COCIR TELEMEDECINE TOOLKIT

FOR A BETTER DEPLOYMENT AND USE OF TELEHEALTH

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COCIR

SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

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TELEMEDICINE:
WHY IT MATTERS TO COCIR MEMBERS?

The **COCIR Telemedicine Focus Group** was set up in 2009 as COCIR members felt that there was a vacuum and a lack of centralised tools to clearly demonstrate the benefits of telemedicine. As COCIR and its members are convinced that telemedicine will secure better access, empower patients, reduce health inequalities and optimise efficiency of the total healthcare system, we have taken the initiative to share that view through a number of user-friendly tools.

After some intense work with COCIR members, we are proud to share this **COCIR Telemedicine Tool Kit** which is composed of three key elements described hereafter.

- **Firstly**, the COCIR's vision on telemedicine is articulated around five concrete recommendations on how industry together with other key stakeholders can contribute to disease prevention, leveraging information technology as outlined in the COCIR White Paper 'Towards a sustainable healthcare model'.

- **Secondly**, and based on the need to develop common terminology, COCIR has prepared a unified **glossary of terms** for telemedicine.

- **Third**, in order to respond to the need expressed by COCIR members at both global and local levels, COCIR compiled a **list of referenced studies** providing a source of evidence on the cost-effectiveness of telemedicine solutions. COCIR strongly believes this database of referenced studies will become an essential reference tool for other key stakeholders such as payers and healthcare professionals.

By providing this COCIR Telemedicine Toolkit, COCIR wants to shed light on the opportunities this technology brings for empowering patients, particularly in the management of chronic disease and better cooperation with key stakeholders towards a sustainable healthcare model.

Nicole Denjoy,
COCIR Secretary General

COCIR POSITION PAPER

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COCIR welcomes the European's Commission's Communication COM(2008)689 on telemedicine for the benefit of patients, healthcare and society.

This Position Paper provides additional recommendations relating to two of our priority objectives 'Focus on disease prevention' and 'Leverage information technology' outlined in the overarching strategic COCIR White Paper 'Towards a sustainable healthcare model' published in November 2008[1].

Changes, including an increase in the numbers of citizens with chronic diseases requiring long-term care, are changing Europe's healthcare needs. The demand for more and better health services will require spending on healthcare to grow faster than projected GDP growth. Clearly this situation will not be sustainable.

Integrated and preventive healthcare is better and consistently cheaper than emergency medical treatment. Physicians and nurses require supporting technology solutions, while citizens and patients need to become empowered to take an active and responsible role in managing their health. Additionally, it is envisaged that Europe will face a shortage of healthcare professionals and carers in the next 10-20 years.

COCIR believes current efforts to deploy healthcare IT driven solutions within EU health systems to address the projected financial and staffing shortfalls must be accelerated. Telehealth (a component of telemedicine) can help provide solutions.

COCIR'S 5 RECOMMENDATIONS FOR BETTER DEPLOYMENT OF TELEHEALTH ARE:

1. European Commission and Member States to establish an appropriate legal framework with effective transposition at country level
2. Strengthen cooperation between healthcare stakeholders to "best practice health strategies" supporting telehealth adoption in routine clinical practice
3. Finance more and sustainable large scale projects with health economic evaluation to assess the impact of telehealth solutions
4. Integrate telehealth into existing care delivery structures and ensure interoperability of telehealth solutions
5. Establish sustainable economic model for telehealth by starting dialogue between healthcare stakeholders

1. See COCIR's White Paper on sustainable healthcare 'Towards a sustainable healthcare model'

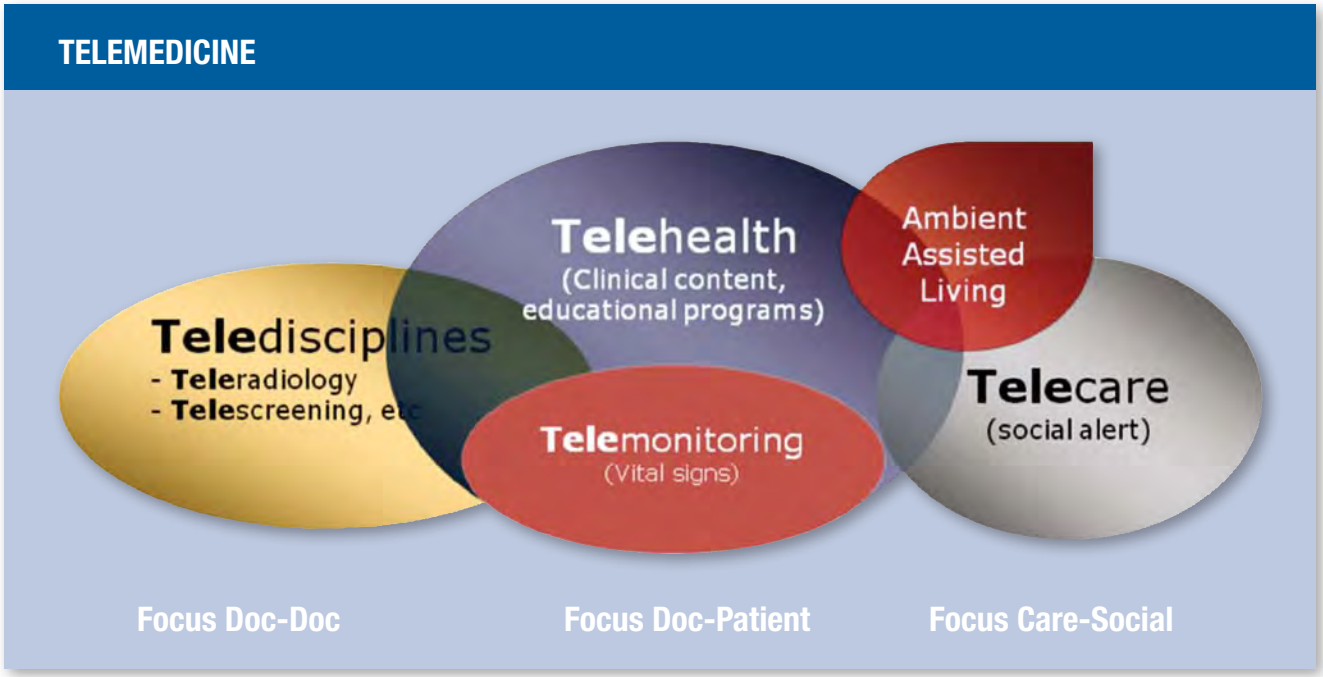
DETAILED BRIEFING

COCIR'S DEFINITION OF TELEMEDICINE[2]

