Tele Monitoring Home Program in Patients with Cystic Fibrosis: Results after 15 Years

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The Cystic Fibrosis

Genetic, hereditary and chronic disease, widespread among the Caucasian population, resulting in fatal outcome.

Affects about one child every 1,500 births.

In Italy more than 4,000 people currently affected.
The Cystic Fibrosis

Defect: production of an abnormal protein (CFTR) that regulates the amount of salts secreted in body fluids.

Effects: thickening of mucus with impaired activity of many systems (digestive, respiratory, endocrine, reproductive organs).
The Cystic Fibrosis

- **Natural history:**
  - recurrent episodes of respiratory infection
  - progressive pulmonary damage
  - decay of long-term lung function leading to death

- **Goal of home follow-up**
  - short term: prevention and control of lung infections
  - long-term: slow down the decline in pulmonary function
The Cystic Fibrosis: clinical manifestation

- **Trend of Spirometry**
  - 2% /year decrease of FEV1 (forced expiratory volume)
  - long term decrease of FVC (current Volume)

- **In case of infectious relapse**
  - pulmonary function modifications often precede the clinical symptoms
  - monitoring variations in Spirometry is useful both in FC children and in adults

- **An early antibiotic treatment**
  - prevents more serious complications
  - limits the pulmonary damage in the long term
  - allows less invasive antibiotic therapies (orally)
**Telemedicine**

*Clin Ter 2011; 162 (4):e121-124*

**Remote telematic control in cystic fibrosis**

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**Abstract**

*Introduction.* In this study we describe and discuss the way we daily act in remote telematic tracking of CF outpatients, a procedure which has been improved through our daily experience in telemedicine.

*Materials and methods.* Currently, there are almost 30 patients involved in our telemedicine project.

We describe and discuss intervention parameters and the way we manage a register of performances in spreadsheet format.

We also describe the training program for the patients and their parents and the procedures through which we maintain contacts with patients and ViviSol assistance and the periodic satisfaction surveys.

*Results.* (from 15 of February 2010 to 24 of May 2011).

- Total transmissions 882, Spirometry 1317, SaO2/291, Compliance (transmission/patient day) 8.6.6.72.
- Hospital controls 10.
- Total contacts 128.

**Introduction**

Recent advances in technology gave us the possibility to receive, even at great distances, clinical information directly from patients such as record of biological parameters. This possibility shed new light in terms of continuity of care and optimization and standardization of clinical procedures.

Even if in the past years those technologies were principally used to assist people who live in hardly reachable places their use is gradually expanding in daily assistance for chronic patients.

Main benefits of the use of new informatics technologies to the follow-up of chronic patients may be reassigned as follow:
At home

Patient:

- Pulse oximetry by night
- Spirometry in the morning, after chest FKT and answering a questionnaire about pulmonary subjective symptoms
- Data transmission

- **Recommended frequency of transmissions**: twice a week.
- Patient may autonomously decide to send data
In hospital

Healthcare professionals daily:

- download the data in a protected way
- interpret the data through the application software
- print and store every transmission in a paper archive.
Application software provides:

- spyrometric curves and main parameters (FEV1, FVC, PEF, FEF25-75)
- comparison with previous parameters
- variations expressed as % difference.
- trend of FEV1 short, medium and long term
- graph of the night SaO2 and hearth rate (mean, minimum and maximum SaO2, T90 and T89)
Intervention parameters

we consider significant:

• Acute reduction of FEV1 (>10% compared to previous values recorded in stable clinical conditions)

• Reductions below 90% of the maximum value of oxygen hemoglobin saturation and of mean SaO2, increase of T90.
Flow work

• Every patient is called back to retrieve anamnesis data and to share the results.

• Anamnesis data and graphs are discussed in a mid-day briefing between clinicians for
  • overall evaluation
  • any therapeutic action
Decisional flow

• Patients with significant decrease of SaO2 and/or FEV1 are invited to transmit soon further test.
• In some cases antibiotic home therapy is prescribed on the basis of the last sputum culture collected in hospital.
• In other cases patients are invited for a clinical evaluation, to perform further testing, or to be admitted.

