TELEMEDICINE ENHANCES QUALITY OF FORCED SPIROMETRY IN PRIMARY CARE

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Abstract

**Background:** Forced spirometry is pivotal for diagnosis and management of respiratory diseases, but its use in primary care is suboptimal

**Objective:** To assess a web-based application aiming at fostering high quality spirometry in primary care.

**Design:** Randomized controlled trial with 12 intervention primary care units (PCI) and 6 control units (PCC) studied during 12 m

**Methods:** All 34 naïve nurses (PCI and PCC) received identical training. The PCI units had access to educational material and remote expert support. Quality of spirometries and usability of the web application were assessed.

**Results:** We included 4.581 patients (3.383 PCI and 1.198 PCC). At baseline, quality was similar (PCI, 71% and PCC, 67% high quality tests). Through the study, PCI showed higher percentage (71.5%) of high quality tests than PCC (59.5%) (p<0.0001). PCI had 73% more chances of high quality performance than PCC. The web application was better to assess quality of testing than the automatic feedback provided by the spirometer. Professional’s satisfaction and usability were high.

**Conclusions:** The web-based remote support to primary care by specialists generated a sustained positive impact on quality of testing. The study expands the potential of primary care for diagnosis and management of patients with pulmonary diseases.

**Key words:** Forced Spirometry, Information Technology, Primary Care, Quality Control, Telemedicine.
Introduction

Forced spirometry (FS) is viewed as a first line test for clinical assessment of patients with respiratory symptoms. Because its high applicability and information content (1,2), FS plays a pivotal role in the diagnosis and follow-up of chronic obstructive respiratory diseases (1-4). It is of note that relevant clinical guidelines indicate the need of a widespread use of spirometry in primary care for early detection and appropriate management of asthma and chronic obstructive pulmonary disease (COPD). There is, however, a great deal of controversy(5-8) regarding the quality of the tests performed in primary care by non-expert professionals; the bottom line being a suboptimal deployment of FS. Consequently, effective training of health professionals ensuring high quality of FS in primary care is crucial to generate reliable results preventing unnecessary test duplications across the health care system.

Quality of FS strongly depends on adherence to international recommendations(9,10). The American Thoracic Society (ATS) /European Respiratory Society (ERS) documents establish well defined quality control criteria for both equipment and tests, but they do not include indications on strategies to ensure sustained quality assurance in clinical settings wherein non-expert professionals are likely to perform the tests. Previous experiences on remote support of FS (11-14) seems to indicate both feasibility and positive outcomes, but none of them shows scalability and potential for generalization.

The current randomized controlled study carried out in five areas of Spain throughout one-year follow-up examines efficacy, acceptability and usefulness of a web-based application(15) providing remote assistance to non-expert professionals for both quality assurance and support to interpretation of the tests.
Material and Methods

The research was carried out from 2007 to 2008 in five different areas of Spain that were organized for the study purposes as independent nodes located in: Extremadura (South Western region of Spain), Basque Country (North of Spain) and three nodes in Catalunya (North Eastern area of Spain). At baseline, a survey on available resources to perform FS and the perceived need of the test in primary care was administered to the general practitioners participating in the study(16).

Each node (Figure 1) had a reference centre (lung function laboratory) from a tertiary hospital with a specialized lung function professional playing the role of coordinator of the primary care units of the node. He/she was responsible for blindly scoring (from A, best score, to F, worse score, see Table 1) (17) all spirometric tests done in the area for both intervention and control groups.
Table 1. Quality scores for spirometric manoeuvres according to ATS/ERS standardization\(^{(9,10,17)}\)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>3 acceptable manoeuvres, and best 2 matched with differences in FVC and (\text{or FEV}_1) (&lt;150 \text{ ml})</td>
</tr>
<tr>
<td>B</td>
<td>3 acceptable manoeuvres, and best 2 matched with differences in FVC and (\text{or FEV}_1) (&lt;200\text{ ml})</td>
</tr>
<tr>
<td>C</td>
<td>2 acceptable manoeuvres, and best 2 matched with differences in FVC and (\text{or FEV}_1) (&lt;250 \text{ ml})</td>
</tr>
<tr>
<td>D</td>
<td>1 acceptable manoeuvre</td>
</tr>
<tr>
<td>F</td>
<td>None acceptable manoeuvres</td>
</tr>
</tbody>
</table>