Telemedicine can be defined as the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a healthcare professional and a patient (e.g. telemonitoring of the chronically ill such as those with diabetes and heart conditions, telepsychiatry etc).

Telemedicine includes all areas where medical or social data is being sent/exchanged between at least two remote locations, including both Caregiver-Patient/Citizen as well as Doc-to-Doc communication.

It includes:
- **Telehealth and Remote Patient Management**
- **Telecare**
- **Teledisciplines (including teleradiology, teledermatology, telescreening, etc)**



WHAT IS TELEHEALTH?

The term telehealth covers systems and services linking patients with care providers to assist in diagnosing, monitoring, management and empowerment of patients with long-term conditions (chronic patients).

Telehealth solutions use devices (interactive audio, visual and data communication) to remotely collect and send data to a monitoring station for interpretation and to support therapy management programs and to improve patients' knowledge and behaviour.

2. See COCIR's Glossary of terms

Telehealth solutions comprise systems and components (patient interfaces in hardware and software; sensors/peripherals; operating software and applications intended for care provider usage; clinical content and intelligence; data transmission, storage and intelligent routing) as well as supporting services (system operation; logistics; financial services etc). Input data sources are typically patients' self-assessments ("subjective data") as well as dedicated peripherals to measure vital parameters ("objective data"). Telehealth solutions address healthcare delivery, diagnosis, consultation and treatment as well as education/ behavioural modifications and transfer of medical data.

BENEFITS OF TELEHEALTH

Telehealth with an interactive health support platform will fill a crucial gap in the continuum of care. Flexible telehealth solutions are designed to support a multi-dimensional model of care for individuals with chronic conditions, particularly those with multiple, complex needs who are often either elderly and frail and/or disabled.

For this purpose telehealth provides a clinical management model with clinical-intelligence capabilities based on underlying algorithms: a telehealth program based on a timely and evidence-based knowledge for physicians and supporting care providers to make appropriate interventions.

The benefits of telehealth listed below are of immediate, tangible and significant benefit to clinical staff, patients and society.

- **Reduced Mortality:** Telehealth patients live longer, compared to people receiving usual care (15-55% compared to people receiving usual care)
- **Reduced Hospitalisations:** The use of telehealth results in a more stable population in which enrolled members in programmes utilise less acute healthcare resources: reduced hospitalisations (30-50%), and reduced hospital length of stay (24-48%)
- **Increased quality of life of patients:** Patients in telehealth programmes have a better quality of life. This is due to improved and stabilised health as well as peace of mind, better connection to their care team and involvement in the healthcare process.
- **Early detection of exacerbations, impairment of health:** The system regularly gathers information from various sources on vital signs, symptoms, behaviour and the patient's knowledge about their condition, as well as environmental status and psychosocial context. This information is analyzed and risk-tagged, allowing care coordinators to triage and facilitate targeted, expedited, interventions that can prevent acute-care-related emergency room visits and hospitalisations. (Up to 35% reduction of exacerbations)
- **Individualized interventions:** Because of the regular assessment of the patient's vital signs and symptoms, and disease specific knowledge and behaviour, clinicians can target interventions to the exact situation and aspect of the patient's illness, behaviour, understanding of symptoms and psychosocial/home situation. Interventions can be individualized both in terms of content and timing to maximize the impact of the intervention to immediately improve the member's health status and stabilise their condition/avoid future degradation.

- **Patient empowerment, education, behavioural reinforcement and motivation:** Information delivered via the telehealth system is targeted to specific knowledge deficits or areas of recommended behavioural modification. This information is tailored to the individual patient's need and directly delivered to the home of the patient, thus reducing the amount of time clinicians must spend on the phone or road delivering content and reinforcing necessary behavioural change. Patients understand their medical condition and treatment better and become empowered to manage their chronic conditions. Positive feedback and a personalised approach are important for the patient's motivation in relation to their treatment.
- **Efficient, exception-based interventions:** Telehealth systems enable clinical staff to be in regular contact with larger member caseloads compared to standard telephonic models for individuals with complex chronic conditions. On the patient side, each member is connected to the telehealth system, is assessed, given feedback and positive reinforcement when needed – a model that is not feasible by traditional models of telephonic clinical management (because of personnel capacities necessary and related costs), even for individuals at high acuity levels.

BARRIERS HINDERING THE DEVELOPMENT OF TELEHEALTH

While the potential benefits of telehealth are enormous, a number of barriers continue to hinder the introduction of telehealth, or prevent them from achieving optimal benefits.

