

Horizon Scanning report N°2

Tele-Home Care System based on Digital Video Broadcasting Terrestrial technology (THC-DVBT)

June 2009

Methods:

Agenas is a public body. Its mission is to promote innovations and developments within the Italian national healthcare service and develop a Horizon Scanning (HS) function within healthcare technologies.

A full description of the methods used and the process phases undertaken for HS, can be found at www.agenas.it

This report should be cited as follows:

Cavallo A, Cerbo M, Jefferson T, Lo Scalzo A, Migliore A, Ratti M. Tele-home care system based on digital video broadcasting terrestrial technology. Agenzia nazionale per i servizi sanitari regionali (Agenas). Rome, June 2009.

Full or part reproduction of the report is not allowed. The intellectual contents of the report is the property of the Ministero del Lavoro, della Salute e delle Politiche Sociali.

For further information contained in this report please contact:

Agenas – Agenzia nazionale per i servizi sanitari regionali

Sezione Iss – Innovazione, sperimentazione e sviluppo

Via Puglie, 23 - 00187 Roma

e-mail: hta@agenas.it

Limitations:

This report is based on information available when the searches were made and does not contain data on subsequent developments or improvements of the evaluated technology. The observations made on effectiveness, safety or cost-effectiveness of the technology evaluated in the report are to be considered temporary.

Authors:

This report was prepared by the following:

Antonella Cavallo

Marina Cerbo

Tom Jefferson

Alessandra Lo Scalzo

Antonio Migliore

Marco Ratti

Acknowledgements:

Prof. Luigi Raffo (Università degli Studi di Cagliari)

Prof. Carlo Lai (Struttura Complessa di Cardiologia UTIC del Presidio Ospedaliero Santissima Trinità, ASL 8 – Cagliari)

Dr. Luciano Carboni (Servizio di Diabetologia, Presidio Ospedaliero Santissima Trinità, ASL 8 – Cagliari)

Name of the technology/procedure: Tele-Home Care System based on Digital Video Broadcasting Terrestrial technology (THC-DVBT)

Target population

Tele-Home Care system based on Digital Video Broadcasting Terrestrial (DVB-T) technology is aimed at chronic patients, out patients after discharge from hospital, elderly people and at risk patients (patients with cardiac failure, diabetes and/or hypertension) who require monitoring within the home. Homecare assistance is aimed at those patients who require assistance at home, this includes house visits by GPs, nurses, rehabilitation and welfare service. It is graded on the specialist care required by the patient. At present there are three indications which patients need to fulfill, as follows:

- Patient with hypertension (usually with few symptoms): he/she has to come to the hospital for examination every six months. Between visits it is suggested that the patients visit their doctor's surgery monthly, to assess the effectiveness of their anti-hypertension medication.
- Patient with heart failure (which is a more serious, frequently symptomatic pathology): the pathway is similar to the first indication, however the consultant would normally be a cardiologist, not a family doctor. For this type of patient it is important that the body weight is linked to an increased fluid intake which is characteristic of the disease or marks its progression or if the therapy is not sufficient a rapid intervention needs to be made.
- Diabetic patient: the control periods needed for insulin or non insulin-dependant patients is different and varies from two to three months. The patient however is able to test their own glucose levels more than once within a day period and decide depending on the results how much insulin is needed. The patient also needs to acquire data in between visits to present to the diabetic center at follow up and discuss these from one visit to the next.

Description of the procedure and technology

The Tele-Home Care (THC) is the use of technologies based on ICT (*Information and Communication Technology*) to support and manage the medical assistance for patient homecare. One of the functions of THC includes remote monitoring of the patient. The patient from their home can communicate electronically with the healthcare provider and receive some

services for example monitoring of his/her health. The interaction modality can vary (e.g., *real-time* or *off-line*) and can be in various forms (voice, video, voice-video) and can use various forms of communication (phone, internet etc.) [Dellifraigne, 2008; Tran, 2008].