In any case the next data transmission is scheduled
Evolution of technology in respiratory telemedicine

2001: Project Oxytel
- Pulse oximeter external spyrometer

2005: Project Spirotel
- Pulse oximeter integrated spyrometer

2012: Project INTEL
- Central Unit + oxymeter, spyrometer, Weight, BP, T_C, questionnaire

2013: Project ADIPED
- Central Unit + pulse oxymeter, spyrometer, Weight, BP, diet, questionnaire, online visit

2014: Project Spirotel2
- Pulse oximeter integrated spyrometer
Oxytel – at patient’s house

• Pulse oximeter
• External spyrometer
Oxytel®
the telemonitoring system

Peripheral unit of data collection and transmission (patient’s house)

Data processing centre (hospital)
<table>
<thead>
<tr>
<th>Data Acquisizione</th>
<th>Ora</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercoledì</td>
<td>20/03/96 05:09</td>
<td></td>
</tr>
<tr>
<td>Giovedì</td>
<td>21/03/96 18:20</td>
<td></td>
</tr>
<tr>
<td>Venerdì</td>
<td>22/03/96 05:09</td>
<td></td>
</tr>
<tr>
<td>Sabato</td>
<td>23/03/96 05:07</td>
<td></td>
</tr>
<tr>
<td>Domenica</td>
<td>24/03/96 05:07</td>
<td>Lievi desaturazioni dopo le ore 04:00</td>
</tr>
<tr>
<td>Lunedì</td>
<td>25/03/96 05:07</td>
<td></td>
</tr>
<tr>
<td>Martedì</td>
<td>26/03/96 05:06</td>
<td></td>
</tr>
<tr>
<td>Giovedì</td>
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<td></td>
</tr>
<tr>
<td>Venerdì</td>
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<td>Dispnea</td>
</tr>
<tr>
<td>Sabato</td>
<td>30/03/96 05:06</td>
<td></td>
</tr>
<tr>
<td>Domenica</td>
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<td></td>
</tr>
<tr>
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<td>01/04/96 05:06</td>
<td></td>
</tr>
<tr>
<td>Martedì</td>
<td>02/04/96 05:06</td>
<td></td>
</tr>
<tr>
<td>Mercoledì</td>
<td>03/04/96 05:06</td>
<td></td>
</tr>
<tr>
<td>Giovedì</td>
<td>04/04/96 05:07</td>
<td>Monitoraggio notturno con desaturazioni significative...</td>
</tr>
<tr>
<td>Venerdì</td>
<td>05/04/96 05:07</td>
<td>Monitoraggio notturno</td>
</tr>
<tr>
<td>Sabato</td>
<td>06/04/96 05:06</td>
<td>ATENZIONE! Sensore posizionato male.</td>
</tr>
<tr>
<td>Venerdì</td>
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<td></td>
</tr>
<tr>
<td>Venerdì</td>
<td>12/04/96 18:40</td>
<td></td>
</tr>
<tr>
<td>Venerdì</td>
<td>12/04/96 18:48</td>
<td>Grave desaturazione</td>
</tr>
</tbody>
</table>
# Oxytel – OBG experience (2001-2005)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>n. of treated patients</td>
<td>17</td>
</tr>
<tr>
<td>Male/Female</td>
<td>6/11</td>
</tr>
<tr>
<td>Age at the beginning</td>
<td></td>
</tr>
<tr>
<td>Years (mean ± sd)</td>
<td>15.74 ± 5.8</td>
</tr>
<tr>
<td>FEV1 at the beginning</td>
<td></td>
</tr>
<tr>
<td>% of exp. value (mean±sd)</td>
<td>67.48 ± 21.28</td>
</tr>
<tr>
<td>Follow-up duration</td>
<td></td>
</tr>
<tr>
<td>Months (mean±sd)</td>
<td>29.30 ± 13.32</td>
</tr>
</tbody>
</table>
Fev1 monthly averages in 5 years
Fev1 monthly average

