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Actually, I am talking about three processes defined in this project. In fact, it was transformed into a terminology adopted by the European Commission. If we think electronic prescribing as an umbrella, there are three main elements in it.

I. Electronic Transfer of Prescriptions

II. Electronic Medication Records

III. E-Prescription Informed by Decision Support System (e-Rx)

When we close this cycle, we can get all these positive results such as saving life, bettering patient health. We need to see that it is actually a more complicated process. It is not only a system just including the electronic transfer of the prescriptions. Of course, it needs to be process embedded in a network infrastructure.

What is happening in practice? Let's look at the situation in Germany. The prescription is recorded in an account, the patient goes to a pharmacy and gets her medication. So, the system does not change so much. Of course, the pharmacist can see the drugs used in the past and give more information to the patient. And of course, the physician can obtain more information about the patient. There might occur other processes. For instance, the patient might be on vacation and might go to a pharmacy in the vacation area. The pharmacist can download the prescription and gives the drug thanks to the interoperability. Thus, several systems were established in Europe while they are more in the starting phase in Germany.

Although these examples are from Germany the presentation is more about the whole Europe. People got such a right with the legal amendment made in the beginning of 2006. It is being tested in all seven regions. Seven regions each of which include 10 thousand people. The first test was conducted for the offline system in which there was only prescription transfer. The online services will be brought in next year. The project is a little bit late. And it will be widespread in 2012. Compared to Germany, certain services realized more fast in Germany. That is maybe because of the fact that several infrastructures were already

established in Scandinavian countries. The e-prescribing system in Sweden is based on a pharmacy system called Apotekit that is a kind of messaging system. A database complements this system. So, this database includes the treatment records for every patient. On the other hand, drugs are dispensed within the system. Denmark is one of the advanced countries in terms of e-prescribing. As you see, there are two lines. There is a blue line. This blue line shows the situation in 2006 that reached around 100. And on the other side, Denmark brought another system into force in the last two year that is national drug treatment database in order to improve the drug treatment quality.

There is such a big project in England. It is a complicated system, actually it started as a complicated system. As you see here, there are a barcode and an authority of prescription pricing in the first round. This is a payment system that is not a part of the first part of the system. They passed to the second phase now. They will start using electronic prescriptions within this nationwide system.

In order to provide an overall view, let me show the European Union countries in terms of the explained systems. We are evaluating them in three levels: e-prescribing decision support, electronic prescription transfer and electronic health records.

eRx Implementations EU

	DENMARK	SWEDEN	GERMANY	SLOVENIA	ENGLAND	NETHERLANDS
INFORMED eRx WITH DECISION SUPPORT	Implicitly	n/a	System Islands	Implicitly	Plans	Pilots
ELECTRONIC TRANSFER OF PRESCRIPT	Fully Established	Ca. 60%	Offline Tests Since 2007	Plans	Roll Out Phase 1 (Barcode)	In Use for liss then
ELECTRONIC MEDICATION RECORD	National Database (09.2006)	National Database New eRx	Optional for Patients	Roll Out on HIC (06/2006)	Part of Spine	Roll Out in 2008

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Electronic transfer of the prescription is completely established in Denmark while it is used 85 percent in Sweden. Germany is in the test phase. Slovenia is preparing for it but it is not operating yet. They started to create the national health records in their health cards in 2006. National electronic health records will be a part of national infrastructure (Spine) in the United Kingdom. In the Netherlands, the use of electronic health records is less than 50 percent. In sum, the picture is mixed in Europe in general. What does inter-operability mean in terms of e-prescribing in current situation? I have described it in four levels for e-prescribing. Of course, there are diverse frameworks for prescribing drugs in Europe due to different national legal systems. I know that similar things are happening in Turkey and particularly the internet pharmacies' being part of the system is very important. Reimbursement is more important in the organizational level. I will talk about semantic level later. There is the normal internet communication in the technical level .

Semantic is very important. Semantic is translated as the study of meaning into Turkish. Here we focus on the comprehensibility of the prescription. In other words, is the patient going to take two capsules three times a day or take three capsules two times a day. It is very important to understand this.

