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Prenatal Telemedicine: A New System for Conventional and Computerized Telecardiotocography and Tele-Ultrasonography

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1. Introduction

Telemedicine is the delivery of health care and the exchange of health-care information across distances using both information technology and telecommunications. More simply, Telemedicine is medicine at distance. It encompasses the whole range of medical activities including diagnosis, treatment and prevention of disease, continuing education of health-care providers and consumers and research. Telemedicine should always aim to support health workers providing care as close to the patients as possible. This means information resources should be provided to all levels starting at primary care and clinical Telemedicine should be used where possible to prevent referrals to district or tertiary hospitals and support care at the more local level. Used in this way, Telemedicine can strengthen care at the primary care and district level (Viegas, 1998; Barrett & Brecht, 1998). Prenatal

Telemedicine is a branch of Telemedicine, born from the combination and application of healthcare instrumentation, informatics and telecommunication technologies to prenatal care. It aims to extend medical expertise to pregnant women who cannot access to specific prenatal clinical services, either because of logistical difficulties and emergencies. In the field of the prenatal care, the most widespread applications of Telemedicine are Telecardiotocography and Tele-Ultrasonography. This chapter will illustrate the state-of-art of these two applications and then will focus on the organization and activity of the first and unique Prenatal Telemedicine network in Italy, based on a system called TOCOMAT.

2. The origins of cardiotocography

The era of modern obstetrics started in 1821 with the discovery of auscultation of fetal heart by Jacques Alexandre Lejumeau Visconte of Kergaradec. His observation was a kind of revolution, since, for the first time, the presence of the living child in utero became perceptible. It passed from the situation of the fetus as an 'object' to the one of the fetus as a 'subject'. During the next thirty years, or so, everything within the field of obstetrical auscultation was ready to be discovered and described, i.e. the description of the obstetrical stethoscope, the determination of the mean fetal heart rate frequency, the recognition of its general lack of relationship with the maternal heart rate, and its usefulness for the diagnosis of fetal life or death, the existence of twin pregnancy, and fetal presentation and position. Until the second half of the 20th century, nothing new was been added and the assessment of the fetal condition depended on very limited means: the growth of the uterus and its contents, the movements of the fetus perceived by the mother and the listening of the fetal heart beat with a stethoscope. Sudden absence of fetal movements in the second half of pregnancy was, at that time, a serious diagnostic problem. Usually one had to wait for some weeks in order to observe if the uterus would grow before the decision could be reached to induce labour. The sign of Spalding at X-ray examination, showing overlapping of the fetal skull bones like roof tiles as a result of advanced maceration of the fetal tissues, was one of the few helpful objective diagnostic signs of fetal demise. This recurrent dilemma, whether or not the fetus was died in utero, formed the major impulse for the development of cardiotocography. Initially fetal abdominal electrocardiography and phonocardiotocography were pursued, but failed, primarily due to technical problems. It was only when the fetal heart beat could be rather easily detected by means of ultrasound or through the application of direct electrocardiography, that cardiotocography became popular as the method to monitor the condition of the fetus (Sureau, 1994). Currently, the majority of obstetric decisions to assist delivery of the baby by artificial means (caesarean section, forceps or vacuum extraction) for suspected fetal distress, relies on information gathered through the application of cardiotocography. It is the obstetrician's reassurance that when the fetal heart rate (FHR) pattern is normal there is nearly 100% certainty that the fetus is in a good condition, which has made cardiotocography so attractive and has induced its widespread use. This development is very understandable considering the dependence on indirect signals from the fetus and the problems concerning the very limited means to monitor the condition of the fetus prior to the introduction of cardiotocography. Nowadays, cardiotocography is the most common method of monitoring fetal well being, both before and during labour. Cardiotocography during pregnancy, together with ultrasonography, fetal biophysical profile evaluation and Doppler-velocimetry of the maternal-fetal vascular district, not only allows to diagnose the fetal distress, but also to

confirm the fetal wellbeing and to obtain an early diagnosis of any fetal state deterioration. The aim is to carry out well-timed obstetric interventions to reduce both fetal morbidity and mortality.

3. Conventional and computerized cardiotocography

Cardiotocography is the simultaneous recording of fetal heart rate and uterine contractions using two separated transducers placed on the maternal abdominal wall. The fetal heart rate is recorded using an abdominal Doppler ultrasound transducer, while uterine contractions are estimated using an abdominal wall pressure sensor. This technique is used during the third trimester of pregnancy, especially near term, and during labour, to monitor the fetus and to early diagnose any change of its condition due to a deterioration of the status of oxygenation. Traditionally, cardiotocographic trace is interpreted in a visual manner, but with high intra- and interobserver variability. The computerised analysis, if compared with the visual reading, allows a more objective interpretation since is based on predefined criteria, provides further parameters, such as short-term variability and approximate entropy, more specifically related to fetal hypoxia, and seems to be associated with less time spent in testing and with a reduction in the number of additional examinations to be performed for the fetal well-being evaluation. Moreover, the computerised analysis allows the repeatability of the results obtained from different centres. Practically, all pregnant women at high risk undergo electronic fetal monitoring in the last half of pregnancy, with a frequency ranging from daily to weekly. Usually, intensive antepartum fetal surveillance is requested in pregnancies where there is a high risk of antepartum fetal death, as a result of either maternal conditions (i.e. hypertension, diabetes) or pregnancy-related conditions (i.e. decreased fetal movements, oligohydramnios) (Di Renzo et al., 1994; Van Geijn, 1996).

4. The Italian experience with the TOCOMAT system

The use of the cardiotocographic recording in pregnant women at high risk often requires them to travel, which is particularly stressful for patients who live far from suitably equipped health centres. For this reason, Telemedicine has been used in cardiotocography to avoid the referral too much pregnant women to clinics or hospitals and to reduce long hospitalization for high-risk patients. An early description of a long-distance cardiotocographic transmission, in 1983, referred to the use of telemetry applied to cardiotocographic recording. Subsequently, computerized networks for the remote transmission and analysis of cardiotocographic traces have been described. Campania is one of Italian regions with a high birth rate. In the last few years, an increasing number of pregnant women, both at high risk and at apparent low risk, have crowded health centres to undergo cardiotocographic monitoring. Because adequately equipped health centres are often located far from patients' homes, pregnant women, who need intensive cardiotocographic monitoring, are forced to travel long distances or to undergo to long hospitalization. Moreover, health workers increasingly request the computerized analysis of cardiotocographic traces because, based on literature 's evidences, it is more accurate and objective than the traditional visual analysis and shows a better correlation with fetal health. In spite of this growing demand, the number of computerized systems for cardiotocographic interpretation available in Campania is very low, due to their high cost and to the need of adequately trained personnel. On these grounds, the first Italian system for antepartum

Telecardiotocography, called TOCOMAT, began in 1998 at the Prenatal Care Unit of the Department of Obstetrical-Gynaecological and Urological Science and Reproductive Medicine of the University Federico II of Naples, with the main aim of extending specialized medical expertise to pregnant women who are at high risk requiring antepartum electronic fetal monitoring and who live far from adequately equipped health centres (Di Lieto et al., 2001). At the beginning, the activity of the network was cofinanced by the University Federico II of Naples and the Campania Region. Subsequently, the activity of the TOCOMAT system has been included in several projects and then financed by the Campania Region (project NEUROMATIC, 2000; project CYBERFETUS, 2000) and the European Union (European Project of Telemedicine, 2003) (Di Lieto et al., 2002; Di Lieto et al., 2003; Ippolito et al., 2003; Romano et al., 2006; Ferrario et al., 2009).

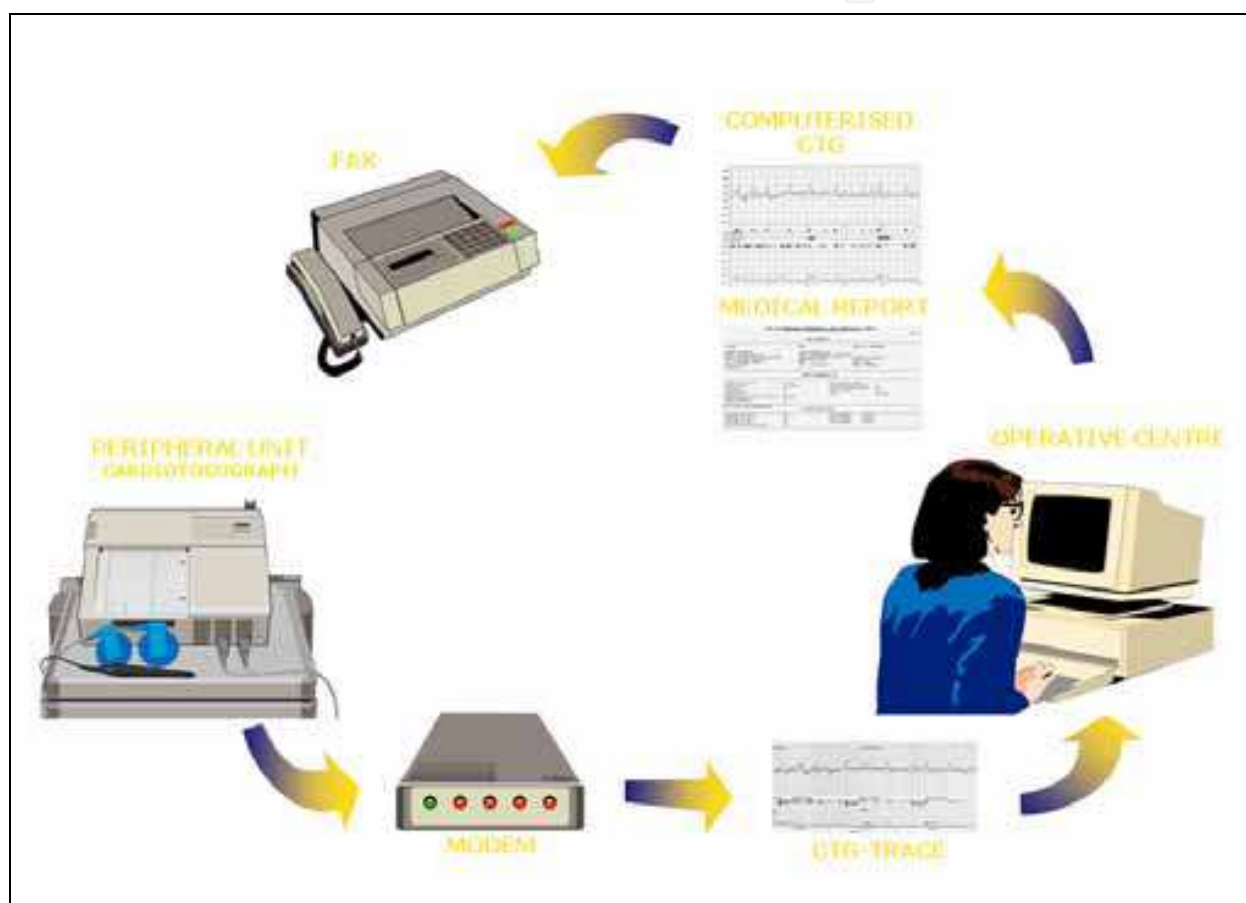


Fig. 1. The organization of the first version of the TOCOMAT system.

The system has been also included into the EUROTOCOMAT project (2004), based on a scientific cooperation between the University Federico II of Naples and the Semmelweis University of Budapest (Hungary) (Di Lieto et al., 2008). In its first version, the TOCOMAT network connected nine peripheral units located in small hospitals and consulting rooms in Campania. The network operations centre is located in Naples, the regional capital, at the University Federico II.