High quality spirometries, A and B scores, correspond to, \((A, 3 \text{ acceptable manoeuvres with differences in FVC and/or FEV}_1 \,<150 \text{ ml})\) \(\text{and (B, 3 \text{ acceptable manoeuvres with differences in FVC and/or FEV}_1 \,<200 \text{ ml})}\); C to high variability among manoeuvres; D only one acceptable manoeuvre; and, F none acceptable manoeuvre

In each primary care unit, patients eligible for the study were selected among those with respiratory symptoms that required testing based on the general practitioner’s criteria, without any restriction related with age, gender or clinical status. Forced spirometries were carried out by naïve nurses. No information on clinical status of the patients was used for the purposes of the study.

The eighteen primary care centers included in the trial were randomly allocated, within each node, either to intervention (PCI 12) or control (PCC 6). Up to 34 nurses, 5 coordinators, 3 telecommunication engineers and approximately 150 general practitioners participated in the study.

The research was approved by the Ethical Committee of the Hospital Clínic i Provincial de Barcelona and the corresponding Ethical Committee of each participating node.

The study protocol included a two-day training course for all nurses of the two groups (PCI and PCC) using a methodology close to that applied by the National Institute for Occupational Safety and Health.
(NIOSH) in USA (18). The training course was carried out in each node at the beginning of the study. At the end of the training, all participants had made several forced spirometries and they had participated in the discussions on standardization of FS(10).

The nurses of the intervention group (PCi) were instructed in the management of the website and got accessibility to its functionalities during the whole study period. The educational content was specifically designed to empower the professionals to perform high quality testing. It included description of the spirometers used in the study, international recommendations on FS and educational videos.

The application provided a forum facilitating accessibility among professionals (general practitioners and nurses) and with the node’s coordinator. The nurses were able to generate specific questions to the coordinator related to quality or interpretation of the test and they received regular individualized feedback from the coordinator regarding the quality of the spirometries loaded into the system.

The coordinator of each node was also responsible for the evaluation of each test loaded into the system, following the classification described in Table 1 and he/she generated, on a weekly basis, a report addressed to each PCi nurse including information on several aspects of quality control of the tests analyzed, namely: repeatability of the maneuvers, characteristics of the curves, check of starting (back extrapolation) and end (expiratory time) of those maneuvers accepted by the primary care professionals. The quality assessment was based on visual analysis of both flow-volume and volume-time
manoeuvres. All node coordinators were instructed to follow strictly identical criteria for grading the tests throughout the study period. There was a general supervision of the node coordinator’s tasks done by FB assessing for homogeneity of the coordinators grading criteria. In contrast, the professionals included in the control group did not have access to the web application. The two-day face to face training course was the only support provided to them throughout the entire study period.

Technical setting
We used two types of spirometric systems conforming the recommendations of the ATS/ERS(9,10). In all cases, the system was connected to a personal computer. In two out of the five nodes, we used a disposable and pre-calibrated pneumotachograph-based spirometer (Datospir 110, Sibelmed, Barcelona, Spain); whereas in the three remaining nodes an ultrasound transit-time based spirometer (Easy-One; NDD Medical Technologies, Sonmedica, Barcelona, Spain and Zurich, Switzerland) was used. The FS equipment had the original software without any modification except for the potential to export data of all tests in XML format. Briefly, each node used the same type of spirometer independently of being intervention or control. In all cases, the nurses were instructed to use the automatic quality messages generated by the equipment. Although the two systems had a built-in capacity to generate automatic messages, only those of the Easy One spirometer were explicit for the users. Consequently, the comparison between remote reviewer and automatic feedback was only reported for those nodes using Easy One spirometer.
The application tested in the current study is one of the modules of the ICT platform used to support management of chronic patients (15,19). Such platform provided traceability of all the actions taken during the follow-up period. A VeriSing™ Trust Node security system was used to ensure confidentiality of encrypted data shared through internet. After the end of the follow-up, we assessed acceptability of the web-based quality control program by the general practitioners involved in the study. Usability of the web application was also assessed (SUMI, Software Usability Measurement Inventory. University College Cork, Ireland) (20) by the nurses that performed the tests.