- **Lack of reimbursement and sustainable funding:** Many programmes are stopped after a successful testing period due to a lack of reimbursement for services.
- **Lack of efficient business model:** Telemedicine providers have not yet established successful business models enabling them to maintain telehealth programmes after the initial trial phase. This is also due to the current infrastructure of care in existing healthcare systems.
- **Lack of recognised IT standards for telehealth:** Telehealth applications and infrastructure have been developed and tested throughout Europe for at least a decade in isolation. The result is an innovative field, however only with isolated applications that have challenges of interoperability. Such systems, when in place, must have the capability of exchanging data with other systems, at least countrywide. Resolving interoperability is no longer a technical issue as the technical standards are emerging e.g. IHE[3] or Continua[4]. The remaining challenge is a political, behavioural and acceptance issue which requires promotion to overcome.
- **Insufficient awareness and confidence:** Many patients as well as medical experts are not convinced yet by the benefits of telehealth. To ensure a high level of acceptance from physicians and patients, the content has to be developed with medical experts following and supporting medical guidelines. Also the intuitive use of the telehealth solution ("usability") for both patient and medical personnel is a key requirement.

3. IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information.

4. The Continua Health Alliance is an open industry coalition on personal telehealth. Continua's mission is to establish a system of interoperable personal telehealth solutions that fosters independence and empowers people and organizations to better manage health and wellness.

- **Need for integrated solutions:** Industry needs to develop end-to-end telehealth solutions in cooperation with the medical community to cover all the needs for a full home care service. However this is not always an easy task when patients do not understand the direct link between fully integrated solutions and the quality of the care/attention they receive.
- **Need to integrate telehealth services into care delivery structure:** One of the primary challenges confronting telehealth today is the lack of effective workflow integration into existing care delivery structures. In order to enable payers, providers and patients to fully benefit from telehealth, it needs to be seamlessly woven into existing delivery structures. Best Practise concepts still need to be identified.
- **Uncertain legal responsibility:** The lack of legal clarity in the area of telehealth is an obstacle to its wider use. This is a major challenge in particular with regard to liability, jurisdiction and to licensing, accreditation and registration of telehealth services and professionals. In addition, cross-border provision of telehealth services also require legal clarification with regard to privacy. These issues are primarily the responsibility of the Member States, and thus require action at their level. Member States will be supported by the Commission at Community level, e.g. by a European platform to share information on current national legislative frameworks and proposals for new national regulations relevant to telehealth.

5. See COCIR's database of reference studies on telemedicine

BUILDING EVIDENCE ON THE EFFECTIVENESS OF TELEHEALTH

THE SITUATION TODAY: A LIMITED BUT GROWING EVIDENCE BASE

Although an increasing number of studies and clinical trials demonstrate the effectiveness of telehealth solutions (see figures below), the lack of reliable scientific evidence remains a barrier to the wider deployment of telehealth. Indeed many clinicians, patients and payers, partially question the evidence available and do not trust telehealth applications to support and improve the delivery of good quality healthcare.

This lack of trust is based on the fact that the results of existing studies are only partly known and many of the results are not directly comparable, because of the size, duration or overall design of the respective studies.

COCIR has started to collect and summarise the peer reviewed evidence from telehealth projects and studies to support consistent communication on the quality of care and cost-effectiveness of telehealth solutions[5] .

SUMMARY OF RELEVANT STUDIES

There are a growing number of good large-scale scientific telehealth evaluations reaching completion and publication in peer reviewed journals. These studies will, over time, help establish telehealth within routine care. In general, most of these studies indicate that telehealth has a positive effect on reducing hospital admissions, length of stay, mortality, and improving patients' quality of life. The actual economic benefits differ, depending on the respective care delivery systems, and thus needs to be evaluated in reference to the associated care delivery structure.

Given today's sources of information for patients with **heart failure** (e.g. Meta-analysis of telemonitoring and structured telephone support)[6], the indications are that telehealth will:

- Reduce mortality (in the range of 15-55%)[7]
- Reduce hospital admissions (for cardiovascular reasons 50%)[8]
- Reduce hospital length of stay (broad range of values taken from various studies -26%-48%)

Three recent studies for telehealth systems (two with medical content) in the field of **Chronic Obstructory Pulmonary Disease (COPD)** show the following results:[9-10-11]

- 35% reduction of exacerbations
- Between 15% to 43% reduction of hospitalisation
- Detection of exacerbations
- Reduction of costs (up to 52%)
- Improvement of quality of life

Positive results of a systematic review (17 studies with different telehealth systems) for patients with **diabetes**[12]:

- Reduction of HbA1c
- Reduction of complications
- Good receptiveness by patients and patient empowerment

6. Clark et al. 2007 / 7. Clark et al. 2007 / 8. Giordano et al. 2009 / 9. Trappenburg et al. 2008 / 10. Koff et al. 2009 / 11. Vitacca et al. 2009 / 12. Jaana 1 Pare 2007

THE FOLLOWING 5 KEY RECOMMENDATIONS SUMMARISES WHAT COCIR PROPOSES TO FACILITATE THE USE OF TELEHEALTH:

1. European Commission and Member States to establish an appropriate legal framework with effective transposition at country level
2. Strengthen cooperation between healthcare stakeholders to "best practice health strategies" supporting telehealth adoption in routine clinical practice
3. Finance more and sustainable large scale projects with health economic evaluation to assess the impact of telehealth solutions
4. Integrate telehealth into existing care delivery structures and ensure interoperability of telehealth solutions
5. Establish sustainable economic model for telehealth by starting dialogue between healthcare stakeholders

1. EUROPEAN COMMISSION AND MEMBER STATES TO ESTABLISH AN APPROPRIATE LEGAL FRAMEWORK ALLOWING EFFECTIVE TRANSPOSITION AT COUNTRY LEVEL

As telemedicine is an emerging field, it is evolving faster than the legal framework regulating it. The lack of an appropriate legal framework at both the EU and national level is a barrier to the adoption of telemedicine by healthcare professionals. It is essential to bring legal clarity on some crucial aspects such as licensing/authorisation, health data protection, liability of healthcare professionals, reimbursement, conflict of jurisdiction (in case of cross-border care).