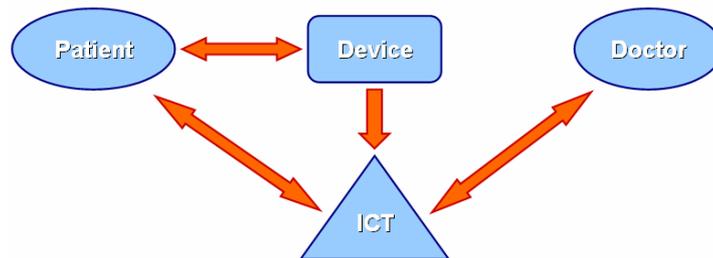


Figure 1: Graphic model of the THC system.

The measured parameters depend on the disease (typical parameters are glycemia, heart rate, blood pressure and body weight). When measured automatically or by a healthcare professional, the measurements are transmitted to the health centre. When this type of technology is used it is important that all the physical and procedural system's elements are available and functioning (e.g. procedures to receive and process patient data).

The present Horizon Scanning report looks at technologies using DVB-T technology to transmit and video signal as mean of interaction. For a functioning system an interactive DVB-T TV-decoder is required (the patient's home system needs to be able to receive DVB-T signal) [Lamminen 2002; Angius 2008].

Clinical importance and burden of disease

The percentage of the population who have heart disease is approximately 2%. Within the age group 65+ the prevalence rises to 5% [Tarantini, 2005]. Of these, 50% is able to measure their own levels of glycemia, blood pressure and body weight.

In the age group 65+, 20% of the population has an episode of heart failure [A.V., 2003]. The percentage of case of diabetic mellitus in Italy is 6%. 27% of these are treated with insulin [www.ministerosalute.it]. In the age group 70 and above, 40% of the population are affected by metabolic syndrome (which may be an indicator of pre-diabetic risk).

This technology was developed for diabetic patients with cardiovascular complications. These patients require frequent monitoring of glycemia, heart rate, blood pressure and body weight which are usually measured by the patient, a family member or helper. These data need then to be transmitted to the doctor in charge.

The system based on DVB-T can also be used to help the patient to learn about his/her disease, to look after themselves and improve their own condition and their psychological state.

Manufacturers, distributors and approval

We could identify only one manufacturer of THC-DVBT systems: TechOnYou Srl. With the KeepInTouch system, the patient has a personalised smart-card (smart-KIT) to insert into the digital TV decoder (into the pay-per-view slot) which is connected wireless to a base unit (base-KIT). This is linked to the diagnostic instruments for outpatients (glucometer, weighing scales, and sphygmomanometer in the basic version). In this way the instruments communicate with the TV decoder which allows a visual interface and the data are transmitted automatically to a remote assistance centre. The software application (firm-KIT) is loaded via the TV decoder which manages acquisition and transmission of data. The software is automatically updated.

The patient has a personal record of their own data which is recorded on the smart-card, this can be viewed by using the remote control and also transmit data via the telephone line. The data are transmitted to a remote assistance centre. The remote assistance centre collects the data automatically and updates the database. The database can be used in particular to signal alerts and transmit these to the relevant specialist physician and send messages to the patient if needed (care-KIT) [Angius 2008; www.techonyou.com]. The database can be organised in such a way that other software applications can be added.

The first tests with the KeepInTouch system will be carried out by the Videolina station which covers the whole of Sardinia.

Manufacturers	Distributors	CE Mark	RDM	FDA
TechOnYou Srl	TechOnYou Srl	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Key: RDM = Repertorio nazionale Dispositivi Medici (Italian medical devices inventory); FDA = US Food and Drug Administration

Setting

The technology is principally aimed at patient use within their own home. The data measured are sent by the patient to their dedicated healthcare worker, be it within the hospital or their own doctor.