Fev1 (mean + 2DS) controls

06-08 April 2016
The International eHealth, telemedicine and Health ITC forum
for education, networking and business
Five years of Telemedicine in Cystic Fibrosis Disease

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¹Cystic Fibrosis diagnosis and treatment Unit, ²Epidemiology Unit, ³Information Systems and Organization Department, Children’s Hospital Bambino Gesù, Research and Care Institute, Rome, Italy

Abstract

Aims: We studied the effect of Telehomecare (THC) in a group of Cystic Fibrosis (CF) patients, with the aim to early recognize the relapses of pulmonary infections. Data obtained with Vivisol (OXYTEL) instrumentation were collected from 2001 to 2005.

Materials and Methods. The study has involved 17 patients (11 f, 6 m) affected by CF, treated with THC, in addition to the usual therapeutic protocol, for an average period of 29.6 months ± 13.5. The mean age for THC enrolment was 15.74 years ± 5.8. As controls, the study has involved the same patients during the 12 months prior to THC start-up and 28 patients affected by CF treated at our Unit (13 f, 15 m; average age 14.77 ± 5.22).

Results: The results show a statistically significant decrease of outpatient accesses and increase of therapy cycles, and a trend of higher stability of the respiratory function in THC treated subjects.

The natural history of Cystic Fibrosis (CF) is characterized by a progressive lung destruction, caused by obstruction of the airways due to dehydrated thickened secretions, resultant endobronchial infection and an exaggerated inflammatory response leading to development of bronchiectasis and progressive obstructive airways disease (4). Prevention and control of lung infections is one of the main objectives of therapy in CF patients with the aim to slow down the progressive decline in pulmonary function with time (5).

An acute decrease of FEV1 >10% is considered a significant sign of infections pulmonary relapse (6).

Many researchers demonstrated that, in case of infectious relapse, pulmonary function modifications often precede the clinical symptoms and that monitoring variations in pulmonary function can be useful in children and in adults.
Oxytel – OBG experience (2001-2005)

Results:

in THC treated subjects compared to controls
• statistically significant decrease of outpatient accesses and increase of therapy cycles
• trend of higher stability of the respiratory function.

Conclusions:

• Telehomecare seems to increase in general the rate of access to health care without any clear effect of pulmonary function.
Spirotel® - at patient’s house

- Pulse oximeter
- Integrated spyrometer
Spirotel – data transmission
Spirotel – tele monitoring system

Peripheral unit (patient’s house)

Data processing unit (Web)
Instrumentation today

- small (70x80x30 mm)
- light (<100 g)
- rechargeable battery
- data sent by email

It provides:
- spirometry (FVC, FEV1, FEV1%, PEF, FEF 25-75, FET, flow-volume and volume-time curves)
- pulse oximetry with registration of oxygen saturation (SaO2), heart rate and enhancement of desaturation events
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The International eHealth, telemedicine and Health ITC forum for education, networking and business
### Spirotel: Balance of Enrolment

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>enrolled</td>
<td>52</td>
<td></td>
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<tr>
<td>active</td>
<td>29</td>
<td>55.77%</td>
</tr>
<tr>
<td>drop-out</td>
<td>23</td>
<td>44.23%</td>
</tr>
<tr>
<td>poor adherence</td>
<td>14</td>
<td>60.87%</td>
</tr>
<tr>
<td>died</td>
<td>5</td>
<td>21.74%</td>
</tr>
<tr>
<td>other</td>
<td>4</td>
<td>17.39%</td>
</tr>
</tbody>
</table>

### Spirotel: Active and Drop-out

- Active: 56%
- Drop-out: 44%

### Spirotel: Causes of Drop-out

- Poor adherence: 61%
- Died: 22%
- Other: 17%
Spirotel Results: Trend of Median Fev1

During the 9 years of observation, we received 6647 spirometry analyses. Including all patients enrolled (39) for the entire period (9 years) of observation is shown the normal course of the disease (-2% / Year).