COCIR believes that:

- The European Commission should support the Member States in the development of a single legal framework for telemedicine in Europe
- Member States should work together on current and future legislative frameworks relevant to telemedicine
- Member States should adapt the existing legal framework to allow telemedicine to be used locally

2. STRENGTHEN COOPERATION BETWEEN HEALTHCARE STAKEHOLDERS TO "BEST PRACTICE HEALTH STRATEGIES" SUPPORTING TELEHEALTH ADOPTION IN ROUTINE CLINICAL PRACTICE

Successful implementation of sustainable telehealth solutions requires close cooperation between all healthcare stakeholders. Patients, medical professionals, payers and solution providers can reach higher mutual benefits when building a closed system rather than continuing to work separately. COCIR will support "best practice health strategies" introducing telehealth into routine clinical practice by sharing information, encouraging dissemination of successful projects, bringing partners together and motivating stakeholders to cooperate as close as possible.

3. FINANCE MORE AND SUSTAINABLE LARGE-SCALE PROJECTS WITH HEALTH ECONOMIC EVALUATION TO ASSESS THE IMPACT OF TELEHEALTH SOLUTIONS

The lack of sustained incentives is a recurrent problem. Existing funding schemes finance small-scale and short-term projects with no or little connection between each other. This results in a duplication of efforts, where the outcomes of the projects are not well-disseminated, not comparable and not significant enough to be considered real evidence on the effectiveness of telehealth. COCIR thus calls for more and sustained funds with a view to finance large-scale cross-border long-term initiatives, including an economic evaluation to measure the impact of telehealth.

This will avoid the current fragmentation of efforts and allow for better exploitation of results.

4. INTEGRATE TELEHEALTH INTO EXISTING CARE DELIVERY STRUCTURES AND ENSURE THE INTEROPERABILITY OF TELEHEALTH SOLUTIONS

While the emergence of new technologies and the development of telehealth solutions allow for considerable improvements in healthcare for the benefits of both patients and healthcare professionals, there is a very low level of integration of these solutions in existing clinical practice and care delivery structures. Telehealth solutions remain in the domain of pilot projects and are not integrated in clinical practice. This is partly due to the fact that healthcare stakeholders (healthcare professionals, patients, insurers etc) need to adapt their usual working method to include all stakeholders (i.e. the empowered patients, the monitoring centre).

A better recognition of the role of each stakeholder in the new healthcare cycle, and better cooperation between them, is a must to move telehealth from the pilot project scheme into everyday clinical practice scheme.

Ensure interoperability of telehealth solutions

Interoperability allows the different technological solutions to communicate with each other, allowing patients and doctors to exchange medical information across healthcare settings, and across borders, even if they use different devices (medical software, computer, phone, medical equipment) or ICT providers (broadband provider etc).

It is thus crucial that telehealth solutions are interoperable:

- For the patient's safety and mobility
- To facilitate the work of healthcare professionals
- To remove barriers (i.e. borders) for the deployment of telehealth

COCIR thus welcomes the work of IHE and the Continua Health Alliance on interoperability and calls on authorities to support interoperability-driven initiatives.

5. ESTABLISH SUSTAINABLE ECONOMIC MODEL FOR TELEHEALTH BY STARTING DIALOGUE BETWEEN HEALTHCARE STAKEHOLDERS

Telehealth solutions cannot and will not become part of the existing healthcare delivery structure if there is no clear understanding on 'who invests and who pays'. A dialogue on how to finance/reimburse telehealth has been initiated, but this dialogue is still in the starting blocks and needs to be taken to another level. This dialogue should include all stakeholders: healthcare professionals, patients, insurers, governments, national/regional health authorities. This dialogue should establish who benefits from telehealth and who should pay for it, with a view to establishing a fair and sustainable funding/reimbursement system. Over the last years, the healthcare technology industry has been investing heavily to develop adequate telehealth solutions without any return on investment. Although the healthcare technology industry is keen to innovate and propose technological solutions that can improve healthcare, it cannot continue to invest in innovation without the promise of a sustainable business model.

COCIR GLOSSARY OF TERMS

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INTRODUCTION

Telemedicine is an emerging field in healthcare with many unknowns.
The COCIR Telemedicine Focus Group considers of utmost importance to develop a centralized glossary of terms to provide clear definitions and bring coherence to the various interpretations of the terms used in the field of telemedicine. The COCIR glossary is the foundation to clearly articulate strategic directions throughout the care cycle.
The glossary includes a table outlining the level involvement of the various actors in the telehealth care cycle[1]. This glossary is a living document and will be updated on a regular basis.

PART I: TELEMEDICINE DEFINITIONS

1. TELEMEDICINE[2]

Telemedicine is the overarching definition spanning Telehealth, Telecare and Teledisciplines. Teledisciplines include - but is not limited to- Teleradiology, Telescreening etc.

Telemedicine can be defined as the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a health care professional and a patient (e.g. telemonitoring of chronically ill such as those with diabetes and heart conditions, telepsychiatry, etc).

Telemedicine includes all areas where medical or social data is being sent/exchanged between at least 2 remote locations, including both Caregiver-Patient/Citizen as well as Doc-to-Doc communication.

2. TELEHEALTH (Includes REMOTE PATIENT MANAGEMENT or "RPMT")

The term telehealth covers systems and services linking patients with care providers to assist in diagnosing, monitoring, management and empowerment of patients with long-term conditions (chronic patients).

Telehealth solutions use devices (interactive audio, visual and data communication) to remotely collect and send data to a monitoring station for interpretation and to support therapy management programs and to improve patients' knowledge and behaviour.

1. *See Annex 1 page 4.*
2. *This COCIR definition of telemedicine is in lign with the World Health Organisation and European Commission terminologies*

Telehealth solutions comprise systems and components (patient interfaces in hardware and software; sensors / peripherals; operating software & applications intended for care provider usage; clinical content & intelligence; data transmission, storage and intelligent routing) as well as supporting services (system operation; logistics; financial services; etc.).