From 2004, two remote units, located at the Department of Obstetrics and Gynaecology of the Semmelweis University of Budapest (Hungary) and at the Hospital of Tripoli (Greece) have also been working with the Operation Centre.

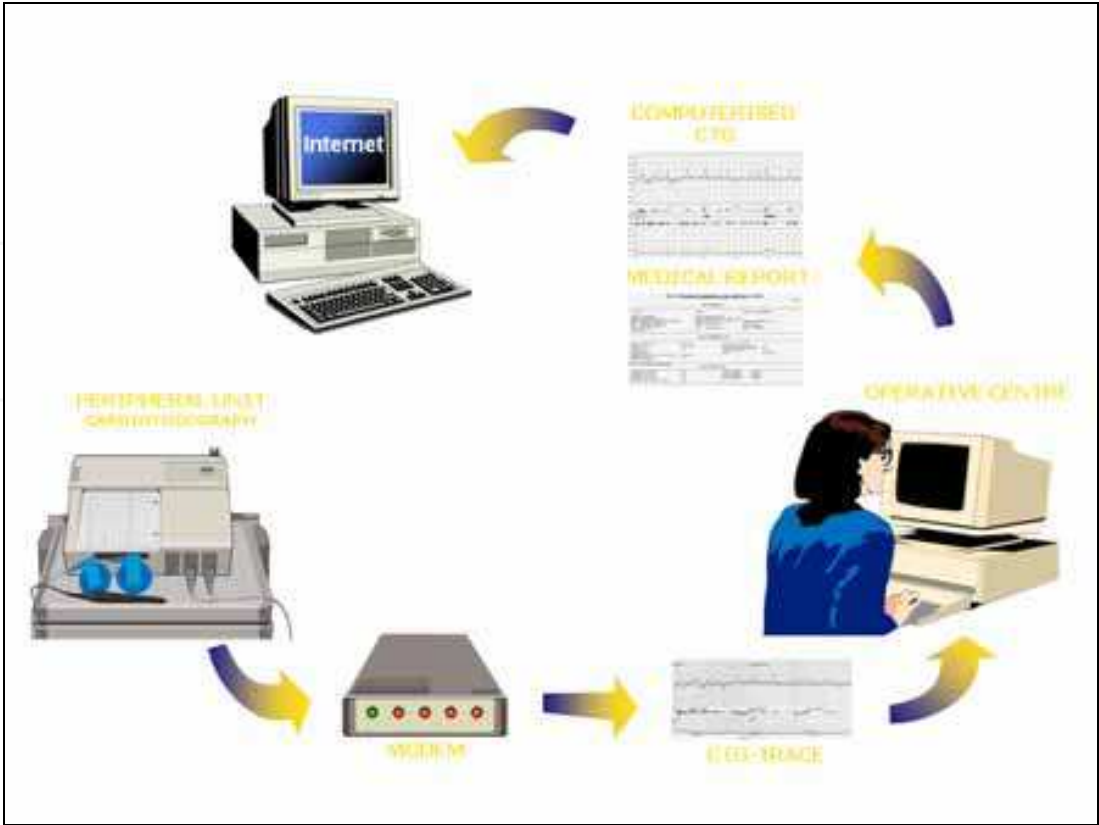


Fig. 2. The first updating of the TOCOMAT system (2005). The medical report is transmitted by e-mail to the remote unit.



Fig. 3. The TOCOMAT system in Europe.
Peripheral units are equipped with a traditional cardiotocograph able to transmit via modem both fetal heart rate traces and data about patients to the Operation Centre. Transmission takes 40-60 seconds.



Fig. 4. The cardiotocograph used at the remote units.

At the Operation Centre, data are received, displayed and stored in a system called OB TraceVue (Philips Medical Systems) and then analysed by the 2CTG system, a software which provides the computerized analysis of the traces. Within few minutes, the computerized trace, together with the analysis and medical reports, is sent back to the peripheral unit by fax or by e-mail. Until December 2009, 3194 patients have been monitored with the TOCOMAT system, and about 10000 traces have been recorded and analysed. Admissions were efficiently planned, as a consequence of a continuous interaction between peripheral units and the Operation Centre.



Fig. 5. The University Operation Centre.

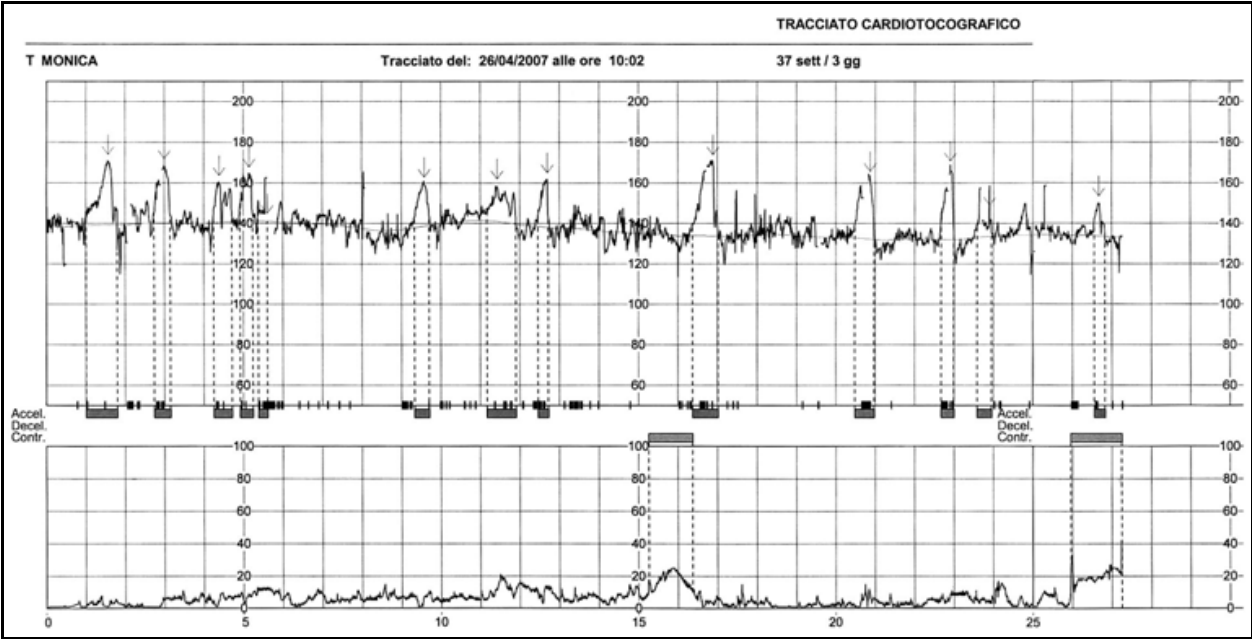


Fig. 6. A cardiotocographic trace elaborated by the 2CTG system at the Operation Centre.

TRACCIATO CARDIOTOCOGRFICO

T MONICA

Num. registrazione: 9312

Cognome coniugata:

Indirizzo:

Ultima mestruazione: 07/08/2006

Numero gravidanza: 1

Eseguito il: 26/04/2007 alle: 10:02

Data di nascita: 10/11/1977

Tel:

Gestazione: 37 set / 3 gg

Parità:

Durata: 27 minuti

Codice paziente: 020420071016

Correzione ecografica:

Analisi automatica del CTG

	Totali	/Ora
FCF basale Media (FCFB bpm)	136.50	
Rapporto grandi / piccole accelerazioni	---	
Numero decelerazioni > 20 bpm per 30 sec o > 10 bpm per 60 sec	0.00	---
Numero movimenti (marker)	0.00	---
Numero grandi accelerazioni > 15 bpm per 15 sec	13.00	---
Numero piccole accelerazioni > 10 bpm e < 15 bpm per 15 sec	0.00	---
Numero contrazioni	2.00	---

Analisi automatica parametri Frequenza Cardiaca Fetale (FCF)

	Media	Mediana	Interquantile 25%	Interquantile 75%
FCF basale (FCFB bpm)	136.50	136.51	133.77	139.51
Variabilità breve periodo (STV msec)	7.26	6.13	5.67	9.04
Variabilità lungo periodo (LTI msec)	23.82	25.73	22.78	26.63
Ampiezza della variabilità (Delta msec)	45.22	41.00	35.70	55.87
Interval index (II)	0.79	0.77	0.66	0.87
Entropia approssimata (ApEn)	1.45	1.33	1.29	1.64
Contributo spettrale bassa frequenza (LF)	76.74	78.92	68.05	83.61
Contributo spettrale media frequenza (MF)	13.21	11.60	9.59	18.31
Contributo spettrale alta frequenza (HF)	10.05	9.48	6.80	13.64
LF/(HF+MF)	2.26	1.85	0.00	3.94

Qualità del segnale CTG: 5

Percentuale tracciato analizzato: 54%

Operatore:

ID cardiotocografo:

Note: DH 3702 EPISODI DI SINCOPE RICORRENTE

Campo utente 1:

Campo utente 2:

Fig. 7. The report of the computerized analysis of the cardiotocographic trace.

5. Some technical and scientific results obtained with the TOCOMAT system

5.1 Agreement in cardiotocogram interpretation between the 2CTG computerized system and experienced and inexperienced observers involved in the TOCOMAT network

As previously indicated, computerized cardiotocography could overcome some of the limits of the conventional visual reading of cardiotocographic traces. It is based on predefined criteria, and therefore provides a reproducible and objective reading and allows repeatability of the results obtained in different centres. In a study performed (Di Lieto et al., 2003), as a part of the research activities related to the TOCOMAT network, we evaluated the agreement in the interpretation of traces between the 2CTG computerised system and experienced and inexperienced observers involved in the Telecardiotocography project. 150 antepartum traces were randomly chosen from the 457 recorded during the first working year of the TOCOMAT system. The traces were analysed to assess the statistical agreement between the observers and the computer about the interpretation of some parameters, detectable by both visual and computerized analysis. The expert were two operators of the Operation Centre; the midwives working at the remote units were included in the study as inexperienced observers. We found good agreement among the observers and between the observers and the computer for some parameters (fetal heart rate baseline, assessment of accelerations) whose evaluation seems to be not more accurate of the computerised analysis. On the contrary, we found lack of agreement among the observers and between the observers and the computer in the evaluation of the fetal heart rate variability, probably because the computerised analysis gives exact values, overcoming the interobserver poor reproducibility. The disagreement between experienced and inexperienced observers could also be influenced by the different degree of professional experience. Finally, the experience of the observers resulted crucial in the evaluation and definition of fetal heart rate decelerations. In conclusion, we demonstrated that the use of a computerised system provides exact values for most cardiotocographic parameters; the experts of the Operation Centre, however, should rely both on clinical features and on the computerized interpretation to make decision about the management. Therefore, the use of a computerized system for the analysis of cardiotocographic traces obtains a decrease in the intra- and interobserver variability also in our prenatal Telemedicine system.

5.2 Level of satisfaction of operators and patients

After the first four years of experience with the TOCOMAT system, we evaluated the acquisition of specific skills and the satisfaction of the operators working at the remote units (one doctor at each unit) (Di Lieto et al., 2006). We asked them to answer two questionnaires. The first one, submitted twice a year, was a test about the interpretation of a cardiotocographic trace. The second one, submitted once a year, concerned the job satisfaction of the operators.