When we look at the interoperability issues with e-prescribing, we see that we need organisation and inter operability. Particularly the authorisation of the physicians is a very important issue which has not solved yet. There is a Directive addressing whole Europe but we need to consider the issue of reaching electronic health identity in daily life in whole Europe. In other words, the issue of reaching prescriptions in other countries. On the other hand, reimbursement claims should be written. A pharmaceutical classification is needed for the interoperability in the semantic level. There are so many brands for the same drug compositions and even different drugs under the same brand. Therefore, this is something developing day by day, because the drugs are getting only one name in European Union and the correct information should be written concerning drugs. But there is still so many drugs in the market. Drug compositions, prospectus, directions and dosage are among very important issues which should be solved.

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In 2006, we found the opportunity of analysing Slovenia as a part of the first health project. The analysis was about writing the electronic health records to the smart cards. A conference was organised in 2006 during that we received valuable recommendations as well. Actually, e-prescribing is a system based on interoperation of all actors including the Ministry of Health and on the other hand a complex process that relies on the interaction of multiple professions.

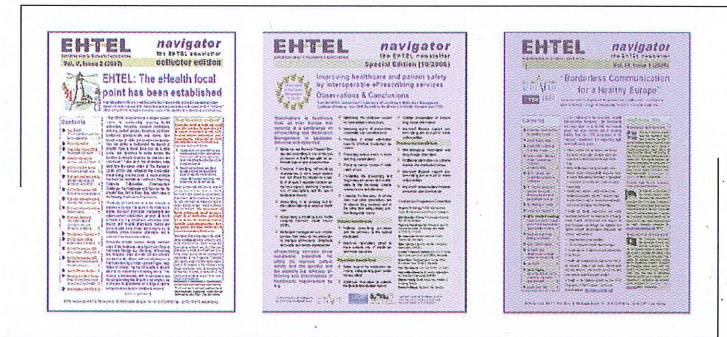
As can be seen here, there are several recommendations, but things may confuse due to national borders because it is difficult to take the regulations on patient confidentiality from a country and adapt them to another one. Why? Because there are different identity systems. It would take more time to establish these and accommodate the needs of confidentiality. This is one of the cases that we will face in the e-prescribing process. On the other hand, there is the issue of health professionals' identification and authorisation. Besides the international identification of health professionals, reimbursement of cross-border prescription. At the same time, the semantic part of the system should be a part of that and it is getting a part of that in the sense of digital prescribing. We do not want to create a digital prescribing because the prescriptions should be in paper form. On the other hand, the semantic side also has to be a part of it - and that is how it develops. We do not want to create a digital prescription because if it is created throughout Europe or in one of its countries it has to be put on paper and these papers may be readable - but if they are not the prescriptions will be lost. This problem has to be tackled.

How will these laws be applied? By walking or jumping? We have several approaches concerning steps that should be taken for development. One of the approaches suggests to get basic profiles of European Union, to have certain profiles which can be applied by everyone and set up bilateral/multilateral agreements. These processes might be gone through until reaching this level throughout Europe. And of course, we cannot expect from every country to go on with the same speed.

Another important issue is to make a decision on it. That is to have a basic prescription information in the same way. In other words, same prescription format in everywhere.

There is general information about what would happen after that. At the same time, the identity identifiers should be reliable. On the other hand, for physicians to be able to write prescription and pharmacists to give those prescribed drugs the identity identifiers should be reliable. We should prepare such a system that is really reliable. Both the persons prescribing and supplying drugs need to trust the system and those persons should be identified by digital certificates.

EHTEL is a part of this project as you should have understood from the presentations. We have published documents on this issue. This is a document about the navigators in the middle.



As you have understood, the project was ended. What is happening at the moment? The last document was the declaration of the European Commission about interoperability⁹. It was about the interoperability of the electronic health record systems that was published in July 2008. The Commission adopted a four step approach concerning the interoperability in practice, which is also a related with the outputs of our project. If you look that analysis, if you ask what is the content of that decision you would see the points I have already mentioned. *Political commitment, organisational framework, the process, technical compatibility, semantic interoperability, educating users and raising awareness...*

9 C (2008) 3283 (July). ...Commission's Recommendation on cross-border interoperability of electronic health records.

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There is a drawing of our project here. In this last level, there are several educational works. EHTEL conducted these works. How it was applied? There are projects recently started, initiated in the middle of this year. I wrote an article under the title of interoperability in Europe. The project started after the Commission's deceleration in July.