Input data sources are typically patients' self-assessments ("subjective data") as well as dedicated peripherals to measure vital parameters ("objective data").

Telehealth solutions address health care delivery, diagnosis, consultation and treatment as well as education / behavioural modifications and transfer of medical data.

3. TELEMONITORING

Telemonitoring designs systems and services using devices to remotely collect/send vital signs to a monitoring station for interpretation.

Telemonitoring is the remote exchange of physiological data between a patient at home and medical staff at hospital to assist in diagnosis and monitoring (this could include support for people with lung function problems, diabetes etc). It includes (amongst other things) a home unit to measure and monitor temperature, blood pressure and other vital signs for clinical review at a remote location (for example, a hospital site) using phone lines or wireless technology.

4. TELECARE

Telecare designs systems and services capable of social alert and social services. Telecare is used mainly to monitor the situation of people dependent on external help (i.e. elderly or disabled people) in the home setting.

5. AMBIENT ASSISTED LIVING

Systems, services and devices providing unobstrutive support for daily life based on the context and the situation of the assisted persons.

6. TELECONSULTATION

Teleconsultation is a medical act which is carried out in the presence of the patient who dialogues with the physician and/or the physicians consulting at distance as necessary.

7. TELE-INTERVENTION

Tele-intervention is a therapeutic medical act which is performed remotely by a physician on a patient, without or with the local presence of other healthcare professional(s) (e.g. telesurgery).

8. TELE-ASSISTANCE

Tele-assistance can be a medical act when a doctor remotely assists another doctor carrying out a medical

or surgical act. The doctor can also assist another health professional who carries out an act of care or imaging, even within the framework of an emergency, to remotely assist a first-aid worker or any person providing medical assistance someone in danger while waiting for the arrival of a doctor.

9. TELE-EXPERTISE

Tele-expertise is a remote medical act between at least two healthcare professionals without the presence of the patient for decision purpose.

10. TELEDISCIPLINES

The term telediscipline covers the various medical disciplines (e.g. radiology, dermatology, etc.) performed at a distance either between a doctor and a patient, or between two healthcare professionals through the use of ICT.

ACTORS INVOLVED R: required O: optional					**ACT**			
Remote HCP	Active patient	Passive patient	HCP near patient	Expert	**Prevention**	**Monitoring**	**Diagnostic**	**Therapy**
R		R			Telehealth			
		R			Telecare			
R		R				Telemonitoring (e.g. telecardiology)		
R	R		O				Teleconsultation (e.g. telepsychiatry)	
R		R	R	O				Tele-assistance
R				R			Tele-expertise (e.g. teleradiology)	
R		R		O				Tele-intervention (e.g. telesurgery)
		R			Assisted Ambient Living			

PART II: TELEDISCIPLINES DEFINITIONS

1. TELEDISCIPLINES

The term «telediscipliines» is being introduced as an umbrella to describe various approaches to provide medical services over a distance with the help of ICT. It covers various medical disciplines performed at a distance between two healthcare professionals through the use of ICT. A «telediscipline» typically is restricted to a specific medical discipline. In contrast to a «telediscipline» the terms «telemedicine» or «telehealth» have a more general meaning.

The following is a non-final list of «telediscipliines»

2. TELESCREENING

Telescreening describes the use of first or second opinion through a remote connection in screening programmes. Either medical data are transferred to a remote specialist for primary evaluation, e.g, in the case that a specific medical qualification is required. Another scenario would involve a second opinion in order to increase the quality of the screening process. An example in the form of teleradiology would be the use of screening centres in mammography screening. The data transmitted during tele-screening can take any form from digital x-ray images to video files or ECG or laboratory data.

3. TELEPATHOLOGY

Telepathology enables remote staff pathologists, and third-party providers, to securely share images of anatomical pathology specimens to complete primary and non-primary diagnostic evaluation, and to also seek expert second opinions, and primary interpretation of urgent cases, from operating rooms.

4. TELERADIOLOGY

Teleradiology Information Systems (IS) enables secure remote evaluation of digital diagnostic studies (CT scans, MRIs and X-Rays). This technology enables both remote staff radiologists and third-party providers to complete primary and non primary diagnostic studies from any location. It encompasses hospital-to-home teleradiology for off-hours health care coverage i.e. remote working for radiologists being part of the hospital radiology department. It also covers outsourcing to other imaging centers or commercial teleradiology companies that provide outsourcing services for image interpretation (night and/or day reads).

5. TELECARDIOLOGY

Telecardiology covers the remote collection of cardiology data, mostly ECG data, and their transmission to a service centre. In the centre, the data are being evaluated by qualified staff who are giving advice to a patient or another healthcare provider. In emergencies, the service centre may also trigger rescue measures. Data transmission can either take place continuously or at clearly defined points of time. Data collection can take place either at the patient's home or mobile.

6. TELEDERMATOLOGY

Teledermatology decribes the transmission of visible light images (photos or videos) of disorders of the human skin for classification and diagnosis. It can take the form of primary as well as secondary diagnosis. Detection and classification of skin cancers is a typical example. Since dermatology is a highly specialised discipline and many patients will see a general practitioner first, the use of teledermatology offers great potential to shorten the diagnostic process and speed up the start of appropriate treatment.

7. TELE-OPHTALMOLOGY

Tele-ophtalmology describes the remote diagnosis of medical conditions of the human eye. Similar to teledermatology, patients may not have immediate access to an opthalmologist. Ophtalmology not only diagnoses typical diseases of the eye but can also generate useful information on other diseases, e.g. diabetes and cardiac conditions and related secondary symptons. Data typically take the form of photos or videos.