Are included patient compliant and not compliant: probably because of the old technology used, with transmission problems that have not allowed the continuous monitoring of the patients. In addition, some subjects were excluded from the study due to unexpected health problems or to non-adherence to the treatment.
Spirotel Results: Trend of Median Fev1

2nd Analysis: patients more compliant with 5/6 years of transmissions.
The graph shows an increase of median Fev1

![Graph showing trend of median Fev1 over different years, with an increase visible over time.]
### Spirotel Results: Trend of Median Fev1

#### 3th Analysis: 17 patients with 4 years of continuous transmissions.

Graph shows a better increase of Fev1

<table>
<thead>
<tr>
<th>Patient N°</th>
<th>Year I</th>
<th>Year IV</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2,060852</td>
<td>1,923715</td>
</tr>
<tr>
<td>2</td>
<td>3,171714</td>
<td>3,29</td>
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<td>3</td>
<td>1,992222</td>
<td>2,757895</td>
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<td>4</td>
<td>4 1,79</td>
<td>1,186429</td>
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<td>5</td>
<td>1,946667</td>
<td>2,02551</td>
</tr>
<tr>
<td>6</td>
<td>2,62433</td>
<td>3,623636</td>
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<tr>
<td>7</td>
<td>7 4,95</td>
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<td>3,093704</td>
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<tr>
<td>9</td>
<td>9 0,67</td>
<td>0,703889</td>
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<tr>
<td>10</td>
<td>10 3,175</td>
<td>2,078182</td>
</tr>
<tr>
<td>11</td>
<td>1,859333</td>
<td>3,106667</td>
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<td>12</td>
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<td>1,239167</td>
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<td>13</td>
<td>2,379734</td>
<td>2,425</td>
</tr>
<tr>
<td>14</td>
<td>3,27</td>
<td>4,222</td>
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<tr>
<td>15</td>
<td>1,968462</td>
<td>2,741163</td>
</tr>
<tr>
<td>16</td>
<td>2,87</td>
<td>1,444</td>
</tr>
<tr>
<td>17</td>
<td>3,81</td>
<td>3,613333</td>
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</table>
INTEL® project (2012-2014)

- Central Unit
- Oximeter
- Spyrometer
- Weight
- Blood pressure
- Temperature
- Questionnaire
## Intel - 2012 - 2014 Summary

<table>
<thead>
<tr>
<th>Period</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>Total</th>
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<tbody>
<tr>
<td>Patients n.</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4,0</td>
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<tr>
<td>Days</td>
<td>84</td>
<td>230</td>
<td>155</td>
<td>469</td>
</tr>
<tr>
<td>Data transfers</td>
<td>103</td>
<td>347</td>
<td>165</td>
<td>615</td>
</tr>
<tr>
<td>Adherence %</td>
<td>77,51</td>
<td>93,24</td>
<td>66,53</td>
<td>79,10</td>
</tr>
</tbody>
</table>

### Data transfers

![Bar chart showing data transfers for 2012, 2013, and 2014](image)

### Adherence

![Line chart showing adherence for 2012, 2013, and 2014](image)
INTEL: trend of Fev1

**PATIENT #1**

**PATIENT #2**

**PATIENT #3**

**PATIENT #4**

bipulmonary transplant

06-08 April 2016

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Telemedicina

The application of telemedicine in the follow-up of lung transplantation in a patient with cystic fibrosis

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¹High Specialization in Continuity of Care in Chronic Diseases; ²Hospital Information Services Department, Pediatric Hospital Bambino Gesù, IRCCS

Abstract

The Cystic Fibrosis (CF) Unit of Children’s Hospital Bambino Gesù in Rome (Italy) has more than 25 years of experience in diagnosis and treatment of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) related diseases. The CF Unit actively collaborates with the Transplantation Division for the follow-up of patients with CF who undergo lung transplantation, performed in our Unit since 1991. We present the case of a 19 year-old girl with CF, with severe respiratory failure for which it was subjected to two lung transplant. During the follow-up the remote monitoring has allowed the identification of an early episode of pulmonary relapse and graft-versus-host reaction even before the onset of symptoms, allowing an effective intervention and a complete recovery of lung function. Clin Ter 2014; 165(5):e382-383. doi: 10.7417/CT.2014.1769

Key words: cystic fibrosis, lung transplantation, telemedicine, 25-75, FET, flow-volume and volume-time curves; pulse oximetry with registration of oxygen saturation (SaO₂) and heart rate also in 24 hours recordings with regard to desaturation events.