**Data Analysis**

Characteristics of the sample were presented as number and percentage for categorical variables, or mean and standard deviation for continuous variables (since all of them followed normal distributions). A comparison of socio-demographic and lung function variables between intervention and control group was made using Chi-square or ANOVA tests, as appropriate. Effects of the intervention in the quality of the spirometry were tested by comparing both at each month and during the whole study period the percentage of quality grade A and B spirometries between PCI and PCC using Chi-square test. Additionally, multivariate logistic regression analyses were built with quality of the spirometries as the outcome and intervention as the main exposure, adjusting for differences between PCI and PCC subjects. Data analysis was conducted using Stata 10.1 (StataCorp, College Station, TX, USA). A p value < 0.05 was considered statistically significant.

**Results**
Study groups

We examined four-thousand five-hundred eighty one subjects whose main anthropometric characteristics, age and lung function results are displayed in Table 2. Each subject had been scheduled only once for a visit in Primary Care and FS was done following the criteria of the general practitioner.

Table 2 Main characteristics of the two study groups

<table>
<thead>
<tr>
<th></th>
<th>All 4581</th>
<th>Intervention 3383</th>
<th>Control 1198</th>
<th>p values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men, %</td>
<td>55.7</td>
<td>55.2</td>
<td>56.8</td>
<td>0.335</td>
</tr>
<tr>
<td>Age, yrs</td>
<td>53.6 (18.9)</td>
<td>54.5 (18.0)</td>
<td>51.1 (21.0)</td>
<td>0.000</td>
</tr>
<tr>
<td>Height, cm</td>
<td>163.2 (10.5)</td>
<td>163.5 (10.0)</td>
<td>162.2 (11.7)</td>
<td>0.030</td>
</tr>
<tr>
<td>FEV₁ % pred</td>
<td>78.5 (22.8)</td>
<td>78.5 (22.9)</td>
<td>78.3 (22.4)</td>
<td>0.784</td>
</tr>
<tr>
<td>FVC % pred</td>
<td>83.5 (19.6)</td>
<td>83.8 (19.6)</td>
<td>82.5 (19.3)</td>
<td>0.037</td>
</tr>
<tr>
<td>FEV₁/FVC, %</td>
<td>71.6 (13.1)</td>
<td>71.2 (13.3)</td>
<td>72.6 (12.6)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Results are expressed either as mean ± standard deviation or as percentage in the corresponding category (last file). FVC% pred, percentage of predicted of forced vital capacity. FEV₁ pred, percentage of predicted of forced expiratory volume during the first second.

We observed that subjects in the intervention group were slightly older and moderately taller than those in the control group. Mean FEV₁ expressed as percent of predicted was moderately abnormal with no differences between groups. In contrast, FVC was within the reference interval, but slightly lower in controls than in the intervention group.

The main results of the self-administered baseline questionnaire(16) to assess the status of the forced spirometry in primary care are displayed in Table 3. It was answered by one hundred forty six general practitioners (99% response rate) from the eighteen PC centres participating in the study.

Table 3 Status of FS among participating GPs at baseline
Availability of FS equipment 26%
Use of FS among those that had equipment 73%
Specific training on FS 65%
Knowledge of the equipment 7%
Performance of the calibration routines 12%

Results are expressed as percentage in the corresponding category. FS, forced spirometry. GP, general practitioners.