<input checked="" type="checkbox"/> Home	<input type="checkbox"/> Hospital	<input type="checkbox"/> Out patients
<input type="checkbox"/> Accident and Emergency	<input type="checkbox"/> Other:	

Roll out in Italy

The KeepInTouch system is not yet on the market either in Italy or worldwide. The first region to use the technology will be Sardinia (Sardinia is the first region to have terrestrial digital coverage in 2008). Twenty patients will be enrolled for the test [<http://www.techonyou.com/progettoASL.html>].

<input checked="" type="checkbox"/> Pre-marketing	<input type="checkbox"/> On the market for 1-6 months	<input type="checkbox"/> On the market for 7-12 months
<input type="checkbox"/> On the market for more than 12 months	<input type="checkbox"/> Not identified	

Comparators

The major comparators are:

- Other THC systems (with similar objectives for the same type of patients);
- Conventional homecare assistance;
- Outpatient based treatment.

There are no comparative studies available which report effectiveness of the system versus the comparators.

Effectiveness and safety

We carried out a literature search of the CRD (DARE & HTA) and EuroScan databases looked for reports in English on *Horizon Scanning* and *rapid Health Technology Assessment*. Our searches did not identify any documents on Tele-Home Care systems based on digital terrestrial technology.

We looked for studies carried out over the last 10 years (January 1999 to June 2009) by searching EMBASE, Medline, and the Cochrane Library. The search found 6 potential studies which were then excluded as they were not reporting systems based on DVB-T.

As we are reporting an emerging technology, we also searched grey literature, by looking for published and unpublished abstracts and presentations. In Italy, the first region to test a THC system based on DVB-T technology (in particular the KeepInTouch system) in everyday practice will be Sardinia [<http://www.techonyou.com/progettoASL.html>].

Potential benefits to patients

This technology could potentially reduce the number of hospital/outpatients or GP visits needed by patients who require regular monitoring. This system allows the specialists to have complete and updated data relevant to the disease area (e.g., hypertension and stroke).

With the KeepInTouch system the patient can monitor and transmit their own glycemia, blood pressure or weight levels once a day or weekly or more frequently as required.

<input type="checkbox"/> Mortality reduction or increased survival	<input type="checkbox"/> Reduction of the morbidity	<input checked="" type="checkbox"/> Improved quality of life (patient/user)
<input checked="" type="checkbox"/> Improved patient monitoring	<input type="checkbox"/> Other:	<input type="checkbox"/> Not identified

Cost of the technology/procedure

There are no data presently available on the cost of KeepInTouch (not yet on the market) for the national health service. The cost for the manufacturer will be mainly to sustain the design and production of the system (*smart-KIT and base-KIT*). Chronic patients already own devices such as glucometers, while other patients have to pay for other equipment (e.g., sphygmomanometer and scales).

<input type="checkbox"/> Increased costs compared to alternative treatments	<input checked="" type="checkbox"/> Increased costs due to increased demand	<input type="checkbox"/> Increased costs due to the required investments
<input checked="" type="checkbox"/> New costs	<input type="checkbox"/> Other:	

Potential structural and organisational impact

Structural impact

Presently the technology can only be used when a DVB-T connection is available. In 2012 the service will be available throughout Italy [www.dgtvi.it] and the 27 member states of the European Union [www.dvb.org]. The national health service supplies their patients with measurement instruments for some chronic diseases (diabetics). The other instruments have to be able to interface with personal computers.

<input type="checkbox"/> Increase in requirement of instruments	<input type="checkbox"/> Always be used	<input checked="" type="checkbox"/> Can be used only under specific circumstances
<input type="checkbox"/> Decrease in requirement of instruments	<input type="checkbox"/> Other:	<input type="checkbox"/> Not identified

Organisational impact

New care units will have to be created (made up of one or more healthcare workers) within the hospital or surgery to monitor the data sent by all patients. The software should eliminate routine data collection. The GP needs to have a visualization system to check the data.