The projects are called EPSOS ve CALLIOPE. They are all about the interoperability of electronic health records. This is a project about information and communication technologies and political support which was prepared by combining the former programmes. We are trying to bring these projects into practice. It is a very big project at least in financial terms. It had six partners in the beginning, now it has 12. Its goal is to develop a practical e-health framework and ICT infrastructure that will enable secure access to patient health information, particularly with respect to a basic patient summary and e-prescription, between European healthcare systems. However, it was separated into four levels that were already mentioned. The project was initiated in July and ensured the whole cooperation. It was a project carried out under the cooperation of the ministries of health and the authorised institutions in the countries. CALLIOPE means a call for interoperability¹⁰. It is a sister project of EPSOS. They have common and very similar goals. This is again about improving the e-health services. It is quite smaller projects compared to EPSOS in financial terms.

The states were working together to find a solution for a common problem in EPSOS. On the other hand, CALLIOPE was like a discussion room and gathered the countries that were not parts of EPSOS. They formed a discussion platform in this forum area. CALLIOPE would conduct communication studies, contribute the improvement of communication and be a discussion platform. At the same time, studies would be carried out on the issues such as spesifications and standartizations.

CALLIOPE creates a structured and open forum for discussions. It is a multi-stakeholder platform. If you deal with interoperability across Europe you can apply to join this process. Because, as you see in the below, it is open to the

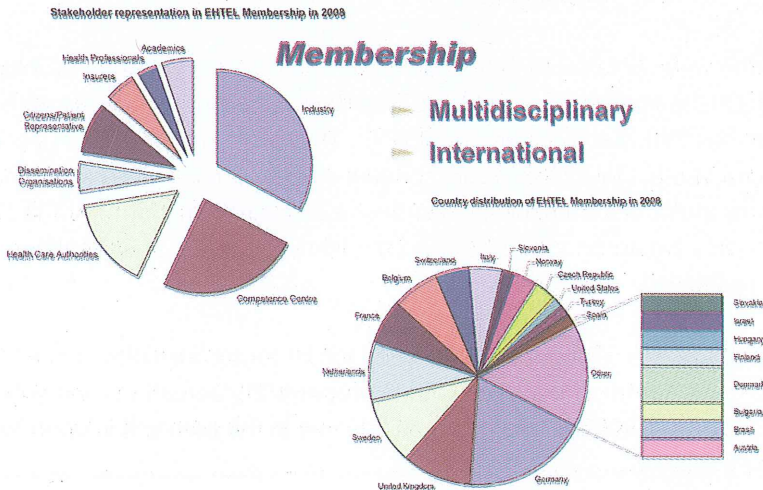
¹⁰ CALL for Interoperability.

participation of the organizations. Ministries, organisations of health professionals can participate the project. In other words, Pharmacists' Association can be represented in this project as a player of the game.

These are the things I would like the tell about interoperability.

I was impressed from the presentations conducted yesterday and wanted to show a bigger picture of the tele-medicine. There might be very profound developments in clinical care and management thanks to the tele-medicine services. As I said before, next year will be the 10th anniversary of our organisation. We have had 10 years dedicated to the e-health. Thus, I would like to say few things on our future plans and expectations.

We are establishing a network in order to create collaborative perspectives for all stakeholders striving for better health and care and to create trust, coherence and consensus between all stakeholders. This can clearly be seen from our members. So many stakeholders are represented here. It is written as industry here at the up right, but our members include competence centers, health authorities, citizens, academicians. We heave members as well from Turkey, Brazil and the United States of America besides from Europe.



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What is our work organisation? We have permanent working groups, ministries of health groups and a network of competence center. We have patients, citizens and consumers long-run working group. Besides those, we have special task forces that focus on certain issues, which are open to both members and non-members. Task forces enable expertise share on certain subjects. There is a board of directors and a management team. I am a member of management team.