8. TELESURGERY

Telesurgery describes the remote controlling of surgical apparatus, e.g. a surgical robot, by an experienced surgeon or the remote advice provided by an experienced surgeon to the surgeon on duty in the operating theatre. In the latter case, a live video connection and an audio connection between the two surgeons is sufficient. In the former case, a data link between the surgical apparatus on site and the remote manipulation tool is required.

9. TELEPSYCHIATRY

Telepsychiatry is a form of teleconsultation by a psychiatrist of a patient suffering from mental disorder.

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COCIR COMPILATION OF REFERENCED STUDIES

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1. INTRODUCTION

Telemedicine is an emerging field in healthcare with many unknowns.
COCIR has established a dedicated Focus Group on telemedicine to respond to the many questions and doubts remaining about telemedicine.

COCIR defines telemedicine as the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a health care professional and a patient (e.g. telemonitoring of chronically ill such as those with diabetes and heart conditions, telepsychiatry etc).

Telemedicine includes all areas where medical or social data is being sent/exchanged between at least two remote locations, including both Caregiver-Patient/Citizen as well as Doc-to-Doc communication.

2. PURPOSE

Although an increasing number of studies and clinical trials demonstrate the effectiveness of telemedicine solutions, many clinicians, patients and payers, partially question the evidence available and do not trust telemedicine applications to support and improve the delivery of good quality healthcare. This lack of confidence is also a barrier to the integration of telemedicine in healthcare infrastructure and to the reimbursement of telemedicine services by health insurance companies.

This lack of trust is based on the fact that the results of existing studies are only partly known and many of the results are not directly comparable, because of the size, duration or overall design of the respective studies.

To address this situation, COCIR has started to collect and summarise the peer reviewed evidence of telemedicine projects and studies to support consistent communication on the quality of care and cost-effectiveness of Telemedicine solutions.

3. CRITERIA

The references that are listed below are all completed and published relevant studies in well-known scientific publications.

4. PERIODICITY

This database is a living document and will be updated regularly with new studies.

5. ABBREVIATIONS

BDOC . . . . . Bed Days Of Care

CCQ . . . . . Clinical COPD Questionaire (measure of HRQoL)

CHF . . . . . Congestive Heart Failure

COPD . . . . . Chronic Obstructive Pulmonary Disease

ECG . . . . . Electrocardiogram

ER . . . . . Emergency Room

GP . . . . . General Physician

HF . . . . . Heart Failure

HHA . . . . . Home Health Agencies

HRQoL . . . . Health Related Quality of Life

HTM . . . . . Home Telemonitoring

LVEF . . . . . Left Ventricular Ejection Traction

NYHA . . . . . New York Heart Association (NYHA) functional classification (extent of heart failure)

RCT . . . . . Randomised Controlled Trial

SGRQ . . . . . St George's Respiratory Questionnaire

TM . . . . . Telemonitoring

UC . . . . . Usual Care

3 COCIR COMPILATION OF REFERENCED STUDIES

TABLE 1 CHRONIC OBSTRUCTIVE PULMONARY DISEASE

REFERENCE OF STUDY	STUDY TYPE	PATIENTS POPULATION	STUDY DURATION	STUDY OUTCOME	TYPE OF INTERVENTION	LINK
Koff P et al. (2009): Proactive Integrated Care Reduces Critical Care and Improves Quality of Life in COPD, European Respiratory Journal 34 (Suppl. 53):p. 75s	RCT; monocentric, Setting: COPD and General Pulmonary Clinic at the University of Colorado Hospita	Intervention group: 270 patients; control group: 130 patients; Inclusion Criteria: GOLD Class III and IV or FEV1 > 50% predicted with a recent exacerbation; Exclusion Criteria: Asthma, Significant co-morbidities including HIV infection, interstitial lung disease, end-stage liver or renal disease or dementia Diseases likely to result in death within 2 years, Exclusion Criteria: Asthma,	9 months follow-up; study period: 2006-07; enrollment 2 pt. per day	• Significant reduction in critical care utilizations • Reduction in gross costs depending on differing hospital reimbursement rates (High Reimbursement Rate: -450$ p.p.p.m., Middle: -210$ p.p.p.m., Low: -150$ p.p.p.m.); • Significant improvements in health-related quality of life (measured with SGRQ), 6 min walk distance, oxygene saturation and shortness of breath; • Decreased mortality (4 % vs. 1%, p=0.046)	Proactive Integrated Care with disease-specific education, teaching of self-management techniques, enhanced communication and remote home monitoring with Health Buddy; monitoring from Monday to Friday for changes in symptoms, SpO^2, FEV1 and steps in 6 min walk test	http://www.ersnet.org/learning_resources_player/abstract_print_09/files/66.pdf
Vitacca et al. (2009 Tele-assistance in chronic respiratory failure patients: a randomized clinical trial. European Respiratory Journal; 33: 411-418	RCT, monocentric Setting: Italy	101 patients (57:44)	12 months	43% reduction of hospital admissions (0,17 vs 0,3 per patient per month) ; reduction of costs 52% (UC: 24743 Euro/Year vs. TM: 9886 + 2000 Euro (service/ devices))		
Koff P et al. (2009): Proactive Integrated Care Improves Quality of Life in Patients with COPD. European Respiratory Journal, 33(5), 1031-8.	RCT; monocentric Setting: COPD and General Pulmonary Clinic at the University of Colorado Hospital	Intervention group: 19 (mean age 67y), control group: 19 (age 65y); GOLD stage III and IV; no statistical significant baseline characteristics	First patient enrolled: Nov 2004; last patient enrolled: June 2005; follow-up 12 weeks; outcomes compared to prior 12 weeks	• Quality of life (SGRQ): intervention) 10.3 points improved (19%), control) 0.6 points improved (1%), p=0.018; • Costs: no stat. signif. differences; exacerbations and hospital admissions not analyzed; detection of exacerbations (9 vs. 2 patients)	Proactive Integrated Care with disease-specific education, teaching of self-management techniques, enhanced communication and remote home monitoring with Health Buddy; monitoring from Monday to Friday for changes in symptoms, SpO^2, FEV1 and steps in 6 min walk test	http://erj.ersjournals.com/cgi/content/short/09031936.00063108v1
Trappenburg J.C.A. et al. (2008): Effects of Telemonitoring in Patients with Chronic Obstructive Pulmonary Disease. Telemedicine and e-Health, 14(2), p. 138-146.	Non-randomized controlled comparison; multicenter	Intervention group: 68 (mean age 69y), control group: 56 (age 70y); GOLD stage III and IV; history of at least 1 COPD exacerbation in the preceding 6 months; more exacerbations, outpatient visits and hospital admissions in intervention than in control at baseline	First patient enrolled: May 2004; last patient enrolled: August 2005; follow-up 6 months; outcomes compared to previous 6 months	• Rate of exacerbation: intervention group 1.0 -> 0.65 (-35%), control group 0.69 -> 1.01 (+46%), p=0.004; • Rate of hospitalization: intervention 0.76 -> 0.65 (-15%), control 0.48 -> 0.75 (+ 56 %), p=0.02; quality of life (CCQ): no statistical significant differences	Health Buddy intervention with daily questions to patients that both monitor their disease symptoms, medication compliance, and knowledge; and provide education about their condition; answers reviewed from Monday to Friday by respiratory nurse; usual access to physician, GP or clinic; no additional case management or education	http://www.liebertonline.com/doi/abs/10.1089/tmj.2007.0037