<input checked="" type="checkbox"/> Increase in the number of procedures	<input checked="" type="checkbox"/> Re-organisation required	<input checked="" type="checkbox"/> Training required for users
<input type="checkbox"/> Reduction in the number of procedures	<input type="checkbox"/> Other:	<input type="checkbox"/> Not identified

Conclusions

A THC system based on digital TV can be considered an emerging technology for Italy and world-wide. The use of interactive systems for homecare assistance of patients with chronic diseases has been tested in various settings [Dellifrane, 2007; Tran, 2008]. Even if many benefits have been observed in some cases (data monitoring, reduction in mortality, quality of life, patient satisfaction, fulfilling treatment course) [Tran, 2008]), care needs to be taken in the assessment of different applications of the technology. Both technology and processes can only be successful if implemented properly.

The system presented in this HS report has many potential advantages and benefits when integrated with elements that are already existing (measurement devices supplied by the Italian NHS; DVB-T TV decoder; management of patient data; education and training of GPs or paramedics). Another important aspect to consider is that this system allows complete patient involvement and appears acceptable as a new way of monitoring their own health.

The system is in the experimental stage and needs to be fully tested. In addition the success of this system is linked to the coverage of DVB-T signal over the whole of Italy (the switch-off from the conventional TV system should be completed by 2012). At present the use of this system is limited to regions linked to this type of service.

Future prospects

- **Population:** With the roll-out of digital TV over the whole of Italy, this type of technology will become available to an ever increasing number of patients.
- **Intervention:** In addition to patient self measurement, the technology will most likely be also used to educate the patient (e.g., a dedicated TV station).
- **Comparators:** The widespread use of ICT, could help with the development of a greater variety of THC monitoring which could take advantage of various channels of interaction.
- **Outcomes:** Availability of realtime data on blood pressure, glycemia and body weight will assist the GP in making swift and meaningful decisions.

Evidence searches

The searches were made using combination of the following terms: *digital TV; telehomecare; home monitoring; telehealth; remote monitoring.*

Bibliography

Dellifraigne JL, Dansky KH. Home-based telehealth: a review and meta-analysis. J Telemed Telecare. 2008;14(2):62-6.

Tran K, Polisena J, Coyle D, et al. Home telehealth for chronic disease management [Technology Report number 113]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.

Lamminen H, Lugmayr A, Niiranen S, Kalli S. Proposed model of a digital video-based home telecare system. Telemed J E Health. 2002 Winter;8(4):387-94.

Angius G, Pani D, Raffo L, Randaccio P. A DVB-T framework for the remote monitoring of cardiopathic and diabetic patients. Computers in Cardiology, 2008; 35:1001-1004.

Tarantini L.- La prevenzione nello scompenso cardiaco – ISBN 978-88-490-0127-3 – Il pensiero scientifico editore 2005.

A.V. Dati epidemiologici di riferimento - Ital Heart J Suppl 2003; 4 (11): 893-903
<http://www.federcardio.it/informazioneScientifica/LineeGuida/documenti/20030269.pdf>

Ministero della Salute. Epidemiologia del diabete mellito - Ministero della Salute - Giornata mondiale del diabete 2003. <http://www.ministerosalute.it/dettaglio/pdPrimoPiano.jsp?id=196&sub=4&lang=it> (ultimo accesso Lunedì 15 Giugno 2009).

<http://www.techonyou.com>

<http://www.techonyou.com/progettoASL.html>

<http://www.dgtvi.it>

http://www.dvb.org/news_events/dvbscene_magazine/DVB-SCENE_Issue_21_lo_res.pdf pagina 7

Glossary

DVB-T: Digital Video Broadcasting Terrestrial

ICT: Information and Communication Technology

NHS: National Health Service

THC: Tele-Home Care

THC-DVBT: Tele-home care based on DVB-T technology