A similar questionnaire was also mailed to the monitored patients after delivery, to test their compliance and satisfaction. At the beginning, the operators were afraid of losing their professional independence because of their involvement in the project. They also doubted that the trace displayed at the Operation Centre after transmission would be identical to the trace recorded at the peripheral unit. However, their answers showed that they gradually overcame their scepticism during the course of the project. From the beginning of the project, they had positive opinions about the usefulness of computerized cardiotocography

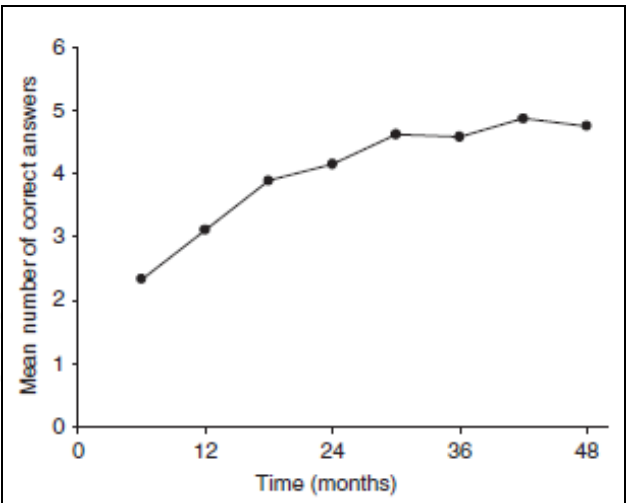


Fig. 8. Mean score of the questionnaire evaluating the acquisition of specific skills.

Question	1st year (n=8)	2nd year (n=8)	3rd year (n=8)	4th year (n=9)
1 Do you think the organization of a telecardiotocography network is useful to improve the management of pregnant women at risk?	50	63	75	89
2 Do you think the computerized interpretation of the traces is really useful to support your clinical decision?	63	63	88	100
3 Do you think you could lose your own professional independence because of your involvement in the telecardiotocography project?	75	63	25	11
4 Do you think the trace displayed at the operations centre is effectively identical to that recorded at the peripheral unit?	25	75	100	100
5 Do you think the interaction with the experts of the operations centre is useful as an experience of continuous distance training?	13	38	63	78

The percentage answering 'yes' is shown.

Fig. 9. Results of the operators' questionnaire.

Question	Percentage of 'yes'
1 Did you regularly receive fetal monitoring at the remote unit involved in the telecardiotocography project?	89
2 Was the transfer to the remote unit stressful for you or your family?	7
3 Did you feel reassured by the fact that the trace was also interpreted by the experts and the computerized systems of the university operations centre?	83
4 Did you wait too long for the results of the computerized analysis performed at the operations centre?	18
5 Did your trust in your own doctor diminish as a consequence of your participation in the telecardiotocography project?	11

Fig. 10. Results of the patients' questionnaire (n = 1098).

in the management of high-risk pregnancies. Finally, they expressed an increasing appreciation of the project as a method of continuous education. As regards the patients, the answers to the questionnaires showed a moderate level of satisfaction. They appreciated the

organization of the Telecardiotocography system and felt reassured by the interaction between their own consultant doctors, the operators working at peripheral units and the Operation Centre.

5.3 Efficiency of the TOCOMAT system and cost study

Reviewing the first years of experience with telemonitoring of patients with high-risk pregnancies using the TOCOMAT system, we demonstrated as a high number of patients at high risk underwent computerized cardiotocographic monitoring in their own environment and were hospitalized only when necessary (Ippolito et al., 2003). Admissions were efficiently planned, as a consequence of a continuous interaction between peripheral units and the Operation Centre. The neonatal outcome overall was good. An increase number of preterm births and of caesarean sections are frequently cited as collateral effects associated with the widespread adoption of cardiotocographic recording. However, in spite of the substantial number of cases, mainly high risk patients, we found a caesarean rate of 49%, in comparison to the rate observed in Campania which is 61%. Telecardiotocography allowed the decentralization of prenatal surveillance, with a gradual decentralization of obstetric surveillance and subsequent improvement in the quality of life for mothers and newborns.

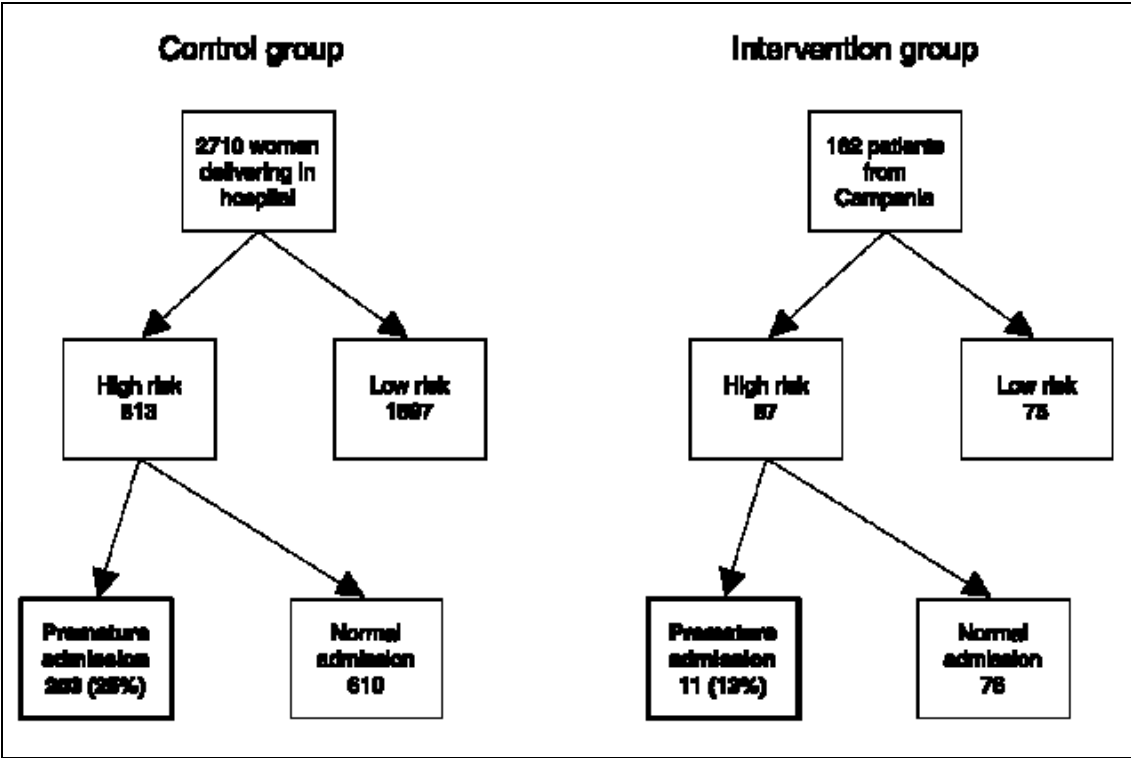


Fig. 11. Cost study design.

To make a cost study of the TOCOMAT network, we compared the hospital costs of high-risk patients monitored with the system during the year 2000 with those of control group, i.e. high-risk patients hospitalized and delivered at the University Federico II of Naples. Costs were calculated for the equipment and the working of the Operation Centre and of five peripheral units. Hospital costs were calculated basing on the length of hospitalization and the resources used. In the control group, 25% of the women were hospitalized prematurely.

	Cost (€)
Allowance for depreciation of the equipment ^a	11,620
Equipment maintenance ^b	3,254
Cost of electricity ^c	120
Cost of medical personnel ^d	50,355
<i>Total annual cost</i>	<i>65,349</i>

^aThe cost of the server was €46,486 and it was amortized over four years.
^bThe annual maintenance charge was 7% of the total cost of the server.
^cThe server required 360 W.
^dThe CTG monitoring needed one physician for 1560 hours per year, at an hourly remuneration of €32.28.

Fig. 12. Annual cost of cardiotocographic recording at the Operation Centre.

	Cost (€)
Allowance for depreciation of the equipment ^a	2066
Equipment maintenance ^b	578
Cost of electricity ^c	8
Cost of telephone line	2820
Cost of modem	52
Annual cost of medical personnel ^d	50,355
<i>Total annual cost</i>	<i>55,879</i>

^aThe total cost of the peripheral unit was €8263, which was amortized over four years.
^bThe annual maintenance charge was 7% of the total cost of the peripheral unit.
^cThe peripheral unit required 25 W.

Fig. 13. Annual cost of a remote unit.

	Cost (€)
Cost of the operations centre	65,349
Cost of the five peripheral units	279,395
Cost of modem ^a	52
<i>Total annual cost</i>	<i>344,796</i>

^aThis modem is located at the operations centre, to receive information from the peripheral units and to send them the medical report and the trace analysed by the computerized system; this cost has to be calculated, because the cost considered in Table 1 refers to an autonomous unit, not included in a telemedicine network, so it does not need the modem.

Fig. 14. Total annual cost of the Telemedicine project.

In the case study group, a lower proportion of the women were hospitalized prematurely (13%). If we apply the same effect of monitoring to the control group, then a smaller number of patients would have been hospitalized prematurely, with a notional saving, which is purely indicative, of about € 358.00,00.

In conclusion, the organization of the TOCOMAT system for the computerized recording of fetal heart rate traces increases the efficiency of the service provided to the patients. Such a system involves a rationalization of the costs of prenatal surveillance, as there is a decrease in the probability that high-risk pregnant women will be unnecessarily hospitalized and in the length of hospitalization. Moreover, it allows peripheral units, although located far from the University Operation Centre and provided with modest resources, to use computerized analysis at very low costs.

6. Technologies

The organization of the TOCOMAT network was made possible by the availability of technologies capable of transferring data from the remote units to the Operation Centre in short time and without constraints due to the distance. Information can be stored and transmitted as either analogue or digital information. Analogue information uses a continuously varying signal. Digital information reduced everything to a series of discrete numerical values which in the computer are represented as a series of 1's and 0's. Examples of analogue technologies are broadcast radio and television, traditional telephone, gramophone records, audio cassette players and, in health's field, X-ray machines and ECGs. Examples of digital technology are computers, audio CDs, digital television, digital mobile telephone and, in health's field, CT scanning and MRI scanning. It is generally possible to convert information from analogue to digital and vice versa. A computer modem is an example: it is a device which connects a computer (digital) to the telephone network (analogue). The modem converts the digital computer signal into an analogue signal for transmission and then reverses the process at the receiving computer. Data transfer from the remote unit to the Operation Centre in the TOCOMAT network is based on this principle. Telecommunication technologies are moving towards digital signals because: audio, video, graphics and other data can be all converted into digital signals and then transmitted through the same digital network (i.e. multimedia capability); digital information can be transmitted more accurately, analogue information always degrades more the further it is sent; digital signals can be transmitted at extraordinarily fast rates; digital signals can be switched and routed more cheaply and flexibly than analogue signals. The technologies involved in Telemedicine can be divided into two main groups, those that are involved in the transmission and receiving of the information (i.e. running the network), and those which represent end-user devices able to generate and present the information (i.e. computers, televisions, telephones.). Generally, the end-user only needs to understand how using the end-device and confirm that the network support the service. Details of the networking technology are generally irrelevant. For instance, it is not necessary for an internet user to know the details about internet's functions, but he has only to know if telephone line can carry sufficient bandwidth to the Internet Service Provider.