Effects of the intervention

After the first quarter, monthly percentages of high quality forced spirometries were significantly and consistently higher in the intervention than in the control group (Figure 2). The intervention group presented an average of 71.5% high quality spirometries throughout the whole study period, with no differences between month 1 and month 12. In contrast, the control group showed a lower mean percentage (59.5%) (p<0.001) of high quality tests during the whole study period with a statistically significant fall between month 1 (67%) and month 12 (62%) (p=0.011). Throughout the study, the difference in percentage of high quality tests between intervention and control groups increased from 4 units at month one up to 16 units at month 12 (p<0.05). No differences between groups were seen in score C (Table 1). However, while the amount of tests within the lowest score (F) increased from 9.3 to 16.2% in the control group, we observed a decrease in the intervention group, from 15.2 to 5.2%. The results of the logistic regression analysis indicated that the effects of the intervention remained after adjusting for baseline differences (age, lung function and gender), such that tests in the intervention group had 73% more chances of high quality performance than those of the control group. We noticed that PCI professionals performed a higher number of spirometric maneuvers than those of the PCc group. Up to 3% of intervention subjects
made eight maneuvers whereas the maximum amount of maneuvers in the control group was six.

**Automatic assessment of quality**

In the subset of primary care centers using EasyOne, we compared quality scores automatically generated by the system with those provided remotely by experienced professionals.

Automatic quality assessment presented a pattern indicating statistically significant effects of the intervention similar to those indicated in Figure 1, but the absolute figures of spirometric manoeuvres identified as acceptable tests were consistently lower than those seen with remote assessment by experienced professionals, as indicated below. At the beginning of the study, automatic quality assessment did not show differences in percentages of acceptable maneuvers between intervention and controls, whereas at the end of the follow-up the amount of high quality spirometries in the intervention group (55%) was higher than in the control group 43% (p=0.035) with an average difference of 13.5 units. The equivalent figures using the same equipment but with the remote professional assessment were 71.5% (intervention group) and 59.5% (control group) (<0.0001) with a similar mean difference of 12 units between intervention and control. Accordingly, underestimation of acceptable spirometric maneuvers generated by automatic quality assessment as compared to assessment carried out by expert professionals showed an average of -16% units.

**Acceptability of the web application**

The results of the survey carried out among the general practitioners (n=126, 86% response rate) one month after the end of the study indicated an acceptable level of
global appreciation of the web functionalities (97% were satisfied with a score of 7.3±2, from 0 to 10) together with a rather low percentage (26%) of GP’s indicating problems of implementation of the intervention. Overall, the GPs expressed that the web application provided added value both enhancing quality of the tests and providing support for interpretation.

Finally, the usability of the web application was examined administering the SUMI (20) questionnaire to the 34 nurses that carried out the tests with an 87% response rate. Figure 3 displays the results obtained for the five dimensions assessed in the questionnaire, namely: efficiency, affect, helpfulness, control and learnability, as well as the score of global satisfaction. Notice that except, for control, all the scores were above 50 representing an acceptable degree of usability. As expected, Control (Figure 3) was uniformly below 50 consistent with the fact that the tested software, by study design, did not allow choices to the users.

DISCUSSION
The principal aims of the current research were to examine efficacy, acceptability and usability of a web-based application covering three main functionalities: a) accessibility to educational material for continuous professional development, b) remote support for quality assurance of the tests performed by non-experts; and, c) remote assistance to lung function interpretation. We acknowledge that previous reports(11-14) have indicated the potential of telemedicine to enhance both quality of testing and diagnosis of FS carried out by non-expert professionals, but none of the studies shows potential
for generalization across the healthcare system due technological and/or logistic factors precluding their scalability.

Our research clearly indicates a sustained beneficial impact of the intervention increasing high quality tests (A+B) by approximately 20% (Figure 2) and decreasing the percentage of very low quality spirometries (score F) through the follow-up period. Also the professionals acknowledged the usefulness of the web application as a tool for remote assistance on interpretation of the tests and to empower non-expert professionals increasing their skills to perform high quality FS in primary care. It is of note, however, that the impact of the application on diagnosis was beyond the scope of the current research.

**Does the intervention fulfill unmet needs in Primary Care?**

The baseline survey carried out with the participating GPs indicate that the professionals acknowledged the need for support on training and on interpretation of the tests in order to achieve the full potential of FS when used in primary care. Moreover, international clinical guidelines are endorsing extensive use of high quality FS in primary care. Unfortunately, despite enhanced awareness on the problem over the last years, COPD is still associated with marked under-diagnosis without a significant decrease during the last decade(21) (from 78% to 73 % between 1997-2007). Still too often diagnosis of COPD is done after an episode of severe exacerbation or during the first hospital admission.