3 COCIR COMPILATION OF REFERENCED STUDIES

TABLE 2 DIABETES

REFERENCE OF STUDY	STUDY TYPE	PATIENTS POPULATION	STUDY DURATION	STUDY OUTCOME	TYPE OF INTERVENTION	LINK
Chumbler et al. (2009): Mortality risk for diabetes patients in a care coordination, home-telehealth programme. Journal of Telemedicine and Telecare, 15(2), 98–101	Retroperspectively matched controlled comparison using propensity scores	774 patients (387 for each group), mean age 68 y, slightly higher comorbidity score and pre-enrollment outpatient visits in intervention group	4 years	• Reduction of 4-year all-cause mortality: hazard ratio 0.69, 95% CI 0.50–0.92, p=0.013 • Mean survival time: intervention 1348 days versus control 1278 days, p=0.015	Veterans Health Administration (VHA) care coordination/ home-telehealth (CC/HT) program using Health Buddy as communication device for education and monitoring of symptoms and health status; Care coordinators (registered nurses and nurse practitioners) monitored the answers from the devices daily so that early interventions could be made	http://jtt.rsmjournals.com/cgi/content/abstract/15/2/98
Chumbler et al. (2005): Evaluation of a care coordination/ home-telehealth program for veterans with diabetes: health services utilization and health-related quality of life. Eval Health Prof, 28(4), 464-78.	Uncontrolled, pre-post evaluation Setting: VA sites in the Florida, Southern Georgia, and Portsmouth region (USA)	445 patients, 2 or more hospitalizations or ED visits in the 12 months preceding enrollment,	12 months	• Hospitalizations: -50% • ER visits: -11% • BDOC: -3days, improvement of HrQoL	Veterans Health Administration (VHA) care coordination/ home-telehealth (CC/HT) program using Health Buddy as communication device for education and monitoring of symptoms and health status	http://ehp.sagepub.com/cgi/content/abstract/28/4/464

TABLE 3 MULTIPLE CHRONIC DISEASES

REFERENCE OF STUDY	STUDY TYPE	PATIENTS POPULATION	STUDY DURATION	STUDY OUTCOME	TYPE OF INTERVENTION	LINK
Darkins et al. (2008): The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veterans with Chronic Conditions. Telemedicine & e-Health, 14(10), 1118-1126.	Non-controlled pre-post evaluation Setting: Care Coordination/ Home Telehealth as a routine non institutional care services	17025 patients, veterans, with diabetes, hypertension, CHF, COPD, depression, postraumatic stress disorder or other mental health	12 months	• 25% reduction in numbers of bed days of care • 19% reduction in numbers of hospital admissions • 86% mean satisfaction score rating	Different telemonitoring system	http://www.liebertonline.com/doi/abs/10.1089/tmj.2008.0021