6.1 Transmission technologies

Wires and cabling

Digital signals are sent as streams of electrical impulses. The existing telephone networks are generally built around copper wires and co-axial cables. The amount of information

which can be carried (bandwidth) depends on the type of cable or wire. The major factors for district health facilities are the connection of the local exchange to the country's telecommunications backbone and the quality of the connection from the health facility to the exchange. The potential bandwidth of the connection to the exchange falls rapidly with distance. Most computer networks within a health facility (local area network or LAN) are connected with co-axial cable.

Fibreoptic cable

Fibreoptic cable is very fine set of glass fibres which carry digital signals as pulses of light. Fibreoptic cable has revolutionized telecommunications because it is able to carry enormous volumes of information. It is also not subject to electrical interference. The initial roll-out is expensive and its main use is in providing the telecommunications backbone which links all country's telephone exchanges.

Radio-based technologies

This technology uses radio waves to send information through the air. The fixed equipment required is a transmitter and a receiver. Radio frequencies are regulated in each country with frequency bands, reserved for various purposes. It may be used for radio broadcast or point-to-point telephony as in the mobile phone network. Its range varies with frequency and the power of the transmitter and there are often areas of poor reception if the radio waves are blocked by mountains or buildings. Its advantages are mobility and the independence from wires and cabling. Its disadvantages are low bandwidth and lack of reliability.

Microwave links

Microwaves can be used to send digital information in a similar way as radio. It is of a higher frequency than a radio and is totally dependent on line of sight from transmitter to receiver. It is usually used on a point-to-point basis over distances up to 50 kilometres. Quite high bandwidths can be achieved.

Satellite technology

Satellites are able to receive radio signals from earth and then transmit them back. The device is a satellite transponder. The geographic area covered by the satellite signal is known as the satellite's footprint. Most communications satellites are in geostationary orbit over 40,000 kilometres above the equator and have footprints covering very large regions. The equipment required to transmit a signal to a satellite in geostationary orbit is expensive. The equipment required to receive the signal from the satellite is much less expensive. For this reason, satellite technology is often used to broadcast signals, e.g. television or as a means of "trunking" an aggregated signal between telecommunications hubs. Satellite charges have been falling as their numbers and overall capacity have increased. There are initiatives under way to use satellites in lower orbits. For example, the Iridium network plans to use 66 satellites orbiting at 780 kilometres to provide a mobile phone and the network covering the whole world. The lower orbit means that hand held phones will be powerful enough to both transmit and receive signals.

6.2 Networks

Local Area Network (LAN)

A LAN is used to connect digital devices, such as personal computers and mainframe computers, over a localized area such as a building or campus of a hospital, university or

factory. LANs are normally installed and maintained by the organization and are essentially a small private computer network. Distances covered are small, 1-2 kilometres at the most, and this allows high data transmission rates. LANs are used to share information throughout an organization. In a hospital they are often used to access a Patient Master Index, medical record tracking, appointment booking systems and clinical test results. In some workplaces, they are used to streamline and control workflows. Any organization with two or more computers will generally have them networked.

Wide Area Networks (WAN)

A wide area network is a network which covers a greater geographic area than a LAN. Generally, the dispersed sites are linked by lines leased from the telephone companies. Because of the distance involved, WANs have lower transmission rates than a LAN. Banks, for instance, run WANs connecting their bank branches to their central databases. Credit card companies run WANs which cover the entire globe. In health's field, a typical WAN connect the LANs of all the hospitals in a city or region.

Public Switched Telephone Network (PSTN)

This is the analogue telephone network which is the largest network absolute. It can be used to carry voice and, by using a modem, data as well. It consists in a large number of carriers whose networks are interconnected. Telecommunications companies are continually developing and offering an expanding range of value-added communication services beyond the basic telephone service. For district hospitals, ISDN (integrated services digital network) services are the most relevant additional service. An ISDN connection is required for video-conferencing and also for high bandwidth access to the Internet.

Private Automatic Branch Exchange (PABX)

Many organizations have a PABX to automatically switch calls between telephone extensions in an organization, and to and from the public telephone network.

Internet

The Internet is a global network of computer networks. Individual computers or entire networks connect to the Internet via a gateway which converts the information to the required format (TCP/ IP) and routes the information. The backbone of the Internet is run by the telecommunications companies. Individuals normally connect their computer using a modem and phone line via an Internet Service Provider. The Internet services include e-mail, file transfer protocol, and access to the World Wide Web.

6.3 End-user equipment

Telephone

A number of added services are possible. Multi-point audio conferencing involves three or more telephones dialing into a bridge which gets the multiple feeds in and relays the appropriate signal out. This is often useful for administrative meetings or educational sessions. Voice-based interactive information services provide prerecorded information to a caller by allowing them to navigate through menu choices by dialing individual digits.

Facsimile (Fax)

Fax is a device which electronically transmits documents and reproduces them at the other end over phone lines. It is possible to have a device which operates as both a fax and a

phone as required. Because of their cheapness fax devices are widespread in most organizations.

Video-conferencing

Video-conferencing is similar to a telephone call except that there is a video picture together with audio. The equipment for video-conferencing consists of a video camera and microphone, a 'TV', and a codec at each end with an ISDN connection. Cost varies with the quality, size and sophistication of the system. There are a large range of add-ons such as a document camera, electronic white board and slide projection equipment which can be included in the package. The video and audio signal are sent to the codec (a specialized computer) which performs analogue/ digital conversion and then compresses the signal. The compressed signal is sent over an ISDN line to the other destination where another codec decompresses the signal and converts it to audio and video for viewing on the TV monitor. The minimum bandwidth for video-conferencing is 128 kilobits per second. At this bandwidth a compression ratio of 600: 1 is required. The resulting picture is adequate for interpersonal communication; however, there is some degradation of picture quality and when there is a lot of movement the picture degrades further for a number of frames. A higher quality can be

achieved by using a higher bandwidth such as 256 or 384 kilobits per second. Video-conferencing using an ISDN connection is analogous to using the telephone. The other parties' number is dialed and the call is automatically connected when the call is answered. At the end of the call the parties hang up. The advantages of video-conferencing as opposed to the telephone are that people form a better rapport and communicate better when can see each other. A doctor can take a better medical history from the patient and physical signs and symptoms can be visually demonstrated or inspected. This also applies to administrative meetings.

Television

Television is not an interactive media but is suitable for passive education. It is usually delivered by terrestrial broadcasts, satellite broadcast, or videotapes. Public TV is a major influence and educator of the general public and is important in health promotion and preventive health strategies.

Radio

Like television, radio broadcasts are not interactive (except talkback radio) but can have a major role in health promotion and preventive health strategies.

Computers

Computers are capable of storing, processing and presenting a lot of information in a variety of formats. They are extremely flexible and can be programmed to do virtually any information processing task. PCs (personal computers) are commonly placed on workers' desktops and their main uses, relevant to health facilities, are word processing, spreadsheets, database services, data analysis, e- mail communication and Internet access. There are many peripheral devices which can be used with computers. Printers are the most common peripheral devices. A scanner is a device which scans and digitizes pictures. In health's field, they can be used to digitize X-rays. CD ROMs (compact disc -read only memory) are able to store over 600 megabytes of data on one disc which is sufficient to store the entire Encyclopaedia Britannica. The CD ROM reader is quite a cheap peripheral device. Sound card

and speakers are required for audio output from the computer. A modem is required to connect a computer to other computers including the Internet using telephone lines.

6.4 Internet services

Internet is a system of interconnected networks which spans the globe. Most businesses, universities and other organizations, as well as many individuals, are able to access and use Internet. It has been estimated that the number of users is greater than 250 million but such estimates are always out of date owing to the phenomenal growth of use. An individual user connects via an Internet Service Provider using a computer, a modem, and an ordinary telephone line. Organizations generally have their own computers operating through a LAN and connect the LAN to the Internet via a single computer which operates as a gateway for the others. For rural and remote users the existence of a reasonably priced local Internet Service Provider may be a limiting factor as long-distance phone charges may make it financially impractical if there is no local Internet Service Provider.

E-mail (Electronic Mail)

E-mail is a system whereby computer users send electronic messages to each other over computer networks. The messages can be stored, read and printed by receiver. Internet uses an e-mail addressing system organized on a world-wide basis. E-mail messages are delivered electronically and an e-mail from one country to another will take only a matter of minutes to arrive. The cost of e-mail is encompassed as part of the Internet connection charge and so the marginal cost approaches zero. E-mail has great potential in health to allow health workers to communicate and keep in touch with each other.

The World Wide Web (WWW)

The WWW is a system organized on a world-wide basis whereby resources on remote computers are downloaded and made available to users of the WWW. Most commonly the user downloads a "page" from the remote computer. This page may contain text, graphics, animations, audio, video, and forms. The downloaded page will contain words or pictures known as hyperlinks which when clicked on with the computer mouse result in another WWW page being downloaded (from the same or a different computer). In this way, the WWW forms a "web" of interlinked pages spanning the globe. The massive amount of material linked by the WWW is a problem in itself. Much of it is advertising and promotional material and there are no controls on quality. Nevertheless it is an extremely cheap method of publishing and sharing information. There is an increasing amount of high quality health-related resources on the WWW.

7. Limits of the conventional Telemedicine and new perspectives

Currently the main applications of Telemedicine fall within the conventional Telemedicine, which consists of connecting two different locations using a wired connection. This type of connection means that the conventional Telemedicine is not suitable for mobility, flexibility and portability. These three aspects of conventional Telemedicine encourage the use of wireless connections. When the Telemedicine equipment become mobile, flexible and portable, the chances of delivering a health consultation increase and are especially useful in case of emergencies. In all cases of emergency, disaster areas and in places where the ratio between patients and doctors is very high, the use and benefit of flexible and mobile

equipment is substantial. Conventional Telemedicine currently uses PSTN (Public Switched Telephone Network, analogical) and ISDN (Integrated Service Digital Network, digital) connections to transmit data and allow the acquisition and remote transmission of data in real time. Therefore, if the patient or the doctor does not have available the proper equipment, it remains the problem of displacement and cost of this. So, despite the impressive performance of conventional Telemedicine, there is still much work to do to make Telemedicine available for a larger number of users.