Our data confirm that accessibility to appropriate support facilitating quality assurance of the tests performed at primary care level or at patient’s home is needed. It is classically accepted that approximately 10% of patient’s data may need to be
disregarded in Lung Function Laboratories because of technical inadequacies. Such percentage can be as high as 40% in epidemiological surveys without a proper quality assurance strategy (4). We must acknowledge, however, that the figures alluded to above show a marked decline when efforts to ensure quality control are adequately implemented (4, 22).

It is well accepted that training constitutes a pivotal element to achieve high quality FS done by non-experts. Recent data on a centralized quality control program carried out as part of the Platino study (23) fully endorse the statement. In the primary care setting, Walters JA et al. (24) recently showed that the percentage of high quality FS tests with trained nurses was approximately 76% whereas that percentage dropped to 44% in non-trained professionals. Different authors (6, 25-27) have elaborated on the need of transferring well established quality assurance programs from lung function laboratories to the primary care setting to ensure quality of the tests. There is evidence (28, 29) suggesting that external quality assurance to primary care needs to be implemented. In an extensive review of FS done in primary care, it was found that general practitioners identified approximately 90% of their own tests as acceptable; whereas the opinion of an expert decreased the acceptance rate to 64%. Moreover, a recent report (30) indicates that conventional training does not ensure sustainability of high quality testing. Interestingly, our research found that the effects of the intervention were also seen by automatic assessment of quality. But such modality of assessment generated marked underestimation (-16% units) of acceptable spirometric maneuvers as compared to assessment by experienced professionals.

To our knowledge, the current study constitutes the first attempt to successfully implement a web-based standard training program reinforced by tele-collaboration tools allowing remote assistance to primary care professionals by specialists. In this regard,
the intervention was conceived to provide long-term sustainability of the training program through continuous empowerment of primary care professionals. The results generated by the current research endorse the vision and they suggest that the current approach covers the requirements for an extensive adoption of FS in primary care.

**Limitations of the study**

The quality assessment was based on visual examination of the curves which, in some cases, may limit accurate identification of end-of-test. We acknowledge that implementation of an automatic algorithm should be considered as a useful decision support tool for the node’s coordinator. As indicated above, the study is not addressing the impact on remote assistance to diagnosis of FS. Moreover, we did not aim to perform a detailed analysis of factors modulating extensive deployment and adoption of the intervention. The latter would have required a specific design including several types of chronic patients covering a broad spectrum of disease(s) severity.

**Conclusions**

The current study shows that tele-collaboration between primary care professionals and lung function specialists has a positive impact on quality assurance of forced spirometry done by non-experts. We would like to emphasize that the intervention assessed in the current study seems to show high potential for generalization across the healthcare system such that future studies aiming at examining adoption of the proposed strategy should be encouraged.
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Figure Legends
Figure 1 – Structure of each node. The twelve Intervention Primary Care Units (PCI) had a bidirectional communication with the Lung Function Laboratory playing a role as support centre; whereas the six Control Primary Care Units (PCc) only transferred information to the support centre without any feedback. The five nodes were Bilbao (2 PCI and 2 PCc), Cáceres (2 PCI and 1 PCc), Vic (3 PCI and 1 PCc), Badalona (2 PCI and 1 PCc) and Barcelona (3 PCI and 1 PCc).

Figure 2 - Percentage of high quality tests including scores A and B (3 acceptable manoeuvres and best of two with differences in FVC and/or FEV₁ <150 ml and 3 acceptable maneuvers and best of two with differences in FVC and/or FEV₁ <200 ml, respectively) in the intervention and the control groups throughout the study period.

* p< 0.05. † p< 0.001.
Figure 3 - Medians and 95% confidence interval of the different dimensions of the SUMI questionnaire (National Physical Laboratory report DITC 169/90, Teddington, Middx., UK. (12) to assess usability of the web application (see text for further explanations)