Recently, we started using a new equipment that, in addition to the parameters of respiratory function, it also provides information on other organs and systems, useful for monitoring other aspects of chronic multi organ, especially in special situations such as pregnancy and lung transplantation, or monitor other concomitant chronic diseases, such as hypertension.

The CF diagnosis is performed in our FC Centre using the sweat test and the CFTR Gene Mutation Analysis according to current criteria (1).

Parents are in charge of monitoring, managing, and supporting a complex home-based treatment. A decrease of FEV1>10% is considered a significant sign of infection.
ADIPED project 2012-2015

- Central unit
- Pulse oximeter
- Spyrometer
- Weight
- Blood pressure
- Glycemia
- Diet control
- Therapy control
- Videoconference
- Questionnaire
- E-mail
## ADIPED: trasmissions

<table>
<thead>
<tr>
<th></th>
<th>Count of SaO2 (%)</th>
<th>Count of FEV1 (litri)</th>
<th>Count of P.A. minima (mmHg)</th>
<th>Count of F.C. (Bpm)</th>
<th>Count of Glucosio (mg/dL)</th>
<th>Count of Peso (Kg)</th>
<th>TOTALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paziente 1</td>
<td>26</td>
<td>133</td>
<td>152</td>
<td>151</td>
<td>4</td>
<td>130</td>
<td>596</td>
</tr>
<tr>
<td>Paziente 2</td>
<td>15</td>
<td>35</td>
<td>10</td>
<td>10</td>
<td>35</td>
<td>10</td>
<td>115</td>
</tr>
<tr>
<td>Paziente 3</td>
<td>2</td>
<td>11</td>
<td>6</td>
<td>6</td>
<td>13</td>
<td></td>
<td>38</td>
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<td>Paziente 4</td>
<td>5</td>
<td>16</td>
<td></td>
<td></td>
<td>11</td>
<td>5</td>
<td>37</td>
</tr>
<tr>
<td>Paziente 5</td>
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<td>11</td>
<td></td>
<td></td>
<td>5</td>
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<td>24</td>
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<td>Paziente 6</td>
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<td>14</td>
<td></td>
<td></td>
<td></td>
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<td>15</td>
</tr>
<tr>
<td>Grand Total</td>
<td>50</td>
<td>220</td>
<td>173</td>
<td>172</td>
<td>63</td>
<td>147</td>
<td>825</td>
</tr>
</tbody>
</table>
Trend of Fev1
Discussion

In the most of cases the patients followed in telemedicine showed in general a lower decay of respiratory function compared to those in follow-up only with the traditional method.

The data show an increase of examinations sent although the number of patients in remote monitoring has remained virtually constant.
Discussion

One of the critical aspects in the follow-up of chronic patients is poor adherence to therapy.

We observed over time a considerable percent increase of adherence to telemonitoring. The telemonitoring has been accepted in most cases positively by patients. The percentage of telephone responses (≈ 80%) is to be considered high (as if the patient waiting for the contact with the center) but insufficient to consider the phone a completely reliable means of communication.
Conclusion

In our experience, however, telemedicine is certainly a useful method in the follow-up of chronic conditions because it allows:

• a minor deterioration of lung function, resulting in less need to use invasive therapies;
• a radical change of the motivations of the accesses to the hospital, which have become more rational and less demanding both for the patient and for the staff that follows it;
• overall a better quality of life.
THANKS FOR THE ATTENTION