The main problem with conventional Telemedicine is its reliance on “wired” connections. These connections depend on the big telecommunications companies and are therefore extremely expensive. In addition, they exclude the mobility or portability of Telemedicine equipments, precluding the use of Telemedicine service based on the location of the patient and, therefore, limiting their use to health care institutions that already have such systems. Wireless Telemedicine is a form of Telemedicine that can be supplied through a wireless network. It involves the use of wireless telecommunication technologies connected to the Internet, in order to allow that teleconsultation happen in any geographical region covered by a wireless network. In this way, some critical problems of conventional Telemedicine, like immobility, lack of flexibility and portability, can be overcome. Another advantage of wireless Telemedicine systems is the lower cost compared to a conventional’s one, since a wired connection between the Telemedicine system and the Internet is not required. A further potential of wireless Telemedicine systems is represented by the different types of equipment. The software and hardware for wireless systems are clearly more accessible, especially for facilities with fewer economic resources. In fact, most kits require a simple

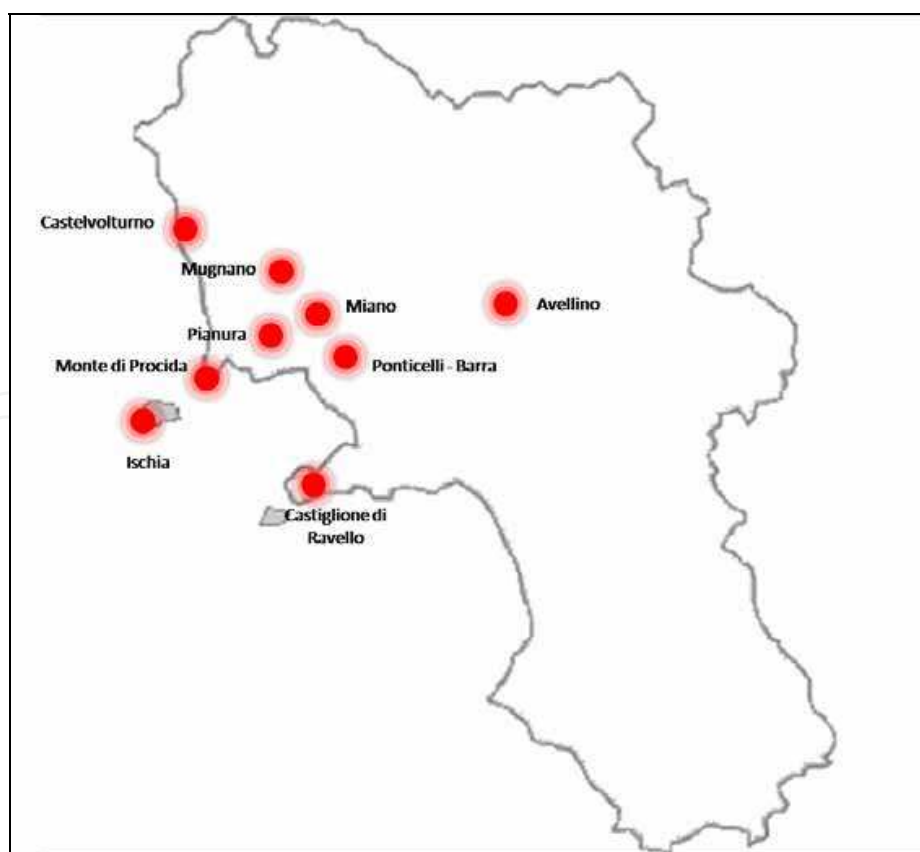


Fig. 15. Remote units of the new TOCOMAT network in Campania.

wireless connection, a laptop or tablet computer, a digital camera, some simple devices and sometimes a camera and a microphone.

8. The new TOCOMAT system

The availability of new technologies for the organization of wireless Telemedicine networks represents the ground of the recent updating of the TOCOMAT system, in order to allow intensive cardiotocographic monitoring of fetuses at risk independently from the mother and doctor location. In this way, the remaining space limitations related to the Prenatal Telemedicine network can be overcome.

8.1 The network

The remote units

In the new network, each remote unit is equipped with a last generation, small, user-friendly cardiotocograph (Corometrics 170, General Electrics).



Fig. 16. The fetal monitor used at the remote units included in the new TOCOMAT network.

This equipment has a weight of about 3.6 kg and is able to transmit the cardiotocographic traces and the data related to the patient and her pregnancy to a T-Mobile MDA GPRS Smart Phone using a Bluetooth wireless port.

The Smart Phone is equipped with the software TRIUM Application (TRIUM, München, Germany), which allows receiving all signals coming from the cardiotocograph and sending them in real time to the Operation Centre. Moreover, the Smart Phone receives via e-mail the medical report and the report of the computerized analysis from the Operation Centre. This new system does not use a traditional telephone line for data transmission. So, it overcomes the considerable space limit of the old system, and could allow trace recording and transmission also of patients at home.



Fig. 17. A Smart Phone is used for the data transmission in the new TOCOMAT network.

The Operation Centre

The Operation Centre, located at the Prenatal Care Unit of the University Federico II of Naples, is equipped with the new system TRIUM CTG Online. It was born from the cooperation between the engineers of the General Electrics and the creators of the 2CTG (SEA, Monza, Italy) software for the computerized analysis of cardiotocographic recordings. The system has been expressly developed to receive, display and store cardiotocographic traces and patients' data recorded by the remote units and to send them to the 2CTG2-Trium option software for the computerized analysis.

Trium CTG Online

Trium files are located into a shared folder on the hard disk of the 2CTG workstation, whose path will be available to the 2CTG software user. The database structure of the 2CTG uses an external identification field to univocally distinguish between different patients coming from other software devices. In order to allow that exams concerning the same patient can be stored together and to avoid data redundancy, the Trium software generates and exports a unique key for each patient. When loading a new exam, the 2CTG reads this ID and searches for a corresponding instance in the current database. If the patient already exists in the database, then the new exam will be imported and associated to that patient.

Data concerning the cardiotocographic exam are stored in the Trium analyze file, composed by a series of formatted lines corresponding to each acquired sample. In each line, the 2CTG extracts the values corresponding to: time in seconds of the sample; fetal heart rate (FHR); tocodynamometry; fetal movement profile (FMP); signal quality (SQ). FHR is expressed as a floating point number corresponding to the value in beats per minute (bpm) in the range [0-300] bpm with resolution of 0.25 bpm. In the same way, the tocodynamometry is represented as the real toco value in the range [0-127] with a resolution of 0.5. FMP is a

single character which is coded as following: 0 = no movement registered, 1 = movement registered. Only the first ASCII character composing the SQ string is interpreted, following the rule: SQ = 2 means good quality (green in the 2CTG representation); SQ in (0, 1) means insufficient quality (red in the 2CTG representation). In order to store and analyze recording in its common internal representation, the 2CTG requires that tracings are sampled at a frequency of 2 Hz, that corresponds to a time lag between two contiguous samples of 0.5 seconds. The data file provided by Trium has a sampling frequency of 4 Hz. Therefore 2CTG decimates the time series coming from the Trium system during the import procedure.

2CTG Trium option

This software was born from an update on the 2CTG version 2, in order to allow the computerized analysis of the traces recorded at the remote units of the TOCOMAT network and received by the Trium CTG Online. The software computes a set of standard parameters related to the morphology of the signal (baseline, large and small accelerations, decelerations and contractions) and to the time domain characteristics of the FHR (FHR mean over a minute, FHR standard deviation, Delta FHR, Short term variability (STV), Long term irregularity (LTI), Interval Index (II). Moreover, it is able to compute frequency domain indices and regularity / non linear parameters. In particular, among the regularity and nonlinear parameters, the Approximate Entropy (ApEn) and the Spectral Analysis are included in the standard clinical version. The time and frequency domain indices can be evaluated only with the computerized analysis of the traces and are more precisely related to the fetal oxygenation status.

Medical report

Within few minutes, the trace displayed by the computerized system, the medical report and the report of the computerized analysis are sent back to the remote unit via e-mail.



Fig. 18. Actual organization of the updated TOCOMAT network for Telecardiotocography.

8.2 First results with the new system

Starting the activity of the new TOCOMAT system, we equipped six of the remote units included in the network with last generation monitors and Smart Phones. One of these units has been used for home monitoring. During the first six months of activity with the updated version of the TOCOMAT system, 112 patients (age 26 ± 6 [SD] years, parity 0.63 ± 1.2 [SD]) with pregnancies at high risk received cardiotocographic monitoring. 25 of these patients have been monitored at home. The most common reason for cardiotocographic monitoring

was preterm labour. In total, we recorded 185 traces. 8 of the 185 recorded traces (4.3%) were repeated because of technical problems or inadequacy. Excluding them, we analyzed 177 traces of good quality. The personnel involved in the activity of the remote units was the same employed in the previous system. It just received a short training to use the new equipment. The home monitoring unit employed a midwife who performed the cardiotocographic recording at patients' home. The updating of the system did not require any change in the activity of the Operation Centre, because the way of display, analyze and store the traces was the same as the previous version.

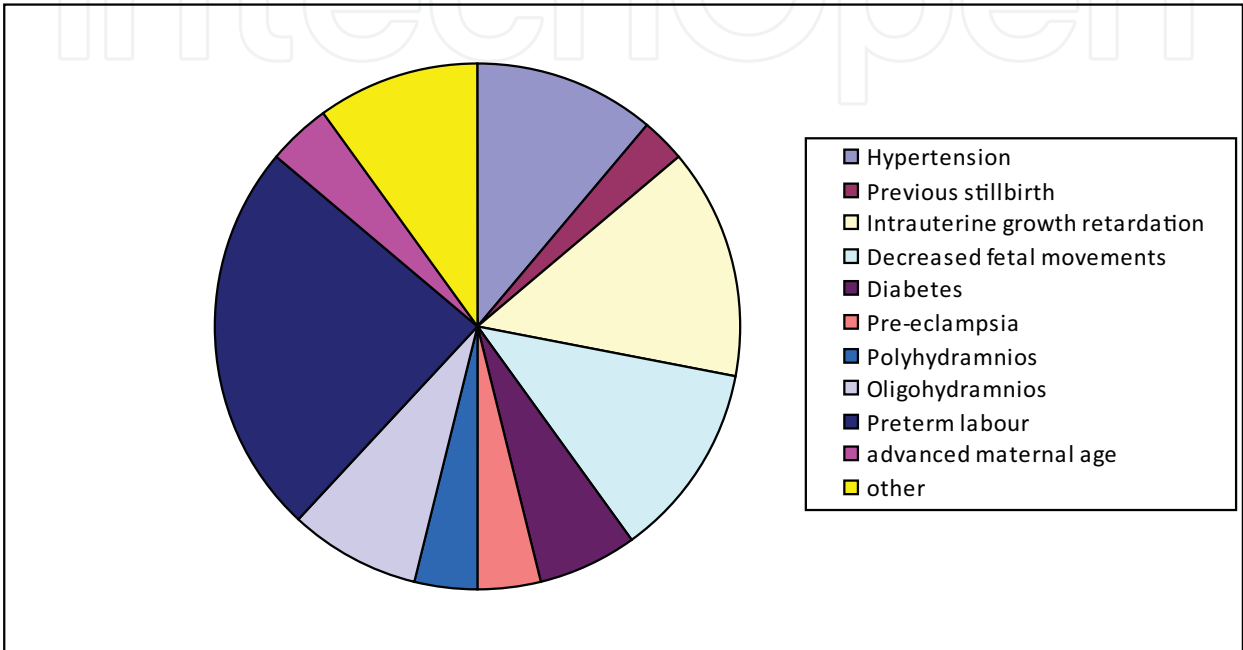


Fig. 19. Reasons for cardiotocographic monitoring with the new TOCOMAT network.

The new organization of the TOCOMAT system, with the introduction of the Bluetooth and the GPRS technology, adds an important added value to cardiotocographic monitoring at distance. As a matter of fact, it becomes independent from any space limit and allows to record the traces and perform the computerized analysis everywhere, including the patients' home. During the year 2009, we recorded 1231 traces from 640 patients using the old TOCOMAT system. During the first year of activity with the new system, we expect to monitor at least 250 patients using six remote units. Moreover, we expect to use the remote units mainly for remote home monitoring of patients at high risk. This system could improve the quality of life of pregnant women at high risk and allow the development of a wide network able to extend computerized telecardiotocography to geographic area lacking of this kind of service.