Now I would like to mention more on task forces: *Interoperability initiative, patient safety and e-medication, health professionals, clinical process management* are the current task forces. A newly initiated task force is the sustainable tele-medicine services and chronic disease management. We organized a conference in Rome in 2006 which was about improving the care for chronic conditions and the added value of e-health

We are trying to combine these activities with the sustainable tele-medicine. Again we have several guiding principles. Tele-medicine is an important direction. There were very important stories related to the use of information and communication technologies (ICT) in the beginning. Now we can even build a virtual hospital in patient house, which is really an interesting perspective.

When people become less mobile they see their houses as their castles. Therefore, we need to bring the services to them, to their livingrooms. Here there is an example. An old patient suffers from diabetes and chronic heart disease. She has many journeys for her health checks. This lady is a part of tele-homecare project that is carried out in Italy. Several tools by which she performs automatic checks of her blood sugar, her weight, her blood pressure, and even the ECG with guidance over the interactive television set. Such an old lady can stay permanently at her home and enjoy a high quality life. In addition, she feels secure. That is the main idea.

EHTEL has a briefing paper on this issue. It is about the tele-medicine applications in health. Our goal here is to have interconnected services integrated into clinical and non-medical use cases.

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Let me return to the European Commission again. .Communication number 689 [COM(2008) 689] was issued in November, which is the latest document about this subject. Its title is “*Communication on Telemedicine for the Benefit of Patients, Healthcare Systems and Society*”. It is beneficial to the patients having chronic diseases and old people. Main actions here are *building confidence in and acceptance of telemedicine services, bringing legal clarity and ensuring interoperability*. As EHTEL, we want to stay as a part of this process and European 2020 vision and integrated tele-medicine system.

Health Professionals need clarity on their responsibilities and revenues to invest their time and effort into telemedicine services. At the same time, a culture of interdisciplinary and cross-sectoral collaboration should be established by a true interdisciplinary telemedicine service framework. Because, people are still deviating to the ancillary roads. In other words, the important thing is not to string out cables, utility lines but to cause people become closer and find a new way to work together.

We have only had a short overview of the picture. It is obviously understood from your project that you are a part of European process. However, the language obstacle should be overcome. I understood from what told yesterday and today about your activities you are closely connected with the developments in Europe. Communication is very advanced but the real actors of the health should be in collaboration at the same time. EHTEL is a European platform and hopes to provide support for you in the collaboration process.

Thank you again. Do you have any questions?

QUESTION- Thank you very much for the presentation. I would like to ask about the check and follow the patients at home. You contact with a physician in such cases in Europe but do you also contact with a pharmacists?

Secondly, a physician diagnoses an illness after the examination. What are the responsibilities of physicians and pharmacists in the process? There might be something missed. To see a patient in person is not the same to examine from a distant. How is your system working? Thank you.

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Dr. STEPHAN SCHUG- Thanks. You had two questions. Concerning pharmacists, that is necessary and being established. Normally, there is a widespread communication among the partners in the first step health services. There are nurses about whom we have not talked about as well. Pharmacists are also a part of the systems I know. Of course physicians are in the forefront but pharmacists have an important role.

Your second question is an interesting one. Who has responsibility in such a case? The lawyer who made the second presentation in the morning can tell many things on this subject. The concrete question here is whether the responsibility is transferred to a distant physician from the local one. As we understood from the court cases, the distant physician has the responsibility in some cases. There are several court decisions but the laws are diverse on this issue. In addition, the European Commission is working on it. All the legal regulations in Europe are being collected. I do not know whether Turkey is included in this study. The outcomes of this study is expected to be published by the European Commission in 2009 within the framework of the activities supporting tele-medicine. Is there any question else?

QUESTION- It is not actually a question but I would like to comment on a point about tele-medicine and responsibility. As you said, the European Commission has a document about legal issues on tele-medicine. In addition, a debate will be carried out about the ethical issues on tele-medicine. We will have more knowledge on the subject after maturing these debates. It is early to answer your question now but we will have more resources one year later.

PRESENTER- Thank you Dr. Stephan Schug. Now we are having a lunch break.