TABLE 4 CONGESTIVE HEART FAILURE

REFERENCE OF STUDY	STUDY TYPE	PATIENTS POPULATION	STUDY DURATION	STUDY OUTCOME	TYPE OF INTERVENTION	LINK
Giordano et al. (2009) Multicenter randomised trial on home-based telemanagement to prevent hospital readmission of patients with chronic heart failure. Int J Cardiol;131:192-9	multicenter (n=5) RCT	460 patients randomized 1:1 to UC (n=230) or TM (n=230) Diagnosis of CHF, left ventricular ejection fraction (LVEF) <40%, at least one hospitalization for acute HF in the previous year, clinically stable: symptomatically improved, without intravenous therapie for at least 7 days, stable oral therapy (maximally tolerated doses of angiotensinrenin inhibitor and beta-blocker, no dose change for 5 days) and stable weight(no change >1Kg).	one year follow up	• Primary Outcome: significantly lower risk of heart failure related readmission - 50% (TM:n=43, UC:n=73, p=0,0001), • Secondary Outcome:- 55% reduction in cardiovascular mortality (p=0,06), 31 % decrease in episodes of hemodynamic anstability (TM: 101 episodes, UC: 147 episodes, p< 0,001), mean cost of hospital readmisison 35% lower in TM-group (TM: €843+/-1733, UC: €1298+/-2322, p=0,01)	All patients: education about HF, advice on daily weight, self-measurement of blood pressure, rate of carrying out blood examinations, dietry restricitions, signs and symptoms of a heart failure decompoensation. UC: referation to their primary care physician TM: portable advice (Card-Guard 2206) transferring from a fixed or mobile phone, one-lead-trace to a receiving station with a doctor or nurse available 24 h, 7 days/week. scheduled appoinments every week or every 15 days Nerve Center: 4 Hewlett Packard server, WEB server, firewall , computerized call center 15 IAN workstations. Technological and organistaional support. 5 Centers: Terminals linked with the call center, configured to share the application programme interface of the Central Station with On line license. Managemnet of clinical activity. Cardiogolist and nurse: meeting once a week to sum up the course of the patients	
Mortara et al. (2009) Home telemonitoring in heart failure patients: the HHH study (Home or Hospital in Heart Failure). Eur J Heart Fail; 11(3):312-8	Multinational, multicentre, randomized controlled clinical trial, additional post hoc test Setting: UK, Poland, Italy	416 patients, randomized (1:2) to usual care (n=160) or TM(n=301); 18<age<85; NYHA II-IV aetiology: ischaemic, idiopathic, hypertensive, or valvular <40%; abnormal diastolic echocardiographic pattern from E/A<1;hospital admission in the previous 12 month;optimized medical therapy	12 month follow up	• Feasibility: 92 % practical recordings (of 1630/2078), compliance unrelated to NYHA (p=0.1) or older age (p=0,25) • Efficacy: (p=0,5) no siginificant effect in reducing bed days occupancy, cardiac death plus hospitalization or number of re- hospitalizations • Post hoc: heterogenous effect in the countries in the number of hospitalizations and cardiac death + hospitalization. Italy has a 52% reduction of the combined endpoint death and CHF related hospital admission. Only about 10% cardiac mortality rate in both intervention and controll group.	3 strategies in the TM group; strategie 1 (n=106): answering machine + nurse telephone contact, strategie 2 (n=94): answering machine + nurse telephone contact + weekly vital signs, strategie 3 (n=101): answering machine + nurse telephone contact + weekly vital + NICRAM; TM-groups: portable device to report ECG, respiration and physical acticity over 24 h, additional reported symptoms, weight, heart rate, systolic blood pressure and unspecisfied blood test	
Ramaekers et al. (2009): Adherance among telemonitored patients with heart failure to pharmacological and nonpharmacological recommendations. Telemedicine & e-Health;15: 517-24	RCT; multicentric Setting: Telemonitoring via University of Maastricht (NL); Patients recruited from 3 Dutch hospitals and provided with usual care	101 patients	3 months follow-up	• Disease specific knowledge improved significantly in two of the three hospitals (p<0.001 and p=0.040). • Adherence in terms of fluid restrictions (p=0.012), daily weighing (p<0.001), physical exercising (p=0.034), and alcohol restrictions (p=0.040) improved significantly in the telemonitoring group; • Substantial but statistically not significant decrease in depression.	Health Buddy CHF programme w/o additional peripherals	http://www.liebertonline.com/doi/abs/10.1089/tmj.2008.0160
Goernig et al. (2009) Ambulatory Disease Management in Cardiac Patients: 12 month follow-up of Home Care Telemedicine in Thuringia by the Management Program Zertiva®. Phys Rehab Kur Med; 19: 9-13	RCT	95 patients, 5 with suspected paroxysmale tachycardia, 90 with chronic heart failure;randomized to UC (n=90) and TM (n=90); at least one hospitalization for HF in the previous 6 month, members of one statutory health insurance	12 months	• No drop outs • Good compliance • Significant fewer hospitalizations -43% (UC: n=143, TM: n=62, p=0,001) • 68% reduction of bed days of hospital care (UC:1328, TM:424, p= 0,001) • Costs reduction -77% (UC:1371408€ TM: 317033€, p=0,001) in the TM-group.	TM: mobile 12 channel EC (Viapac TM from SHL)G, NYHA III patients additionally received a wage, pulse- and bloode pressure measurement and transmitted vital parameters weight, blood pressure and pulse on adaily base; Information meaterial about phatophysiologie, nutrition and animation; electronic patient record viewable for patients and physicians	

3 COCIR COMPILATION OF REFERENCED STUDIES

TABLE 4 CONGESTIVE HEART FAILURE FOLLOWING

REFERENCE OF STUDY	STUDY TYPE	PATIENTS POPULATION	STUDY DURATION	STUDY OUTCOME	TYPE OF INTERVENTION	LINK
Soran et al. (2008) A Randomized Clinical Trial of the Clinical Effects of Enhanced Heart Failure Monitoring Using a Computer-Based Telephonic Monitoring System in Older Minorities and Women. J Cardiac Fail;14:711-7	RCT	315 patients (1:1)	6 months follow up	• Reduction of combined endpoint cardiac mortality and CHF related hospital admission by 34% (p=0,083)		
Morguet et al. (2008) Impact of telemedical care and monitoring on morbidity in mild to moderate chronic heart failure. Cardiology;111:134-9.	MRCT	128 patients (1:3), TM:n=32, UC: n=96, Ejection fraction > 60%,NYHA class II or III	300 days mean follow up	• All cause hospitalization duration (UC: 317, TM: 693 days/100 patients years, -54%, p=<0,0001) and rate (UC:38, TM:77 days/100 patients years, -51%, p=0,034) as well as cardiac hospital • Admissions -69% and bed days of care -87%,(UC:379 TM :49 days/100 patients years, p<0,0001) were significantly lower	All patients: medical instruction about HF, pathophysiology basics, diet and physical exercise; biweekly scheduled telephone calls about symptoms, medication and quality of life TM: transmittion of weight, blood pressure , pulse rate and when required a 12-lead ECG	

GENERAL INFORMATION ABOUT COCIR

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe.

As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide.

COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens.

COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users.

We encourage the use of advanced technology to support healthcare delivery worldwide.

COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

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