9. Tele-Ultrasound

Tele-Ultrasound is an application of Telemedicine to ultrasound scan. Several systems of Tele-Ultrasound has been developed and described all over the world. Current ultrasound technologies provide high resolution images and are relatively reliable. Therefore, they are becoming important in daily medicine from routine examinations to emergency situations. However, the main drawback is that ultrasound scanning requires a

high skilled operator for both probe positioning on the patient's skin and for image interpretation. Furthermore, an examination requires good hand to eye coordination in order to integrate over time and space the information made up on the patient and the acquired 2D ultrasound image. Tele-Ultrasonography applications can rely on three types of scenarios (Vieyres et al., 2003). In the first scenario, ultrasound image data are captured, stored and forwarded for further expert advice. In this case, the examination is performed by a clinical expert standing next to the patient; ultrasound data are acquired and sent to data base station and processed to reconstruct a 3D representation of anatomical regions of interest. In the second scenario, ultrasound data are transmitted in almost real time between the capture site and the expert site via a videoconference link. This mode requires a high bandwidth, at list three ISDN lines, through which the distant operator performed the ultrasound scan under visual control of the expert. These two scenarios can be classified as telemedical protocols during which only local physician can interact physically on the real ultrasound probe positioning and, therefore, on the quality of the acquired ultrasound images. In the third scenario, the examination is remotely controlled partly or fully by the expert. The main advantage of this scenario is that it does not need the presence of skilled expert on the patient site. One of the first Tele-Ultrasonography project, called TERESA, was born from space research, to propose a solution to bring astronauts and remotely located patients on ground quality ultrasound examinations despite the lack of a specialist. The project has been based on the concept of a tele-operated probe holder system integrated in a tele-ultrasonography chain. The chain was composed of an expert station, a patient station and a communication link. The expert station is where the specialist controls the remote probe holder system using a fictive probe and analyses in real time the image sent from the patient site. The patient station is from where a tele-operate robot is set on the chosen anatomical patient area; a general application ultrasound probe is held by the robotic system and connected to a standard ultrasound device. The communication link allows to transfer data and ultrasound images from one site to another using ISDN lines. The results of the TERESA project have been extended to a project on mobile Tele-Ultrasonography called OTELO, whose improvements focused on: the robotic design to better satisfy the user need; the communication link to bring medical ultrasound examination to anyone anywhere, using ISDN communication links but also fixed and mobile satellite link, or 3G mobile; the image quality, by developing specific compression techniques; the graphic, using interface and the input device at the expert centre to bring the best control system of the remote device and also to offer the best rendering on the distant environment including the interaction between the robot and the patient (Courreges et al., 2005). In the field of Prenatal Medicine, obstetric ultrasound is now an indispensable tool for the assessment of fetal anomalies and wellbeing (Chan, 2007). When a fetal anomaly is suspected, accurate diagnosis is essential before management options can be discussed with the parents. The families require accurate, unequivocal information and need high standard of compassionate, professional care during these times of crisis. Referral to tertiary unit with a multidisciplinary team of specialists, such as maternal fetal medicine subspecialists, neonatologists, pediatric cardiologists, neonatal surgeons, geneticists and genetic counselors, is usually indicated. Tertiary fetal diagnostic centers are scarce, and most are situated in capital cities. Telemedicine provides a means of bridging the healthcare gap between the country and the city, as well as improving access to medical education and enhancing the quality of care. In view of the sensitivities in dealing with possible anomalies

in the fetus, and the significance of obtaining all information about a fetus during the ultrasound examination, it is highly recommended that real-time video transmission be used for tele-ultrasonography consultations. The clinician can direct the sonographers at the remote site to obtain all the information needed via a video-conferencing link. The specialist can interpret the findings and then assist in the counseling women and families on subsequent management. One barrier for Telemedicine is that the operational costs are often substantial if high bandwidths are required. The transmission of medical images involves high volumes of data. In general, the transmission of still images does not pose major problems as a slight delay in transmission is usually acceptable. The transmission of real-time moving ultrasound images, however, represents a technical challenge. The high cost of the transmission, in these cases, may inhibit the introduction of such services to remote areas, which are, actually, those most in need. Under the above considerations, the use of portable ultrasound machines for remote consultation has been investigated. This can enable ultrasound consultation to be carried out at really remote sites, where dial-up access to the Internet may suffice. Another ultrasound technique, three-dimensional imaging, is especially suited as a Telemedicine application, as the whole volume of ultrasound data can be acquired in a single sweep and transmitted online for subsequent interpretation. The remote expert can then cut and review any plane of data as required. The availability of technologies able to allow the distance transmission of such data could really improve the potentiality of Telemedicine. M-Health is an emerging concept. It is defined as “mobile computing, medical sensor, and communications technologies for healthcare” and represents the evolution of e-health systems from traditional desktop “Telemedicine” platforms to wireless and mobile configurations. Current and emerging developments in wireless communications integrated with developments in pervasive and wearable technologies will have a radical impact on future healthcare delivery systems. One of the new areas of advanced mobile healthcare applications that has not been explored and investigated in detail is the wireless tele-ultrasonography system.

All these considerations formed the basis for a further upgrading of the TOCOMAT system, aimed to carry out remote tele-ultrasonography consultations.

10. Tele-Ultrasonography in the TOCOMAT system

Historically, images and clinical data management has been thought as a tool for radiologists and it is based on a system consisting of a PACS. PACS means Picture Archiving and Communication System and consists of a hardware and software for archiving, transmitting and showing diagnostic digital images. A PACS system usually consists of archive part, used to manage data and images, and a visualization part, which presents diagnostic image on monitors at very high resolution, where it's possible, to make diagnoses. Recently, with the evolution of networking technology, more and more PACS systems are moving to web-based architecture, giving a simple access to images via the use of Internet browsers, without installation of any application. Obviously, the network technology draws the line at the quantity of data that can be transmitted between different sites due to the limit in bandwidth. The fetal Tele-Ultrasonography system developed at the University Federico II of Naples, as a part of the TOCOMAT networks, is based on the GE ViewPoint system. It is configured as a Mini-PACS system, able to manage ultrasound images, needed in obstetrical and gynecological patient management for maternity

department. Technical limits that can be faced on using a complete PACS system are not present here, because the mean size of data files, containing ultrasound images, is very low and absolutely smaller than radiological images for which PACS systems are created. Plus, GE ViewPoint gives to the physician a complete reporting solution in order to create a full specific case history of the patients, independently by the site where the patients have been examined (main hospital, remote hospital, patient’s home, patient’s bed, etc.). The Tele-Ultrasonography application of the TOCOMAT system consists of two workstations able to share ultrasound clinical data and images via Internet to the hospital network using a secure connection via VPN. We can configure two different modalities to connect the scanners to the hospital:

- The interface between ultrasound devices and the archiving system can be performed in a transparent way to the operator, which should only activate the Internet connection and the VPN access to the hospital network using a remote connectivity device; this device will be able to send images directly to the remote server (Solution 1)
- Using a connectivity device which can directly connect to internet and access to the VPN i.e. a PC (Solution 2)

In the solution 2, the connection between PC (a laptop) and the ultrasound scanner can be physical or wireless; the PC will have to be connected to the hospital network via VPN and must share this connection with the scanner. This configuration will give the operator a reviewing workstation (installed or visible via the laptop which is sending the images) which will let him check the correct archiving and it gives the possibility to make reports and comments.

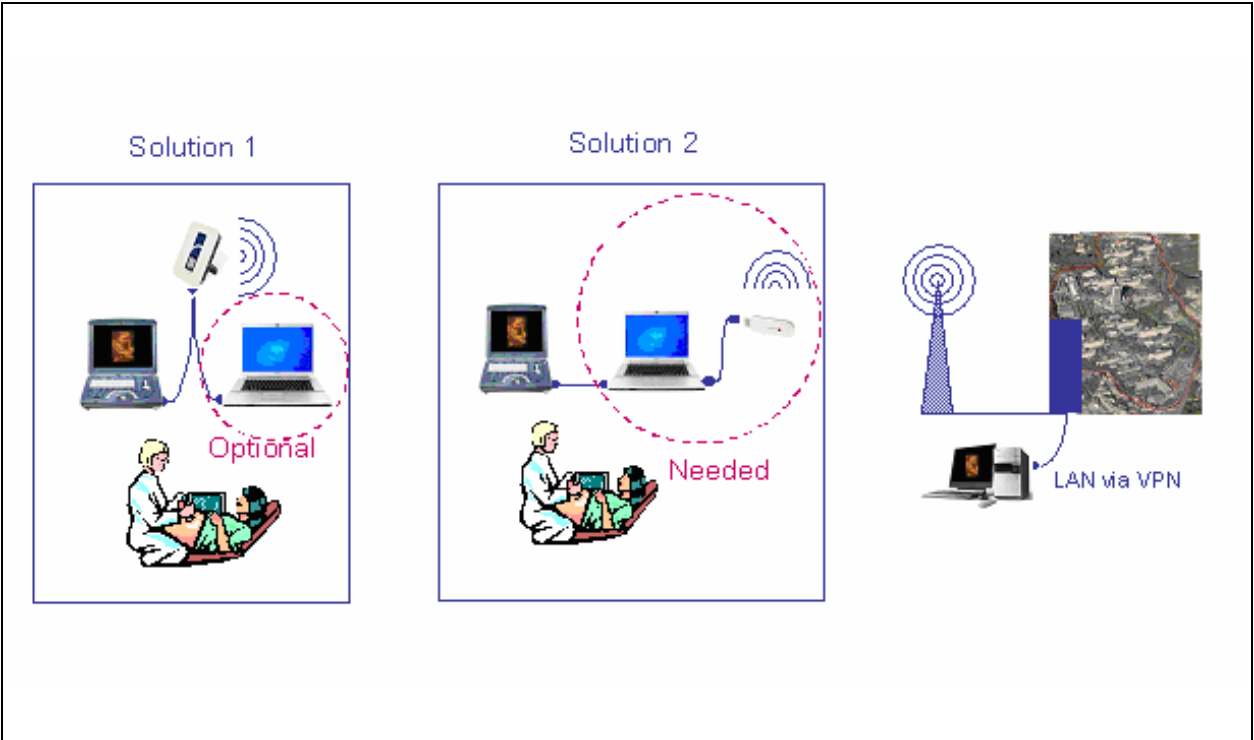


Fig. 20. Two different solutions to connect the ultrasound scanners to the hospital.
Now in the TOCOMAT project we adopted the solution 2, but soon the solution 1 will be supported in terms of feasibility and reliability. Here the workflow is shown:

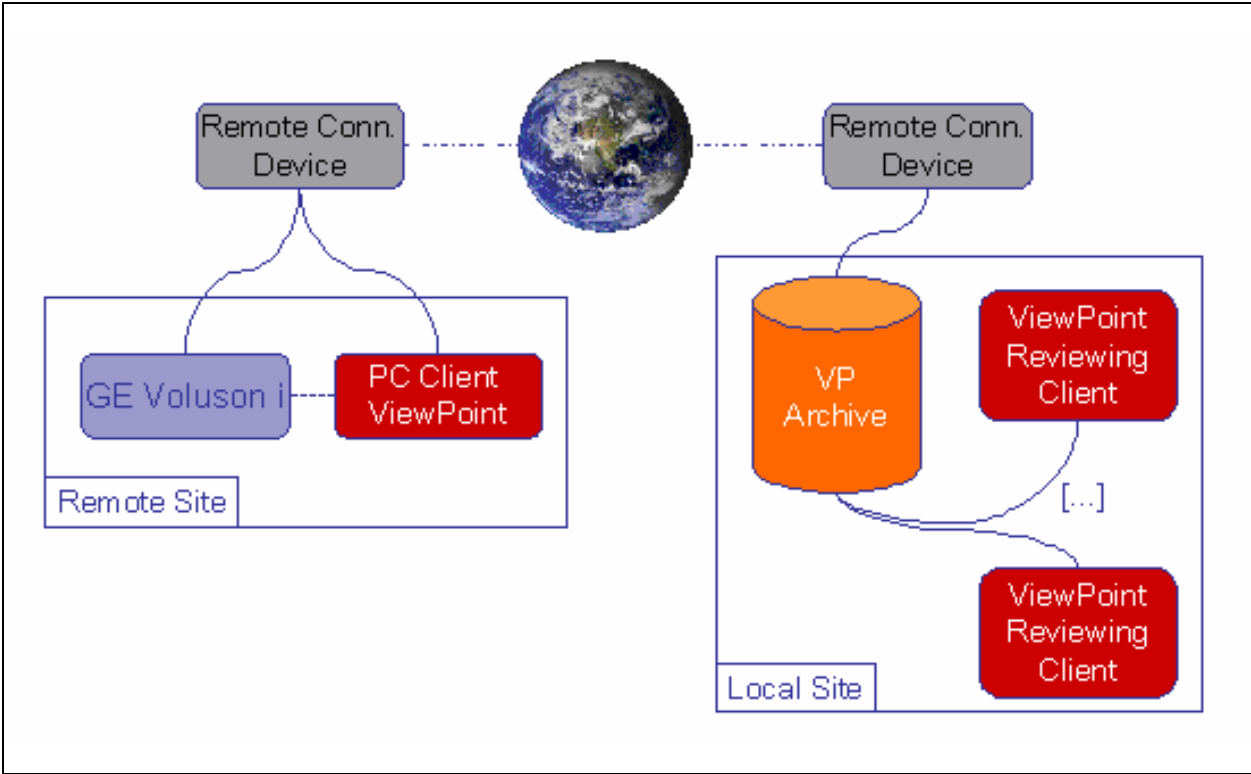


Fig. 21. The workflow of the new TOCOMAT network for Tele-Ultrasound.

Wireless networking is clearly presented as the milestone of this project. It has been implemented via GPRS / UMTS / Satellite and connects the two main blocks: local site (Main Hospital) and remote site (Remote Hospital, Patient’s home, etc.). More than one remote site could be implemented, as far as more than one local site. This gives the operators the possibility to have simultaneous access to the same data, in order to give second opinions and suggestions to operators on site. The ultrasound scanner included into the network is a portable last-generation scanner (GE Voluson-i) able to transmit the scans to the Operation Centre through a T-Mobile MDA GPRS Smart Phone using a Bluetooth wireless port. The availability of a portable scanner allows to perform the examination independently from the location of the remote unit.



Fig. 22. Organization of the new TOCOMAT network for Tele-Ultrasound.

10.1 Preliminary results with the TOCOMAT system for Tele-Ultrasonography

During the first six month of activity with the updated version of the TOCOMAT system (January-June 2010), we recruited 135 patients referred to five of the nine remote units included into the network in Campania. The examinations have been performed by an operator located at the remote unit and then the images have been transmitted to the Operation Centre and evaluated by two expert specialists. The major indications for referral were: detailed assessment for high-risk patients (25%); isolated fetal anomalies (24%); evaluation of markers for anomalies (20%); assessment of growth restriction or fetal wellbeing in the third trimester (21%); complex fetal problems such as twin complications or multiple fetal anomalies (10%).



Fig. 23. A 3D fetal scan obtained and transmitted with the TOCOMAT network.

After the scanning at the remote unit, 22% of the patients were referred to the Operation Centre of the TOCOMAT system, in order to be submitted to deeper examinations needed to confirm the diagnosis. This means that 78% of the patients avoided to move from their living place to perform ultrasound examination. Overall, the consultation resulted in some modifications of the clinical diagnosis in 41% of the cases. 72% of the patients have been delivered. All major anomalies and diagnoses have been confirmed. These preliminary results show that fetal Tele-ultrasonography is technically feasible and welcomed by the clinicians and patients involved. It contributes to diagnosis and management and seems to be an effective strategy for bridging the healthcare gap between periphery and centre.

11. Legal and ethical aspects of Telemedicine

The development and use of new technology or new applications of existing technology have legal and ethical implications that arise subsequent from the of such technology. Often, these legal and ethical implications themselves are not new but their context may be new or changed. Such may be the case in Telemedicine, in which the use of technology to provide

and support healthcare when distance separate the participants alters the context in which healthcare services are provided (Blair et al., 1998). The main legal issues raised by Telemedicine are licensing, medical malpractice and standard of care. Licensing is one of the most confounding issues, because it depends on the laws of each region and state, particularly when a cross-state Telemedicine network is organized. A national Telemedicine licensing scheme would be desirable. Medical malpractice refers to professional misconduct that includes an unreasonable lack of skill or failure to execute professional or fiduciary duties that are owed to a patient. Such misconduct could include, for example, negligence in providing or failing to provide treatment, failure to obtain a patient's informed consent to treatment, or improper disclosure of confidential or private medical information. Two of the most vexing questions concerning malpractice in Telemedicine are exposure to malpractice liability, when Telemedicine practice transcend jurisdictional lines, and whether a Telemedicine encounter suffices to establish the requisite "professional-patient" relationship on which any finding of liability must rest (Herscha, 1996). To compel a health professional to answer in court for alleged malpractice, a court must have personal jurisdiction over the health professional. Such jurisdiction may be difficult to establish based on a Telemedicine encounter in which the consulting or treating health professional was physically located in one state and the patient in another at the time of the encounter. Clearly, those physicians who have frequent Telemedicine contacts in other states should expect to be subject to those states' jurisdiction in malpractice cases. Exposure to liability also depends on whether a Telemedicine encounter is sufficient to establish a professional relationship between the professional being sued for negligence and the patient claiming damages. The existence of a professional-patient relationship establishes the professional's duty to exercise reasonable care in treating his patient. Lack of a professional-patient relationship precludes such a duty and also liability for negligence. Such a relationship may be established by the referral of a patient to a consulting physician, a formal consultation between two or more physicians regarding a patient, or a contractual relationship between a physician and a hospital under which the physician is on-call to provide consultative or supervisory services to other physicians regarding their patients. Standard of care are essentially criteria against which a clinician's conduct pertaining to patient care is measured. Standards of care are used in medical malpractice negligence lawsuits to gauge whether a clinician charged with negligence conformed his or her conduct to the legal fiction of how a reasonable and prudent physician would act under the same or similar sets of circumstances. There is no clarity with respect of the standards of care in Telemedicine practice. This is not surprising because the widespread use of communications technology to provide or support healthcare over distances is relatively new, and there has been little opportunity for the development of standards of care. As regards the ethical issues arisen by Telemedicine, they are centered around maintaining traditional aspects of medical practice (Blair et al., 1998). The main issues are: health professional-patient relationship; confidentiality and privacy; consent to treatment. If physical separation and distance between patients and caregivers retards the development of the patients' trust in the caregiver, the traditional relationship may suffer noticeably. It is therefore important to examine ways in which patient trust can be preserved in a Telemedicine encounter. Change in the professional-patient relationship because of Telemedicine practice depends, in part, on how encounters are designed. For instance, consider a case in which a primary physician and patient in one location consult with another distant physician. Although two physician-patient relationships then exists between

the patient and the presenting physician and between the patient and the consulting physician, the primary relationship typically resides between the presenting physician and the patient. As the patient's primary physician, the presenting physician may have long-term relationship with the patient, and therefore the patient would justifiably expect greater obligation within that relationship. Medical and health professionals can enhance the relationship with patients of remote sites by focusing on empathic medical practice, improving their listening skills, interpreting and using body language effectively, becoming attuned to other nonverbal communication and creating an office environment that visually enhances communication and intimacy between the patient and consultant. Respect for patient privacy and confidentiality is essential to the long-term health of the professional-patient relationship. These are also important issues in the Telemedicine setting, because they can potentially be breached in any of several ways: during the Telemedicine encounter; during transmission of information; when patient records and information regarding the encounter are stored either electronically or on paper. Ideally, the presenter should indicate to the consultant the presence of all persons who are on- or off-camera and vice-versa, and the presence of such external parties would be kept to a minimum. Certain technical safeguards, such as encryption, can be used to help ensure that data obtained without authorization are neither translatable nor linked to identifiable patients. Using passwords and key cards to access patient records may also reduce threats to confidentiality. Informed consent is one of the cornerstones of responsible medical practice and applies equally to Telemedicine practice. Patients always should be informed of and understand the risks and benefits of all treatments and agree to those treatments before those treatments are applied. Insofar as Telemedicine is one of an array of options involved in the medical encounter, informed consent to use Telemedicine during the medical encounter may be necessary. To establish a high level of informed consent for Telemedicine, the document should include certain information relevant to the patient's decision to use this type of encounter, including how Telemedicine works; who will be present during the examination; known or potential risks to privacy and confidentiality of patient information; and the consequences of refusal, including delays in treatment due to the complications of scheduling a hospital visit.

12. Telemedicine in rural areas and in the developing world: future perspectives of the TOCOMAT system

Telemedicine aims at equal access to medical expertise irrespective of the geographical location of the person in need. So, patients can get access to medical expertise that may not be available at the patients' site. In this way, Telemedicine changes conventional medical practice and enables patients to access medical service via telecommunication. Telemedicine thus establishes a new kind of relationship between smaller hospitals and larger ones, and between patients and hospitals generally. Patients and subordinate hospitals may benefit from the resources of large hospitals, via teleconsultation, telediagnosis and telemonitoring. This is particularly beneficial for patients living in rural areas, where the healthcare system is less well developed than in cities. The growing number of Telemedicine networks covering rural areas all over the world confirms the great potential of Telemedicine to help unbalanced and underdeveloped health (Wootton, 2008). An example of rural Telemedicine is the Chinese one (Wang & Gu, 2009). China is the largest developing country in the world in terms of both population and area, and 70% of its people live in rural areas. There are serious disparities in medical resources between rural areas and cities. Only 20% of China's

medical resources are available to the 900 million rural population. Telemedicine has a great potential to help unbalanced and underdeveloped health. Telemedicine in China began in the mid-1980s and the early Chinese Telemedicine activities were mostly based on store-and-forward technologies such as telegraph and email. Real time Telemedicine was not used initially as the telecommunication infrastructure required was not available. In recent years, Telemedicine in China has developed quickly with the rapid growth of telecommunication networks. Now, China has three major Telemedicine networks that allow people living in rural areas to enjoy low-cost Telemedicine services and have a better quality of life. Another example of rural Telemedicine is the purpose of a rural Telemedicine network in South Africa using store and forward Voice-over-IP (VoIP) (Scholl et al., 2009). The advantage of such a system is that it is accessible from devices similar to traditional telephones, and thus can be used by those that lack computer skills. VoIP services can also be developed relatively cheaply using open source software, and can be deployed without fixed infrastructure or support from providers. In this way, some barriers to introducing information telecommunication technology solutions in rural areas, such as cost, poor infrastructures and lack of computer skills among the staff, could be overcome. Also the developing world can benefit from the applications of Telemedicine for educational and clinical purposes (Wootton, 2008). The developing world contains some 5400 million people in 127 countries. Suppose that one in every 10 people sees a healthcare professional each year, and that in one in 100 of these interactions, the healthcare professional concerned would like to seek a second opinion. Then there would be some 5 million referrals to be dealt with each year. Since the present Telemedicine networks collectively are servicing about 5000 referrals per year, at most, this suggests that only 0.1% of the potential demand is being met. Low-cost Telemedicine in the developing world is feasible, clinically useful, sustainable and scalable. However, Telemedicine is not yet being used on a significant scale. The right strategy to obtain a widespread diffusion of Telemedicine in the developing world appears to be to build intra-country Telemedicine networks as soon as practicable. By developing a Telemedicine network under the control of the appropriate Ministry of Health, there can be no question about perceived loss of control. That is, we need Telemedicine networks that rely largely on within-country resources. Such Telemedicine networks might need to begin with support from outside the country, but they should become independent of outside resources as quickly as possible. These are the grounds of the programmed extension of the TOCOMAT network to the rural areas of Kenya and Senegal, called TELEAFRICARE. In Kenya, basic primary care is provided at primary healthcare centres and dispensaries. They are run and managed by nurses and provide outpatient services for simple ailments. Primary care facilities are often under-staffed, under-equipped and have limited medicines. Those patients who cannot be managed by the nurse are referred to the health centres. Sub-district, district and provincial hospitals provide secondary care. Sub-district hospitals are similar to health centres with the addition of a surgery unit for caesarean sections and other procedures. District hospitals usually provide comprehensive medical and surgical services. Provincial hospitals provide specialised care including intensive care, life support and specialist consultations. Third level care is provided at the General Hospitals Moi and Kenyatta, both located in Nairobi. In Kenya, there is on average one doctor per 500 people in Nairobi, but only one per 160,000 in rural Turkana district. Nairobi has three times the national average of hospital beds, but people in the rural areas, that represent the majority of the population, are not so well provided for. Health facilities

are often located in urban areas, far away from rural populations most in need, or are not accessible to large numbers of the population via public transportation. In Senegal, the organizational structure of the national healthcare system is divided in three levels: Regional Hospitals, District Health Centres, Health Posts. The District Health Centres offer some few operational facilities and have about 1 to 2 medical doctors and 15 to 20 people staff. The Health Posts have about 4 to 5 health workers, but there is no medical doctor working. Under each health post, there are numerous health points with 1 or 2 health agents and a midwife. In addition, the country has two university hospitals. Also in Senegal people living in rural areas doesn't have easy access to care facilities owing to the extreme distances and environmental conditions. For 80.5% of the households, the health post is the only accessible health facility in a average distance of 4.3 km and an average travel time of 30 minutes. The next health centre is an average distance of 23.5 km, the next hospital is more than 30 km far. After analysing all this information, we concluded for a project aimed to the improvement of the woman care as a whole, that is Prenatal Care, delivery and labour management, by using tools allowing interventions at the various levels of healthcare in Kenya and Senegal and promoting the awareness of local communities to play their key role to obtain a real change in their health conditions. First of all, basing on the evidence that the high rate of maternal and perinatal mortality, recorded in these countries, above all regards the rural areas, is especially related to a difficult access to health facilities, we imagined to improve the care using Telemedicine. The intervention of the TOCOMAT-TELEAFRICARE system on the African reality materializes not only with an implementation of the health resources immediately reachable by the rural population, but also with an improvement of the level of healthcare offered by the central hospitals connected with the telematic network.

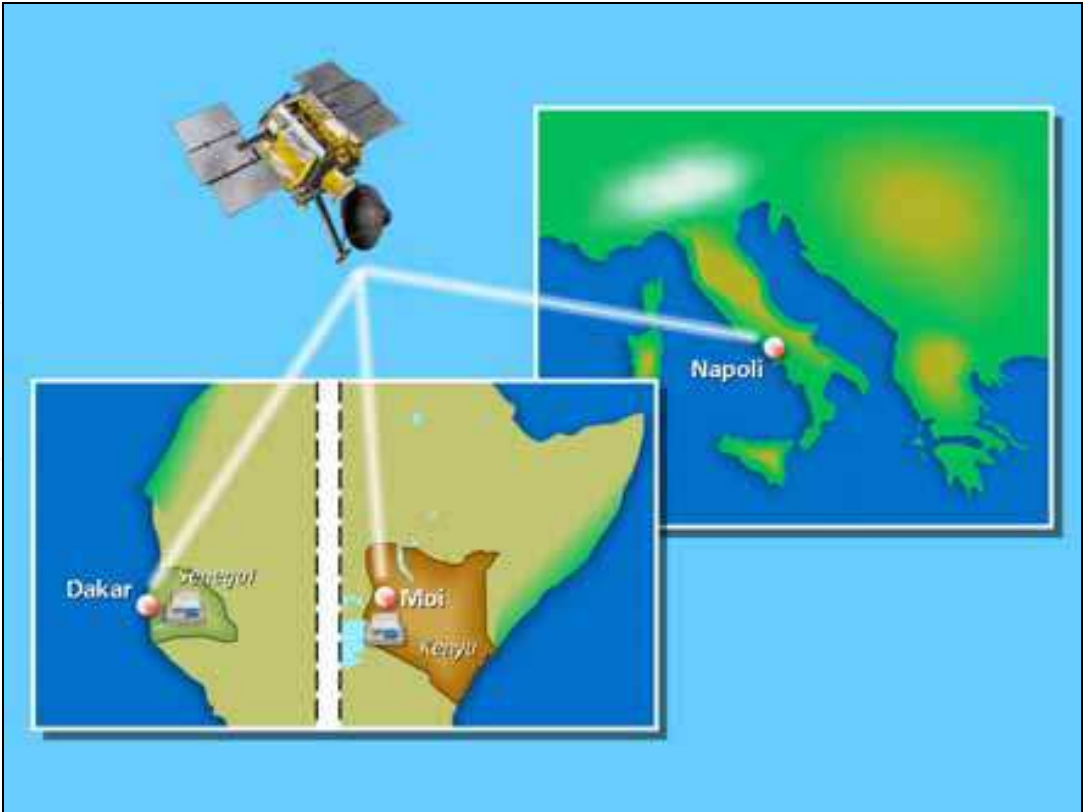


Fig. 24. The TOCOMAT network in Africa.

In this way, the project adapts to the needs and the context of the local communities and proposes an easy and feasible solution for some of the above explained critical situations. The TOCOMAT-TELEAFRICARE system could allow the wide diffusion of cardiotocography in the rural areas of Kenya and Senegal, that lack in this kind of service, and, moreover, could extend to these areas the innovation of computerized cardiotocography, for a more appropriate assessment of the real conditions of high risk fetuses. Another tool offered by the TOCOMAT-TELEAFRICARE system to reach the aim of introducing specific diagnostic innovations is represented by Tele-Ultrasound. Women coming from the rural areas could have access to ultrasound without moving to higher level hospitals. In this way, a wide number of patients could be submitted to this exam, with the chance to have a better management.

The TOCOMAT network is addressed not only to rural areas and peripheral health facilities, but also to the central hospitals. These will become the key points for the delivery of the Telemedicine service, because they will be the sites of the Operation Centres of the network. They will provide the organization and management of the activities connected with Telemedicine and will be the responsible for their operative application. Also in this case, Telemedicine could aid operators through teleconsulting and a continuous interaction with the European partners. African caregivers should reach self-sufficiency also through a basic and advanced training activity promoted by the European partners, not only to transfer the technological know-how, but also to share with the African partners the clinical protocols needed to improve the quality of healthcare provided in their own structures. The aim is to contribute to the diffusion of right procedures for the management of both physiological and pathological conditions before and during pregnancy, during delivery and labour and in the early neonatal care. During the last century, major advances in medical technology have led to a substantial improvement in healthcare. This has come at a cost; the healthcare technology has become complex and expensive which, in turn, has led to a very wide disparity in health resources between those who have the financial resources to benefit from the advanced medical technology and those that do not. The ultimate outcome of this situation is that the majority of the world population does not have access to advanced medical technology and advanced healthcare. The extension of the TOCOMAT-TELEAFRICARE network to some African countries is aimed at find a solution to this disparity in the field of prenatal medicine. But the recent availability of wireless technology and cloud computing could obtain a further improvement of this situation in the future (Meir & Rubinsky, 2009). The key concept is that the computational part (hardware and software) is at a central facility, now called "cloud computing" which does the data processing and provides the most advanced computational service, at any time, to an unlimited number of users, connected through telecommunication to the central processing facility. The devices at the user site have limited or no data processing facility and are used primarily to transfer the raw data to the central processing facility and to display the processed data. The remote devices become a dumb terminal for a central computational facility. This removes the cost and limitations of the computation, manipulation and interpretation of data from the vicinity of the patient and uses instead a central and effectively unlimited computational facility. In the vicinity of the patient only the component that directly interact with the patient and which acquire or use the raw data are needed. This is different from conventional Telemedicine in which the data processing is

still done in the vicinity of the patient and the processed images, for example, are sent on. In the concept of cloud computing, the majority of the processing is done at the central facility that can be at a completely different geographical location than the patient. The central facility serves a large number of remote users and the telecommunication is used to transfer the raw or minimally processed data to this central processing. If applied to the TOCOMAT network, this technology could obtain a decrease in the costs and allow a more simple recording, transmission and analysis of data, thus further promoting the diffusion of Telemedicine in the developing world.

13. Conclusions

In conclusion, the TOCOMAT system, with its recent updating, could contribute to improve the quality of the healthcare given to pregnant women at high risk living far from adequately equipped health centres. It allows to perform intensive computerized cardiotocographic monitoring of fetuses at risk even at patient's home. Moreover, it allows performing distance ultrasonography, in order to avoid the referral of a too high number of patients to centres of third level. The extension of the system to Kenya and Senegal could contribute to the diffusion of a right way to manage the pregnancies at risk, without bearing high costs. The technological innovation could further simplify the organization of the TOCOMAT system. For example, the use of an ultrasound scan connected with a central computer through a cloud computing system could reduce the cost of imaging by orders of magnitude and remove the requirement of having a highly trained imaging expert at the patient site (Meir & Rubinsky, 2009).

14. References

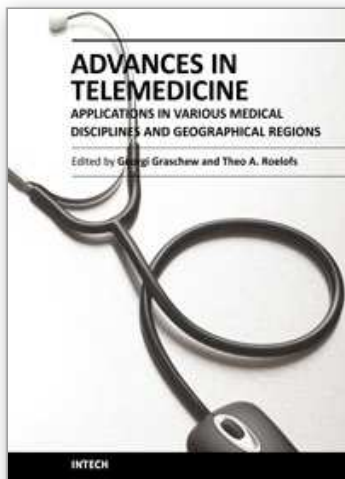
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Innovative developments in information and communication technologies (ICT) irrevocably change our lives and enable new possibilities for society. Telemedicine, which can be defined as novel ICT-enabled medical services that help to overcome classical barriers in space and time, definitely profits from this trend. Through Telemedicine patients can access medical expertise that may not be available at the patient's site. Telemedicine services can range from simply sending a fax message to a colleague to the use of broadband networks with multimodal video- and data streaming for second opinioning as well as medical telepresence. Telemedicine is more and more evolving into a multidisciplinary approach. This book project "Advances in Telemedicine" has been conceived to reflect this broad view and therefore has been split into two volumes, each covering specific themes: Volume 1: Technologies, Enabling Factors and Scenarios; Volume 2: Applications in Various Medical Disciplines and Geographical Regions. The current Volume 2 is structured into the following thematic sections: Cardiovascular Applications; Applications for Diabetes, Pregnancy and Prenatal Medicine; Further Selected Medical Applications; Regional Applications.

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